CT:IQ

A mapping exercise to identify initiatives to support the implementation of decentralised clinical trials including teletrials in Australia

December 2023

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TABLE OF CONTENTS

Published by: CT:IQ

1. Background

Decentralised Clinical Trials (DCTs) are trials in which - *some or all the trial-related activities occur at a location separate from the investigator's location.*[1] In Australia, many DCTs are conducted using the teletrial model developed by the Clinical Oncology Society of Australia (COSA).[2] A teletrial is a trial *that uses telehealth technology to communicate between the Primary Site and Satellite Site(s) and enable delivery of aspects of a clinical trial as defined in the Supervision Plan*.[3] Teletrials may further adopt decentralised approaches, for example by using local healthcare providers for routine blood tests closer to participants' homes.

DCTs are recognised for their potential to improve trial recruitment and retention by broadening access to trials and by reducing barriers to participation, especially the burden of travel.[4] [5] [6] The ability to increase a trial's reach may help to address the current lack of alignment between trial recruitment and disease prevalence, which is often highest in rural and remote areas.[7] In turn, improved access to diverse populations will improve the external validity of trials, so their results are relevant to a broader range of people.

Capacity building activities such as the professional development of clinicians and improvements in trial infrastructure in rural and remote areas as part of the Australian Teletrial Program (ATP) bring additional benefits to the health system. When the risk level of a trial prevents the use of more decentralised models, teletrials offer more convenient access to trials while maintaining personal interaction with health professionals that trial participants value. Evidence that participants accept the teletrial model is emerging.[8]

The use of decentralised trial models can also provide substantial value to commercial trial sponsors. Shorter trial timelines and other financial benefits have been reported. For example, a US study reported a potential expected net present value (eNPV) that roughly equates to a $10 million return on a $2 million investment in decentralised approaches for phase 2 trials and $39 million return on a $3 million investment for phase 3 trials when technology driven DCTs were conducted.[9] With regard to data quality, the development of products in real-world settings improves the evidence of their real-world use.

[1] Common Terminology for Decentralised Trials: ARCS Australia White Paper. May 2023
[2] Clinical Oncology Society of Australia (COSA). The Australian Teletrial Model. Access to clinical trial closer to home using telehealth (2016)
[3] The National Standard Operating Procedures for Clinical Trials, including Teletrials in Australia. (February 2021)
[4] Sommer, Carsten, et al. "Building clinical trials around patients: evaluation and comparison of decentralized and conventional site models in patients with low back pain." Cont. clin. trials comms 11 (2018): 120-126.
[5] Sine, S., de Bruin, A., & Getz, K. (2021). Patient engagement initiatives in clinical trials: recent trends and implications. Therapeutic Innovation & Regulatory Science, 55(5), 1059-1065.
[6]Miyata, B., Tafuto, B., & Jose, N. (2023). 76 Methods and Perceptions of Success for Patient Recruitment in Decentralized Clinical Trials. Journal of Clinical and Translational Science, 7(S1), 21-21. doi:10.1017/cts.2023.160
[7] Rural Health in Australia Snapshot 2021 Demographics; National Rural Health Alliance.
[8] Lee, Jin Joo, et al. "Exploring Australian regional cancer patients' experiences of clinical trial participation via telehealth." Journal of Telemedicine and Telecare 28.7 (2022): 508-516.
[9] DiMasi JA et al. Assessing the Financial Value of DCTs. Ther, Innov, Regul, Sci. 2023 Mar;57(2):209-219.

2. Scope

This project covers teletrials and other types of DCTs.

3. Purpose

This project was initiated by CT:IQ to provide stakeholders with a clearer picture of the activities currently underway in both teletrials and other DCT models. Visibility of current activities and a coordinated approach to progressing future activities will minimise duplication.

The aim was to identify initiatives:

- Underway in Australia - to facilitate knowledge sharing that will support the national implementation of teletrials and other DCTs.
- Yet to be progressed but considered important to support the implementation of teletrials/other DCTs.

4. Data Collection

Grant recipients and other key stakeholders were approached to attend virtual meetings, which were held between mid-September and mid-November 2023. CT:IQ provided introductions to key industry representatives from the medicines and medical devices sectors. 26 virtual meetings, were conducted, attended by 32 stakeholders.

Stakeholder Group	No. of Meetings	No. of Attendees
Grant Holders	14	18
Other non-industry stakeholders	5	5
Industry stakeholders	7	9

5. Teletrial Grant Holders

The Australian Government has invested $125 million to give access to clinical trials to patients from rural and remote areas. **Table 1** is an overview of activity for the three grant recipients.

Table 1

Award	Recipient	Planned Activity
$75.2 million	Department of Health Queensland	To establish Regional Clinical Trial Coordinating Centres (RCCCs) in QLD, WA, VIC, TAS, SA and the NT and to enrol more than 5000 patients into trials in RRR areas. The grant also supports the establishment of new RRR trial locations in each participating state/territory.

$30.6 million	NSW Ministry of Health and ACT Health	To progress infrastructure projects in RRR areas, including work to improve virtual trial capacity, increase trial awareness, improve trial recruitment and retention and professionalise trial services. Three clinical trial support units (CTSUs) support the delivery of trials in regional NSW.
$18.6 million	Border Medical Oncology Research Unit (BMORU): ReViTALISE	To progress several initiatives in areas of unmet need to provide equitable access to cancer trials in RRR Victoria, which focuses on providing access to high-quality trials to regional Victorians and supporting the development of rural infrastructure.

The Australian Teletrial Program (QLD, WA, VIC, SA, NT): The ATP is coordinated by a national office hosted by QLD Health and regional coordinating centres (RCCCs) in participating states and territories. The RCCCs implement the operational components of the Program through incentive grants, capacity building and training. The goal is to develop a consistent and sustainable approach for teletrials. In addition to increasing rural and remote capacity to conduct trials, the Program's outputs will include standardised/streamlined teletrial governance processes, documents and templates, and guidance to support the implementation of the teletrial model in areas such as investigational product supply. Other initiatives underway include work to build awareness of teletrials, a partnership with a GP Network to support trial recruitment, and an evaluation of the Program to inform its sustainability. (**Appendix 1**)

Current activity balances operational consistency (through national office initiatives) with RCCC initiatives to address local needs. Activity includes capability and capacity building in trial-naive areas and the engagement of trial sponsors and sites to support the implementation of the model. Activities to develop streamlined operations are also underway, For example, a workshop to explore ways to streamline teletrial governance activities was run. Evaluations to gauge teletrial start-up times have been conducted to inform trial budget preparation. Work to support the sustainability of clinical trial units (CTUs) and to ensure that research-ready trial sites are visible to sponsors is also underway, as is work investigating other novel and sustainable ways to provide remote and rural populations with access to trials, e.g., administer through a central (metro) unit that utilises agile trial workforce deployment, virtual support and digital solutions.

The NSW/ACT Rural, Regional and Remote Clinical Trial Enabling Program (R3-CTEP Program): The R3-CTEP Program focuses on capacity building activities to increase the number of trials in RRR areas. The Program uses local expertise in teletrials developed during the COSA pilot to increase the number of teletrials. It aims to professionalise trial services, which will be delivered through the 3 new clinical trial support units based in three regional clusters (groups of LHDs). Several initiatives are underway, with the aim of increasing diverse/inclusive recruitment to trials through partnerships that include Consumers NSW and ACT and the Centre for Aboriginal Health. The Program also explores methods to expedite trial conduct, including AI-driven processes for recruitment and retention, GP engagement and trial awareness.

ReViTALISE: Involving eight regional centres in Victoria that partner with metropolitan sites, the Program provides access to high-quality cancer trials in regional Victoria. Projects include improving access to oncology trials for First Nations People, geriatric populations, palliative and supportive care patients, improving research literacy in the regional workforce through the establishment of a Regional Research Teaching Hub, improving access to registry trials and immunotherapy trials, developing a CTU in Mildura and expanding the CTU at La Trobe Hospital.

6. Other Teletrial/DCT Stakeholders

The VCCC Alliance: The VCCC, in collaboration with the Victorian Teletrial Collaborative (VCCC Alliance, Alfred TrialHub and Regional Trials Network Victoria), has produced the Teletrial Toolkit, which consists of educational modules, resources and information to support the set-up and delivery of teletrials and engagement materials for patients investigators, CTUs and sponsors.

Alfred TrialHub: The TrialHub program helps to build regional trial capacity by developing sustainable CTUs within remote and regional hospitals, which includes the development of a Capability Framework and Maturity Model that provides a basis for successful trial unit development and trial implementation.[10] The Alfred TrialHub also raises awareness of trials and upskills the trial workforce, for example through its accreditation program for pharmacists.

Australian Clinical Trials Alliance (ACTA): ACTA delivers capacity building and education for the clinical trial networks (CTNs) and coordinating centres (CCs) that conduct collaborative group trials. ACTA has surveyed CTNs and CCs to gauge current awareness of teletrials and to identify the main barriers and enablers for future success. It also raises awareness of teletrials through webinars and other activities.

The CTNs have begun to conduct teletrials. For example, the Australasian Gastro-Intestinal Trials Group have worked with industry and ATP RCCCs to conduct multi regional teletrials that aim to support diverse and inclusive recruitment.

Commercial Trial Sponsors: Industry sponsors have engaged with the ATP Program and more broadly with the other grant holders as well as the clinical trials networks to conduct industry-supported investigator-led trials. Commercial sponsor also acknowledge the need to prepare for further decentralisation, recognising that emerging technologies, such as wearables, smart phones and other remote data capture solutions increasingly enable the collection of trial data from participants' homes for many trials.

Appendix 2 provides an overview of the linkages between these grant holders and other stakeholders.

7. Examples of Stakeholder Feedback

After being briefed on the project, meeting attendees were shown a draft resource map organised by topic and populated with content from stakeholder websites. The meetings adopted a semi structured approach. Attendees were asked to identify other published or pending resources, as well as resources they would prioritise for future development. This information was used to produce the resource map in Appendix 3.

Common feedback on future resources and initiatives to support the implementation of teletrials and other DCTs included:

[10] Woollett, Anne, et al. "A capability framework to inform the fundamental requirements for clinical trial unit development, growth and long term success in outer metropolitan and rural areas." Contemporary Clinical Trials Communications 32 (2023): 101072.

1. **Emphasizing the *'how to'* of teletrials and DCTs more broadly:** Practical guidance was considered important, as stakeholders felt a lack of awareness and understanding could negatively affect the successful implementation of the Programs. For example, risk-based trial conduct is an integral feature of the teletrial model and is supported by a national supervision plan that provides a framework for risk-based trial supervision/oversight. Without guidance on its use, however, risk-averse approaches may be adopted, e.g., primary site staff supervising activities they can carry out independently. Similarly, ethics and governance training and mentoring programs that enable review bodies to identify the risks and benefits associated with teletrials and other DCTs may help reduce review timelines while ensuring safe and effective implementation.

2. **Implementing enablers for remote trial activity**: This was seen as important for both teletrials and other DCTs. Although some RCCCs have considered more decentralised trial approaches - WA RCCC, for example, described plans for a central unit that provides trial workforce deployment, virtual support, and digital solutions, stakeholders stressed the importance of ensuring that the digital trial systems implemented by states and territories (e.g. CTMS systems) accommodate the requirements of teletrials and other DCTs, as their workflows differ from conventional trials. The interoperability of trial platforms and electronic medical records was also considered crucial. For example, the upload of PDFs to enable the exchange of trial data between primary and satellite sites is labour-intensive.

3. **Ensuring sustainability**: Stakeholders emphasized the need to focus on trial awareness activities to promote the value of the teletrial model (and clinical trials in general) to support their uptake. Commercial sponsors also commented that their global sponsors will require evidence that the additional time/costs associated with the setup of teletrials are offset by improvements in recruitment and data quality. An economic evaluation being conducted between 2021 and 2026 by James Cook University and Queensland University of Technology (Appendix 1) will inform sustainability plans.

4. **Broadening DCT capability:** Stakeholders were unclear whether initiatives to support implementation of other types of DCTs were within the scope of the ATP and NSW/ACT Programs, as most decentralised trials being opened are teletrials. However, stakeholders recognised that the capacity building/professional development activities underway to develop rural and regional trial infrastructure will benefit all types of DCT. They were, however, aware that most international sponsors will develop DCTs with more technology-based approaches in line with international regulatory authorities guidance.[11] [12] In these DCTs, some or all trial activities are conducted in participants' homes or by local health/service providers.

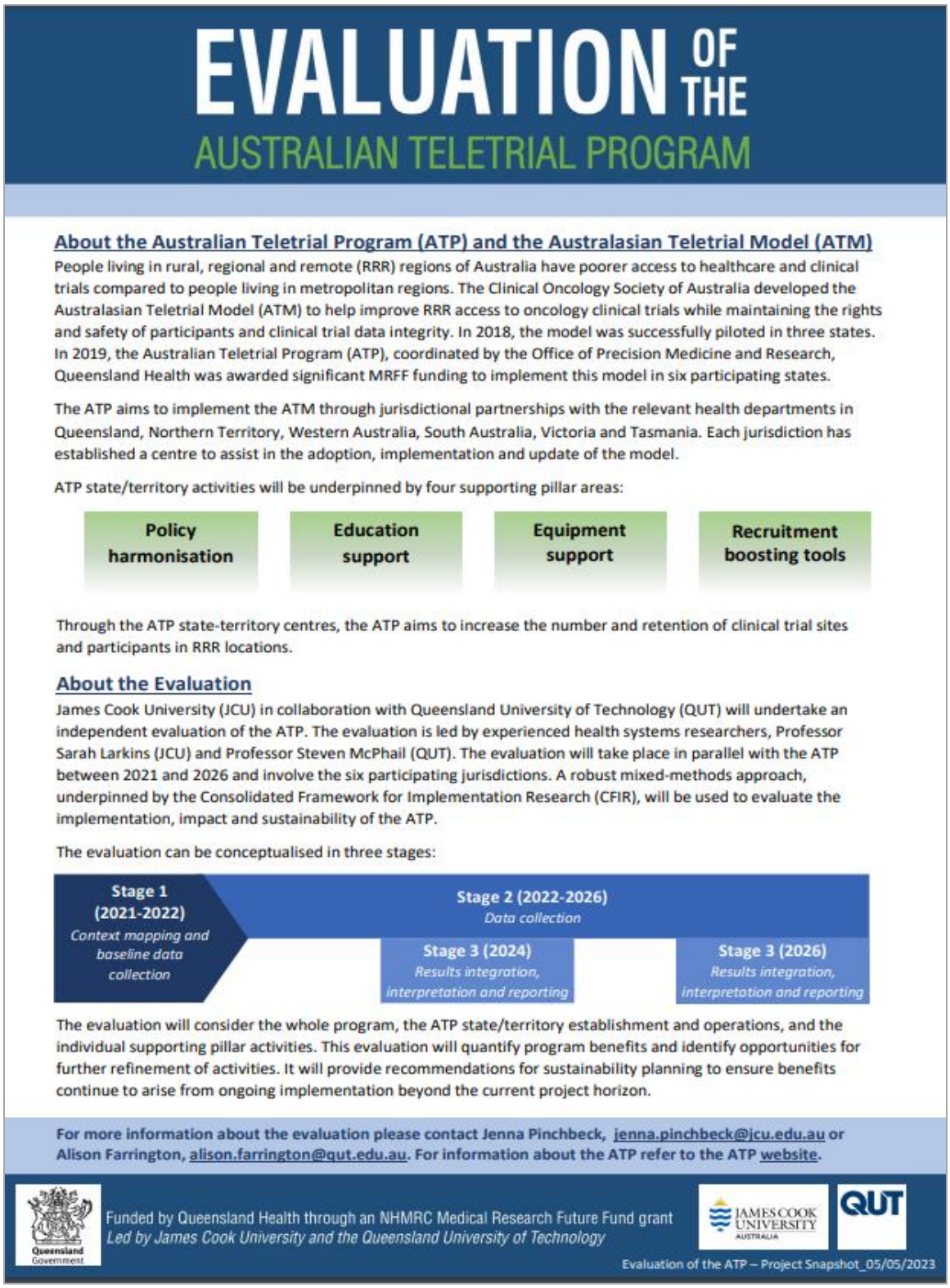
5. **Improving site visibility**: Stakeholders from both commercial and non-commercial organisations stressed the importance of ensuring the visibility of sites that have developed the capacity to conduct teletrials so that difficulty finding these sites does not delay the start-up process. There is currently no established process for identifying potential clusters. One stakeholder suggested that a list of teletrial-ready organisations could be published by each jurisdiction. This could provide details, such as site capabilities, who's who in research-active departments and the research interests of investigators.

[11] U.S. Department of Health and Human Services, Food and Drug Administration: Decentralized Clinical Trials for Drugs, Biological Products, and Devices Guidance for Industry, Investigators, and Other Stakeholders. May 23.
[12] European Medicines Agency. Recommendation paper on decentralised elements in clinical trials. December 22.

6. **Ensuring visibility of all teletrial/DCT initiatives:** Stakeholders suggested that all key resources/initiatives should be easy to find and access and ideally in a single location – *'there should be one ring to bind all of this work' (industry representative).*

The work to embed teletrials in the health system is progressing and a wide range of resources and documents are available to support their conduct. Ensuring awareness of these assets and easy access will maximise their value for the Australian clinical trial community. Regarding other types of DCT, stakeholders identified few specific resources other than the ARCS Common Terminology for DCTs White Paper. However, plans to update the National Standard Operating Procedures to incorporate other types of DCTs are being discussed.

8. Appendix 1: Evaluation of the teletrial model



EVALUATION OF THE AUSTRALIAN TELETRIAL PROGRAM

About the Australian Teletrial Program (ATP) and the Australasian Teletrial Model (ATM)

People living in rural, regional and remote (RRR) regions of Australia have poorer access to healthcare and clinical trials compared to people living in metropolitan regions. The Clinical Oncology Society of Australia developed the Australasian Teletrial Model (ATM) to help improve RRR access to oncology clinical trials while maintaining the rights and safety of participants and clinical trial data integrity. In 2018, the model was successfully piloted in three states. In 2019, the Australian Teletrial Program (ATP), coordinated by the Office of Precision Medicine and Research, Queensland Health was awarded significant MRFF funding to implement this model in six participating states.

The ATP aims to implement the ATM through jurisdictional partnerships with the relevant health departments in Queensland, Northern Territory, Western Australia, South Australia, Victoria and Tasmania. Each jurisdiction has established a centre to assist in the adoption, implementation and update of the model.

ATP state/territory activities will be underpinned by four supporting pillar areas:

- **Policy harmonisation**
- **Education support**
- **Equipment support**
- **Recruitment boosting tools**

Through the ATP state-territory centres, the ATP aims to increase the number and retention of clinical trial sites and participants in RRR locations.

About the Evaluation

James Cook University (JCU) in collaboration with Queensland University of Technology (QUT) will undertake an independent evaluation of the ATP. The evaluation is led by experienced health systems researchers, Professor Sarah Larkins (JCU) and Professor Steven McPhail (QUT). The evaluation will take place in parallel with the ATP between 2021 and 2026 and involve the six participating jurisdictions. A robust mixed-methods approach, underpinned by the Consolidated Framework for Implementation Research (CFIR), will be used to evaluate the implementation, impact and sustainability of the ATP.

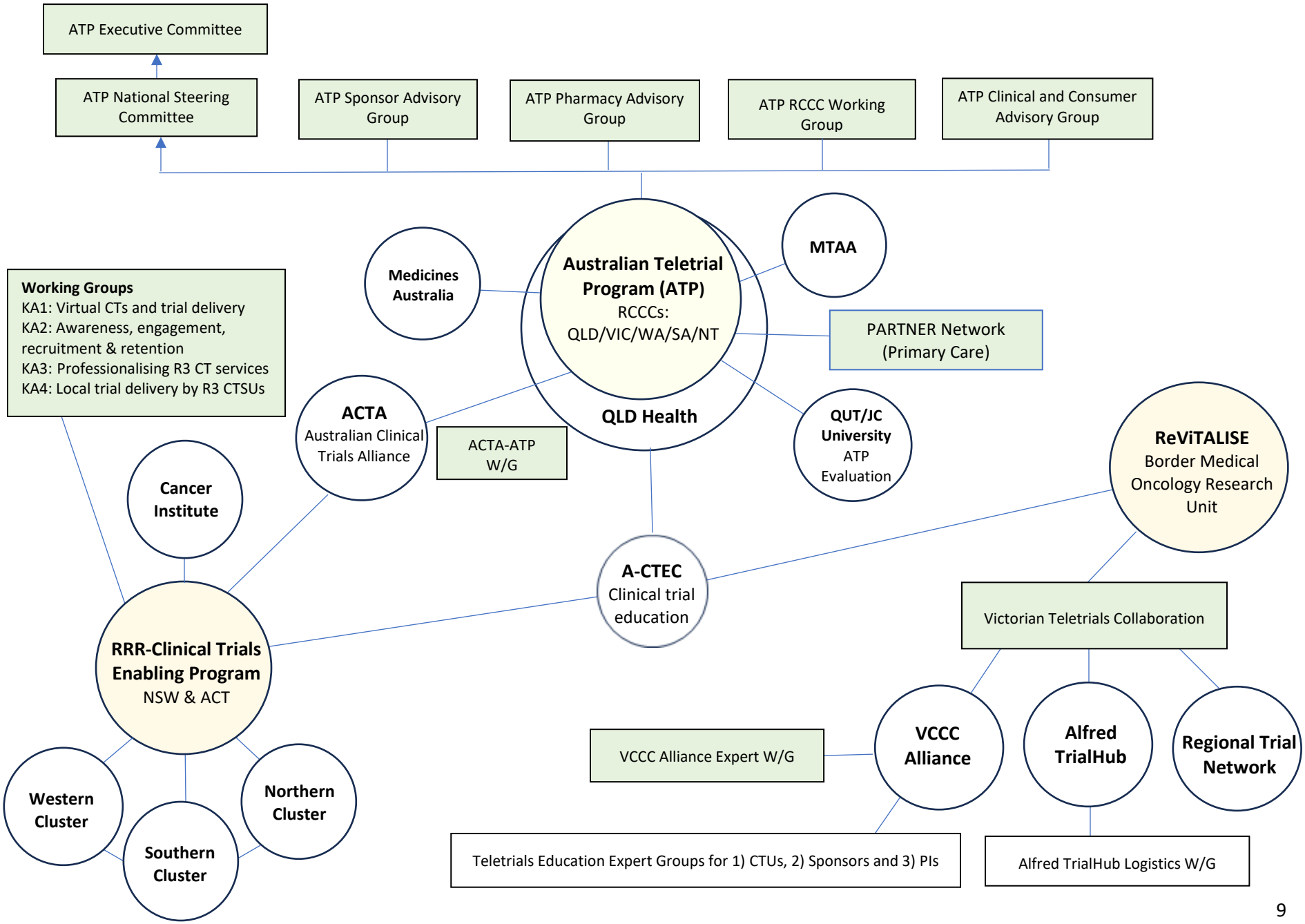
The evaluation can be conceptualised in three stages:

The evaluation will consider the whole program, the ATP state/territory establishment and operations, and the individual supporting pillar activities. This evaluation will quantify program benefits and identify opportunities for further refinement of activities. It will provide recommendations for sustainability planning to ensure benefits continue to arise from ongoing implementation beyond the current project horizon.

For more information about the evaluation please contact Jenna Pinchbeck, jenna.pinchbeck@jcu.edu.au or Alison Farrington, alison.farrington@qut.edu.au. For information about the ATP refer to the ATP website.

Queensland Government
Funded by Queensland Health through an NHMRC Medical Research Future Fund grant
Led by James Cook University and the Queensland University of Technology
JAMES COOK UNIVERSITY AUSTRALIA
QUT
Evaluation of the ATP – Project Snapshot_05/05/2023

9. Appendix 2: Overview of grant holder/stakeholder linkages



10. Appendix 3: Resource map and stakeholder suggestions for further work

Topic	Key Resource Identified	Resources under development	Stakeholder suggestions for further work
General Guidance/Q&As	ATP: Frequently Asked Questions MA: COSA/QLD Teletrials FAQs MA: PS Site Q&A Steps to establish the Tele-Trial Model MA: SS Q&A steps to establish the Tele-Trial Model COSA: Australasian Tele-Trials Model DOH: National SOPs for clinical Trials Including Teletrials ARCS: Common Terminology for DCTs (White Paper)	• **ATP:** Sponsor information pack • **ATP**: Sponsor resources • **ARCS** Common Terminology for DCTs White Paper V2 • **R3-CTEP**: Guidance documents for researchers	Guidance on how to write a teletrial component into a trial protocol. Workshop to obtain national agreement on accepted terminology for TTs and other DCTs.
Research Governance and Trial Set-Up	**ATP website** • Evaluation of a Trial as a Teletrial • Evaluation of a Site as a Satellite Site • Regional CT Coordinating Centre Workflow Check List • Primary Site Workflow Check List • Satellite Site Workflow Check List **MA website** • Checklist to establish a Tele-Trial cluster for sponsors & sites • Checklist of documents for RGO submission PS and SS • Post approval steps: teletrial amendments for sponsors & sites • PS Q&A Steps to establish the Tele-Trial Model • SS Q&A Steps to establish the Tele-Trial Model • Sponsor Q&A Steps to establish the Tele-Trial Model	**WA RCCC** • Research Governance Guide for Teletrials in WA • Trial Suitability Assessment • Satellite Site Capability Assessment	A repository typical questions or issues arising during trial set-up – How these questions were answered and issues resolved in a risk-proportionate manner. A central repository for all teletrials and DCT resources for sponsors, sites, governance staff & HRECs Standardised, industry-endorsed Site Capability Document to facilitate site identification.

Contracts, Agreements & Indemnity	• Clinical Trial Research Agreement – Tele Trials Subcontract (Primary and Satellite sites) WA Health Clinical Trial Research Agreement and Teletrial Sub-Contract (Commercial) • Data Transfer Agreement (WA Health)	• MTAA-specific subcontract • National CDA template • Investigator-Initiated Trial Research Agreement • QLD CTRA for IIT trials (head agreement and subcontract (IIT bespoke CTRA for TTs) • Updates on MTAA and MA standard research agreements. • WA Health CTRA and CTRG sub-contract • A national concord/policy relating to sponsor indemnification of Satellite Sites to be added to Compendium/SOPs	
Policies and Procedures	**DOH:** The National Teletrials Compendium (National SOPs) **COSA:** Teletrials Primary Site IMP Handling SOP	• **ATP**: Update to National Teletrials Compendium	Extension of National SOPs to other DCTs following GCP E6 R3 release
Delegation and Supervision Plans	**ATP / MA websites** • Supervision Plan – Sites without Medical Specialist • Supervision Plan – Sites with Medical Specialist • Supervision Plan – Sites with Clinical Trials Experience **VCCC** • Supervision Plan • Supervision Plan Template for sites with clinical trials experience_v5.docx • Supervision Plan Template for sites with medical specialist but no trials experience_v6.docx • Supervision Plan Template for sites without medical specialist_v5.docx **Parkville Cancer Clinical Trials Unit** • Delegation log including teletrials • Delegation of site specific tasks	• **ATP:** Supervision plan with drop-down options to define oversight arrangements.	Guidance material and education package to accompany the ATP supervision plan. A repository of exemplar supervision plans for different trial types and risk levels.

Trial Finance and Costings	• Primary Site Workload • Primary Site Workflow checklist VIC • Schedule 2 information for Subcontract June 2018 **REVITALISE** • Time and Motion Study – Teletrial start-up to quantify additional time taken.		Create a national trial costing tool for teletrials/DCTs to reduce time for contract negotiations (e.g. adapt NSW Health Clinical Trial Costing Tool)
Ethics	**QLD Health** Notification to reviewing HREC of a Satellite Site joining a teletrial Checklist	• **ATP:** Part A of the draft supervision plan (HREC Information)	Ethical considerations for HREC review of DCTs. Delineation of the role of HREC and governance office relating to the teletrial/DCT component of a trial. (NHMRC?)
Consent	**MA** • Sample PICF for Teletrial Clusters • Remote consent process in Teletrials **ATP** • Stand Alone Teletrial Participant Information Sheet and Consent Form (PICF) • Guidance for the use of optional Teletrial Wording in PICF templates. **WA RCCC** • Master Teletrial PICF (adult) • Master Teletrial PICF (child) **COSA** • Tele-Trials Remote Consent Process (Jan 2020)		Development of the CTIQ InFORMed template as an alternative PICF option Creation/collation of exemplar templates for First Nations Consent including a repository of suitable graphics.

Capacity Building and Sustainability	**ATP** Recruitment of staff (including a coms lead) and systems to support the development of regional CTUs. **REVITALISE** Workshop to establish clinician engagement in Phase 1 teletrials – confirmed feasibility of hybrid models even in higher risk trials.	**QLD RCCC:** Site Readiness Mapping Sheet to provide transparency in clinical trials and teletrials activity in local health organisations. **WA RCCC** Trial Suitability Assessment	Consolidated guidelines to bring together work/ideas on sustainability planning to achieve ATP program long-term goals. Training/mentorship to support business modelling and revenue generation for new regional CTU staff.
Diversity and Inclusion	**REVITALISE** Aboriginal and Torres Strait Islander People with Cancer - Clinical Trial Access Initiative: Consultancy Report 2022 **CALDREN MRFF Application** Application that if successful will lead to the development of a data platform: The Culturally and Linguistically Diverse Research Engagement Network		Work to facilitate the collection of broader diversity and inclusion information in trials.
Consumer Involvement for DCTs/Teletrials	**VCCC / ATP / Alfred Health TrialHub**: Consumer Brochure (teletrials) **ATP / R3-CTEP / REVITALISE** Consumer advisory groups/committees		Guidance in the specific aspects of a teletrial/DCT that consumers could inform.
Digital Solutions	**Alfred Health TrialHub** Solutions (SharePoint) for secure data transfer between PS & SS **CTIQ / Medicines Australia / MTAA/ AusBiotech** Electronic Signatures and Clinical Trial Research Agreement execution in Australia REVILATLSE: The Registry trial initiative To gather data from regional VIC populations	**WA RCCC:** Digital transformation plan	Guidance to clarify expectations for electronic signatures in consent, delegation logs and other trial records. Lower-burden solutions to enable contemporaneous documentation in both primary and satellite sites.

Awareness/ Engagement	**VCCC / ATP / Alfred Health TrialHub** • Patient webpage and Consumer-Led Brochure for Teletrial **ACTA** • Survey to understand CTN and CC awareness of teletrials and the main barriers and enablers. • Webinar on teletrial experience **Melbourne Academic Centre for Health** • First Nations The Victorian Aboriginal Health, Medical and Wellbeing Research Accord	**ATP:** Appointment of a communications specialist to develop a communications plan/initiatives.	Resource/video explaining the benefits of clinical trial participation for all stakeholders
Pharmacy	**Medicines Australia / COSA** IMP management in Tele-Trials **Alfred Health TrialHub** Clinical trials pharmacy credentialling: A train-the-trainer program to provide accreditation for pharmacists to be able to be involved in trials in their regional sites.	**Led by WA RCCC:** • National IMP transport guidelines • Pharmacy education, training and competency • Building e-prescribing models for CTs – prescribe on an e-platform. • MOU for creating a 'trial supplies hub' co located in a hospital pharmacy. • Feasibility analysis and costings for a state-wide pharmacy CTMS • Creation of pharmacy work instructions, templates for Satellite Sites and development of training on this guidance.	Document clarifying legislation/barriers to teletrials relating to IMP. e.g., cross border compounding. Mentorship process to support pharmacy staff new to trials in states/territories

Training modules and mentoring	**VCCC**: Teletrial Online Module*: Improving Patient Care Through Teletrials* (aimed at researchers) Business Skills for Clinical Trial Research Managers **A-CTEC**: Capacity Building General Clinical Trial Modules **VCCC**: Clinical trials mentoring program **Northern Australian Regional Digital Health Collaborative:** Digital Health for the Rural and Remote Health Workforce Micro-credential (Not TT/DCT specific). Accessed free (EOI form)		Leadership training/revenue generation education for new CTU managers Bespoke training/mentorship program for governance staff Trials management training (for trial managers)
Primary Care	**ATP** Engagement with the Partner GP Network using data mining algorithms to identify eligible patients from GP records. **R3-CTEP:** GP engagement through comms and advisory groups.		State/territory maps of trial-active GPs
Evaluation	**ATP** Evaluation of the teletrial program by James Cook University (JCU) and the Queensland University of Technology (QUT)		Initiative to encourage trial sponsors to collect equity and diversity data