Schedule 2 Reporting requirements

Appendix 1

Medical Research Future Fund: National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant - progress report requirements

Progress Report 1

Reporting Period: 5 October 2021 to 31 March 2022

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Commonwealth reserves the right to amend or adjust the requirements.

You must submit your report via the business.gov.au portal when it is complete.

Project Information

Grant ID: MRFRR000005
Institution/Organisation: Queensland Health
Grant Title: Australian Teletrial Program
Month and Year: 5 October 2021 – 4 October 2026
Australia New Zealand Clinical Trials Registry Trial ID (where relevant):

Project Progress

1. ***Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement or (if applicable) previous progress report, and any additional approved milestones.***

The Comments field should summarise progress at the end of the reporting period towards completion of the agreed research activities relevant to each milestone/objective, and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
Y1 – Execute Contracts	4/10/22	20/1/22	100%	Subcontracts executed with all jurisdictional partners.
Y1 – Convene Steering Committee and relevant Advisory Groups	4/10/22	31/5/22	50%	Executive Committee met 4 times during the reporting period – 21/10/21, 18/11/21, 16/12/21, 17/2/22 Members invited for the Clinical and Consumer Advisory Group and meeting date set for 8/4/22 Members invited for the Sponsors Advisory Group and meeting date set for 28/4/22

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
Y1 – Begin harmonisation activities	4/10/22	4/10/22	100%	Harmonisation activities have begun: A Teletrials Toolkit has been developed for Queensland and implemented across Queensland sites. This has been shared across all jurisdictions to standardise processes. A national standalone Patient Information Consent Form (PICF) for teletrials was drafted and provided to the National Mutual Acceptance (NMA) group for endorsement. Queensland has engaged broadly on the teletrials model across the Queensland Health system, including with the Chairs of all certified Human Research Ethics Committees (HRECS), HREC Administrators, Research Governance Officers, and Clinical Research Coordinators. Victoria government (Department of Jobs, Precincts and Regions) Coordinating Office for Clinical Trial Research (COCTR) leads a statewide framework for regulatory approval of clinical trials and research. COCTR leads national initiatives regarding a new national SSA form in anticipation of a national IT platform called the One Stop Shop. Victoria government provide advice to rural and regional health services that conduct clinical trials to address the Australian Commission for Safety and Quality in Health Care (ACSQHC) and support research to commence in year 2. All partner jurisdictions are represented on the NMA (expansion) Advisory Committee to further streamline single ethics review.
Y1 – Establish the national project office	4/10/22	10/1/22	100%	National Project Office team recruited and commenced

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
Y1 – Establish RCCCs in QLD, Vic/TAS, WA, SA/NT	4/10/22	4/10/22	80%	Queensland recruited all RCCC staff by 31/1/22. South Australia recruited RCCC Manager and Clinical Director. Northern Territory has created two positions that will lead the implementation of the Program in NT. Western Australian, Victoria, Northern Territory and Tasmania currently recruiting. In addition, governance mechanisms have begun to be put in place across all states. For example, in Tasmania, teletrials have been placed under the governance of the Research and Innovation Subcommittee. Tasmania is also a member of the Victorian CTRSS-ATP Project Advisory Group and the Industry Engagement Group. Regular meetings commenced between the South Australia team and the Northern Territory team.
Y1 – Begin National Education and Promotion Program delivery	4/10/22	4/10/22	100%	Education and promotion activities have begun: Each jurisdiction partner is planning education and training offerings. National promotion program to be informed by Advisory Group discussions.
Y1 – Local context mapping	4/10/22	4/10/22	0%	During the reporting period, the evaluation teams at QUT and James Cook University finetuned implementation plan. Commencement of the evaluation component scheduled for 1/4/22 in line with supplier contract
Y1 – Begin Teletrial Support Program	4/10/22	4/10/22	50%	Draft guidelines for the Teletrial Support Program were circulated and discussed by Executive Committee. Implementation plans ongoing and engagement has commenced with stakeholder groups with expected commencement of first round by 4/10/22

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
Y1 – Finalise and socialise evaluation framework with all stakeholders	4/10/22	4/10/22	0%	During the reporting period, the evaluation teams at QUT and James Cook University finetuned implementation plan. Commencement of the evaluation component scheduled for 1/4/22 in line with supplier contract
Y2 – Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities	4/10/23	4/10/23	0%	n/a for this reporting period
Y2 – RCCCs deliver support in each jurisdiction to embed teletrials in rural, regional and remote locations	4/10/23	4/10/23	0%	n/a for this reporting period
Y2 - Evaluation program continues	4/10/23	4/10/23	0%	n/a for this reporting period
Y3 – Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities	4/10/24	4/10/24	0%	n/a for this reporting period
Y3 – Interim analysis of evaluation study	4/10/24	4/10/24	0%	n/a for this reporting period
Y3 – Strategic targeting of global biopharma to attract commercial clinical trials to teletrial sites	4/10/24	4/10/24	0%	n/a for this reporting period

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
Y4 – Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities	4/10/25	4/10/25	0%	n/a for this reporting period
Y4 – Establish RCCCs in TAS and NT	4/10/25	4/10/25	0%	n/a for this reporting period
Y5 – finalisation of data collection for evaluation	4/10/26	4/10/26	0%	n/a for this reporting period
Y5 – Finalise delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities	4/10/26	4/10/26	0%	n/a for this reporting period
Y5 – Final impact analysis	4/10/26	4/10/26	0%	n/a for this reporting period

2. ***Describe progress towards completion of any additional research activities undertaken during the reporting period that are not captured in the table above.***

At this early stage of the program, there have not been additional research activities undertaken during the reporting period that have not been captured in the table above.

3. ***Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during the reporting period.***

There are no significant risks to the completion of milestone/objectives during the reporting period.

4. ***Complete the following table for all variation requests approved, submitted (pending approval) or in draft (pending submission) for this grant to date****.*

Description of Variation	Current Status (Approved/Submitted/In Draft)
n/a	**n/a**

5. ***Provide a statement on your <u>overall</u> progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay.***

   At this stage, the Research Activity is on track to be completed by 4 October 2026.

6. ***Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes.***

You should include information about your proposed approach and any key enablers or barriers to implementation.

At this early stage of the Program and during this reporting period, we have been in discussions with research teams at James Cook University and QUT who will lead the evaluation and impact component of the Program. These discussions have progressed the proposed activities for the evaluation and impact component with a view for this to commence on 1 April 2022 (the next reporting period).This work has an implementation science focus to address contextual barriers and facilitators to enhance the teletrials innovation uptake.

7. ***Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.***

Question 7 applies to grants where the funded organisation is responsible for supporting research projects led by other organisations.

Partner Organisation	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided	Start Date of Project	% Project Complete
n/a	n/a	n/a	n/a	n/a	n/a	n/a

Project Expenditure

8. ***Provide details of all expenditure incurred during the reporting period.***

Expenditure should be divided into the same categories as the budget in your grant agreement. The table should indicate budgeted and actual expenditure for the current reporting period. The Comments field should justify any differences between the budgeted and actual expenditure.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or contact us if you have any questions about expenditure.

Expenditure Item	Budget (AUD)	Actual (AUD)	Comments
Minor Capital Works	$0	$0	
Materials for Construction	$0	$0	
Equipment	$0	$0	
Labour including on-costs	s47G		

Contract	$0	$0	
Travel and Overseas	$0	$0	
Other eligible expenditure	s47G		

9. ***Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, explain why.***

   Expenditure incurred during the reporting period is eligible expenditure in accordance with the grant opportunity guidelines.

10. ***Provide details of the estimated expenditure for the next reporting period.***

Expenditure Item	Budget (AUD)
Minor Capital Works	$0
Materials for Construction	$0
Equipment	$0
Labour including on-costs	s47G
Contract	$0
Travel and Overseas	$0
Other eligible expenditure	s47G

11. ***Provide details of any partner contributions received during the reporting period.***

The Comments field should indicate whether each contribution has been made as expected. If not, describe the impact of any delays or changes on the delivery of the Research Activity.

Name of Partner	Type of Contribution	Value of Contribution	Comments
n/a	**n/a**	**n/a**	**n/a**

Project Evaluation

The MRFF Monitoring, Evaluation and Learning Strategy was published in November 2020.

Question 12 must be completed if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines.

12. ***Complete the following table for each outcome or result against which your contribution to the Measures of Success for the MRFF is being evaluated, as specified in the Measures of Success statement provided with your application.***

For each Measure of Success, the table should:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

You may list several outcomes/results against a single Measure of Success.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress
n/a	**n/a**	**n/a**	**n/a**

13. ***Provide a statement on the most important finding or outcome from your research during the reporting period, including any new or unexpected findings or outcomes.***

Noting that your response may be used in public communications about the MRFF, please indicate whether any of the information you provide is commercial in confidence.

It is too early in the program to report yet but with the establishment of an implementation science evaluation framework, we will be in a position to answer this in future progress reports.

14. ***Describe any enablers or barriers to the translation or implementation of your research that could be used to inform future MRFF funding opportunities****.*

It is too early in the program to report yet but with the establishment of an implementation science evaluation framework, we will be in a position to answer this in future progress reports.

Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.

you are aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Appendix 2

Medical Research Future Fund National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote (RRR) Clinical Trial Enabling Infrastructure grant opportunity: monitoring indicators progress report

When you complete your progress report in the portal, you will be required to attach this document in Word or pdf format. The Commonwealth reserves the right to amend or adjust the requirements.

Measure One: Increased focus of research on areas of unmet need

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies areas of unmet need and facilitates more research into these areas
- leads to new health treatments, drugs, interventions, devices and diagnostics
- embeds such approaches into clinical practice

What approaches have been employed to ensure key areas of unmet need (as identified by the Grantee) are being met?
The Australasian Teletrial Model was successfully piloted in expanding oncology clinical trials to RRR patients prior to the grant being awarded to Queensland Health for the Australian Teletrial Program. One of the priorities for this Program, and an area of unmet need, is to **broaden the teletrials model to all therapeutic areas**. This has begun already in the following ways: • Barwon Health in Victoria setting up and conducting trials in the South Western Victorian region in Gastroenterology, Urology, Orthopaedics, Ophthalmology, Public Health that include telehealth and remote components. While only in the very initial stages of this project implementation there is considerable scope for expansion of this program in the future. Barwon Health is also actively canvasing for trials in; Dementia and aged care, Dermatology, ICU, and Anaesthetics. Furthermore, Barwon Health is working on collaborative efforts to establish phase 1 healthy volunteer studies in the Geelong Region. All these approaches will ensure areas of unmet need are identified and facilitated. While the COVID-19 pandemic has delayed implementation until quite recently there is now also an overarching, consistent approach proposed for the conduct of trials at Barwon Health that will standardise and embed trials into the core business of the health service. The existing strategic research plan for Barwon Health puts clinical trials with a remote and telehealth capacity as a central pillar in the strategy. • Bendigo Health is focussing on escalating research into endocrinology/renal health, paediatrics and geriatrics under this Program. • Grampians Health has identified the health challenges for RRR communities include increased rates of hospital admission for cancer, cardiovascular disease, chronic obstructive pulmonary disease and diabetes. Improvement in these therapeutic areas is of interest at Grampians Health under the Program. • Northeast Health Wangaratta is responding to identified opportunities for trials in delirium and stroke models of care. This is informed by Health Round Table Data and Health Service development. • The Queensland RCCC is planning to explore enrolling clinical trials staff in ISO 14155:2020

- Clinical investigation of medical devices for human subjects — Good clinical practice (GCP) training to enable the Teletrial model to advance into devices and procedures to allow increased access for RRR patients.

The Program has also identified an unmet need of **engagement with Aboriginal and Torres Strait Islander communities**. To address this the following activity has commenced:

- The Bendigo Health team under this Program are facilitating discussions between key members of Alfred's TrialHub and Renal Medicine department and relevant Bendigo Health clinicians to adopt and expand upon the Alfred's established renal clinical trials program with a focus on building engagement with Aboriginal stakeholders. This work is underpinned by the strong partnership that has been developed between the Alfred TrialHub and Bendigo Health's oncology program that has led to growth in both the breadth of the clinical trial program and the local clinical trials workforce.

Clinician and clinical trials team readiness for clinical trials and teletrials across each state is also an area of unmet need. Under the teletrial model and its implementation in this Program, there are staff in RRR hospitals, health services and primary care settings that may not have been involved in a clinical trial or teletrial before. Some activities that have commenced to ensure that clinicians and clinical teams are aware and appropriately trained are:

- Establishment of key positions across each state to support clinical teams to offer and deliver clinical trials closer to home
- Commencement of engagement with stakeholders in each state to understand the level of awareness of clinical trials and teletrials. For example:
    - Northeast Health Wangaratta presentation to Pain Management Reference Group (31/3/22)
    - A Queensland Teletrial Steering Committee has been established and establishment of a Clinical trials/teletrials as a standing agenda item at the clinical network steering committee meetings (agenda items include - suitable trials, activity, barriers and enablers)
    - Queensland RCCC team has engaged with clinical networks, Directors of Research across all sixteen Hospital and Health Services. Stakeholder engagement activities have commenced through the NT Health Research Committee which includes members from across the Top End region of the Northern Territory. A Northern Territory Advisory Committee is currently being established which will include consumers and representatives from primary health care and regional health services (Katherine, Gove, Alice Springs and Tennant Creek).
- Liaison with sponsors to promote the Program, the teletrials model, and sites such as Townsville, Mackay, Goulburn Valley Health discussing specific clinical trials and teletrials for RRR patients.
- Development of training and resources for clinical trial teams in each state, including training on research ethics and governance applications.
- Linking Clinical Trial Coordinators across states to collaborate under this Program.
-

Access to clinical trials for RRR patients is another area of unmet need. The challenges are site capability, variability to conduct clinical trials due to resourcing, education, and lack of support. Prior to this Program, there has also been a lack of funding to provide couriers to deliver drugs to smaller RRR sites. The implementation of this Program (including the establishment of the RCCC) and the Australasian Teletrial Model addresses the situation of smaller RRR sites being daunted by taking on clinical trials. An example of how this is being addressed by the Program is the establishment of new satellite sites in RRR areas such as Sunshine Coast (MMM1), Rockhampton (MMM2), Darling Downs (MMM5), Mackay (MMM2), and Winton

(MMM7). All sites and coordinators have been provided with clinical trial and teletrial training including GCP and an RCCC education program. QRCCC is embedding TT into clinical practice by engagement of clinical networks, Directors of Research and HHSs.

Measure Two: More Australians access clinical trials

This measure considers the extent to which outcomes of MRFF-funded research:

- create better opportunities for Australians to access clinical trials by funding activities that support research to progress to the clinical trial stage, and directly supporting additional clinical trial activity
- builds Australia's clinical trial capability and leadership at the national and international level

Please complete the tables on the following pages to record:

- the number of new or improved clinical trial **sites** (TABLE 1),
- the number of new clinical trial **participants** (TABLE 2), and
- the number of new **clinical trials** (TABLE 3);

directly linked to your project activities.

TABLE 1: Number of new or improved[1] clinical trial sites by state or territory and MMM Code

(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

Note: enter 'N/A' in the respective State or Territory field if it does not apply to your project.

State/ Territory		**Target** for achievement by Project Completion	**Actual number of new or improved sites (cumulative total, project to date)**							
			MM1	**MM2**	**MM3**	**MM4**	**MM5**	**MM6**	**MM7**	**Total**
ACT	New Sites									
	Improved Sites									
NSW	New Sites									
	Improved Sites									
NT	New Sites	32	0	0	0	0	0	0	0	**0**
	Improved Sites	11	0	0	0	0	0	0	0	**0**
QLD	New Sites	851	1	10	0	0	1	0	0	**12**
	Improved Sites	283	3	10	0	0	0	0	0	**13**
SA	New Sites	332	0	0	0	0	0	0	0	**0**
	Improved Sites	111	0	0	0	0	0	0	0	**0**
TAS	New Sites	32	0	0	0	0	0	0	0	**0**
	Improved Sites	11	0	0	0	0	0	0	0	**0**
VIC	New Sites	972	3	3	1	0	0	0	0	**7**
	Improved Sites	324	0	5	0	0	0	0	0	**5**
WA	New Sites	211	0	0	0	0	0	0	0	**0**
	Improved Sites	70	0	0	0	0	0	0	0	**0**
Total	**New Sites**	**2430**	**4**	**13**	**1**	**0**	**1**	**0**	**0**	**19**
	Improved Sites	**810**	**3**	**15**	**0**	**0**	**0**	**0**	**0**	**18**

[1]clinical trial sites with improved capacity (i.e. increased trials) and/or capability (i.e. new types of trials)

TABLE 2: Number of clinical trial participants by state or territory and MMM Code
(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

State/ Territory	**Target** for achievement by Project Completion	Actual number of new clinical trial participants (cumulative total, project to date)							
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
ACT									
NSW									
NT	68	0	0	0	0	0	0	0	0
QLD	1750	0	s47F						14
SA	682	0	0	0	0	0	0	0	0
TAS	68	0	0	0	0	0	0	0	0
VIC	2000	0	s47F						51
WA	432	0	0	0	0	0	0	0	0
Total	**5000**	**0**	s47F						**65**

TABLE 3: Number of new clinical trials by state or territory and MMM Code
(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

State/ Territory	**Target** for achievement by project completion	**Actual number of new clinical trials (cumulative total, project to date)**							
		MM1	**MM2**	**MM3**	**MM4**	**MM5**	**MM6**	**MM7**	**Total**
ACT									
NSW									
NT	3	0	0	0	0	0	0	0	0
QLD	71	s47F		0	0	0	0	0	13
SA	28	0	0	0	0	0	0	0	0
TAS	3	0	0	0	0	0	0	0	0
VIC	81	0	s47F		0	0	0	0	34
WA	17	0	0	0	0	0	0	0	0
Total	**203**	s47F			**0**	**0**	**0**	**0**	**47**

For new clinical trials generated by your project activities, please provide the number of clinical trials by:

- Demographics of population (e.g. ATSI, CALD)
- Age group of target population (i.e. youth/paediatric; adult; older people)
- Disease type (e.g. oncology)
- Sponsor type (i.e. investigator initiated, commercial, etc.)

You may either provide the information below, or attach it to this report. If you attach a document, please provide the name of the document below.

Victoria

	Barwon Health	Bendigo Health	Northeast Wangaratta	Grampians Health	Goulburn Valley Health	Total
Number of New Trials	s47F		**0**	**0**	s47F	**33**
Age Group						
Paediatric			0	0		s47F
Adult			0	0		31
Disease Types						
Vaccines			0	0		s47F
Endocronology			0	0		
Oncology			0	0		13
Mental Health			0	0		s47F
Public Health			0	0		
Gastroenterology			0	0		
Urology			0	0		
Orthpaedics			0	0		
Pain Management			0	0		
Allied Health			0	0		
Addition Medicine			0	0		
Sponsor Type						
Commercial			0	0		23
Investigator Initiated			0	0		8
Universities			0	0		s47F

Queensland

	Total
Number of New Trials	
Age Group	
Paediatric	0

Adult	14
Disease Types	
Haematology	s47F
Oncology	
Renal	
Neurology	
Sponsor Type	
Commercial	6
Investigator Initiated	8
Universities	0

ATSI, CALD patients- MMM1 to MMM 2 new clinical trials are onboarding satellite sites whose reach for this reporting period will go to MMM 2-7 patients where 6-12% of the populations are ATSI. One patient enrolled on trial at a MMM2 site is from MMM7 where 69 % of the population are ATSI.

Age group of target population is over 18 years for the majority of trials, 25 years and over for 1 trial with no upper age limit for majority of trials. One Haematology trial has upper age limit of 70 years and one trial is 18-55 years inclusive (Renal).

Disease type

Haematology, Medical Oncology including rare cancers x 2 trials, Renal and Neurology

Sponsor type by disease

- Haematology x1 commercially sponsored, x 3 collaborative group

Medical oncology- x 4 trials inc 1 rare cancer commercially sponsored and 1 x collaborative group

Renal- 1 x commercially sponsored, 1 x collaborative group

Neurology- 1 x collaborative group

Describe the progress towards target recruitment numbers and the retention rate for clinical trials.

The following activities and plans have been identified for progressing towards target recruitment numbers and the retention rate for clinical trials:

- Barwon Health are projecting to recruit 420 participants over the coming 12 months on new trials with a telehealth component. Given normal circumstances and a dedicated experienced clinical trials team they expect an 80% retention rate in these trials.
- Northeast Health Wangaratta conducted 6 feasibility assessments and accepted 4 clinical trials which are in stages of start up.
- Grampians Health has been focused on staff training, SOP implementation and participant recruitment.
- Goulburn Valley Health has 4 new trials (across oncology and addition medicine) with a total of 39 expected participants and s47F ecruited for this reporting period.

- Queensland trial sites are being supported by QRCCC with an education program and are being made aware of patient enrolment and retention strategies and the partnership with the patient on trial to coordinate the additional trial activity requirements. Strategies include coordination of visits, trial information via PICF, responsiveness to patient queries, assistance with booking appointments, escorting to pathology, and imaging for specific trial requirements. Follow up via phone to ask for feedback as to how they are going and any issues arising. Being available for the trial patient as a CRC for any queries that arise. Passing on information to PIs and coordination with trial sponsors.

	Target	Actual to date Progress against target
How many staff have been trained on clinical trial related methodology?	5000	**TOTAL - 144** Victoria – 90 Queensland - 54 Tasmania – 0 South Australia – 0 Western Australia – 0 Northern Territory - 0

Measure Three: New health technologies are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health technologies, including precision medicine
- measures the awareness of new health technologies among clinicians and patients
- embeds new health technologies into clinical practice

Where applicable, are new and emerging health technologies[2] being embraced by clinicians and patients involved in the clinical trials funded through this project? If so, how? Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
Clinical trials will test novel medications, vaccines and devices. The following examples show new and emerging health technologies being embraced by clinicians and patients in trials associated with this Program: • Clinicians across Bendigo Health have begun to embrace new and emerging technologies, particularly telehealth and remote-monitoring devices, in the delivery of health care to patients. The *Online and telehealth management of rotator cuff tendinopathy: a randomised controlled trial* was authorised to begin at Bendigo Health in February 2022. This clinical trial utilises new internet-based technologies to deliver 'telerehabilitation' to improve patient access to care.

- Northeast Health Wangaratta is activating a clinical trial that will use wearable devices (activity watch and sleep monitoring headband) and is assessing a clinical trial that will enable participants to complete their "patient reported outcomes" directly into a database from home to limit clinic visits. This trial is also assessing the 'non-inferiority' of a new test to determine the need for chemotherapy in breast cancer. This technology could have huge impacts both to the patient group and the economics of early breast cancer treatment.
- One of the trials in which Goulburn Valley Health became a new satellite site during this reporting period is investigating the application of a 'medicine' following completion of therapies with a curative intent. This trial will compare the effect of the 'medicine' versus placebo on Event-free Survival (EFS) of participants. The findings of this trial will potentially lead to a new health technology being embraced by clinicians and patients.
- In Queensland the RCCC s47F . Several scenarios were explored in order for the patient to be see closer to home under the teletrial model. The conclusion of this was that the Queensland RCCC can now embed into clinical practice the understanding of the Scope of Clinical Practice and credentialling of Medical Officers when using Telehealth. This understanding is now being included in education sessions to advise sites how to allow patients to be treated closer to home while still maintaining protocol adherence and patient safety.

While trial activity has not commenced in Western Australian during this reporting period, the Western Australian Country Health Service (one of the partners in the Program) is investing in new research, led by Curtin University, to look at the future of telehealth technology. This research is being codesigned with consumers, technology providers and clinicians to examine the best next investment in this space. This research will also inform the work of the Western Australian in implementing the Australian Teletrial Program.

[2]A health technology is defined by the World Health Organisation as "the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives."

Measure Four: New health interventions are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health interventions
- measures the awareness of new health interventions among clinicians and patients
- embeds new health interventions into clinical practice

Where applicable, how are the health interventions[3] changing health practice amongst medical practitioners involved in the clinical trials? Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
The Queensland RCCC is supporting a trial where s47F . The IMP (drug) needed to be dispensed to the patient and due to the fact that the satellite site had not yet been authorised, a courier was contracted using the Program funding (via the equipment and logistics component) and the IMP was delivered to the patient. The patient did not have to travel to s47F under this scenario.

[3] A health intervention is defined by the World Health Organisation as an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions.

Measure Five: Research community has greater capacity and capability to undertake translational research

This measure considers the extent to which outcomes of MRFF-funded research:

- increases researcher capacity
- improves the awareness of translational research within the research community
- supports capability development to undertake translational research

	Full Time	Part Time	Casual
Target number of positions to be created	**TOTAL - 46** Victoria - 17 Queensland - 10 Tasmania - 5 South Australia - 2 Northern Territory – 5 Western Australia – 7	**TOTAL - 44** Victoria – 16 Queensland - 21 South Australia - 2 Northern Territory – 4 Western Australia - 1	
Actual number of new positions created	**TOTAL – 22** Victoria – 10 Queensland - 5 Tasmania - 5 Northern Territory - 2	**TOTAL - 25** Victoria – 9 Queensland - 16	

Please provide details on the number and nature of the positions created. This may include, but is not limited to, study coordinators, research nurses, pharmacists, clinicians, and researchers.
Victoria **RCCC VIC** • Project Officer • Program Coordinator **Organisation 1** • 4 Research Assistant positions – primarily in mental health • 4 Study coordinator positions – In gastroenterology, mental health and public health.

Organisation 2
• 1 x full time equivalent clinical trial coordinator
• 1 x full time equivalent regional trial coordinator
• x part time research nurses

Organisation 3
• Clinical Trial Coordinator Position – Nurse 07 March 2022
• Clinical Trial Assistant
• Regional Trial Coordinator appointment-pending
• Recruitment Medical Officer part time role

Organisation 4
• Clinical Trial Project Officer
• Clinical Trial Coordinator appointment-pending

Organisation 5
• 1 x 1FTE Clinical Trial Coordinator
• 1 x part time Clinical Trial Coordinator

Queensland

Teletrial Coordinators (Clinical Research Coordinators) x 16 across Queensland Hospital and Health Services (part time)

Teletrial Liaison Coordinating Officer x 1 (full time)

Cluster Start up Specialist x 1 (full time)

Nurse educators x 2 (part time)

Assistant Director of Nursing/RCCC Director x 1 (full time)

Administration Officer x 1 (full time)

Clinical Director x 1 (part time)

Australian Teletrial Program national office team

Director

Senior Program Manager

Project Officer

Administrative Officer

Tasmania

Project Coordinator

Research Governance Officer

Teletrial Project Officer

Clinical Trials Liaison Officer

ICT System Program Officer

South Australia

2 x Clinical Research Coordinators

Clinical Trials Pharmacy Support (situated in RRR areas of SA)

Northern Territory

Nurse Management Coordinator – Teletrials

Teletrial Program Support Officer

Western Australia

Project Lead – Teletrials

Clinical Teletrials Manager

Clinical Teletrials Coordinator

Research Officer

Research Nurse

Senior Business Officer

Senior Pharmacist

Clinical Lead

For any research roles created by your project, please detail the career stage(s) of the researcher(s) (early, mid or established).

Victoria

Barwon Health
The staff employed thus far are predominantly early career researchers with 1 established coordinator and 1 mid-career coordinator

Bendigo Health
Mid and established

Queensland

Clinical Research Coordinators x 6 at various HHS across QLD – Early x 4 and Mid x 2

Teletrial Liaison Coordinating Officer x 1 - Established

Cluster Start up Specialist x 1 - Mid

Nurse educators x 2 – Established x 1, Mid x 1

ADON x 1 - Established

Administration Officer x 1 - Mid

Clinical Director x 1 - Established

Australian Teletrial Program national office team

Director (Established)

Senior Program Manager (Established)

Project Officer (Established)

Administrative Officer (Established)

Tasmania

Project Coordinator - Established

Research Governance Officer - Established

Teletrial Project Officer - Early

Clinical Trials Liaison Officer - Early

ICT System Program Officer - Early

Provide a catalogue of new infrastructure developed by the project to date and use of infrastructure by researchers in a collaborative manner.

A range of new infrastructure has been developed by the Program including:

- A teletrials toolkit that was developed by the Queensland team and shared across all partner jurisdictions. It is publicly available at: https://www.health.qld.gov.au/hiiro/html/teletrials
- In Victoria a Clinical Trials Research Support Service (CTRSS) toolkit has been created including
    - Site Profile form template
    - Site Feasibility form template
    - Site Specific schedule of fees for trials template
    - CV template
    - CTRSS position description template
- A database is being developed by the Australian Teletrial Program team using REDCap software to collect data to report on teletrial and clinical trial activity under this Program.
- Site specific standard operating procedures (SOPS) are being developed by RRR clinical trial sites to support delivery of clinical trials under this Program. These site specific SOPS are aligned with the national SOPS for clinical trials and teletrials.
- The Queensland RCCC team has developed introduction resources on teletrials for new sponsors, new sites, new clinical research coordinators, and new Principal Investigators. Under this Program, the Queensland RCCC is also building a community of practice for new Teletrial Coordinators in each Hospital and Health Service including fortnightly meetings and education sessions. There have also been shared information sessions on teletrials and clinical trials with universities, new Principal Investigators, Sponsors, and Research Governance Officers.
- In Western Australia, a scoping work has commenced for a whole of health service electronic clinical trial management system, potential digital prescribing solutions and a footprint for managing clinical drug trials.

Please provide the total number of conference presentations, publications, citations, mentions in social media, workshops, etc. generated to date in relation to the project.
Publications o Western Australian Health Translation Network, March 2022, "TeleTrial framework brings clinical trials closer to home for country patients". https://wahtn.org/blog/2022/03/30/8342/ o Sabe Sabesan et al, January 2022, "Teletrials, the new norm? Expert recommendations for teletrials into the future: Findings from the Clinical Oncology Society of Australian Clinical Trial Research Professionals Group Workshop", Asia-Pacific Journal of Clinical Oncology https://doi.org/10.1111/ajco.13737 o Prof Jon Emery and Dr Kristi Milley, March 2022, "Bringing clinical trials to regional patients", Pursuit https://pursuit.unimelb.edu.au/articles/bringing-clinical-trials-to-regional-patients o Northeast Health Wangaratta, January 2022, "Leading the way with clinical trials". https://www.northeasthealth.org.au/2022/leading-the-way-with-clinical-trials/

Measure Six: Health professionals adopt best practices faster

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or establishes best practices
- assesses the speed at which best practices are communicated to clinicians and health service administrators
- identifies how best practices are understood and adopted

Where applicable, how well were the best practices[4] understood and adopted and how was/will this (be) evaluated? Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
The following examples show how well best practices are understood and adopted: • Barwon Health has begun the process of standardised budgeting, and SOPs clinical trials practice including under the Program. The overarching supervision as required by the National Clinical Trials Governance Framework process will implemented by Barwon Health over the next year. • Queensland Health has developed a Clinical Trials Action Plan that includes the delivery of clinical trials closer to home as a key priority. This Action Plan broadly addresses engagement and interaction with industry, development of crucial clinical personnel, standardisation of governance processes, and reporting. Northeast Health Wangaratta includes clinical trial questions in the organisation's Best Practice Clinical Learning Environment (BPCLE) Survey to gauge levels of understanding of staff throughout the organisation and compare each year as the service expands. • Good Clinical Practice (GCP) is best practice. An example of the benefits of this in RRR sites can be seen in Goulburn Valley Health. Upon completing training, a senior nurse was interested in becoming involved in clinical trials at Goulburn Valley Health. The nurse was able to be involved in a medical clinical trial with an understanding of the running and proper conduct for clinical trials that was absent before GCP certification.

- The Queensland RCCC facilitates pre and post evaluations of each education session, as well as for the external providers delivering GCP training.

[4] WHO defines Best Practices as “exemplary public health practices that have achieved results, and which need to be scaled up so as to benefit more people”.

Measure Seven: The community engages with and adopts new technologies and treatments

This measure considers the extent to which outcomes of MRFF-funded research:

- involves the community in prioritising, designing and conducting research
- promotes community awareness of new technologies and treatments, and their benefits
- promotes community support for new technologies and treatments

How were the community members and consumers engaged in prioritising, designing and conducting research through means such as public consultations?
The Program governance includes two advisory groups - the Clinical and Consumers Advisory Group and the Sponsor Advisory Group. There are two consumers who are confirmed members of the Clinical and Consumer Advisory Group: S47F

S47F

Partner jurisdictions under this Program are exploring the establishment of statewide teletrials committees with membership that includes consumers. For instance a Northern Territory Advisory Committee is currently being establish which will include consumers and representatives from primary health care and regional health services in Katherine, Gove, Alice Springs and Tennant Creek.

Barwon Health has engaged community and received input in the design and conduct of seven clinical trials for this reporting period. Two of the trials had disease specific interest groups advising on trials design, one has established an advisory group made up of consumers to provide feedback on trials conduct and four have enabled feedback from consumers via social media. One of the trials was completely funded by a community group with input into every stage of the research project.

The Queensland ATP Steering committee has consumer membership.

Comments

You are welcome to provide any further feedback relating to the monitoring indicators or evaluation outcomes for your project to date.

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Progress Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through progress reports. For varying your grant and grant agreement please refer to the MRFF Grant Variation Policy.

Please ensure that you are using the latest version of the Progress Report template. You must submit your report on the business.gov.au portal. You can enter the required information in stages and submit when it is complete.

Project Information

Grant ID	MRFRR000005
Grant Opportunity Name	Medical Research Future fund – National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant
Administering Organisation	The State of Queensland acting through Queensland Health
Chief Investigator A / Project Lead	Kaye Hewson
Grant Title	Australian Teletrial Program
Grant Agreement Start and End Dates	[From 19/09/2021] - [To 12/02/2027]
Research Activity Start and End Dates	[From 05/10/2021] - [To 04/10/2026]
Australia New Zealand Clinical Trials Registry Trial ID (where relevant)	
Reporting Period	[From 01/04/2022] - [To 30/09/2022]
If the Commonwealth Commercialisation Clauses apply to this project, have there been any changes to the Commercialisation Plan?	N/A
Do you plan to execute any new agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	No

Project Progress

1. *Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement.*

The comments field should clearly summarise progress at the end of this reporting period towards completion of the agreed research activities relevant to each milestone/objective and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Y1 – Convene Steering Committee and relevant Advisory Groups	01/04/22	30/09/22	100%

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Comments: (A) Executive Committee: Met Six times during this reporting period (14/04/22, 12/05/22, 09/06/22, 07/07/22, 04/08/22 and 08/09/22). A new governance structure has been proposed which will see Executive Committee membership elevated to a higher *decision making and policy execution* position (e.g.: Executive Director or equivalent). This will enable smoother progression of the program. Executive Committee meetings will be held twice a year. (B) The current Executive Committee will be renamed to 'Working Group' and will continue to facilitate and monitor the Program's activities and progress against objectives, including the progress of deliverables. (C) National Steering Committee: Met twice during this reporting period (09/05/2022 and 25/07/22). The National Steering Committee guides and directs the activities of the RCCCs and partner jurisdictions to ensure alignment with the four pillars of the Program. (D) Clinical and Consumer Advisory Group: Met twice during this reporting period (08/04/2022 and 05/08/22). The Clinical and Consumer Advisory group provides advice to the National Steering Committee on the delivery of clinical trials closer to home from a clinical, consumer and community perspective. (E) Sponsor Advisory Group: Met once during this reporting period (28/04/2022). The Sponsors Advisory Group represents a broad spectrum of clinical trial sponsors and provides advice to the National Steering Committee on ways to strengthen teletrials and clinical trials in Australia through sponsor engagement. (F) Monthly national RCCC meetings commenced in May 2022. This group will harmonise Teletrial processes across partner jurisdictions and draw on each other's experiences in this early establishment phase.			
Y1 – Establish RCCCs in QLD, VIC/TAS, WA, SA/NT	01/04/22	30/09/22	100%
Comments: Regional Clinical Trial Coordinating Centre (RCCCs) in each partner state or territory have been established. These centres support clinical trial teams in each state to deliver teletrials. Northern Territory: All positions including the Manager and the Project Support Officer role have been established and are currently active. Queensland: All QRCCC roles including Clinical Director, Manager, two start up specialists, two nurse educators and an admin officer have been established and are currently active. South Australia: All SARCCC roles including Clinical Director, Manager, one Teletrial Liaison Officer and one Start-up Specialist have been established and are currently active. Currently recruiting for a second Teletrial Coordinator. Tasmania: All positions including the Manager, one Teletrial Liaison Officer and one Teletrial Coordinator position have been established. The Manager role is currently active and interviews for the two other positions have taken place and recruitment is underway. Victoria: Victorian Regional Clinical Trials Coordinating Centre has been established in the Dept of Jobs, Precincts and Regions. The Program Manager and Program Coordinator from the Victoria RCCC liaise with two Cluster Start Up Specialists based in regional Victoria. The two Cluster Start Up Specialists provide support and assistance across the seven clinical trials hubs located in regional, rural and remote areas of the State. All the positions have now been recruited. Western Australia: All WARCCC roles including Clinical Director, Manager, one Teletrial Central Pharmacist and one Teletrial Research and Governance Project Officer been established and are currently active.			
Y1 – **Begin National Education and Promotion Program delivery**	01/04/22	30/09/22	100%

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Comments: The ATP National Education Program is well underway. Northern Territory: Delivered Clinical and Teletrial specific education and training to 72 participants including s47F MM3-MM7 category locations. The modules include GCP Training for New Coordinators and Researchers and Project Management Fundamentals for Research and Clinical Trials. Queensland: Queensland RCCC has delivered and provided clinical and teletrial specific education and training to 497 participants including 44 from MM3-MM7 category locations. The modules include online and face-to-face Essential GCP Training for New Coordinators and Researchers, GCP for device trials, Effective Clinical Trial Study Start-up, Clinical Trial Design, Essential Documentation in Clinical Trials, Managing Financial and Personnel Resources in Research and Clinical Trial Project Management. South Australia: Jurisdictions have prepared a detailed education implementation plan and have submitted that to the ATP National Office and are currently in the process of procurement. Tasmania: Developing implementation plan for education and training Victoria: Victoria has delivered and provided clinical and teletrial specific education and training to 520 participants including 214 from MM3-MM7 category locations. The modules include Good Clinical Practice, Consumer and Community involvement in Clinical trials and Applying implementation science in rural health. Western Australia: Delivered Clinical and Teletrial specific education and training s47F participants, all from MM3-MM7 category locations.			
Y1 – **Local context mapping**	01/04/22	30/09/22	100%
Comments: The Australian Teletrials Program Evaluation Team, led by Professor Sarah Larkins and Professor Steven McPhail (James Cook University (JCU) and Queensland University of Technology (QUT) respectively), has completed the local context mapping. This report details the process and summary findings of the initial evaluation work to establish the baseline context and current state of play of the clinical trials landscape in Australia. This work included review of clinical trials activity in Australia in 2021, a series of consultations with key stakeholders incorporating national and jurisdictional perspectives and a desktop analysis and environmental scan of the current clinical trial context. This baseline summary, which includes consideration of the ATP supporting pillars of policy harmonisation, education and training, recruitment and incentives, and equipment and infrastructure, highlighted that most current clinical trials activity, experience and capacity is anchored in the metropolitan and, to a lesser extent, regional centres. Themes and commonalities around the strengths, opportunities and challenges in the current trial environment are identified. A large volume of data from multiple data sources was collected as part of the desktop analysis, environmental scan and stakeholder consultations. To ensure the accurate and useful integration of the information a process of triangulation of information from each data source and from core reference materials was completed. This data are presented in clinical trial activity and jurisdictional dashboards and pillar summaries. Due to the variation in systems and reporting across the six jurisdictions, criteria for reviewing research capacity and readiness were chosen based on data available and reported across all services, and that would support a holistic review of a service's capacity in relation to clinical trial readiness and systems maturity. The JCU-QUT evaluation team has presented the findings to the ATP National Office and to the National Steering Committee. The National Office has shared the report to the partner State and Territories for their review and action. The report confirms that currently there is significant variation in regional Australia of clinical trial activity and very little in rural and remote Australia.			
Y1 – **Begin Teletrial Support Program**	01/04/22	30/09/22	100%
Comments: Round-1 of the Teletrial Support Program (TSP) has commenced. Guidelines for Round-1 of the Teletrial Support Program have been published on the ATP website (https://australianteletrialprogram.com.au/clinical-teams/). Prior to the launch of Round-1 of the TSP, the ATP National Office discussed and presented the process and eligibility guidelines at the Executive Committee meetings. The TSP covers trials under the ATP Program from the commencement of the program in October 2021.			
Y1 – **Finalise and socialise evaluation framework with all stakeholders**	01/04/22	30/09/22	100%

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete

Comments: The evaluation framework has been finalised after discussion across ATP State and Territory partners. In June 2022 ethics approval was received from the Townsville Hospital & Health Service HREC, approval number s47G(1)(a) , to conduct a series of consultation interviews with key stakeholders in the Australian clinical trial and teletrial space. Stakeholders who agreed to participate were asked a set of open-ended questions relating to their clinical trial and teletrial experience, their opinion on adopting the ATM and their related experience within the 'supporting pillar' activity areas. Questions were tailored to suit the stakeholder and their industry/occupation background.

At this time, some of the key strengths identified are:

- the work currently being done to streamline Human Research Ethics Committee (HREC) processes through National Mutual Acceptance (NMA) scheme,
- the adoption of minimum standard of Good Clinical Practice (GCP) training,
- uptake and experience of telemedicine nationally to provide clinical services, and
- the roll out of the National Clinical Trials Governance Framework.

It is acknowledged that more work is needed and underway to continue to strengthen the clinical trial sector.

The national 'One Stop Shop' initiative, established clinical trial training platforms, and appetite for clinical trials across rural, regional and remote areas of Australia provide opportunity for continued development and leverage.

The main challenges facing the clinical trial sector currently is the high degree of variation of research experience, activity and processes across jurisdictions, in addition to the strains already on the public health sector such as workforce and resourcing issues.

2. *Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)*

RCCCs have developed and piloted steps to convert an existing clinical trial to a teletrial within a metro/regional cluster set-up. This allowed a patient to receive care closer to home; and to have their clinical trial related survival data collected provided to the sponsor.

During WA RCCC initial site visits and focus group meetings, the Silhouette Star camera, used to quantitatively score diabetic foot ulcers, has been identified as a new technology which may enable the conduct of diabetic foot ulcer clinical trials and wider Telehealth clinics in Regional, Rural and Remote (RRR) hospitals. The WA RCCC is reviewing the technology and its utility for delivering clinical trials remotely. This will potentially allow for earlier intervention on foot ulcers treatments and minimise hospital admissions.

3. *Complete the following table for all variation requests under the MRFF Grant Variation Policy approved, submitted (pending approval) or in draft (pending submission) for this grant to date.*

Type of Variation	Description of Variation	Current Status
N/A	N/A	N/A

4. *Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)*

- The Governance structure for the ATP National Office has been revised.

  The current Executive Committee members have transitioned to the ATP Working Group who will facilitate and work together to progress the program deliverables across the areas of harmonisation, education and training, equipment and infrastructure and resource building tools monitoring outputs and proving for final endorsements to the Steering Committee.

The new membership for the Executive Committee comprises of Executive Director level representatives from the Departments of Health (or equivalent) in each partner jurisdiction. This change allows for Executive Committee members to effect changes recommended by the ATP Working Group, ATP National Steering Committee and Clinical and Consumer Advisory group.

The National Steering Committee has updated its Terms of Reference and will meet more regularly to ensure a fully formed and consistent view of operational model and sustainability as outcomes are achieved.

- A REDCap reporting database has been developed by the ATP National Office for capturing teletrial activities across the partner State and Territories and to effectively manage the Teletrial Support Program.
- The JCU-QUT evaluation team is progressing with RRR Infrastructure Mapping and IQVIA is progressing market research activities to explore Sponsor appetite and requirements, as well as barriers & challenges to implement the program in each participating State and Territory. The JCU-QUT program evaluation team has submitted Progress report 1 and 2 and IQVIA has provided Phase 1 progress report.
- A Risk Registry has been developed for the ATP National Office and a separate risk registry template has been developed for the jurisdictional partners which they will also share with the National Office along with their detailed implementation plan.
- WA has experienced ongoing legal barriers around the utilisation of the Teletrial CTRA sub-contract. There is a risk of delayed implementation in that State, due to wording of their Health Services Act (2016). This risk is being addressed by two mechanisms: a parliamentary review of the Health Services Act is underway, and WA RCCC is awaiting legal advice to develop an alternative approach for implementation of the Teletrial program in WA. The legal review will shortly be available from the State Solicitors Office.
- Delays to recruitment and staff turnover may pose a risk to the timely implementation of activities and the program. All jurisdictional RCCCs are continuing to work through the recruitment process and all key positions are now in place.

5. *Provide a statement on your <u>overall</u> progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)*

At this stage, the Program is on track to be completed by the agreed end date.

Regional Clinical trial Coordinating Centres (RCCCs) have been established at all participating States and Territories and all key positions have been recruited and are currently active. New and emerging clinical trial sites are being funded and supported by RCCCs through equipment purchase and infrastructure development, education and training, and through coordination of cluster set up for the expansion of the trial activities and the Australian Teletrial Model (ATM).

Trial set up/conversion of existing trials and patient recruitment are progressing well in Victoria and Queensland. These two states are leading the way with the scale-up of the teletrial model within the program. This is due to the number of existing clinical trial sites and teams, as well as the experience gained in the Teletrial pilot. Queensland and Victoria share their expertise with all States and Territories under the Program.

The ATP National Office is progressing and supporting policy and document harmonisation activities through the review of documents currently in use (or under development) by a specific partner State and Territory, and then discussing these documents in the RCCC network as a team to provide feedback and adapt these processes/documents to be used across participating States and Territories with minimal modification.

Activities are currently underway to implement a national education and training pathway for all partner States and Territories. Clinical trial and Teletrial related education is being provided or funded by respective RCCCs across partner State and Territories. A total of 1093 participants including 266 from MM3-MM7 category locations have received education and training in this reporting period.

Each of the jurisdictional RCCCs is currently assessing respective sites/Hubs/HHSs requirements and processes, and initiatives are either underway or have been completed to fund equipment and logistics for sites/Hubs/HHSs to increase capacity and capability by respective RCCCs.

Round 1 for the Teletrial Support Program (TSP) has commenced to boost patient recruitment and includes a Teletrial Cluster Management Payment for eligible Primary sites (maximum of $10,000) and Teletrial Per Participant Payment for Satellite sites ($700/eligible participant per annum for a maximum of two years).

A national consumer engagement strategy has been developed and presented to the National Steering Committee and to the Clinical and Consumer Advisory group. The National ATP Steering Committee has requested a more comprehensive and co-design approach to engaging Aboriginal and Torres Strait Islander Peoples in the ATP. The National ATP Steering Committee has requested a more comprehensive and co-design approach to involving Aboriginal and Torres Strait Islander Peoples in the ATP.

6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)*

Research capacity and readiness

- Victoria and Queensland have existing teletrial activity and are progressing well with setting up teletrials and recruiting patients. Other partner jurisdictions are progressing well with promotion of the Australian Teletrial Model (ATM) and employing and training teletrial coordinators within their respective jurisdictions. They are on track to set up new trials.

Policy harmonisation

- All jurisdictions are part of the national Mutual Acceptance (NMA) scheme.
- All jurisdictions are working towards the National Governance Framework for Clinical Trials Research.
- Monthly meetings of the jurisdictional RCCCs who collaborate to problem solve challenges and to ensure similar processes across the country.

Education and training

- There is a requirement for trial staff to complete Good Clinical Practice (GCP) training and the Australian Teletrial Program enables participating States and Territories to fund clinical trial relevant education and training including GCP training to the clinical trial workforce.

Equipment and infrastructure

- Equipment and infrastructure support provided through the Australian Teletrial Program in the participating States and Territories are increasing capacity and capability of the regional and remote sites.

7. *Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.*

This question applies only to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
N/A	N/A	N/A	N/A	N/A	DD/MM/YY	X%

Project Expenditure

8. *Provide details of all expenditure incurred using MRFF funding during this reporting period and the estimated expenditure for the next reporting period.*

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Expenditure should be divided into the same categories as the budget in your grant agreement.

The table should indicate for each expenditure item (A), the approved budget (B) and the total expenditure: in this period (C), to date for the budget item (D) and estimated for next period (E). The comments field (F) should justify any differences between the budgeted and actual expenditure for the current reporting period, including any details of anticipated expenditure or any downstream effects of these differences.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact mrff@industry.gov.au.

(A) Expenditure item	(B) Approved Budget (AUD)	(C) Actual expenditure for this period (AUD)	(D) Total expenditure to date (AUD)	(E) Estimated expenditure for next period (AUD)	(F) Comments
enter approved budget item	*enter amount in $AUD*	*enter amount in $AUD*	*enter amount in $AUD*	*enter amount in $AUD*	*enter comments justifying differences between the budgeted and actual expenditure*
Minor Capital Works					
Materials for Construction					
Equipment					
Labour *(Excluding On-costs)*					
On-costs (capped at 30% of Labour costs)					
Contract					
Travel					
Other eligible expenditure					
TOTAL					

s47G

Commentary:

- Of the total $75.2M budget, total actual expenditure is s47G .

Please note: Commencement of the Teletrial Support program (Site set-up Payment for Primary sites and Per-patient payments for Satellite sites) has been delayed due to financial process constraints within each partner state and territory. However, it has now commenced and variation of the funding sub-contracts between Queensland Health and partner States and Territories to accommodate the process is underway.

Also, most of the partner jurisdictions have faced delays in recruitment of the key positions which has affected expenditure of salaries, on-costs, and equipment costs. However, all key positions are now in place.

- The budget is distributed by financial year and does not provide a breakdown for individual reporting periods. The six-monthly reporting periods crossover financial years and this creates a difficulty in alignment between reporting and forecasting.
- Programs of this size follow a curved trajectory of expenditure. This is categorised by an initial phase of relatively small expenditure that grows into significant expenditure during implementation and execution phases; before tapering off towards the end of the project life. To date, actual ATP expenditure is progressing in line with this

expectation, and the $s47G forecast for the next period shows an expected upward trend when compared to prior periods.

9. *Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)*

All expenditure incurred during the reporting period is eligible under the scheme Guidelines.

10. *Provide details of any partner contributions received during this reporting period and indicate whether each contribution has been made as expected. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.*

If a contribution has not been made as expected, describe the impact of any delays or changes to the delivery of the Research Activity. If the project does not have partners that committed to make cash or in-kind contributions, select N/A in the table below.

Name of Partner	Type of Contribution	Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
N/A	N/A	N/A	N/A	N/A

Project Evaluation

11. *Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the MRFF Monitoring, Evaluation and Learning Strategy (November 2020) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were required to be submitted with the application, select N/A in the first row of the table below.*

For each Measure of Success applicable to your project:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.)
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

Add rows as necessary.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress
N/A	enter outcome/result from application	enter comments summarising anticipated progress	enter comments summarising actual progress to date
Select			

12. *The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)*

Within this reporting period, some of the key strengths identified are the work currently being done to streamline Human Research Ethics Committee (HREC) processes through National Mutual Acceptance (NMA) scheme, the adoption of minimum standard of Good Clinical Practice (GCP) training, uptake and experience of telemedicine on a national scale to provide clinical services, and the roll out of the National Clinical Trials Governance Framework. It is

acknowledged that more work is needed (and is currently underway) to continue to strengthen the clinical trial sector. The national 'One Stop Shop' initiative, established clinical trial training platforms, and appetite for clinical trials across rural, regional and remote areas of Australia provide opportunity for continued development and leverage. The main challenges facing the clinical trial sector currently is the high degree of variation of research experience, activity and processes across jurisdictions, workforce retention and anticipated lack of capacity of the jurisdictions and RCCCs to manage teletrials post-grant without a continued national support framework or initiative.

The Australian Teletrials program partners have now established Regional Clinical Trial Coordinating Centres in all partner jurisdictions. The national partners are working together and providing a collaborative approach, leveraging experience and success to date where there are teletrials to provide additional support and guidance to the jurisdictions with large geographical areas and smaller more distributed populations and less mature systems in place. This has strongly been enabled by other work which the program feeds into such as streamlining ethics processes, and the national 'One Stop Shop' initiative, clinical trial training platforms including minimum standards, and appetite for clinical trials across rural, regional and remote areas of Australia providing opportunity for continued development.

Attachments

Attach any agreed evidence required above (e.g. updated risk management plan).

Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Appendix 2

Medical Research Future Fund National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote (RRR) Clinical Trial Enabling Infrastructure grant opportunity: monitoring indicators progress report

When you complete your progress report in the portal, you will be required to attach this document in Word or pdf format. The Commonwealth reserves the right to amend or adjust the requirements.

Measure One: Increased focus of research on areas of unmet need

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies areas of unmet need and facilitates more research into these areas
- leads to new health treatments, drugs, interventions, devices and diagnostics
- embeds such approaches into clinical practice

What approaches have been employed to ensure key areas of unmet need (as identified by the Grantee) are being met?
Northern Territory: Northern Territory (NT) Health has five regional health services: (i) Top End Regional Health Service, (ii) Big Rivers Regional Health Service, (iii) East Arnhem Regional Health Service, (iv) Central Australia Regional Health Service, and (v) Barkly Regional Health Service; with six public hospitals (Royal Darwin Hospital, Palmerston Regional Hospital, Katherine Hospital, Gove District Hospital, Alice Springs Hospital, and Tenant Creek Hospital), and the primary health care clinics. Currently there are 47 authorised/active clinical trials across NT Health; all conducted predominantly in Darwin. Nil teletrials have been established to date, however stakeholder engagement activities have commenced for both internal and external key stakeholders to promote/raise program awareness. Barrier analysis activity is currently being undertaken to identify gaps across all regional health services. This barrier analysis will form an action plan to guide best approach for implementation of the Australian Teletrial Program (ATP) across the Northern Territory.
Queensland: • The unmet need: o Access to clinical trials for Rural, Regional, and Remote (RRR) patients within QLD o Site capability, variability to conduct clinical trials due to resourcing, education, and lack of support. The Queensland RCCC has: o developed and implemented an education program for the Qld Teletrial Clinical Research Coordinator (TT CRC) network. o collaborated with Queensland Clinical Trial Coordination Unit (QCTCU) to co-fund accredited clinical trial education including ICH-GCP training, with approx. 254 staff attending training from within the HHSs in QLD, and a total of 497 modules completed.

- implemented fortnightly meetings (minuted) alongside incidental training for any CRC in Qld who needs/ requests support
- provided onsite training for CRCs and organises for them to attend the Primary site to observe a busy clinical trials service. QRCCC Cluster Start Up Specialists (QSUS) then re-visit the Satellite Site (SS) to assist with patient visits for new TT activity.
- set up several clinical trials for new Principal Investigators (PIs) and a new TT CRC at an HHS in Qld and sites that have expanded outside of Oncology. If they are a single site only awaiting Research Governance Office (RGO) authorisation, suitable trials will be converted to teletrials if/when a participant's home postcodes require them to be converted, to prevent the patient from having to travel and to allow them to receive care closer to home (ICU, Renal and Neurology).
- set up a whole cluster for a rare cancer clinical trial which has now received RGO authorisation at the Primary Site (PS) and one of the Satellite Sites (SSs) (RGO authorisation of another SS is pending). This had extended RGO approval timeframes
- developed steps for converting a clinical trial to teletrial within an existing cluster and at an already approved Qld hospital SS. Human Research Ethics Committee (HREC) and RGO processes reviewed, agreed, and piloted, resulting in RGO authorisations
- ensured its nursing team have completed GCP, Medical device training- ISO14155 in order to facilitate clinical trials with medical devices as a teletrial within Qld. A draft Device Trial Supervision Plan is under development and will be piloted with a regional Satellite Site

- All HHSs within QLD have signed their agreements and have either recruited to their CRC TT or recruitment is underway.
- Several HHSs have signed agreements to receive funding for purchase of equipment to assist with setting up the clinical trial units at their HHS. Specific TT support funding has been allocated funding to purchase centrifuges, freezers, and patient treatment chairs to allow satellite site(s) to complete activities for the clinical trial protocol in the future.
- Funding support for Clinical trial management system license purchase and set up of offices at the HHSs.
- Four remote HHSs in QLD are receiving additional support from QRCCC to facilitate them being able to partake in clinical trial/teletrials: 0.5 FTE RGO and 0.5 FTE TT CRC will be supported.

South Australia:

South Australia has ten Local Health Networks (LHNs) that manage the delivery of public hospital services as well as community-based health services, determined by the State Government. Four LHNs are located in metropolitan Adelaide and six LHNs cover regional SA. Currently within South Australia there are no research units in any of the regional LHNs and there is no clinical trial or teletrial activity. There is one Research Governance Officer that covers the six regional LHNs due to the low number of research applications including clinical trials. Despite this lack of maturity across SA, the Australian Teletrial Program is still in the early stages of implementation and the SA/NT Regional Clinical Trial Coordinating Centre is progressing the clinical trials capacity and capability in regional SA and supporting the activities within the Australian Teletrial Program.

As part of the Australian Teletrial Program, the SA/NT Regional Clinical Trial Coordinating Centre will be employing three full time Clinical Trial Nurse positions to be based in three of the regional LHNs. These roles will be crucial to enable clinical trials and teletrials to be accessed in the regional LHNs by supporting the groundwork such as recruitment, informed consent, and clinical assessments. Site visits have occurred to the three regional LHNs where the clinical trial nurses will be located to meet with executives and other key stakeholders, and also to assess the infrastructure to determine how the SA/NT RCCC can support the setup of these sites as satellite sites.

The SA/NT RCCC will support the capacity and capability building in the regional LHNs by providing clinical trial workforce, infrastructure such as equipment, and training to support clinical trial and teletrial activity.

To date, there has been no specific clinical trial education or training activities offered across South Australia. As a result of the Australian Teletrial Program, the SA/NT RCCC has collaborated with Health Translation SA (HTSA) to provide the Victorian Clinical Trials Education Centre (V-CTEC) learning management system to all South Australians with no cost to the end user. The SA/NT RCCC and the Office for Research are funding this program and HTSA are supporting the promotion of the program.

Tasmania:

Teletrials under the governance of the Research and Innovation Subcommittee.

Member of the Victorian CTRSS-ATP Project Advisory Group and the Industry Engagement Group.

Victoria:

(A) Organisation 1

Barwon Health (BH) has established clinical trials programs in cancer services, infectious diseases, endocrinology, cardiology, intensive care and mental illness. Our goal is to improve regional access to these programs. As per our previous report, we are also working toward building clinical trials activity in gastroenterology, urology, orthopaedics, paediatrics and public health.

Currently, Barwon Health are exploring avenues to create a trained / job ready casual clinical trial nursing workforce. This will allow for new investigators / researchers to commence trials in untapped therapeutic areas across the organisation that align with the BH strategic plan.

Consultation with the BH nursing bank managers has commenced and more work is required in this area, this will continue over the coming months and may take some time as we await the appointment of a new Director for the Nursing and Midwifery Workforce Unit. The development of this new workforce unit will ensure dedicated supply, development, retention and support of nurses and midwives across Barwon Health, including research. BH have previously been constrained by workforce and staffing issues (especially with the pandemic) and it is a key reason why we have made limited progress into the areas of unmet needs with regards to research.

BH research is also undergoing a restructure which will hopefully ensure different therapeutic areas will have a dedicated research lead. This research lead will consult with the Director of Research regarding new research initiatives and clinical trials and progress towards tapping into these unmet areas / gaps at BH and ensure clinical trials are embedded into clinical care across

the organisation. We are also progressing discussions with colleagues at Colac Area Health to consider how BH could support improved trials access to the Colac community.

(B) Organisation 2

- Endocrinology/Renal Health: The existing partnership between Alfred Heath Trialhub and Bendigo Health Oncology clinical trials has led to the exploration of expansion of the partnership into a Renal Clinical Trial Program. The Bendigo Renal Health Team, led by s47F is keen to build the capability and capacity for clinical trials. Discussions and contractual negotiations continue to develop a renal clinical trials program that specifically focuses on engaging local Aboriginal and Torres Strait Islander populations, who suffer significant health burdens due to renal disease (a key area of unmet need) in the Loddon-Mallee region.
- Geriatrics: Bendigo Health is currently investigating becoming members of "Dementia Clinical Trials Australia" to address a key area of unmet need in the Loddon-Mallee population.
- Infectious Diseases: Prior to this reporting period, the Infectious Diseases department had no experience in participating in clinical trials. Discussions and initial paperwork are underway to initiate the first clinical trial within the next reporting period.

(C) Organisation 3

The following approaches have been undertaken to address areas of unmet need:

- Responding to key clinical priorities as indicated by data (presentations/Health round table data/rRiskman) – ie. Delirium, stroke models of care, nurse practitioner roles in clinical trials
- Invitation to attend reference group meetings – ie Pain Management Reference group
- Implement electronic document management system (SiteDocs) to improve communication between all members of the trials (Coordinators, PI's, Supporting Departments, Sponsors)
- Input to the development of the NHW Research Communication Plan and participation in activities for promotion of Clinical Trials (ie. International Clinical Trials Day, Research Week)
- Development of Site Profile Document inclusive of all relevant clinical departments and provided to sponsors
- Development of core documents to enable teletrial capacity and capability
- Establishing networks within CTRSS-ATP consortia, Metropolitan Health Services and sponsors to raise the profile of NHW to improve our teletrial options and expand research opportunities including new therapeutic areas
- Establishment of a shared clinical trial email inbox to increase efficiency and timely responsiveness

(D) Organisation 4

Health challenges in rural and regional Victoria, compared to metropolitan Victoria, include increased rates of hospital admission for cancer, cardiovascular disease, chronic obstructive pulmonary disease and diabetes. Hence, improvement in these therapeutic areas are of interest at Grampians Health.

Approaches that have been employed within the initial phase of the ATP at the Grampians Health site are more broadly focused and include updating and implementing SOPs in relation to

Teletrials, scouting for possible satellite sites and staff training. It is envisioned that a more targeted approach towards areas of unmet needs will be of more focus once initial processes are established.

(E) Organisation 5

Areas of unmet needs include organisation wide tele-trial readiness and resources, clinical trials in non-oncology therapeutic areas, and availability, resources, and access to trials (tele-trials and clinical trials) in these therapeutic areas. Patients with many differing medical diagnoses / ailments / problems are not able to access clinical trials without having to travel to metro locations.

GV Health predominantly runs oncology clinical trials at this time, therefore patient access to benefits of tele-trials/clinical trials is limited if they are not an oncology patient. Furthermore, although there are mostly oncology trials being conducted at GV Health, a broader range and number of oncology clinical trials is required to meet needs of local patients with various types and stages of cancer.

Access to an organisation wide CTMS for collection of reportable metric data is also an unmet need.

The following approaches are being employed to meet areas of unmet need:

- Employment of 1FTE CTRSS-ATP clinical trials coordinator for organisation-wide clinical trials and tele-trials support.
- Liaising with the regional ATP start up specialist for the Northeast to bring more tele-trials to the region.
- Liaising with commercial sponsors to promote GV Health as a site for both non-oncology and oncology clinical trials/tele-trials.
- Offering and providing all aspects of clinical trial coordination support for current and potential investigators/trial staff, departments (both clinical trial active and potentially active departments), and supporting departments.
- Offering advice and training for ethics and governance applications and their submission via ERM for junior/senior doctors and researchers, direct assistance in ERM submissions.
- Offering and providing clinical trial and research training and education to current and potential trials and research staff.
- Offering assistance and advice with clinical trial budgets, research agreements, and regulatory requirements.
- Circulation of ERM training updates, as well as forwarding Coordinating Office for Clinical Trials news update and related training opportunities.
- Working in collaboration with other Clinical Trial Coordinators, other regional hospitals that are under this grant, and DJPR to progress tele-trial readiness.
- Fully executed agreement with Trialdocs for Site Docs Portal in process of implementation.

(F) Organisation 6

Latrobe Regional Hospital (LRH) is located in the Gippsland Region of Victoria, 160 km east of Melbourne. It provides multidisciplinary care for a population of more than 290,000 people.

LRH has a capacity of 313 beds and treatment chairs. Our medical services include elective surgery, emergency care, aged care, obstetrics, mental health, pharmacy, rehabilitation, specialist consult suits and medical and radiation oncology. We have four operating theatres specialising in General Surgery, Orthopaedic, Ophthalmology, Gynaecology, and Obstetrics. WE also conduct ear, nose and throat surgery and urology and act as Gippsland's specialist referral and trauma

centre. LRH currently employs more than 1,900 staff with a $217 million redevelopment project underway.

Our region statistics:

- Avoidable deaths from cancer are higher in Gippsland than Victoria wide (35.6/100,000 population compared to 28.2)
- People living in the Gippsland are 8% more likely to be diagnosed with cancer and 24% more likely to die
- Aboriginal and Torres Strait Islander people have lower cancer screening rates
- Avoidable deaths due to diabetes double the state average
- 38% increase in avoidable deaths due to heart related issues
- Incidence of smoking nearly double the state average (24% vs 13%)
- Higher rates of long-term health conditions including arthritis, asthma, cancer and heart disease than the state average.

Our current trial and therapy portfolio includes: Cancer Services (Medical Oncology, Haematology, Radiotherapy); Orthopaedic Surgery; Renal Services; Palliative Care and Teletrials, with considerable scope for expansion into our therapeutic areas in the future as supported by recruitment potential and community need.

Latrobe Regional commenced the CTRSS-ATP program at the end of March 2022 which has enabled expansion of our trial capacity in areas of need including non-cancer domains. The program assists in our ability to set up and conduct trials in a regional setting. Community engagement and Indigenous health are areas of identified priority for clinical trials at our site.

As such the CTRSS program has supported us as a junior site with education and mentoring opportunities.

Industry forums and connection to sponsors; actively reviewing trials suitable for implementation on site, invitations to present to sponsors.

Access to SiteDocs as a data management system.

Support of a VCCC intern onsite.

Opportunity to open trials in cancer and non-cancer domains serving residents in rural regions.

Latrobe Regional Hospital also has representation on the CTRSS-ATP Operations Advisory Group and steering committees. This contributes to the development or core documents and processes such as reviewing existing applicable clinical trial and teletrial SOPs (standard operating procedures) including those developed by ATP, CTRSS-ATP sites and those contained in the National Teletrials Compendium.

LRH has several valuable partnerships that foster our growth in clinical trials including TrialHub, RTN and Monash Health, however these relations provide support primarily to our trials in cancer services. Our CTRSS-ATP agreement is supporting our expansion in the non-cancer domain. Together these relations have enabled considerable growth in our local workforce and enhanced our capacity to expand our trials portfolio.

(G) Organisation 7

South West Healthcare has identified a need to improve the capacity and capability of the organization and clinical staff in conducting clinical trials outside of the oncology specialization, and to promote South West Healthcare broadly as a potential site for clinical trials.

To this end, a Clinical Trials Project Officer was employed from September 2022, who is currently in the early stages of establishing CTRSS-ATP. As no trials have yet commenced through CTRSS-

ATP support, it is not possible to yet comment on development of new interventions or changes to clinical practice.

Western Australia:

Regional patients in Western Australia are underrepresented in clinical trials due to geographical barriers, vast distances to travel, lack of facilities and reduced trials expertise in less populated regions.

The WA Country Health Service (WACHS) approach to implementation of the Australian Teletrial Program (ATP) is targeted to address this area of unmet need.

This approach includes establishment of the WA Regional Clinical Trial Coordinating Centre (WA RCCC), utilisation of Telehealth technology, provision of education and equipment and harmonisation of policy.

The WA RCCC has been established to facilitate the delivery of clinical trials at Satellite Sites in regional areas. The WA RCCC will coordinate communication between the Primary and Satellite Sites to ensure the expertise of the Primary Site is delivered to the patient in the Satellite Site.

Telehealth technology will aim this communication and oversight. The WA RCCC will also assess Satellite Site capabilities for delivering clinical trials and access funding and resources to embed the required staff, training, equipment and logistics to ensure the successful delivery of clinical trials and optimum patient care.

The WA RCCC prepared a novel MRFF submission for a new digital approach to connect all clinical trial pharmacies state-wide on an electronic Investigational Product Management System (IPMS) to make more interventional clinical trials available to regional patients. Having connected pharmacies ensure site to site transfer of Investigational Product can be electronically managed; interstate Sponsors can remote into the system to monitor trial activity in remote locations; capacity at current sites can increase; and remote, inexperienced sites can be virtually managed. This is particularly important in WA as no hospital site within regional WA currently has clinical trials experience and must be completely supported centrally. Whilst the MRFF submission was ultimately unsuccessful in the first instance it has provided a conversation starter in WA and is being actively pursued.

We have actively engaged local hospital champions and strategically aimed to recruit patients currently on follow up therapy. This has produced several positive benefits. Firstly, without the pressure for active treatment, sites are willing to navigate the more time intensive processes and provide higher quality feedback on their experience. Secondly, Investigators and coordinators are less concerned about the ability of the new program to maintain appropriate governance as there is less risk. This allows us to build trust with the organisation and develop Proof of Concept (PoC) case studies for our 2023 Roadshow. We have engaged early as part of our Change Management approach with multiple departments to ensure the vision of an all-clinical specialties, all-patient populations approach is clearly communicated. We have requested involvement with diabetic multi-disciplinary team with podiatry, infections disease and endocrinology clinicians. This has led to the proposal and progression of three investigator led studies in diabetic foot, amputated and aboriginal rheumatic heart disease populations.

We have engaged medical oncology with our medical lead champion to identify patients for two collaborative group studies for rectal, testicular cancer (both for patients in active follow-up) and one investigator led study for circulating DNA screening in regional patients (pending recruitment) in a collaboration with a local university and Cancer Council WA.

Through our newly created WACHS-Curtin Alliance we have connected via our Curtin colleagues with a cardiology team for a rural echocardiography study with GPs. We have also utilised this strategic partnership to identify a rural-based Alzheimer's study.

We have also entered discussions with a hepatology unit for an interventional vitamin E analogue study for non-alcoholic steatohepatitis with a commercial Sponsor. This patient population is over-represented in regional locations.

We believe this approach represents a commitment to engage a wide variety of clinical specialties ensuring that patients' needs in the regional communities are prioritised. Through careful study selection, positive engagement with a variety of clinical networks, and multiple PoC case studies with investigators, collaborative and commercial groups, we are confident that the trial community will trust the vision and processes implemented and encourage major commercial Sponsors to engage in the WA program.

Measure Two: More Australians access clinical trials

This measure considers the extent to which outcomes of MRFF-funded research:

- create better opportunities for Australians to access clinical trials by funding activities that support research to progress to the clinical trial stage, and directly supporting additional clinical trial activity
- builds Australia's clinical trial capability and leadership at the national and international level

Please complete the tables on the following pages to record:

- the number of new or improved clinical trial **sites** (TABLE 1),
- the number of new clinical trial **participants** (TABLE 2), and
- the number of new **clinical trials** (TABLE 3);

directly linked to your project activities.

TABLE 1: Number of new or improved[1] clinical trial sites by state or territory and MMM Code

(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

Note: enter 'N/A' in the respective State or Territory field if it does not apply to your project.

State/ Territory		Target for achievement by Project Completion	Actual number of new or improved sites (cumulative total, project to date)							
			MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
ACT	New Sites									
	Improved Sites									
NSW	New Sites									
	Improved Sites									
NT	New Sites	32	0	0	0	0	0	0	0	**0**
	Improved Sites	11	0	0	0	0	0	0	0	**0**
QLD	New Sites	851	2	10	0	1	0	0	0	**13**
	Improved Sites	283	4	11	0	0	0	0	0	**15**
SA	New Sites	332	0	0	0	0	0	0	0	**0**
	Improved Sites	111	0	0	0	0	0	0	0	**0**
TAS	New Sites	32	0	0	0	0	0	0	0	**0**
	Improved Sites	11	0	0	0	0	0	0	0	**0**
VIC	New Sites	972	2	1	1	0	0	0	0	**4**
	Improved Sites	324	25	6	7	0	0	0	0	**38**
WA	New Sites	211	0	0	0	0	0	0	0	**0**
	Improved Sites	70	0	0	0	0	0	0	0	**0**
Total	**New Sites**	**2430**	**4**	**11**	**1**	**1**	**0**	**0**	**0**	**17**
	Improved Sites	**810**	**29**	**17**	**7**	**0**	**0**	**0**	**0**	**53**

[1]clinical trial sites with improved capacity (i.e. increased trials) and/or capability (i.e. new types of trials)

TABLE 2: Number of clinical trial participants by state or territory and MMM Code
(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

State/ Territory	Target for achievement by Project Completion	Actual number of new clinical trial participants (cumulative total, project to date)							
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
ACT									
NSW									
NT	68	0	0	0	0	0	0	0	0
QLD	1750	s47F							22
SA	682	0	0	0	0	0	0	0	0
TAS	68	0	0	0	0	0	0	0	0
VIC	2000	359	46	67	9	16	0	0	497
WA	432	0	0	0	0	0	0	0	0
Total	**5000**	s47F							**519**

TABLE 3: Number of new clinical trials by state or territory and MMM Code
(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

State/ Territory	Target for achievement by project completion	Actual number of new clinical trials (cumulative total, project to date)							
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
ACT									
NSW									
NT	3	0	0	0	0	0	0	0	0
QLD	71	s47F							12
SA	28	0	0	0	0	0	0	0	0
TAS	3	0	0	0	0	0	0	0	0
VIC	81	15	11	11	0	0	0	0	37
WA	17	0	0	0	0	0	0	0	0
Total	**203**	s47F							**49**

For new clinical trials generated by your project activities, please provide the number of clinical trials by:

- Demographics of population (e.g. ATSI, CALD)
- Age group of target population (i.e. youth/paediatric; adult; older people)
- Disease type (e.g. oncology)
- Sponsor type (i.e. investigator initiated, commercial, etc.)

You may either provide the information below, or attach it to this report. If you attach a document, please provide the name of the document below.

Northern Territory:

Discussions have occurred with both SA and NT clinicians interested in setting up clinical trials as teletrials in the clinical specialities of cardiology, oncology, renal, neurology and endocrinology and consist of both investigator initiated and commercially sponsored research.

South Australia:

Currently there are no new clinical trials or teletrials that count towards project activities. Discussions have occurred with clinicians interested in setting up clinical trials as teletrials in the clinical specialities of cardiology, oncology, renal, neurology and endocrinology; and consist of both investigator initiated and commercially sponsored research.

Queensland

The QRCCC is supporting the establishment of Satellite Sites in remote HHSs. Populations in these remote HHSs are from MMM2-7 postcodes and there is an increased percentage of Aboriginal and Torres Strait Islander peoples (6-12%). An Aboriginal and Torres Strait Islander senior health worker has been employed in one remote HHS to develop an engagement strategy for First Nations Peoples.

The target age group for all trials in this report is 18 years or older.

Teletrials are being conducted in the following clinical areas: Haematology, Medical Oncology, Radiation Oncology, ICU, Renal and Neurology. Of these, 3 are commercially sponsored and 7 are collaborative group trials.

Describe the progress towards target recruitment numbers and the retention rate for clinical trials.

Northern Territory:

As of 30 September 2022, the SA/NT RCCC is reviewing and working towards setting up teletrials for seven clinical trial protocols.

Due to there being no current teletrials in both SA and NT, this is a new process that will take time to work through the checklists and regulatory approvals.

NT has been working closely with SA for a potential first teletrial (across jurisdiction-oncology trial between Queen Elizabeth Hospital, SA and Royal Darwin Hospital, NT), currently going through feasibility process.

Queensland:

The QRCCC is:

- supporting staff in Qld Health HHSs by way of a tailored education program, including the requirements for setting up a clinical trials unit. Four remote HHSs that do not currently have a clinical trials service have now employed a dedicated TT CRC and are being supported by QRCCC to develop governance processes to comply with the National Clinical Trials Governance Framework (NCTGF).
- conducting an education program which is available to all Qld Health staff via Office 365. Education sessions are conducted via TEAMS every two weeks and have invited guest speakers for expert content. Accredited GCP training has been funded for HHS staff and welcome booklets for HHS staff involved in trials have been developed.
- working closely with HHS executive teams in remote HHSs to lay the platform for their involvement with clinical trial/ teletrials.
- consulting with existing service providers to understand the logistics of service provision. This will complement the HHS profiles currently being conducted.
- presenting at seminars and sponsor / collaborative group meetings as well as to individual HHSs so that teletrials are understood and the benefits that they bring to patients is known.
- attending Primary Healthcare Network (PHN) meetings so that GPs and remote health service staff understand the model, how they can be involved and the benefit to their patients/communities.
- building relationships across health care institutions in Qld, so that the supports provided from the QRCCC are understood, and QRCCC can assess the intent for capacity building at the HHS sites.

South Australia:

As of 30 September 2022, the SA/NT Regional Clinical Trial Coordinating Centre is reviewing and working towards setting up teletrials for seven clinical trial protocols.

Due to there being no current teletrials in SA, this is a new process that will take time to work through the checklists and regulatory approvals.

The SA/NT Regional Clinical Trial Coordinating Centre was established at the end of May 2022 and to date, the focus of the team has been stakeholder engagement activities and recruiting the remaining positions.

Victoria:

(A) Organisation 1

With the 183 number of clinical trials currently running across the organisation we have a retention rate of over 80-90%. The BH trial units actively engage with their participants to ensure they feel valued, listened to, and understand the trial requirements with regards to their participation. We are currently developing a strategy to further build consumer contribution and participation in the BH research program, in part to continue to optimise the relevance, participation and retention rate of our clinical trials program

(B) Organisation 2

- The *"Treatment of cardiovascular disease with low dose Rivaroxaban in advanced chronic kidney disease (TRACK)"* trial commenced recruitment 21st September and has recruited s47F **participant toward the target recruitment number of 20.**

- The *"Online and telehealth management of rotator cuff tendinopathy: a randomised controlled trial"* study has not yet recruited any participants toward the target recruitment number of 10.
- The *"A Randomized, Double-Blind, Placebo-Controlled, Two-Arm Parallel-Group, Multi-Centre Phase 3 Pivotal Trial to Investigate the Efficacy and Safety of Recombinant Human Alkaline Phosphatase for Treatment of Patients with Sepsis-Associated Acute Kidney Injury Recombinant human alkaline phosphatase SA-AKI survival trial (REVIVAL)"* **study has recruited** s47F **participant toward the target recruitment number of 5.**

(C) Organisation 3

Conducted 4 feasibility assessments

Accepted 2 clinical trials that are in stages of start up

Held meetings with a new clinical trial team (potential PI) for palliative care trials.

Assessing suite of trials for potential participation and partnering with s47G(1)(b) for teletrials.

Active trials previously opened and continuing recruitment during this period

Title	Type	Department	Total Patient No	No this period
Extending the time window for Tenecteplase by Effective Reperfusion of peNumbrAL tissue in patients with Large Vessel Occlusion (ETERNAL LVO)	Clinical Trial	A&E	0	0

(D) Organisation 4

Overall, during this initial phase of the ATP, activity at the Grampians Health site has been focused on staff training, SOP implementation and participant recruitment.

(E) Organisation 5

ACTIVE (OPEN TO RECRUITMENT AND ACTIVE FOLLOW-UP) TRIALS 1APR-30SEP 2022					
FULL PROJECT TITLE	**STUDY TYPE**	**CLINICAL TRIAL DEPT**	**EXPECTED NO. OF PARTICIPANTS RECRUITED AT THIS SITE**	**ACTUAL NO OF PARTICIPANTS RECRUITED AT GVH**	**1 APR - 30 SEP 2022**
A phase III study of the impact of a physical activity program on disease-free survival in patients with high-risk stage II or stage III colon cancer: a randomized	Clinical Trial	Oncology	3	s47F	0

controlled trial (CHALLENGE)					
Droplet digital PCR – Using chromosome Rearrangements As Tumour-specific markers In disease mONitoring for lung cancer (DURATION)	Teletrial	Oncology	15	11	0
A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer (NATALEE)	Clinical Trial	Oncology	5	11	0
Aspirin for Dukes C and High Risk Dukes B Colorectal Cancer Protocol (ASCOLT)	Clinical Trial	Oncology	5	11	0
Targeted thromboprophylaxis in ambulatory patients receiving anticancer therapies for lung or gastrointestinal cancers: an investigator-initiated, open-label, multicentre, randomised, phase	Teletrial	Oncology	10	12	0

3 trial (TARGET-TP)					
A Multicenter, Randomized, Double-Blind Phase 3 Study of HBI-8000 Combined with Nivolumab versus Placebo with Nivolumab in Patients with Unresectable or Metastatic Melanoma Not Previously Treated with PD-1 or PD-L1 Inhibitors (HUYA)	Clinical Trial	Oncology	3	s47F	
A Phase 1b open-label, multicenter dose escalation and expansion study of MT-5111 in subjects with previously treated advanced HER2-positive solid tumors (MTEM)	Clinical Trial	Oncology	3	0	0
A Phase III, multi-center, randomized (1:1), open-label, active-controlled study to assess the efficacy and safety of alpelisib (BYL719) in combination with olaparib as compared to single agent cytotoxic chemotherapy, in participants with no germline BRCA mutation detected, platinum-resistant or refractory, high-grade serous	Clinical Trial	Oncology	3	s47F	

ovarian cancer (EPIK-O)					
A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Adjuvant GDC-9545 Compared with Physician's Choice of Adjuvant Endocrine Monotherapy in Patients with Estrogen Receptor–Positive, HER2 Negative Early Breast Cancer, Protocol No. GO42784 (LIDERA)	Clinical Trial	Oncology	15	s47F	
A Prospective Observational Study of Non-Anaemic Iron Deficiency and Treatment Outcomes after Colorectal Cancer Surgery (NATO)	Clinical Trial	Surgery/Anaesthesiology	50	0	0
Adaptive trial of Cannabidiol (CBD) for depression and sleep in the setting of Cannabis Misuse Disorder	Clinical Trial	Addiction Medicine	30	33	33
Can flash glucose monitoring improve blood glucose levels in Indigenous Australians with type 2 diabetes	Clinical Trial	Endocrinology/Medical	40	37	6
Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in	Clinical Trial	Oncology	10	8	

Locally Advanced Rectal Cancer: A Multicentre Randomised Study (DYNAMIC-RECTAL)					
Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage III Colon Cancer: A Multicentre Phase II/III Randomised Controlled Study (DYNAMIC-III)	Clinical Trial	Oncology	10	s47F	
ENZAMET	Clinical Trial	Oncology	6-Jan	7	0
GUIDE: A randomised non-comparative phase II trial of biomarker-driven intermittent docetaxel versus standard-of-care (SOC) docetaxel in metastatic castration-resistant prostate cancer (mCRPC) (ANZUP 1903)	Clinical Trial	Oncology	5	0	0
Reduction Of Chronic Post-surgical Pain with Ketamine (ROCKET Trial) 0	Clinical Trial of a Drug	Anaesthesiology	100	104	s47F
PeriOperative ISchemic Evaluation-3 Trial	Clinical trial-other	Anaesthesiology	50	s47F	0
Volatile Anaesthesia and Perioperative Outcomes Related to Cancer: The VAPOR-C Trial	Clinical trial-other	Anaesthesiology	90		0

Advanced Hormone Receptor Positive Breast Cancer Registry in Australia (ARORA)	Registry	Oncology	10	13	
Alternating oxaliplatin and irinotecan doublet schedules versus continuous doublet chemotherapy in previously untreated metastatic colorectal cancer: A Treatment of Recurrent and Advanced Colorectal Cancer registry-based prospective randomised trial (ALT TRACC)	Registry	Oncology	10		
Analyzing Treatment Patterns and Outcomes (ePAD) from Real World Patients with Castrate Resistant Prostate Cancer (CRPC)	Registry	Oncology	40	44	
Phase III Trial of Extended Temozolomide in Newly Diagnosed Glioblastoma (Ex-Tem)	Registry	Oncology	5	s47F	
Real world evaluation of IMpower150 regimen in patients with metastatic NSCLC (IMPOWER)	Registry	Oncology	15		

Registry-based Study of Enzalutamide vs Abiraterone assessing cognitive function in ELderly patients with Metastatic CastrationResistant Prostate Cancer (REAL-PRO)	Registry	Oncology	15	9	s47F
Study of Clinical Outcomes and Analysis of Bevacizumab use in Metastatic Colorectal Cancer	Registry	Oncology		12	
Treatment of advanced breast cancer in the HER2 positive Australian patient (TABITHA)	Registry	Oncology	1	12	0
Generation Victoria Cohorts 2020s. A longitudinal birth-cohort of babies born in Victoria between 2020 and 2022, and their parents	Registry	Oncology			
A Phase II trial of single agent cabozantinib in patients with locally advanced or metastatic non-clear cell renal cell carcinoma post immunotherapy or who are unsuitable for immunotherapy (UNICAB)	Teletrial	Oncology	4	s47F	0
LIBRETTO-432: A Placebo-controlled Double-Blinded Randomized Phase 3 Study of	Teletrial	Oncology	1	s47F	

Adjuvant Selpercatinib following Definitive Locoregional Treatment in Participants with Stage IB-IIIA RET fusion-Positive NSCLC					
A prospective Phase II study of Isatuximab Rescue for Inadequate response to Lenalidomide and Dexamethasone in transplant ineligible patients with newly diagnosed multiple myeloma (IRIL)	Teletrial	Oncology/Haematology	10	6	s47F
Retrospective analysis of the ENZAMET cohort - Utility of PSMA PET scan quantitation and CT radiomics as prognostic and predictive biomarkers (PET-MET)	Clinical Trial	Oncology	1	s47F	
A Phase 2, Open-Label, Multicenter Study of the Combination of RMC-4630 and Sotorasib for Non-Small Cell Lung Cancer with KRASG12C Mutation After Failure of Prior Standard Therapies (REV MED)	Clinical Trial	Oncology	3	0	0
SNAP	Clinical Trial	Infectious Diseases	20	s47F	

DREAM3R - DuRvalumab (MEDI4736) with chemotherapy as first line treatment in advanced pleural Mesothelioma - A phase 3 Randomised trial	Clinical Trial	Oncology	3	s47F	0
Air or Oxygen for Preterm infants; AN Embedded trial, The AIROPLANE Trial	Clinical Trial	Paediatrics	1	0	0
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE TREATMENT EFFECTS AND SAFETY OF SLS-005 (TREHALOSE INJECTION, 90.5 MG/ML FOR INTRAVENOUS INFUSION) IN PARTICIPANTS WITH ALZHEIMER'S DISEASE (AD)	Clinical Trial	Geriatric Medicine	8	0	0

(F) Organisation 6

A large barrier to trial engagement is travel from a regional to metropolitan site. Providing trials closer to home is enhancing recruitment of regional Victorians onto trials and thus providing alternative care pathways.

Based on internal audits our site estimates target recruitment numbers reflective of our population. Our longer standing trials have recruited as estimated. Our new trials are being promoted through appropriate avenues ie MDMs etc to capture potential participants. Eternally we are also engaged in community events to promote trial activities on site and are developing a communication plan to promote our activities and trial opportunities.

Our retention rates are generally good; disease progression being the biggest influence as to why a participant needs to withdraw from a trial.

(G) Organisation 7

N/A

Western Australia:

The second six months of the WA Teletrial initiative has been focused on ongoing staff recruitment, promotion of the Teletrials program with key researchers as well as reviewing required legal and governance documents for Teletrials in WA.

WACHS has invested staff time from the Director of Research and Innovation, Medical Lead Teletrials and Business Services to establish and recruit new positions within the team. The Senior Pharmacist has been employed full time since March 2022.Since the last report, we have established and recruited two further positions with the Clinical Trial Manager and Governance Project Officer commencing employment in July 2022. The Project lead was filled in April 2022 prior to being vacated in July 2022. Recruitment is well underway for replacement Project Lead with several potential candidates having been identified. Since the last report we have submitted requests for the creation of three WA RCCC positions and are advertising for a Research Nurse, Research Officer and Clinical Trials Coordinator. Ongoing work is being conducted to fully establish the Medical Lead position through the establishment committee.

The WARCCC team has conducted stakeholder sessions with investigators and lead researchers across WA in Medical Oncology, Gastroenterology, Hepatology, Endocrinology, Infectious Diseases, Podiatry and Psychiatry to promote the Teletrial program and seek suitable trials for implementation. We have identified eight potential trials and several patients for possible Teletrial implementation (see Attachment 1 for all trials assessed to date). Our focus to date has been on attracting Collaborative Sponsors / Investigator led trials before moving to entry level commercial Sponsors. Once Proof of Concept has been established within these 2 groups, we will have successful examples to showcase to established commercial Sponsors to encourage WA investment.

The first potential Satellite Site, Albany Health Campus, has been identified. The WA RCCC has visited the site and conducted key informant interviews and focus group meetings. Support for the implementation of Teletrials has been garnered from the Regional Director, Director of Clinical Services and Regional Medical Director. Trial specific capabilities have been discussed with pathology, imaging, cancer services and nursing and a network of personnel essential to the successful conduct of trials is being established.

Preliminary discussions have been held with Esperance Hospital, as a potential second Satellite Site in conjunction with Fiona Stanley Hospital as a Primary Site. Fiona Stanley Hospital Medical Oncology Department have a identified a trial patient living in s47F who may benefit from the Teletrial program. The WA RCCC are working towards having this trial approved as the first Teletrial in WA over the next two months with the first patient visit planned for 12 Dec 2022.

The WA RCCC are engaging with the State Solicitors Office regarding the Teletrials CTRA Subcontract and how to progress this in WA. As it currently stands, the Health Services Act 2016, prohibits WACHS and other Health Service Providers to enter into arrangements on behalf of other entities in the MA CTRA, as agent of the teletrial/satellite sites with respect to the indemnity provisions. Instructions for the provision of contractual arrangements to facilitate collaboration between health services providers have been provided to the State Solicitors Office. A request for

legal avenues for the implementation of Teletrials between the private sector, including universities, and RRR hospitals has also been sought.

	Target	Actual to date Progress against target
How many staff have been trained on clinical trial related methodology?	5000	**TOTAL - 1137** Victoria – 520 Queensland - 308 Tasmania – 183 South Australia – 50 Western Australia – 4 Northern Territory - 72

Measure Three: New health technologies are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health technologies, including precision medicine
- measures the awareness of new health technologies among clinicians and patients
- embeds new health technologies into clinical practice

Where applicable, are new and emerging health technologies[2] being embraced by clinicians and patients involved in the clinical trials funded through this project? If so, how? Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
Queensland: Scope of Clinical Practice and credentialling of medical officers has been explore to identify what is allowed under scope when using Telehealth for TT model Steps to convert an existing clinical trial to teletrial have been developed and piloted within a metro/ regional cluster allowing a patient to receive care closer to home. The patient had expressed desire for this. Teletrial wording for clinical trial protocol development- written and piloted in an HHS in QLD for a pending teletrial implementation. Sponsor feedback sought. Wording is generic enough to support commercially sponsored and collaborative group trials. To be reviewed by QLD TT committee before progressing beyond pilot. --- **Victoria:** (A) Organisation 1

The trials funded by this initiative are at an early stage and it is too soon to comment on whether the new technologies under evaluation have been embraced by clinician and patients.

With regard to new methodologies, s47F leads the NHMRC funded Assessing the Reduction of Recurrent admissions using OM-85 for the treatment of preschool Wheeze (ARROW): a multi-centre, randomised, double-blind, placebo-controlled trial. Over 40 sites around Australia and New Zealand are participating. Although ARROW is not directly funded by the Australian Teletrial Program, it is an important element of our efforts to use new technology to improve clinical trials access. We have developed and implemented a novel recruitment strategy that enables clinicians refer potentially eligible families to a central team via a web-based app. The recruitment and follow up of the Australian participants is then conducted remotely from Geelong. This mechanism has been well received by the clinicians and participants and recruitment is progressing accordingly.

(B) Organisation 2

Not applicable in this reporting period

(C) Organisation 3

Participating in a teletrial with s47G(1)(b) as a secondary site. Telehealth consent enabled in the protocol.

Utilising an electronic tablet to enable randomisation to trials in any department of NHW (ie Recovery Room)

Accepted a clinical trial that will enable participants to complete their "patient reported outcomes" directly into a database from home to limit clinic visits. This trial is also assessing the 'non-inferiority' of a new test to determine the need for chemotherapy in breast cancer. This technology could have huge impacts both to the patient group and the economics of early breast cancer treatment

(D) Organisation 4

N/A

(E) Organisation 5

Funding provided by this project for 1xFTE Clinical Trials Coordinator is enabling clinical trial coordination of a new Alzheimer's Disease trial in geriatric medicine. This trial is investigating the application of a 'medicine' therapy with the intent of disease severity reduction and improve quality of life comparing the effect of the 'medicine' versus placebo. The findings of this trial will potentially lead to a new health technology being embraced by clinicians and patients, both locally and globally.

(F) Organisation 6

Due to locality travel is often a barrier for patient engagement. The use of telehealth is now embedded in practice and facilitates access to trial clinicians from home if suitable to the trial protocol.

Support of technology such as an iPad for use in Clinical trials clinic and development of foundations to improve trial delivery on site. Engagement with metropolitan sites under the teletrial model has also enabled access to care options not currently available at LRH, while certain aspects of the trial can be undertaken closer to home with remote monitoring of patient wellbeing by the satellite site. Inclusion of PRO measures is also important.

(G) Organisation 7

Nothing to report

Western Australia:

During initial site visits and focus group meetings, the Silhouette Star camera, used to quantitatively score diabetic foot ulcers, has been identified as a new technology which may enable the conduct of diabetic foot ulcer clinical trials and wider Telehealth clinics in Regional, Rural and Remote (RRR) hospitals. The WA RCCC are reviewing the technology and its utility for Teletrial Program. This will potentially allow for earlier intervention on foot ulcers and prevent hospital admissions into metropolitan and regional hospitals.

[2]A health technology is defined by the World Health Organisation as "the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives."

Measure Four: New health interventions are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health interventions
- measures the awareness of new health interventions among clinicians and patients
- embeds new health interventions into clinical practice

Where applicable, how are the health interventions[3] changing health practice amongst medical practitioners involved in the clinical trials?

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

Queensland:

QRCCC Cluster Start-Up Specialists (CSUS) have:

- supported a regional clinical trials service (Mackay HHS) by increasing capability of the trial staff at the new site, allowing a complex haematology patient to access clinical care closer to home via teletrial.
- travelled to West Moreton HHS (Qld), and Adelaide RCCC for building capacity and networking for teletrials.

- supported (along with other QRCCC staff) a number of new PIs and AIs to understand the teletrial model
- completed the start-up of new trials in fields of medicine that are new to the Qld HHS

Victoria:

(A) Organisation 1

It is too early to expect practice change from the trials currently underway.

The ARROW trial, described above, is enabling many more end-user to be involved in the referral-recruitment process than would otherwise be the case. The high level of end-user participation will facilitate efficient translation of the trial's findings.

The FIREBRICK trial of nasal povidone for viral upper respiratory tract infections involves general practitioners credentialed as sub-investigators conducting recruitment at two participating satellite sites - one in Geelong and the other in Ballarat. FIREBRICK is the first trial of this type that these sites and sub-investigators have participated in.

(B) Organisation 2

The clinical trials in this report are newly approved and the new health interventions have not yet been embedded into practice.

(C) Organisation 3

N/A

(D) Organisation 4

N/A

(E) Organisation 5

As above (section 1.6), the intervention in this clinical trial seeks to reduce the disease severity and improve quality of life of participants during and/or following completion of therapy.

(F) Organisation 6

Opening of teletrials that enables greater access of regional patients to interventions offered at our metropolitan primary site, thus enabling greater treatment options and access to health care closer to home. Integration of telehealth and flexibility in treatment options/locations is an innovative approach to care. Our clinicians have embraced the opportunity to engage in clinical trials. Acting as a PI or AI often sits outside their normal clinical obligations, and they are eager to under professional development to enhance their own skills while being able to offer their patients more care options.

Community awareness and education on the availability of clinical trials at LRH and what is meant by the term is also key to ensure open access to care options, promote accessibility and reduce possible stigma. Community engagement and community events are a priority for our site with an aim to provide opportunities for improved health outcomes particularity to regional communities and Indigenous populations. We have local ambassadors with lived experience who champion the positive benefits of trial engagement to our community.

(G) Organisation 7

Nothing to report

Western Australia:

The Western Australian Country Health Service (WACHS) has a Research and Innovation Strategy focused on our health service driving the research agenda and translating research. The Australian Teletrial Program (ATP) is being established with this focus in mind with initial trials linked to regional health priorities. Ensuring that co-design of trials happens at the beginning will assist with changing health practice in the future.

For example, a double-blind, placebo controlled interventional vitamin study for diabetic foot ulcer patients has been assessed for implementation as a Teletrial. This is an ideal study to confirm all processes are adequate and well governed, which will boost confidence in primary and satellite site researchers that the ATP model is safe for patients. It represents a significant area of interest for the local patient population. It also affords us the opportunity to work with endocrinology, infectious diseases and podiatry within the single study. We will be able to see patients both at the satellite site and the primary hospital depending on patient preference and provide support using the virtual WA RCCC study coordinator service. The primary investigators do not have study coordinator support so without the WA RCCC this trial would not be available to country patients. We are currently working towards governance approval late in Q4 2022, pending the CTRA legal review.

The same research team have a similar study that is being designed for patients with diabetic amputations. As a result of the positive WA RCCC interaction with the diabetic foot ulcer study, the researchers requested WA RCCC be involved in drafting the new protocol to ensure it is designed to be suitable for ATP RRR patients across WA prior to Ethics submission. The vision would be to have every region involved in this Teletrial.

[3] A health intervention is defined by the World Health Organisation as an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions.

Measure Five: Research community has greater capacity and capability to undertake translational research

This measure considers the extent to which outcomes of MRFF-funded research:

- increases researcher capacity
- improves the awareness of translational research within the research community
- supports capability development to undertake translational research

	Full Time	Part Time	Casual
Target number of positions to be created	**TOTAL - 49** Northern Territory – 5 Queensland - 6 South Australia – 9 Tasmania - 5 Victoria - 17 Western Australia – 7	**TOTAL - 44** Northern Territory – 4 Queensland - 21 South Australia – 1 Tasmania – 0 Victoria – 16 Western Australia - 2	Victoria – 5
Actual number of new positions created	**TOTAL – 27** Northern Territory – 2 Queensland – 6 South Australia - 3 Tasmania – 5 Victoria – 8 Western Australia - 3	**TOTAL - 23** Northern Territory – 0 Queensland – 15 South Australia – 2 Tasmania – 0 Victoria – 5 Western Australia - 1	Victoria – 0

Please provide details on the number and nature of the positions created.

This may include, but is not limited to, study coordinators, research nurses, pharmacists, clinicians, and researchers.

Northern Territory:

Two full-time positions below have been created and filled to support the implementation of the program in the NT

- Teletrial Nurse Management Coordinator as the Program Manager 1.0FTE
- Teletrial Program Support Officer 0.8FTE

Queensland

Teletrial Coordinators (Clinical Research Coordinators) x 16 across Queensland Hospital and Health Services (part time)

Teletrial Liaison Coordinating Officer x 1 (full time)

Cluster Start up Specialist x 2 (full time)

Nurse educators x 2 (part time)

Assistant Director of Nursing/RCCC Director x 1 (full time)

Administration Officer x 1 (full time)

Clinical Director x 1 (part time)

Australian Teletrial Program National Office team

Director x 1 (full time)

Senior Program Manager x 1 (full time)

Project Officer x 1 (full time)

Administrative Officer x 1 (full time)

South Australia:

- Medical Director 0.2FTE
- Project Manager 0.8FTE
- Clinical Trial Liaison Officer 1FTE – located in s47F SA
- Administrative Officer 1FTE
- Cluster Start-up Specialist SA 1FTE
- Cluster Start-up Specialist SA/NT – currently recruiting
- Training and Development Officer – currently recruiting
- Clinical Research Coordinator – South East – will be recruited in the coming months
- Clinical Research Coordinator – Riverland – will be recruited in the coming months
- Clinical Research Coordinator – Whyalla/Port Augusta – will be recruited in the coming months
- Clinical Trials Pharmacy Support – 1FTE to be split across primary and satellite sites

Funding was provided for 2 x Clinical Research Coordinator roles however the SA/NT RCCC team has achieved co-funding arrangements with the Riverland Mallee Coorong LHN and the 3 universities to increase this to 3 FTE and ongoing appointments to attract high quality candidates to build capacity and capability in regional SA.

Tasmania:

The positions created are to establish baseline infrastructure:

Project Coordinator

Research Governance Officer

Teletrial Project Officer

Clinical Trials Liaison Officer

ICT System Program Officer

Victoria:

(A) Organisation 1

- 1 x Clinical Trial Coordinator (funded by ATP funding)
- 10 x FTE positions created (since April 2021) across the organisation for clinical trials staff, principal investigators, and researcher
- Trials with teletrial components:
    - 1 x Project Coordinator (investigator-initiated study)
    - 5 x Research Assistants (investigator-initiated study)
    - 2 x Sub-Investigators (1 at each primary health care site for FIREBRICK),
    - 2 x Medical Students at one site ((Kardinia Health)

(B) Organisation 2

- 1 x full time Regional Clinical Trial Coordinator
- 1 x full time Clinical Trial Coordinator
- 2 x part time research nurses

(C) Organisation 3

Positions as per funding agreement

- 1 x 0.8FTE Clinical Trial Coordinator
- 1 x Regional Teletrial Start Up Coordinator
- 1 x Clinical Lead

(D) Organisation 4

- 1 x full time Clinical Trials Project Officer
- 1 x Clinical Trial Coordinator

(E) Organisation 5

- 1 x full time equivalent Clinical Trial Coordinator
- 1 x part time Clinical Trial Coordinator
- 14 x Investigators involved in new clinical trials (funded by organisation via fractionated research time)

(F) Organisation 6

- 1 x Clinical Trial Coordinator
- 1 x Clinical Trial Support Officer

(G) Organisation 7

1 x Clinical Trial Project Officer

Western Australia:

Proposed Position Title	Classification and Level	FTE	Status	Comment
Project Lead - Teletrials	HSO G9	1	Recruitment underway	Position filled for 3 months and vacated on 17 July 2022. Readvertised.
Clinical Teletrials Manager	HSO G8	1	Recruited	Commenced 15 July 2022
Clinical Teletrials Coordinator	HSO G5	1	Not started	Advertisement in approval process
Project Officer	HSO G6	0.6	Recruited	Commenced 4 July 2022
Research Officer	HSO G5	1	Not started	Advertisement in approval process
Research Nurse	ANF RN 2	1	In progress, for advertisement as RN2	Originally RN1. Now to be submitted as RN2. Advertisement in approval process.
Senior Business Officer	HSO G8	1	On hold	This position may be downgraded to G5 BSO
Senior Pharmacist	HSU P3	1	Recruited	Commenced
Medical Lead	N/A	0.2	Recruited	Commenced

For any research roles created by your project, please detail the career stage(s) of the researcher(s) (early, mid or established).

Northern Territory:

Nil to date. Ongoing consultation with the relevant stakeholders both internally and externally to identify enablers/barriers in participation in clinical trials/teletrials. This barrier analysis will form an action plan to guide best approach implementing the program in the NT.

Queensland

Clinical Research Coordinators x 12 at various HHS across QLD – Early x 6 and Mid x 6

Teletrial Liaison Coordinating Officer x 1 - Mid

Cluster Start up Specialist x 1 – Mid

Cluster Start up Specialist x 1 – Established

Nurse educators x 2 – Established x 1, Mid x 1

ADON x 1 - Established

Clinical Director x 1 – Established

Victoria:

(A) Organisation 1

The Clinical Trials Coordinator employed by ATP funding is an early-mid-career researcher with >5 years of experience.

For trials that have a teletrial component the newly created positions are mid-career for the project coordinators, early career for the research assistants, and mid to established career stages for the clinicians. These positions are funded by the trials and or Deakin University.

(B) Organisation 2

- Mid and established

(C) Organisation 3

- Clinical Trial Coordinator – Established
- Regional Teletrial Start Up Coordinator – Early
- Clinical Lead - Mid

(D) Organisation 4

N/A

(E) Organisation 5

N/A

(F) Organisation 6

- Clinical Trial Coordinator – Mid- but new to trial coordination
- Clinical Trial Support Officer- Mid

(G) Organisation 7

Clinical Trial Project Officer: mid-career researcher

Western Australia:

The medical lead (established) is now an investigator for 3 additional trials. The clinical trial manager (established) and senior pharmacist (established) will undergo protocol development with the endocrinology team.

Provide a catalogue of new infrastructure developed by the project to date and use of infrastructure by researchers in a collaborative manner.

Northern Territory:

Have updated the NT Health Research

https://health.nt.gov.au/data-and-research/nt-health-research/teletrial-program to include a section for the Teletrials program which links to the national website and local contacts.

NT team has also created NT Health Clinical trials register and published it on the website

https://health.nt.gov.au/data-and-research/nt-health-research/nt-health-clinical-trials-register

to provide visibility on all active and authorised trials across NT Health.

Teletrials Toolkit has been adapted specifically for SA/NT with the following documents to be published on the website in the coming weeks:

- Evaluation of a Clinical Trial as Teletrial Checklist
- Evaluation of a site as Satellite Site Checklist
- Primary Site Workflow Checklist
- Satellite Site Workflow Checklist
- Notification to reviewing HREC of satellite site joining teletrial Checklist
- Primary Site RGO Submission Document Checklist
- Satellite Site RGO Submission Document Checklist
- Equipment/Facilities checklist for Satellite sites
- Quick Guide to Establishing a Teletrial

To date, there has been no funding spent on equipment however an assessment was conducted. However, ongoing consultation with the relevant stakeholders both internally and externally to identify enablers/barriers in participation in clinical trials/teletrials. This barrier analysis will form an action plan to guide best approach implementing the program in the NT.

Queensland:

- Funding agreements signed to provide support for equipment purchases to set up a clinical trial unit within some of the HHSs and for specific trial activity e.g., Centrifuges and freezers.
- Extension of license for existing clinical trial management system at one of the larger HHSs in QLD.
- Worked collaboratively with a teletrial cluster and sponsor to support funds for courier fees as collaborative group sponsor unable to fund delivery of IMP to more than one site.
- Collaboration with the four remote HHSs in QLD (Torres, and Cape HHS, North-West HHS, Central-West HHS (CWHHS) and South-West HHS) to provide additional support for funding 0.5 FTE RGO and 0.5 FTE CRC. Due to the remoteness a single CRC or RGO for the size of these remote HHSs cannot lead the change management alone. The CRC

position has been upgraded, supported by the grant, to allow the level of autonomy required and coordination across the HHS.
- Presentations by the ADON QRCCC to all levels of one of the remote HHSs CWHHS to provide the information about clinical trials/ teletrials and secure commitment to the HHS being involved in clinical trial activity in the near future.
- Introduction booklets - New Ethics/ RGO, New Supporting departments, New HHS Clinical staff, New Finance Department under development
- Teletrial Coordinators Meetings and Education Sessions (alternate fortnights)
- Trial and Teletrial shared information sessions with Universities, New PI's Sponsors, HHS, RGO's. Presentations at seminars and meetings. ADON QRCCC presented MHIQ Griffith University 11th August 2022.
- Steps to convert an existing clinical trial to teletrial and exemplar letters to ethics and RGOs.
- First Draft of a Supervision plan for medical device trials- piloted with HHS site.
- NCTGF exemplars of how HHSs can set up for clinical trial activity and collect evidence against standards 1 & 2.

South Australia:

Teletrials Toolkit has been adapted specifically for SA/NT with the following documents to be published on the SA/NT RCCC website in the coming weeks:

- Evaluation of a Clinical Trial as Teletrial Checklist
- Evaluation of a site as Satellite Site Checklist
- Primary Site Workflow Checklist
- Satellite Site Workflow Checklist
- Notification to reviewing HREC of satellite site joining teletrial Checklist
- Primary Site RGO Submission Document Checklist
- Satellite Site RGO Submission Document Checklist
- Equipment/Facilities checklist for Satellite sites
- Quick Guide to Establishing a Teletrial

Education and Training: The V-CTEC learning management system went live in South Australia on 26 September 2022 and is offering clinical trials education to all South Australians at no cost to the end user.

To date there has been minimal funding spent on equipment. However an assessment was conducted during the 3 regional site visits and once the clinical trials nurse positions have been filled, equipment needs will be further identified to ensure clinical trial capability can be provided at the satellite sites.

Tasmania:

Teletrials Standard Operating Procedures are under development in accordance with the National Teletrial Standard Operating Procedures.

Victoria:

(A) Organisation 1

Since the last report, the site now has a fully functional and operational trials centre formally known as the ACCTC (Adrian Costa Clinical Trials Centre). The ACCTC is the overarching system and infrastructure that support clinical trials activity at Barwon Health, with which each of our clinical trials teams is affiliated. The new building has 12 consulting spaces, 5 work areas for CRAs, 3 research fellow spaces, 3 open plan manager cubicles, a main reception area, 2 participant waiting rooms, a meeting / conference room and a well sized PC2 compliant laboratory.

(B) Organisation 2

None since last report due to staff changes at Bendigo Health.

Clinical Trial Coordinators are newly recruited so this will be a focus for the next reporting period.

(C) Organisation 3

- Teletrial Standard Operating Procedures developed for site
- Teletrial working documents (supervision plan etc) developed for site
- Electronic Site File Management System currently being implemented
- New Site Profile Document developed to provide to sponsors
- Business case submission for procurement of -80 freezer
- Retention of equipment for a closed clinical trial (breathalyzer, digital tablet) for continued use of department

(D) Organisation 4

N/A

(E) Organisation 5

- Adopted site specific National Mutual Acceptance Generic Standard Operating Procedures for Clinical Trials including Teletrials – employed organisation wide
- Teletrials Supervision Guide taken from CTRSS toolkit published by Victorian Government
- Teletrials Clinical Consultation Guide taken from CTRSS toolkit published by Victorian Government

(F) Organisation 6

- Research policy and 17 SOP's
- Trial Feasibility and EOI
- Supervision Plan Template
- Start-up flowchart
- Informed consent portfolio
- Site CV

- Fast Facts Template
- Trial Handover Document and Checklist
- Facilitate weekly oncology meetings – now including non-cancer trials
- Site Pre-Selection Visit Checklist
- Site Initiation Checklist
- Clinical Trial Close Out Checklist
- Trial Kick-off meeting with PI Procedure and Checklist
- Investigator Site File & Satellite Site Study File Checklist
- Internal Clinical Trials Working group and coordinator catch-up

(G) Organisation 7

Nothing to report yet.

Western Australia:

The senior pharmacist conducted eight national IPMS demonstrations for states and territories involved in the ATP program as digital infrastructure will be required to manage IMP trials at scale in RRR hospitals. An IPMS is a complete digital solution that facilitates electronic documentation of Investigational Product (IP) activities, eliminating the barriers posed by paper-based records. The system provides a major critical infrastructure upgrade to improve capacity within public hospitals for interventional research and easily facilitate clinical trial activity between public sites and industry at large. It will facilitate remote auditing between industry Sponsors, regulators and sites and facilitate virtual governance of satellite sites by primary sites. This innovative digital technology will allow more Australians to access clinical trials through improved capacity, and embed a new, best practice health technology into clinical trial units. It will also facilitate compliance with the new Australian Commission NSQHS Clinical Trial Framework. WA, SA and NT committed to developing an ATP supported submission to the Medical Research Future Fund (MRFF) National Critical Research Infrastructure grant for state-wide implementation with associated jurisdictional policy and best practice workflow upgrades. WA led the submission process and developed the proposal in full. Unfortunately, the submission was not successful due to the MRFF deadline constraints however a state-wide implementation will be pursued and potentially a national MRFF submission may be considered in 2023.

RRR WA has no infusion manufacturing capability and relies on a Therapeutic Goods Administration approved manufacturer to compound patient treatments. The state aseptic contract that governs this arrangement currently does not include clinical trial interventional therapies. In addition, the compounding clinical trial service has not been established within this contractor. WA RCCC has executed a contract variation to the state aseptic tender to add clinical trials as an accepted contracted good. In addition, WA RCCC is working with the contractor to develop the clinical trial service so that infusion-based trials can be conducted. Once this contract is executed and the service has been established, interventional, infusion based Teletrials can be conducted across all RRR sites with the ability to administer patient treatment.

WA RCCC is leading a procurement process for an education platform for Teletrials (likely V-CTEC). Once procured, this will be available for all researchers in WA to access appropriate

clinical trial training modules to standardise education and support executive reporting of clinical trial training activity for the national framework.

WA RCCC has engaged the State Solicitors Office for legal review of the CTRA Teletrials sub-contract to ensure that a state-wide process will be available that complies with the Health Services Act 2016.

WA RCCC has spearheaded a report with feedback from the state-wide clinical trial pharmacy network to implement an ePrescribing Clinical Trial module for a new state-wide software program. That report has been submitted to the application and WA RCCC is currently leading the working group to design and develop the ePrescribing module. This will ensure that outpatient clinical trial therapies can be prescribed by metropolitan clinicians for dispensing at RRR sites. The current process does not comply with the Medicines Act and Regulations in some sections so the module development will remediate the risk for inter-Health Service governing bodies.

WA RCCC is in the final stages of negotiating a physical central pharmacy, co-located within another public hospital pharmacy. This will act as the central infrastructure point to virtually oversee the regions and receive and distribute IP as required.

Please provide the total number of conference presentations, publications, citations, mentions in social media, workshops, etc. generated to date in relation to the project.

Northern Territory:

Actively promoting the program implementation in the NT through our relevant stakeholders as listed below. NT have also distributed an internal memo/bulletin to raise program awareness to all staff and will distribute regular updates on program implementation activity throughout the program period. Our updated website to include Teletrials program can be found at https://health.nt.gov.au/data-and-research/nt-health-research/teletrial-program

Presentations/workshops have been given to the following internal stakeholder groups:

- NT Health Research Governance Office, including Central Australia Research Governance Office
- Top End, Big Rivers and East Arnhem Clinical Innovation and Research Committee
- Royal Darwin and Palmerston Hospital Division of Medicine Research Committee
- Royal Darwin and Palmerston Hospital Division of Surgery and Critical Care Research Committee
- Royal Darwin and Palmerston Hospital Clinical Trials Unit Committee
- NT Health Virtual Care Steering Committee
- NT Health – Health Direct project team
- NT Health Research peer network
- NT Health Finance
- Territory Pathology
- NT Health Director of Infrastructure
- NT Health Chief Nursing and Midwifery Office

- NT Health Education and Research team
- Royal Darwin and Palmerston Hospital Executive team
- Royal Darwin and Palmerston Hospital Mental Health and Alcohol Other Drugs Senior Leadership team
- Road show to Katherine Hospital – scheduled for 11-12/10/2022
- Road show to Gove District Hospital – tentatively scheduled for 28/10/2022
- Road show to Alice Springs Hospital – scheduled for 16-17/11/2022 Presentations/workshops have been given to the following external stakeholder groups:
- Menzies School of Health Research
- Flinders University
- Aboriginal Community Controlled Health Organisations (ACCHOs)
- GCP Training attendees which consists of internal and external staff
- ASCEND Clinical Trial Team SA and NT
- SA CALHN Ethics/RGO

Queensland:

- Workshops/education- further sessions x 10 to 28th September 2022 available in Office 365 Stream
- TROG presentation- Teletrials 2nd July 2022- QRCCC CSUS
- ARCS conference May 23rd to 25th Teletrials Roadmap QLD & Victoria expert panel – QRCCC NED x 2
- Presentations- 1. CWHHS and 2. CWHHS executive team 8th June 2022-Teletrials- QRCCC ADON
- Presentation- Attendance at Clinical senate meeting 8th June 2022-Teletrials- QRCCC Clinical Director
- Presentation to State-wide Rural and Remote Clinical Network forum held in Gladstone 8th June 2022- QRCCC TTLO
- MHIQ/ Griffith University CTU seminar 11th August 2022- Australian Teletrial Program- QRCCC ADON
- Presentation- Attendance at Metro North and South Brisbane- Teletrial education and networking 2022-Teletrials- 14-18th August 2022-QRCCC Clinical Director
- Visit for one week to CWHHS was converted to virtual week due to outback weather and roads closed- 29th August 2022- QRCCC ADON.
- Presentation at DDHHS Grand Rounds 15th September 2022- Teletrials- QRCCC ADON
- Presentation at QLD CE forum 20th September 2022- Teletrials- QRCCC Clinical Director

South Australia:

Presentations have been given to the following stakeholder groups:

- Commission on Excellence and Innovation in Health Clinical Network Executive Committee 22 August 2022
- Southern Adelaide Clinical Human Research Ethics Committee – 15 August 2022
- CALHN Research Office – 6 July 2022
- WCHN Research Office – 11 July 2022
- NALHN Research Office – 13 July 2022
- Country SA PHN – 14 July 2022
- Radiation Oncology RAH and Australian Bragg Centre – 29 August 2022
- SALHN Research Week – 30 September 2022
- NALHN Research Day – 15 September 2022
- Rural Support Service – Clinical Services – 1 September 2022
- UniSA and University Department of Rural Health – 18 August 2022
- Health Translation SA – 6 September 2022
- ASCEND Clinical Trial Team SA and NT – 14 July 2022
- Southern Adelaide Diabetes and Endocrine Services – 13 September 2022
- Pen CS – 23 August 2022
- Rosemary Bryant AO Research Centre, UniSA – 6 September 2022
- CALHN Haematology – 15 September 2022
- Aboriginal Health Council of South Australia – 15 September 2022
- SA Pharmacy – 30 August 2022

SA/NT RCCC Attendance at the following conferences:

- ARCS Annual Conference 7 – 9 June 2021
- National Rural Health Conference 2 – 4 August 2022

Regional Site Visits

- Mount Gambier Hospital – Mount Gambier Hospital, LCLHN, Flinders University Rural Health SA, Benson Radiology
- Port Augusta/Whyalla – Adelaide University Rural Clinical School, RFDS, FUNLHN, Whyalla Hospital
- Riverland – RMCLHN, RGH Gynaecology, Berri Medical Clinic, SAMI Medical Imaging

Victoria:

(A) Organisation 1

None to date

(B) Organisation 2

s47F presented at the CTRSS Industry Forum in Melbourne on 22/7/22.

Currently the site is planning to present and display a promotional poster at Bendigo Health RESEARCH WEEK during October 2022.

(C) Organisation 3

- Promotion of CTRSS during NHW Research week on NHW Facebook page 7 September 2022

https://m.facebook.com/story.php?story_fbid=pfbid02xCQJTce8E1vi6ZoViuWJ6HXNHArsJqdkC2RADyeoxhkw4TWL4SRiU2Y832SurndMl&id=393904724019334&mibextid=CbyEMU

- Involvement in Research Week Launch Video 5 September 2022
- Presentation by s47F for NHW Research Week Talking Research Event Titled "Delivering clinical trials and teletrials in rural and regional Victoria" 08 September 2022
- Participation in a Regional Health Careers Day in association with Charles Sturt University and TAFE to promote careers in Research and Clinical Trials 03 August 2022

- Promotion of CTRSS on International Clinical Trials day on NHW Facebook page 20 May 2022

https://m.facebook.com/story.php?story_fbid=pfbid027RTXQ4QF2hDpiZgzUJ4fUkDBXeYVZKAv82nzpE56wYiLBbU6x1dDAyq78zzcha5RI&id=393904724019334&mibextid=CbyEMU

- International Clinical Trials day response to Neuroscience Trials Australia Post LinkedIn 20 May 2022

https://www.linkedin.com/posts/nicole-humphreys-21624b123_clinicaltrialsday-ctd2022-icdt2022-activity-6933200452176015360-JuwE?utm_source=share&utm_medium=member_desktop

- VCCC Skilled Internship program – LinkedIn Feature on NHW 20 May 2022

https://www.linkedin.com/posts/victorian-comprehensive-cancer-centre_internationalclinicaltrialsday-clinicaltrials-activity-6933277979678580736-wsfA?utm_source=linkedin_share&utm_medium=member_desktop_web

- Submission to White Coats Foundation "Your Voice Your Story" – International Clinical Trials Day Initiative

https://whitecoatsfoundation.org/initiatives/your-voice/

(D) Organisation 4

Clinical Trials Consumer Awareness Campaign (in collaboration with VCCC Alliance team) - have a Consumer Awareness Campaign scheduled for Oct/Nov – this campaign includes some introduction to Teletrials for a consumer audience.

(E) Organisation 5

N/A

(F) Organisation 6

Introduction to Clinical Trials to Year 12 students

Feasibility and Start Up to the VCCC

What is a Clinical Trial?

Regional & Remote Clinical Trials

Getting Research Projects Approved

Please see attached for full list

(G) Organisation 7

Nothing to report yet.

Western Australia:

WA Country Health Service Annual Report 2020-2021.

Measure Six: Health professionals adopt best practices faster

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or establishes best practices
- assesses the speed at which best practices are communicated to clinicians and health service administrators
- identifies how best practices are understood and adopted

Where applicable, how well were the best practices[4] understood and adopted and how was/will this (be) evaluated? Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

The following examples show how well best practices are understood and adopted:

Queensland:

- Continued Pre and Post evaluations of each Education session provided by QRCCC.
- GCP Training and clinical research training modules-PRAXIS and ARCS – Pre and Post evaluation – external provider for courses from April to September 2022
- Profiling of each HHS in QLD is underway to determine current capacity for clinical trial via teletrials
- Number of clinical trials using teletrial and patients enrolled across QLD
- Onsite support for HHSs in QLD

Tasmania:

Prospectively, the health service is looking at ways to redesign and streamline the conduct of clinical trials for some clinical areas given the small size of the jurisdiction to harmonise research activity. There is to some effect duplication of services. Duplication of pharmacy, pathology and governance reviews, involving duplicating governance submissions, contracts and budgets. The new model would propose that the trial only be opened at one of the health services (likely the tertiary as the primary site) and then operationalised as a teletrial to where the patient resides or nearest regional hospital. There are a cohort of clinical trials currently opened at the main tertiary site that will be piloted using this approach.

Victoria:

(A) Organisation 1

Barwon Health has recently engaged s47G(1)(a) to reimagine the research organisational structure within the BH research directorate and the operations related to it.

Key items for review have been:

- review the organisational structure of research at Barwon to develop recommendations to assist the Director of Research to reform it to achieve optimal efficiency
- review the existing financial structures to identify an optimal structure to underpin financial transparency, accountability and sustainability in line with the requirements of the NCTGF;
- work with the Research Ethics, Governance and Integrity (REGI) office and other relevant stakeholders to develop an organisational approach to delivering "governance by design" to meet the requirements of the NCTGF and to streamline existing operations.

On finalisation of the report and recommendations and endorsement from the executive BH will be able to move forward with creating new operational roles within research. These will assist with the development of SOPs and setting research standards across the organisation to comply with the NCTGF and improve research across the board for current and new researchers as well as consumers,

(B) Organisation 2

Not applicable. It is too early within the program to understand and adopt best practices.

(C) Organisation 3

Clinical Trial Questions included in organisation Best Practice Clinical Learning Environment (BPCLE) Survey to gauge levels of understanding throughout organisation and compare each year as the service expands.

(D) Organisation 4

N/A

(E) Organisation 5

Good Clinical Practice (GCP) is best practice. All staff involved in clinical trials and clinical research at GV Health are required to have GCP certification. GCP certification ensures trial staff an understanding of the running and proper conduct for clinical trials.

In this reporting period, **12 staff completed GCP training. A total of 150 staff are GCP certified.**

(F) Organisation 6

The hospital strives for best practice across all domains and care that aligns with our core values:

- Person-centered care
- Integrity
- Excellence
- Working together

Our Vision is to be a leading regional healthcare provider delivering timely, accessible, integrated and responsive services to the Gippsland community. As such, the site will encourage research that fosters innovation in the delivery of services and care for our patients through implementation of the Research Governance framework. Our vision encompasses clinical, public and evidence-based research resulting in benefit from clinical trials and other research outcomes for a range of health conditions.

Assessment of our hospital standards is included in practices such as hospital accreditation, monitoring visits, internal audits, policies/SOPs, adherence to the NCTGF, clinical learning environment, GCP, clinical competency, and access to the Skilled Intern Program in collaboration with University of Melbourne.

Strong relations with our partners including DJPR, TrialHub and RTN, as wells as Monash And Federation Universities enable education, mentoring and growth opportunities to improves processes towards best practice.

(G) Organisation 7

N/A

Western Australia:

An IPMS is considered best practice software to manage IMP clinical trials and will bring a number of benefits to RRR sites. This will include remote monitoring with clinical trial Sponsors to increase the attractiveness of interventional clinical trials in RRR sites, remote oversight/governance from more established units, and standardised workflows. These benefits were explored in Activity 1 (context mapping and implementation scoping). Proposals have been developed, including a research activity to be conducted by the Curtin University Clinical Trial Centre, for pursuing funding opportunities. The proposal includes policy mapping exercises to receive maximum benefit from investment and streamline the implementation approach.

[4] WHO defines Best Practices as "exemplary public health practices that have achieved results, and which need to be scaled up so as to benefit more people".

Measure Seven: The community engages with and adopts new technologies and treatments

This measure considers the extent to which outcomes of MRFF-funded research:

- involves the community in prioritising, designing and conducting research
- promotes community awareness of new technologies and treatments, and their benefits
- promotes community support for new technologies and treatments

How were the community members and consumers engaged in prioritising, designing and conducting research through means such as public consultations?
Northern Territory: Work is underway to establish an NT Teletrials Advisory Committee and NT Teletrials Steering Committee to support program implementation in the NT. First meeting for the NT Teletrials Advisory Committee is scheduled for Wednesday, 16th November 2022 at Alice Springs. This committee will provide advice to the SA/NT RCCC on the delivery of clinical trials closer to home from a clinical, consumer and community perspective. Nomination for members have been received and are closed to being finalised from organisations/health services and expression of interests have been sought from consumers, carers and/or community to ensure effective partnerships. NT Health engagement of stakeholders operate on three levels – individual consumer level, the community level and the systems level. Up to 3x consumer representatives have been sought to join the advisory committee. Engagement with the Aboriginal Community Controlled Health Organisations (ACCHOs) has been undertaken through NT Health Aboriginal Health Partnership Committee. By having ACCHOs representatives in the NT Teletrials Advisory Committee, this will promote an active partnership to ensure their views are considered and reflected in decision and outcomes throughout the program. **Queensland:** ▪ Teletrials Steering Committee QLD established and to include consumer representatives ▪ ATSI representation (Senior level) on the Committee ▪ QRCCC ADON has actively engaged a number of HHSs in QLD at all levels to provide Teletrial education. ▪ CSUS and NED from QRCCC having been working with sites to provide teletrial education and site set up. **South Australia:** The SA/NT RCCC is in the process of establishing the SA Teletrials Advisory Committee. This committee will provide advice to the SA/NT RCCC on the delivery of clinical trials closer to home

from a clinical, consumer and community perspective. The inaugural meeting for this committee is scheduled for Thursday 10 November 2022.

The SA Teletrials Advisory Committee will have up to two nominees of consumer representatives. An Expression of Interest for the consumer representatives was circulated through the regional LHNs and promoted at the country Health Advisory Councils state-wide conference in Port Augusta on 23 September 2022.

Engagement activities have occurred with the Aboriginal Health Council of South Australia who will also have representation of the SA Teletrials Advisory Committee.

Victoria:

(A) Organisation 1

The mental health focussed clinical trials work with the Consumer Advisory Research Network (CARN) to implement trials.

Establishing more extensive consumer engagement processes is priority of the overarching BH Research Strategic Plan but remains a work in progress.

(B) Organisation 2

- Extensive review of the Bendigo Health website has been undertaken throughout the reporting period by the VCCC SKILLED intern, s47F [redacted]. The website is in the process of being updated. A new section "For Patients and Families" will be launched in October/November 2022.
- Discussions around developing a Clinical Trial Ambassador Program are ongoing. Alfred Trialhub have offered assistance and mentoring to assist in this endeavour.
- A Public Forum will be conducted in Research Week in October 2022 to inform our community about our research and invite their participation.

(C) Organisation 3

2 Consumer members appointed to NHW Research Committee which undertakes a steering role for the CTRSS-ATP program at site.

Consideration given in feasibility process for demonstration in protocol of Consumer Engagement.

(D) Organisation 4

Recruitment is now underway for a Clinical Trials Consumer Partner, to enhance quality of our consumer awareness campaign. This will start the process of engaging consumers within the clinical trials unit's activity.

(E) Organisation 5

A clinical trials advisory group with consumer members from a state-wide point of view was proposed by DJPR. GV Health provided a consumer name for potential membership. To the best of our knowledge, this group is a work in progress.

(F) Organisation 6

As mentioned, community engagement and Indigenous health are areas of identified priority for clinical trial engagement and implementation in the Gippsland region and LRH. This aspect is part of the focus of our partnerships with TrialHub and RTN Revitalise. The site has local champions with lived experience who promote the positive aspects of trials closer to home and has hosted a Community Event in May 2022. Our Koori liaison's at LRH have also provided valuable input for consideration with regard to engaging Indigenous populations and providing trials that meet the need of our local demographics.

(G) Organisation 7

Nothing to report yet.

Western Australia:

The WA Teletrials Program will be governed by an internal to health Executive Committee on a day-to-day basis. However, the site intends to engage the community through a range of mechanisms already established including through our Patient and Consumer Engagement team for all of regional WA. This will be more formally established once the project lead is recruited. South Metropolitan Health Service has offered in-kind support for Albany Health Campus to be added to the ClinTrial refer app. This app is a patient facing clinical trial searching app designed for patients to identify suitable clinical trials.

Comments

You are welcome to provide any further feedback relating to the monitoring indicators or evaluation outcomes for your project to date.

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

Progress Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through progress reports. For varying your grant and grant agreement please refer to the MRFF Grant Variation Policy.

Please ensure that you are using the latest version of the Progress Report template. You must submit your report on the business.gov.au portal. You can enter the required information in stages and submit when it is complete.

Project Information

Grant ID	MRFRR000005
Grant Opportunity Name	Medical Research Future fund – National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant
Administering Organisation	The State of Queensland acting through Queensland Health
Chief Investigator A / Project Lead	Kaye Hewson
Grant Title	Australian Teletrials Program
Grant Agreement Start and End Dates	[From 19/09/2021] - [To 04/10/2026]
Research Activity Start and End Dates	[From 5/10/2021] - [To 30/09/2026]
Australia New Zealand Clinical Trials Registry Trial ID (where relevant)	
Reporting Period	[From 1/10/2022] - [To 31/03/2023]
If the Commonwealth Commercialisation Clauses apply to this project, have there been any changes to the Commercialisation Plan?	N/A
Do you plan to execute any new agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	No

Project Progress

1. *Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement.*

The comments field should clearly summarise progress at the end of this reporting period towards completion of the agreed research activities relevant to each milestone/objective and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Y2-Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities	04/10/2023	04/10/2023	50%

Australian Government
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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Y2-Regional Clinical Trial Coordinating Centre deliver support in each jurisdiction to embed teletrials in rural, regional and remote locations.	04/10/2023	04/10/2023	50%

Comments: The ATP is on track to meet most of the research building infrastructure which includes establishment of Regional Clinical Trial Coordinating Centres (RCCCs) and becoming operational. Most positions are now filled.
All RCCCs were represented in a recent national Sponsor workshop to introduce the staff and role within each jurisdiction.

1. Northern Territory (NT)

- Program Governance structure including an NT Teletrials Advisory Committee has been established.
- The NT RCCC is:
  - currently conducting a barrier analysis study to support the implementation of the ATP
  - engaging with multiple stakeholders to build awareness of the program in NT
  - focusing on supplying adequate support for clinical trial infrastructure outside of Darwin, including cold chain logistics.
- Recruitment to ATP funded roles is in progress – currently recruiting clinical research coordinators in Central Australia and the Big Rivers region, with recruitment for additional roles planned for East Arnhem and Barkly.
- Whilst no teletrials have commenced to date, two are going through Human Research Ethics Committee (HREC) approvals and several protocols are being reviewed for suitability.

2. Queensland (QLD)

- Queensland has discontinued the role of Teletrial Liaison Officer to divert funds to additional Hospital and Health Service staff to support Teletrials or research governance.
- Queensland continues to have success in establishing Teletrials and the Qld RCCC held an information sharing workshop in March 2023 aimed at Clinical Trial Managers, Clinical Trial and Teletrial Coordinators, Research Governance Officers and Principal Investigators.
- The Qld RCCC gives presentations to individual clinical networks regularly and runs a monthly Teletrial Coordinator education and development meeting.
- The ADON and staff travel extensively across the state to support TT coordinators and clinical trial centres to review their business model for increasing capacity.

3. South Australia (SA)

- South Australia has now recruited two out of three Registered Nurses- Clinical Research Coordinators outside of Adelaide to support three of the six regional Local Health Networks.
- A Training and Development Officer has been employed.
- The ATP-SA team has been working to support the start-up of clinical trials in country SA and Northern Territory (NT), including site feasibility, ethics, and governance applications, CTRAs, sponsor liaison, supervision plans training and equipment purchasing that otherwise would not be possible due to lack of research offices established in SA. In laying this groundwork a deal of risk management has been undertaken to ensure the success of the Teletrial program in SA
- Clinical Director plays a strong advocacy and engagement role within SA and Northern Territory and with the team has been engaging with CT stakeholders in state, Australia and internationally.

4. Tasmania (TAS)
   - Tasmania progress has been impacted by staff shortage; A Teletrial Coordinator has now been recruited however there is still a vacant 0.4FTE and Research Governance Coordinator.
   - New policy and procedures are in development for Research Governance, teletrial start-ups, Teletrial conversion steps and Teletrial Department of Health payment protocols -appendix to Supervision Plan underway, addition of sites-CTRA.
   - Identified several new CTs with potential to be included in ATP-Tasmania working with researcher and support staff to progress.
   - Providing centralised support for communication and queries and education sessions planned for next reporting period.
   - The Clinical Director plays a major advocacy and engagement role.

5. Victoria,
   - The Clinical Trial Support Service in which the RCCC two positions were established has recently moved from the Department of Jobs, Precinct and Regions to the Department of Health.
   - The ATP-VIC team has two RCCC positions funded by ATP and four members of the Coordinating Office for Clinical Trial research (Coordinating Office), in-kind contribution to provide centralised services to regions. The four in-kind positions, provide management with a Program Manager, data analyst, trial advisor, and administration.
   - Victoria chose to direct ATP funding to regional Victorian public health services and to form seven 'hubs. There are two study start-up specialists: one located in the north-east (servicing 3 regional 'hubs') and one in central west (servicing four regional 'hubs'). This approach provides a wide reach throughout regional Victoria and vests capability building within these health services. Four 'hubs' are in MMM3, two in MMM2 and one MMM1. A Medical Specialist is located at Northeast Health Wangaratta, and practices within the region, providing clinical trial services to local communities.
   - Two start-up specialists were established in 2022, one is newly recruited and the other vacant.
   - A recent workshop was held in Victoria for Regional Hub Research Clinical trial officers to meet and address the progress towards the National Clinical Trial Governance Framework with the Director ATP and Nursing Director QRCCC invited to present progress of establishing RCCCs and lessons learnt from Queensland.
   - Victoria continues to advance capability in the non-oncology specialities and meet monthly with the Clinical Trial Support service manager and staff for education and support. The seven hubs are at different levels of Clinical trial recruitment capability. The Victorian report in appendix 1 is a site-by-site progress summary.

6. Western Australia (WA)
   - A Program Lead for WA has been appointed. The WA ATP team now consists of a Medical Director, 1.0 FTE Project Lead, 1.0 FTE Pharmacist, 1.0 FTE Clinical Trial Manager, 0.4 FTE Research Governance Officer. Currently recruiting for a 0.5 FTE Research Officer.
   - WA has particular logistics challenges due to its vast area, the available resources in regional and remote areas, and challenges associated with transporting investigational drugs to regional, rural and remote clinics. Much work has been undertaken to address these barriers, including the introduction of ePrescribing software, an Investigation Medicinal Product Management software to connect all clinical trial pharmacies across the State, and contract re-negotiation with Baxter compounding services.
   - The first teletrial is about to commence in WA, targeting patients with diabetic foot ulcers.
   - Other significant work has occurred to develop new governance processes including Teletrials Supervision Plans and Teletrial Participant Information Consent; Pathology negotiations to ensure regional support for Teletrials, training local physicians in Good Clinical Practice, obtaining ethics approvals for this TT, executive discussions raising awareness, ICT approvals and procurement of a new Silhouette camera Albany Campus.
   - The team have also reviewed 18 WA -based trials for Teletrial eligibility, engaged extensively with the community representatives via District Health Advisory Committees, worked extensively to ensure the participation of WA Health Service Providers with legal and risk cover reviews.

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Y2-Evaluation program continues.	04/10/2023	04/10/2023	50%

Comments: enter progress summary to date, justifications for changes or delays and strategies to rectify Embedding customer data collection and operations evaluation -all planning for embedded data collection is complete.

The evaluation team of James Cook University and Australian Centre for Health Services Innovation, Queensland University of Technology has delivered their second progress report which includes:

- An interim analysis of evaluation study for impact and sustainability planning -awaiting stage 2 ethics to manage the secure transfer of data from ATP REDCap database to occur six monthly after initial transfer.
- An RCCC engagement plan is in place with a suite of jurisdictional visits booked for May and June 2023.

By this next reporting period the evaluation team will have completed the following activities that will lead to achieving KPI 3 due on 4 September 2024:

- Obtained additional relevant Human Research Ethics Committee approvals, and local Research Governance
- approvals to carry out Stage 2 data collection in the relevant jurisdictions as per the protocol
- Established ongoing processing and data monitoring of the REDCap data extracts provided by the national ATP National Office.
- Established ongoing data processing and monitoring of RCCC/ATP activity reports provided by the national ATP National Office.
- Commenced regular contact with RCCCs in each jurisdiction for data collection and operations/process evaluation.
- Submitted manuscript on Stage 1 interview results to a peer-reviewed journal.
- Submitted manuscript on Stage 1 clinical trial activity results to a peer-reviewed journal.
- Progressed an evaluation consumer engagement strategy that aligns with the ATP consumer engagement strategy.

2. *Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)*

The Executive Committee met in December 2022 and confirmed jurisdictional commitment to ensuring the Australian Teletrial Model (ATM) is sustainable. The Executive Committee also supported the Director of Research, MRFF to be invited annually to the Executive Committee meetings. A key learning from the program to date is that the Modified Monash index MM used to measure sites eligibility for the Teletrial Support Program (TSP) has not been able to be applied to all teletrials that have no clinical trial infrastructure. The Committee supported the ATP National Office in raising to the MRFF the issue of the MM 3-7 restriction for developing naive sites conducting teletrials. It has been identified by all jurisdictions that the main regional hospitals outside of the metropolitan areas of major cities, which are classified as MM2, are unable to benefit from the TSP, even though they may have little or no capacity to conduct clinical trials. This includes the two partnerships which have been established for Victoria supporting Tasmania (Hobart and Launceston – both MM2) and South Australia supporting the Northern Territory (Darwin as MM2). The ATP proposes a site capability assessment to guide a change to include MM2 classified regional sites for TSP satellite site payments.

A commissioned report by IQVIA received in December 2022: '*Increasing sponsored teletrial uptake, and teletrial sustainability through alignment with Industry needs'*. The report contained several recommendations. The ATP National Office convened a Sponsor's Workshop in March 2023 to raise awareness of teletrials, introduce the RCCCs and showcase the increasing infrastructure and capability building expertise. A sponsor shared their experience being part of the pilot and gave back positive feedback on how far the program has evolved. The aim was to build confidence and commitment of commercial sponsors to use the Teletrial model which will ensure sustainability through ongoing investment

3. *Complete the following table for all variation requests under the MRFF Grant Variation Policy approved, submitted (pending approval) or in draft (pending submission) for this grant to date.*

Type of Variation	Description of Variation	Current Status
Change to expenditure	Variation to contract to incorporate Teletrial Support payment with Jurisdictions from Queensland Government on behalf of Queensland Health.	Submitted

4. *Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)*

A Teletrial is yet to be commenced across Tasmania, South Australia, Western Australia, and Northern Territory. Strategies to manage this include:

- The Jurisdictional Working Group includes nominated agenda items by the jurisdictions and will include longer meetings to workshop challenges such as ethics committee education and accelerated research governance for cluster arrangements for teletrials.
- A TEAMS page allows sharing of documents and events, critiquing the harmonisation of documents. Monthly performance and support meetings are now held between the ATP Director and jurisdictions. Monthly RCCC education and information sessions are held.
- The ATP National Office will coordinate meeting opportunities across jurisdictions when approached by commercial and collaborative researchers to look at feasibility of running teletrials.

Lack of engagement by commercial sponsors to use Teletrial model. Strategies to manage this include:

- Monthly commercial sponsor Q&A sessions.
- Ensure an ATP presence at relevant meetings and conferences to maintain visibility for Sponsors.
- Encourage clinical trial sites to consider the Teletrial Model as a preferred Standard Operating Procedure for all clinical trials and to discuss this with Sponsors during feasibility discussions.

Confusion about different programs for teletrials across Australia. Strategies to manage this include:

- Collaborations with NSW RRR CT program, Revitalise and the Alfred Trial Hub to share and collaborate.
- Invite the above to attend workshops and monthly information sessions with ATP.
- Encourage completion of A-CTEC Teletrial module.
- Nationally agreed Standard Operating Procedures and toolkit documents.

5. *Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)*

The ATP is on track to meet most of the research building infrastructure which includes establishment of RCCCs and becoming operational, with staff recruitment almost complete. All RCCCs are working more collaboratively to share their experience with processes established to provide feedback in the development of key documentation.

The ATP (RedCap) database has been built in collaboration with the ATP Evaluation Team, to capture required information for evaluation and reporting purposes. The database will record not only teletrial activity across partner jurisdictions, but also clinical trials conducted in regional, rural, and remote areas. Training has been provided by the National Office to all jurisdictions.

The PARTNER Network has now signed agreements with an academic GP research group in each jurisdiction (s47G) and the Royal Flying Doctors and employed state coordinators in SA and Victoria. s47F is recruited with twenty-six in various stages of recruitment to participate in the ATP. In this model the academic hub will act as the primary site and GP practices as satellites with cross jurisdictional participation in identified teletrials.

The National Office on behalf of partner jurisdictions, negotiated with V-CTEC for clinical trials related education and training services. V-CTEC has renamed itself as A-CTEC (Australian Clinical Trial Education Centre). Each partner jurisdiction will provide an advisor to A-CTEC for content management and development. A-CTEC will provide open access to all jurisdictional clinical trial staff, clinicians, researchers and governance officers. The PARTNER Network is now collaborating with A-CTEC in the development of education modules appropriate for Primary Health Care clinicians.

ACTA has also now convened an ACTA-ATP project working group and recruitment is underway for an ACTA/ATP Lead coordinator. A survey was conducted across CT networks to ascertain current awareness, identify clinical areas to undertake TTs and identification of perceived barriers.

6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)*

The National Office establishment a new governance framework and the convening of an Executive Committee with representation from each jurisdiction has been an effective way of communicating major achievements and identifying risks to the program. This Committee is strongly motivated to achieve sustainability of the program.

The ATP Working Group now has standing agenda items on harmonisation, education and training, recruitment boosting tools and status reports by the Jurisdictions consistent with reporting on milestones, key deliverables and achievements, risks, and mitigation strategies. A “lessons learnt” approach is applied as more advanced jurisdictions support the development of others.

In receiving the report from IQVIA, recommendations are being acted on with the first being an information awareness workshop to begin addressing what industry views as factors which will ensure success such as rapid research governance approval for clusters of clinical trials. ACTA and the jurisdictions will work together to streamline processes to maximise efficiencies, whilst *North Queensland Better Together Health* alliance will provide a demonstrator as proof of concept.

Each jurisdiction is committed to undertaking education sessions with their certified HRECs on the teletrial model to ensure approvals are maximised in the program for the conversion of clinical trials to teletrials and teletrial cluster approval upfront where satellites are identified.

7. *Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.*

This question applies only to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
Melbourne University	PARTNER Network	PARTNER is a national practice-based research network resource for primary care clinical trials development and participation in rural areas. The establishment of PARTNER will deliver: • increased patient and public access to clinical trials in rural areas, providing equity of clinical trial access and the resulting improvements in patient health outcomes • more capacity for high-level clinical trials research in rural general practices • research readiness improved through training and data infrastructure • assist in maintaining rural workforce and encouraging careers in rural healthcare provision	s47F	To date: s47(1)(b)	27/01/2022	10%

		• improved researcher / investigator access to rural populations for a broad range of primary care research and industry-led trials • improved facilitation of multi-state rural clinical trials in primary care • practice identification, patient identification and recruitment are rapid and easy across state and territory boundaries • resulting statistical power and improved evidence base.				

Project Expenditure

8. *Provide details of all expenditure incurred using MRFF funding during this reporting period and the estimated expenditure for the next reporting period.*

Expenditure should be divided into the same categories as the budget in your grant agreement.

The table should indicate for each expenditure item (A), the approved budget (B) and the total expenditure: in this period (C), to date for the budget item (D) and estimated for next period (E). The comments field (F) should justify any differences between the budgeted and actual expenditure for the current reporting period, including any details of anticipated expenditure or any downstream effects of these differences.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact mrff@industry.gov.au.

(A) Expenditure Item	(B) Approved Budget (AUD)	(C) Actual expenditure for this period (AUD)	(D) Total expenditure to date (AUD)	(E) Estimated expenditure for next period (AUD)	(F) Comments
Minor Capital Works	S47G				
Materials for Construction					
Equipment					
Labour (Excluding On-costs)					
On-costs (capped at 30% of labour costs)					
Contract					
Travel					
Other eligible expenditure					
TOTAL					

Comments:

i. Expenditure on equipment was approximately 89% under budget in the current reporting period. Given that the expenditure on equipment is heavily reliant on identification of teletrial sites and commencement of teletrial activities, the delay in commencing these activities by

partner jurisdictions explain the shortfall in expenditure on equipment. As explained in point no.(vi) below, other partner jurisdictions are expecting to commence teletrial activities in the next reporting period. Accordingly, expenditure on equipment has been forecasted to increase by over 300%, thereby minimising the variance against the budget in the next reporting period.

ii. During the current reporting period, a shortfall of approximately 17% was noted for expenditure relating to Labour (excluding on-costs) compared to the budget. Notwithstanding the shortfall, expenditure on labour is showing an increasing trend from one reporting period to the other as recruitments are still happening across different jurisdictions. This increasing trend is expected to continue and therefore the labour cost has been forecasted to increase by a further 24% in the next reporting period. As a result, expenditure relating to labour (excluding on-costs) is expected to be broadly in line with the budget in the next reporting period.

iii. Expenditure relating to On-costs was limited to 22% of the labour cost in the current reporting period and a similar trend has been forecasted for the next reporting period.

iv. Expenditure under "Contract" primarily includes subcontracting expenses and was originally budgeted under "Other eligible expenditure". Expenditure under this item accrues as per the payment terms under the contract with different sub-contractors. This expenditure item has been added to "Other eligible expenditure" for the purpose of calculating variance against the budget.

v. Travel expense for the current reporting period was broadly in line with the budget.

vi. "Other eligible expenditure" also includes payments against the TSP (Site set-up Payment for Primary sites and Per-patient payments for Satellite sites). Other eligible expenditure, after including expenditure against "Contract" (as per point no. iv above) and the TSP was short by approximately 15% compared to the budget for the current reporting period. We note that only one partner State started its teletrial activity in the current reporting period while other partner jurisdictions are expecting to commence teletrial activities in the next reporting period. Accordingly, payments against the TSP have been forecasted to increase by 20x in the next reporting period. Similarly, there are a series of events planned in the next reporting period which include awareness campaigns. The payments relating to the TSP, together with additional expenditure for various events, will help in narrowing the variance against the budget in the next reporting period.

vii. During the current reporting period, total expenditure was under budget by approximately 22%. This was primarily due to the delay in recruitment of team members as well as the delay in commencing the teletrial activities by partner jurisdictions. However, as the project progresses towards execution phase, total expenditure for each reporting period is likely to increase significantly as demonstrated by the increasing trend of expenditure from one reporting period to the other. There is a likelihood that the expenditure in future reporting period(s) may exceed the budget for the respective reporting period. Whenever such situations arise, we have plans to use the unspent funds from prior reporting periods to cover the gap between the budget and actual expenditure in future reporting periods. It will however be ensured that the budget for an expenditure item will only be used to fund the gap for that expenditure item.

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Department of Health and Aged Care

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9. *Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)*

   All expenditure incurred during the reporting period is eligible under the scheme Guidelines.

10. *Provide details of any partner contributions received during this reporting period and indicate whether each contribution has been made as expected. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.*

If a contribution has not been made as expected, describe the impact of any delays or changes to the delivery of the Research Activity. If the project does not have partners that committed to make cash or in-kind contributions, select N/A in the table below.

Name of Partner	Type of Contribution	Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
enter name of partner organisation	Select	enter amount in $AUD	enter amount in $AUD	enter comments describing the impact of any delays or changes to the delivery of the Research Activity
N/A	N/A	N/A	N/A	N/A

Project Evaluation

11. *Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the MRFF Monitoring, Evaluation and Learning Strategy (November 2020) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were required to be submitted with the application, select N/A in the first row of the table below.*

For each Measure of Success applicable to your project:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.)
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

Add rows as necessary.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress
N/A			
Select			

12. *The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)*

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

Note that your response may be used in public communications about the MRFF, and that you may be contacted to expand on your response below. Please indicate whether any of the information you provide is commercial in confidence.

The ATP has increased in momentum since the official launch of the program in November 2022 with increased engagement with clinicians, consumers, and commercial sponsors. The establishment of RCCCS in each state is seen as a very positive capacity building step and was praised by commercial sponsors attending a recent national workshop to raise awareness of the model.

An important part of our program is being able to educate our workforce. ATP negotiated a national contract with the Victoria Clinical Trial Education Centre (V-CTEC) which strongly influenced it being renamed to the Australian-CTEC. The development and delivery of education to run clinical trials is now freely available across our jurisdictions with each partner providing an education advisor to continue to build in the nuances of teletrials.

Importantly the engagement with the PARTNER Network to support teletrials in Primary Health care has started to recruit General Practice clinics and help us to understand the pivotal and important role primary health care plays in building community awareness and support for clinical trials.

Working with the Australian Clinical Trials Alliance (ACTA) will continue to utilise and build new clinical trial networks and provide awareness and training in the teletrial model for clinicians. Consumers continue to inform the program and building appropriate resources will be a focus for this period of implementation.

Attachments

Attach any agreed evidence required above (e.g. updated risk management plan).

Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Jurisdiction	All partner jurisdictions
Reporting Period	1 October 2022 to 31 March 2023

Part 1 – Commonwealth MRFF Monitoring Indicators

Measure One: Increased focus of research on areas of unmet need

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies areas of unmet need and facilitates more research into these areas
- leads to new health treatments, drugs, interventions, devices and diagnostics
- embeds such approaches into clinical practice

1	**What approaches have been employed to ensure key areas of unmet need (as identified by the Grantee) are being met?**

Northern Territory

Program governance structure was developed including the establishment of NT Teletrials Advisory Committee with representatives from all NT Health regional health services, academic partners including universities and research institutes, Aboriginal Community Controlled Health Organisations and consumers. The inaugural meeting was held in November 2022 at Alice Springs Hospital with positive feedback and support received from the members. Planning is now underway for the #2 meeting to be conducted in mid-2023.

ATP-NT team is currently conducting a barrier analysis study to support the implementation of the Australian Teletrial Program (ATP) across the NT. Authorisation from Human Research Ethics Committee of NT Health and Menzies School of Health Research (NT HREC) and NT Health Research Governance Office (NT Health RGO) was granted in February 2023. Consultations with unit heads, co-directors, general managers and/or key clinicians/investigators across the five regions are currently underway. The findings will form the most comprehensive evaluation to date of clinical trials landscape across NT Health. It will identify opportunities for further refinement of activities and provide recommendations for sustainability planning to ensure benefits continue beyond the program period.

Extensive stakeholder engagement and relationship building has also been undertaken with both internal and external stakeholders to promote awareness/benefits of the program. The ATP-NT team represented at the ATP National Sponsors Workshop recently in Brisbane (March 2023) organised by the ATP National Office. The workshop brought together sponsors, clinical research organisations, RCCCs and consumers from across the country to build relationships and identify opportunities. There was positive engagement from the industry sponsors (including s47G) to collaborate and provide equity access to clinical trials for NT populations. Participating in commercially sponsored clinical trials is very pivotal to the NT to build on financial sustainability and develop a self-sustaining clinical trials system within the health service.

The key milestones for ATP-NT team are:

- System transformation to embed clinical trials into routine business in our learning healthcare system
- Networked clinical trials system across the NT and nationally
- Improved workforce capacity and capability in undertaking clinical trials through recruitment and education/training
- Adequate clinical trials infrastructure and logistics support for all NT sites
- Expedited regulatory approval systems (Research Governance Office/RGO) to allow for cluster approval approach. We now have single RGO approval process across all five regions which is very attractive to industry sponsors
- Participation in commercially sponsored clinical trials

- Recruitment of our diverse geographical and culturally diverse populations into quality clinical trials
- Advanced health literacy in clinical trials for both health professionals and public
- A self-sustaining clinical trials system

Queensland

- Increased engagement with sponsors and presentation at sponsor workshop 23rd March 2023.
- Qld workshop 21st March 2023 for 80-100 Qld health staff across clinical research at all levels to increase engagement and uptake of the Teletrial model. Qld steering committee requested the workshop.
- Completion of in-house QRCCC education program. In-house program aligned with Australian College of Nursing, Clinical Nurse Research standards. More than 100 staff now trained in ICH- GCP and up to 200 more staff trained in Clinical trials/teletrials.
- Process for conversion of existing clinical trial to teletrial developed, piloted, and implemented successfully.
- Fourteen of sixteen Hospital and Health Services have a Clinical Research Coordinator specifically for teletrials and funded by QRCCC.
- Several abstracts submitted and presentations at State-wide and national conferences and workshops.
- New private and public cluster start up in process for a palliative care trial with a nine-site cluster planned.
- Remote HHSs in QLD x 4 are having additional supports from QRCCC to facilitate them being able to partake in clinical trial/teletrials. 0.5 FTE RGO and 0.5 FTE CRC TT to be recruited to in March 2023.

South Australia

South Australia has a population of 1.7 million and of this approximately 30% (500,000 people) live in rural, regional and remote locations. The South Australian health system is divided into ten Local Health Networks (LHNs) with six of these LHNs located in regional South Australia. The Eyre and Far North LHN in the north west of the state is geographically the largest in size but also has the lowest and most vulnerable population that includes the APY lands.

To date, very little research activity has occurred outside metropolitan Adelaide with the biggest unmet need being rural regional and remote South Australians unable to access clinical trials due to geographic location. The regional LHNs have no research units and very few research professionals employed with one Research Governance Officer supporting the six regional LHNs. As part of the capacity building for the Australian Teletrial Program, three country locations were selected to place a Registered Nurse – Clinical Research Coordinator due to their size and distance from Adelaide and geographic location to give coverage across the state. Two of these nurses have now commenced in these roles. Additionally, the Rural Support Services that support the six regional LHNs has recently appointed a full time Medical Oncologist for clinical trials to be based in s47F . The development of this workforce will enable patients to participate in clinical trials closer to home that they would have otherwise either had to travel to a metropolitan location or missed out completely.

A Training and Development Officer has been employed as part of the ATP-SA team to develop training plans for current and potential clinical trial and research staff. There has also been increased uptake of the Victorian Clinical Trials Education Centre (V-CTEC), now Australian Clinical Trials Education Centre (A-CTEC) since been launched in South Australia on 26 September 2022. A face-to-face GCP training session was organised and sponsored by ATP-SA at the Southern Adelaide Local Health Network on 7 October 2022.

The ATP-SA team has continued to engage with clinical trial stakeholders not only within South Australia but also Australia and internationally to promote teletrials within South Australia and advocate for rural regional and remote South Australians to gain access to clinical trials. The team has engaged with enthusiastic researchers to support the start up of clinical trials in country SA and NT including site feasibility, ethics and governance applications, CTRAs, sponsor liaison, supervision plans, training and equipment that otherwise would not have been possible.

Tasmania

We are building relationships with established clinical trial units, which cover a broad range of specialities, and gathering information regarding which patient cohorts are travelling for treatment and why within our state. This

is being used to highlight gaps in patient care options, which will help us facilitate research appropriate to patient needs based on the cohort requiring local trial options the most.

Exploring options with the PARTNER network, to provide access to clinical trials for patients via their GP and other outpatient facilities.

Victoria

Organisation wide clinical trial readiness and resources (human and physical)

- Employment of 1 x FTE CTRSS-ATP clinical trials coordinator for organisation-wide clinical trials and tele-trials support.
- Actively working towards accreditation for the National Clinical Trials Governance
- Workshop ways to support improved clinical trials access to catchment communities.
- Utilisation of software to assist with clinical trials management
- Engagement of additional staff through the VCCC Skilled Interns program
- Development of institutional SOPs in relation to Tele-Trials, and establishing possible satellite sites
- Undertake a teletrials / clinical trials related staff training program.
- Contact new clinical staff as they onboard, to determine their clinical trials experience and motivations

Access to more clinical trials and teletrials and in more therapeutic areas
Liaison with:

- regional ATP start up specialists to bring more tele-trials to the region
- commercial sponsors to consider regional sites for both non-oncology and oncology clinical trials/tele-trials
- other Clinical Trial Coordinators, other regional hospitals and Department of Health to progress tele-trial readiness.
- Sponsors and other clinical trials site to set up clinical trials that target known areas of need in the community

Review of all current clinical trials to ascertain if they can be converted to a teletrial.

Development of site metrics

- Obtain reports from ERM regarding site metrics for HREC approvals and research governance authorisations
- Develop and distribute Site Profiles, updated to include potential new therapeutic areas for clinical trials

Embedding clinical trials and teletrials into standard practice
Provision of:

- clinical trial coordination support for current and potential investigators/trial staff, departments (both clinical trial active and potentially active departments), and supporting departments
- advice and training for completion and submission of ethics and governance applications for junior/senior doctors and researchers
- clinical trial and research training and education to current and potential trials and research staff
- advice with research agreements, development of clinical trial budgets, and regulatory requirements.

Establishment of a site-specific clinical trial webpage, detailing which clinical trials are being undertaken at the site.

Western Australia

Teletrials is a new mode of research for Western Australia. Our clinicians and health system have invested heavily in telehealth services to improve access to health services across country WA. The next step is to use this established infrastructure and clinical models to bring clinical trials to country regions. The WA Country Health Service *Research and Innovation Strategy 2019-2024* has focused on developing a regional research agenda and translating research into practice. The existing telehealth infrastructure and a supportive research environment for the rural health workforce in WA ensures that the system is ready to adopt new clinical trial models.

The Australian Teletrial Program – Western Australia (ATP-WA) is a small, growing team who have deep

expertise in research and clinical trials. The ATP-WA is focused on establishing the governance processes for Teletrials and promoting the program amongst researchers. Further team members will join in 2023, with some to be based in regional centres depending on future workforce demands.

Patient Needs

There is only one WA Country Health Service site (Bunbury Hospital) that has the capacity to offer clinical trials, which leaves the remainder of the Western Australia population with an unmet need in relation to clinical trial participation, for any technology or intervention. Patients from regional, rural and remote locations must travel vast distances to either Bunbury or Perth to participate in trials.

First Teletrial

In the last 6 months, ATP-WA has focused on establishing the very first Teletrial in WA. This trial is led from Fiona Stanley Hospital by s47F and s47F and links Albany Health Campus into this research team. The trial will focus on nutritional deficiencies noted in patients with diabetic foot ulcers, with the aim of reducing wound area.

Work to date on this trial includes:

- New governance documents and processes including the Teletrials Supervision Plan and Teletrials Participant Information Consent Form
- Pathology negotiations to ensure that regional Pathwest clinics can support Teletrials. This includes negotiating changes to Pathwest operating procedures so that lab sample transport costs can be accounted for and establishing a process for validated transport of frozen samples.
- Training local site clinicians in Good Clinical Practice
- Obtaining ethics approval for the amended trial to include a regional satellite site
- Executive discussions at both central and regional sites
- ICT approvals and procurement of a new Silhouette Camera for Albany Health Campus

Final governance approvals are now underway and it is expected that the first patient will be recruited in April 2023. A total of 10 patients are expected to be recruited through this trial. The lessons from this trial will be used to inform future Teletrials. The FSH research team also has further trials that build on VITAFOOT and it is anticipated that these will also be converted into Teletrials and extend patient recruitment numbers.

Other patient support initiatives include:

- Promoting the Teletrial model through a variety of clinical networks, investigators and commercial sponsors
- Reviewed 18 WA-based trials for Teletrial eligibility
- Informed community representatives via District Health Advisory Committees in each Region
- Engaged WA Country Health Service (WACHS) and Department of Health Executives to understand rural health strategic priorities

Contracts and Governance Needs

ATP-WA have focused on developing and seeking approvals for key agreements, templates and guidelines relating to Teletrials within the WA Health public system.

Key achievements:

- The Medicines Australia Clinical Trial Research Agreement (CTRA) and CTRA Teletrial Sub-contract had to be revised before the six WA Health Service Provider entities could collaborate on trials. Legal and RiskCover reviews have been completed and final legal sign off meeting is set for April.
- Baxter is currently contracted to manufacture sterile and chemotherapy infusion services for WA Public Hospitals. Current TGA licensing, in addition to the WA state contract, restricts their ability to conduct clinical trial services from their WA facility. As a result, clinical trial infusions are manufactured within each tertiary hospital and limited for use at their own site. WACHS is leading contract variation discussions to allow for the preparation of clinical trial infusions from the Baxter WA site. Once approved, this will increase access to clinical trial infusion access for all WA Public Hospitals.
- Upskilling Research Governance Managers on the Teletrial Model and co-designing Teletrial templates

Service Needs

In addition to supporting regional sites in relation to trial start-up and training of local team members, the focus for WA has been on developing digital solutions for collection of trial data and management of investigational products, important in the WA context where support from metropolitan sites of new to research, remotely-located satellite sites will be required.

Specifically, an assessment of the following digital platforms was undertaken:

- An Electronic Investigator Site File (eISF) that provides a secure portal for the provision of clinical trial eConsent, document certification, remote Source Data Verification, rapid safety reporting of Serious Adverse Events and Principal Investigator oversight of documentation. Currently, in WA, most sites utilise a paper based ISF, with occasional studies utilising a Sponsor provided electronic ISF (eISF).
- An Investigational Product Management System (IMPS) to connect all clinical trial pharmacies state-wide. An IPMS is a complete digital solution that facilitates electronic documentation of Investigational Product activities, eliminating the barriers posed by paper-based records.

Key achievements:

- Educating pharmacy workforce (including the regional and metropolitan workforce, WACHS regional Chief Pharmacists, state-wide clinical trials Pharmacy specialty group, National Teletrials Clinical Trials Pharmacy Working Group)
- Secured pharmacy real estate space co-located with Fremantle Hospital
- Development of national clinical trial pharmacy and study coordinator training program and competency framework via the ACTEC working group committees
- Liaising closely with the existing Telehealth services across the WA Country Health Service

Liaising with Regional Directors to understand regional, rural and remote service needs

Measure Two: More Australians access clinical trials

This measure considers the extent to which outcomes of MRFF-funded research:

- create better opportunities for Australians to access clinical trials by funding activities that support research to progress to the clinical trial stage, and directly supporting additional clinical trial activity
- builds Australia's clinical trial capability and leadership at the national and international level

1.2 Please complete the tables on the following pages for your jurisdiction only to record:

1) the number of **new** (satellite site per protocol count) or **improved** (primary site per protocol count) clinical trial sites (TABLE 1),

2) the number of new clinical trial participants (TABLE 2), and

3) the number of new clinical trials (primary site per protocol count) (TABLE 3); directly linked to your project activities.

TABLE 1: Number of new or improved* clinical trial sites by MMM Code

	Target for achievement by Project Completion	Actual number of new or improved sites **(cumulative total, project to date)**								
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total	**Cumulative Total**
Northern Territory										
New Sites	**32**	0	0	0	0	0	0	0	0	**0**
Improved Sites	**11**	0	0	0	0	0	0	0	0	**0**
Queensland										

New Sites	**851**	5	20	3	1	0	0	0	29	**29**
Improved Sites	**283**	8	16	0	0	0	0	0	24	**24**
South Australia										
New Sites	**332**	0	0	0	0	0	0	0	0	**0**
Improved Sites	**111**	0	0	0	0	0	0	0	0	**0**
Tasmania										
New Sites	**32**	0	0	0	0	0	0	0	0	**0**
Improved Sites	**11**	0	0	0	0	0	0	0	0	**0**
Victoria										
New Sites	**972**	0	0	2	0	0	0	0	2	**15**
Improved Sites	**324**	2	1	5	0	0	0	0	8	**47**
Western Australia										
New Sites	**211**	0	0	0	0	0	0	0	0	**0**
Improved Sites	**70**	0	0	0	0	0	0	0	0	**0**

TABLE 2: Number of clinical trial participants by MMM Code

	Target for achievement by Project Completion	Actual number of new or improved sites **(cumulative total, project to date)**								
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total	**Cumulative Total**
Northern Territory	**68**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**
Queensland	**1750**									
Previous Report		s47F							22	
This report									66	**66**
South Australia	**682**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**
Tasmania	**68**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**

Victoria	**2000**									
Previous Report		373	144	30	12	13	0	0	572	
This report		6	12	56	12	25	0	0	111	**683**
Western Australia	**432**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**

TABLE 3: Number of new clinical trials by MMM Code

	Target for achievement by Project Completion	Actual number of new clinical trial participants (**cumulative total, project to date**)								
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total	**Cumulative Total**
Northern Territory	**3**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**
Queensland	**71**									
Previous Report		s47F							15	
This report									25	**25**
South Australia	**28**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**
Tasmania	**3**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**
Victoria	**81**									
Previous Report		40	20	16	0	0	0	0	76	**110**
This report		s47F							21	**131**
Western Australia	**17**									
Previous Report		0	0	0	0	0	0	0	0	**0**
This report		0	0	0	0	0	0	0	0	**0**

1.3 For new clinical trials generated by your jurisdiction's project activities, please provide the number of clinical trials by:

- Demographics of population (e.g. ATSI, CALD)
- Age group of target population (i.e. youth/paediatric; adult; older people)

- Disease type (e.g. oncology)
- Sponsor type (i.e. investigator initiated, commercial, etc.)

You may either provide the information below, or attach it to this report. If you attach a document, please provide the name of the document below.

Northern Territory

N/A- nil established clinical trials/teletrials to date

Queensland

- ATSI and CALD patients live in the regions within the clusters.
- All trials target participants aged 18 years and over.
- Clinical areas: three renal trials, one infectious disease and sixteen oncology trials
- Twelve of the trials were commercially sponsored and eight were collaborative group trials.

South Australia

Currently there are no new clinical trials or teletrials that count towards project activities.

There are however six clinical trial protocols that are in the process of being set up as teletrials in oncology, radiation oncology, endocrinology and mental health and include commercially sponsored, investigator initiated and collaborative research group sponsors.

Tasmania

N/A – Nil Teletrials established yet

Victoria

EMBER-4: *A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence*	• No specific demographics • Age ≥ 18 years • Oncology • Commercially sponsored
EXTEND-IA DNase: *Improving early reperfusion with adjuvant dornase alfa in large vessel ischemic stroke*	• No specific demographics • Age ≥ 18 years • Emergency Medicine • Investigator-initiated
A Study to Evaluate the Effectiveness of the Avelle® Negative Pressure Wound Therapy System on Chronic Wounds (VAPOR Study) *NB Pending Site activation	• No specific demographics • Age ≥ 18 years • Chronic wounds • Commercially sponsored
The AIROPLANE Trial: *Air or Oxygen for Preterm infants; AN Embedded trial,* **NB Pending Site activation*	• Born between 32+0 and 35+6 weeks' GA • Paediatrics • Investigator-initiated
An Open-Label, Proof-Of-Concept Study to Evaluate the Safety and Treatment Effects of SLS-005 (Trehalose Injection, 90.5 Mg/Ml for Intravenous Infusion) in Participants with Alzheimer's Disease (AD) **NB Pending Site activation*	• Age 50-85 years • No specific demographics • Geriatric Medicine • Commercially sponsored
Can Flash Glucose Monitoring improve glucose management in Indigenous Australians with type 2 diabetes? A randomised controlled trial.	• ATSI • Age ≥ 18 years • Endocrinology • Investigator-initiated
The TRIGS Trial: *Tranexamic acid to Reduce Infection after Gastrointestinal Surgery*	• Age ≥ 70 years • No specific demographics • Anaesthesiology • Investigator-initiated
LOLIPOP - *Long term Outcome of Lidocaine Infusion for Post-operative Pain*	• Female patients • (≥ 18 years, < 80 years) • Anaesthesiology

	• Investigator-initiated
BIONECS	• Not specifically mentioned • Adult • Schizophrenia • Investigator Initiated
ORIGAMA	• No specific demographics • ≥18 years • Lung cancer • Commercially sponsored
Randomised Phase II Trial to Evaluate the Strategy of Integrating Local Ablative Therapy with First-Line Systemic Treatment for Unresectable Oligometastatic Colorectal Cancer *Multi-centre, Teletrial. NHW Satellite Site, Peter MacCallum Cancer Centre, Primary Site*	• No specific demographics • Age group – 18 and over • Colorectal Cancer • Collaborative Group Trial
Sprint national anaesthesia project 3: a study of frailty, multimorbidity and delirium in older people in the perioperative period	• No specific demographics • Age group – 60 and over • Patients undergoing surgery • with a minimum of 1 night stay in hospital expected • Collaborative Group
An umbrella Bayesian optimized phase 2 trial of dornase alfa (Pulmozyme™) in addition to standard intravenous thrombolysis before endovascular thrombectomy within 4.5 hours of stroke onset	• No specific demographics • Age group – 18 years and over • Stroke • Investigator Initiated
Volatile anaesthesia and perioperative outcomes related to cancer	• No specific demographics • 18 years and over • Colorectal or lung cancer • Collaborative Group
QASC (ID 91654):	• ischaemic stroke or intracerebral haemorrhage • No specific demographics • aged 18+ • Stroke • investigator initiated
IRIL (ID 47521):	• Multiple myeloma patients ineligible for high-dose chemotherapy and autologous stem cell transplant • Aged 18+ years • Collaborative group
ADVISE- "Online and telehealth management of rotator cuff tendinopathy: a randomised controlled trial" CONVERTED TO TELETRIAL February 2023	• Aged ≥ 18 years • Physiotherapy • Sponsor: Monash University
SNAP- Staphylococcus aureus Network Adaptive Platform trial	• Inpatients with confirmed blood culture for Staphylococcus aureus • Aged ≥18 years • Infectious Diseases • Sponsor:University of Melbourne
PLATIPUS: Piles Local Anaesthetic Trial Investigating Pudendal nerve block vs Under band infiltration vs Standard care	• Patients having rubber band ligation for haemorrhoids • Aged ≥ 18

	• General surgery • Investigator initiated trial • Sponsor: Austin Health

Western Australia

Not applicable

1.4 Describe the progress towards target recruitment numbers and the retention rate for clinical trials.

Northern Territory

N/A- nil established clinical trials/telerials to date

- 1 renal teletrial submitted to HREC for NT cluster – Mar 2023. Awaiting HREC approval
- 1 oncology teletrial for SA/NT cluster is currently pending Sponsor's approval for HREC submission
- 1 gastroenterology teletrial for SA/NT cluster is being finalised for HREC submission
- Currently reviewing and progressing multiple trials protocols in the area of renal, oncology, cardiology and surgical

ATP-NT team is actively engaging with sponsors, institutions, clinicians and investigators to discuss any potential clinical trial to be conducted in the NT. In parallel, barrier analysis is also underway to have a clear understanding on each site's readiness and identify any challenges/opportunities that can be supported through the program.

40% of NT populations are Aboriginal populations and they are underrepresented in clinical trials. ATP-NT team is currently planning a consumer yarning session to develop culturally and linguistically appropriate educational tools to build on health professionals and public health literacy on research and clinical trials. This will hopefully promote consumers involvements in all phases of clinical trials including trials design and also increase recruitment numbers and retention rates into these trials.

Queensland

The recruitment of participants is increasing as the number of trials increase and we have several new trials for cluster development presently.

South Australia

A significant achievement in the past six months is the recruitment of two Registered Nurse - Clinical Research Coordinators based in country SA with recruitment for the third underway. This is an important milestone as prior to recruitment of these positions there were very few dedicated research roles located in the regional LHNs. This capacity will now enable Mount Gambier located in the Limestone Coast Local Health Network and Berri in the Riverland Mallee Coorong Local Health Network to participate as new clinical trial and teletrial sites and Whyalla is not far away.

The ATP-SA team has been focusing on building relationships to ensure the first teletrial is a success and will be a proof of concept to attract more teletrials to the state. Given there has only been a small number of clinical trials previously been conducted outside of metropolitan Adelaide, there is a big piece work around change management that has been a focus to ensure there is successful activation and retention of clinical trials in regional SA.

ATP-SA is working collaboratively with ATP-NT to set up cross jurisdictional teletrials. Currently there are two protocols that are in the process of being set up as teletrials across SA and NT. The primary sites are located in metropolitan Adelaide with Darwin being set up as the satellite site. There have been significant sponsor delays in setting up this first protocol that have created additional challenges in progressing this site activation.

Tasmania

N/A – Nil Teletrials established yet

Victoria

Since the last reporting period, many of the trials conducted in the regional hubs have ceased recruitment. Most of these trials are not teletrials, but are trials conducted "closer to home", with local hospitals and clinics working as clinical trial sites in their own right.

There are 7 teletrials that are currently recruiting and of these, four have recruited participants during this reporting period. More teletrials are anticipated to open within the next reporting period. Data is not available for retention rates.

As indicated in Table 2 above, Victoria is on track to meet its recruitment targets with 508 participants across a range of teletrials and clinical trials conducted in regional and rural facilities.

Western Australia

As the only Health Service led, and regional led, Teletrials team within the National Program, WACHS will ensure that new trial models work for the populations that we serve. We intend to use the knowledge of our staff as regional community members to design the best approaches to recruitment. In addition, the following activities were undertaken from October 2022 to March 2023 to increase the likelihood of reaching target participant numbers and retention rates once teletrials commence in WA:

- Establishing a skilled ATP-WA team with extensive clinical trial expertise and strong links to the WA research community ensures that regional sites will be supported to identify and retain participants.
- Developed an eligibility framework for accepting teletrials and initiating at sites where most patient benefit is expected. We will be engaging regional consumer councils to inform this eligibility framework during 2023 (further detail in Section 1.14).
- Online clinical-trial education to upskill local teams on how to maximise recruitment, access to online training modules development by the Victoria Health Translation Networks was negotiated. This training will be freely available to the WA Country Health Service workforce and offered alongside other research capacity building education opportunities.
- Liaison and negotiations with supporting organisations such as pathology, imaging, pharmacy to understand the most optimal service delivery for rural participants and avoid any logistic issues which could impact retention rates.
- Working closely with the WA Country Health Service Executive team to assist with rapid approvals for future teletrials in WA
- Presenting 'Teletrial Model and the WA Implementation' to potential investigators to build strong relationships with the research community and understand their recruitment and site requirements, (further detail in Section 1.12)
- Procuring digital solutions to support workflow at sites to streamline the patient experience for and optimise patient retention (further detail in Section 1.11)
- Developing ePrescribing software to ensure patients can collect prescriptions and medications at their local sites
- Established a FIFO ATP-WA staffing model to support remote site recruitment and retention

1.5 Education and training –
Please complete the table below and the spreadsheet provided for education and training details

How many staff have been trained on clinical trial related methodology?	Target	Actual to date Progress against target
Northern Territory	833	93
Queensland	834	474
South Australia	833	204
Tasmania	833	30
Victoria	834	262
Western Australia	833	97

Measure Three: New health technologies are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health technologies, including precision medicine
- measures the awareness of new health technologies among clinicians and patients
- embeds new health technologies into clinical practice

1.6 Where applicable, are new and emerging health technologies[2] being embraced by clinicians and patients involved in the clinical trials funded through this project? If so, how?

[2]A health technology is defined by the World Health Organisation as "the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives."

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
For example, can you please provide a case study of a clinical trial conducted as a teletrial under this Program?

Northern Territory

N/A- nil established clinical trials / teletrials to date

Queensland

Sites have been supported with funding from the QRCCC for the purchase of the license of Trials/site docs to facilitate the cluster Clinical Trial Management System (CTMS). Four sites have been supported by the QRCCC with this health technology to manage their Teletrial clusters and their site information.

South Australia

Currently there are no new clinical trials or teletrials that count towards project

Tasmania

N/A – Nil Teletrials established yet

Victoria

Not applicable

Western Australia

The first Teletrial in WA (due to commence in late April) is *Vitafoot* - a trial that aims to address nutritional

deficiencies noted in patients with diabetic foot ulcers, with the aim of reducing wound area. The Silhouette® camera and system offers a way to systematically and easily collect accurate wound data and will be purchased and installed at the Albany Health Campus (AHC). The camera remains at AHC after the completion of the study as it will benefit patients outside of the Teletrial program.

Measure Four: New health interventions are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health interventions
- measures the awareness of new health interventions among clinicians and patients
- embeds new health interventions into clinical practice

1.7 Where applicable, how are the health interventions[3] changing health practice amongst medical practitioners involved in the clinical trials?

A health intervention is defined by the World Health Organisation as an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
For example, can you please provide a case study of a clinical trial conducted as a teletrial under this Program?

Northern Territory

N/A- nil established clinical trials / teletrials to date

Queensland

Setting up larger clusters that support Remote Hospitals and Health Services (HHS) to be involved in a teletrial cluster as a satellite site. The QRCCC is collaborating with sites and promoting the uptake of the Teletrial model to allow their patients access to a clinical trial and potentially better health outcomes.

South Australia

Currently there are no new clinical trials or teletrials that count towards project activities.

Tasmania

N/A – Nil Teletrials established yet

Victoria

Not applicable

Western Australia

The Albany foot clinic is conducted by Podiatry who have expressed their interest in being involved in VITAFOOT. They report to managing 60-80 patients with diabetic foot ulcers, with approximately 30% of patients who don't resolve within normal time frames progressing to require transport to Perth for treatment.

Patients with diabetic foot ulcers often have complex medical and/or psychosocial issues making travel to Perth for Specialist review difficult. Conducting the VITAFOOT study in Albany is an excellent opportunity to enhance collaboration between Fiona Stanley Hospital and Albany and provide multidisciplinary expertise to an expanding rural service.

Measure Five: Research community has greater capacity and capability to undertake translational research. When answering all questions for this measure, please focus on positions within the Australian Teletrial Program teams, and the implementation of the Program and its activities and components (rather than the research teams and the specific trials under this Program)

This measure considers the extent to which outcomes of MRFF-funded research:

- increases researcher capacity
- improves the awareness of translational research within the research community
- supports capability development to undertake translational research

1.8 Please complete the table below

	Full Time	Part Time	Casual
Northern Territory			
Target number of positions to be created	5	4	0
Actual number of new positions created	4	0	0
Queensland			
Target number of positions to be created	5	21	0
Actual number of new positions created	5	17	0
South Australia			
Target number of positions to be created	9	1	0
Actual number of new positions created	6	3	0
Tasmania			
Target number of positions to be created	5	0	0
Actual number of new positions created	2	5	0
Victoria			
Target number of positions to be created	3	5	0
Actual number of new positions created	3	4	0
Western Australia			
Target number of positions to be created	7	2	0
Actual number of new positions created	3	3	0

1.9 Please provide details on the number and nature of the positions created.

This may include, but is not limited to, study coordinators, research nurses, pharmacists, clinicians, and researchers.

Northern Territory

Recruited to date:

- Program Manager 1.0 FTE since Apr 2022
- Program Support Officer 1.0 FTE since Apr 2022
- Study coordinator Top End Region 1.0 FTE since Jan 2023
- Senior Pharmacist 1.0 FTE – to commence May 2023

Recruitment in progress:

- Study coordinator Big Rivers Region 0.4 FTE
- Study Coordinator Central Australia Region 1.0 FTE

Recruitment in planning:

- Study Coordinator East Arnhem Region 0.4 FTE
- Study Coordinator Barkly Region 0.2 FTE
- Cluster Start-up Specialist 1.0 FTE
- Aboriginal Health Practitioner Top End Region 1.0 FTE
- Aboriginal Health Practitioner Central Australia Region 0.5 FTE

Queensland

1. RGO part-time position for 4 x RRR HHSs (Torres & Cape, North West, South West, Central West Health Services) has been created to provide assistance, support and leave coverage. Ready to recruited.
2. CRC (travelling) part-time position to provide assistance, support and leave coverage. Ready to recruited.

South Australia

ATP-SA roles as at 31 March 2023:

1. Medical Director 0.2FTE
2. Project Manager 1FTE
3. Clinical Trial Liaison Officer 1FTE – located in s47F SA
4. Administrative Officer 1FTE
5. Cluster Start-up Specialist SA 1FTE
6. Cluster Start-up Specialist SA/NT 1FTE
7. Training and Development Officer 1FTE
8. Registered Nurse Clinical Research Coordinator – South East 0.8FTE
9. Registered Nurse Clinical Research Coordinator – Riverland 0.8FTE
10. Registered Nurse Clinical Research Coordinator – Whyalla/Port Augusta – currently readvertising closes 6 April 2023

Tasmania

The positions created are to establish baseline infrastructure:

- Project Coordinator
- Research Governance Officer
- Teletrial Project Officer
- Clinical Trials Liaison Officer
- ICT System Program Officer
- Clinical Director

Victoria

Organisation 1 Goulburn Valley Health

1 x 1.0 FTE Clinical Trials Coordinator

1 x part time Clinical Trials Coordinator

Organisation 2 Barwon Health

1 project site lead directly employed by the CTRSS-ATP funding
(*please note the position reported in the previous report was re-structured specifically for the CTRSS-ATP, and a new employee was hired into this position)*

Organisation 3 Latrobe Regional Hospital

Two part-time CTRSS clinical trial coordinators.

Two full-time VCCC clinical trial interns.

Organisation 4 Grampians Health

0.74 FTE dedicated to Project Officer

0.26 FTE dedicated to Tele Trials Start Up Specialist/Clinical Coordinator

Organisation 5 Northeast Health Wangaratta

VCCC Study Coordinator intern as supported by DH commenced March 2023

Western Australia

- Medical Director 0.2FTE
- Project Lead Fulltime
- Senior Pharmacist Fulltime
- Clinical Trial Manager Fulltime
- Research Governance Officer 0.4FTE
- Research Officer 0.5FTE (currently recruiting)

1.10 For any research roles created by your project, please detail the career stage(s) of the researcher(s) (early, mid or established).

Northern Territory

- Program Manager – established career in research
- Program Support Officer - mid career in research
- Study coordinator - early career in research
- Senior Pharmacist – early/mid career in research

Queensland

14 of the 16 Clinical Research Coordinators (for each individual HHS) have been recruited

South Australia

The Registered Nurse Clinical Research Coordinator roles employed through the Riverland Mallee Coorong Local Health Network are joint appointments with Flinders University and University of South Australia. The South East and Riverland roles have commenced, and incumbents also hold university academic status. Both roles are early-stage researcher roles.

Tasmania

s47F

s47F

Victoria

Not applicable

Western Australia

Not applicable

1.11 Provide a catalogue of new infrastructure developed by the project to date and use of infrastructure by researchers in a collaborative manner. For example, new policies and processes for supporting teletrials in your state.

Northern Territory

- NT Health Research website update to include ATP https://health.nt.gov.au/data-and- research/nt-health-research/teletrial-program
- Ongoing update on NT Health clinical trials register https://health.nt.gov.au/data-and- research/nt-health-research/nt-health-clinical-trials-register to ensure information is current and accurate
- A-CTEC – now live and accessible to the NT at no cost to the end user (since 1st March 2023) https://health.nt.gov.au/data-and-research/nt-health-research/good-clinical-practice- training#
- Ongoing discussion with education team to embed research/clinical trials education into main learning system
- Development of nursing career pathway for research (N4-N7)
- Development of induction packages for new research staff

Recommendations for PATS travel guidelines update to include support for clinical trials activity

Queensland

Teletrial CRC Community of Practice established, meeting monthly and facilitated by the QRCCC.

South Australia

SA Health launched a new clinical trials portal on 20 March 2023 with a fresh new look and updated information: http://www.sahealth.sa.gov.au/saclinicaltrials

New documents and processes that have been developed by ATP-SA:

- Developed and implemented a process for reviewing and executing Confidentiality Disclosure Agreements
- Teletrials document checklist
- Standard Operating Procedure for consenting via Telehealth
- Proforma letters developed:
    - Submission to HREC cover letter
    - Principal Investigator agreement to oversee cluster
    - Satellite Site agreement to participate in the cluster
    - Sponsor agreement for trial to be run as a teletrial
    - Clinical Governance Committee support

Tasmania

- Teletrials Standard Operating Procedures (under development), in accordance with the National Teletrial Standard Operating Procedures.

- Research Governance Streamlined Approval Process – underway
- Teletrial Start Up Guide – Tasmania Specific - underway
- Teletrial Conversion Steps – Tasmania Specific – underway
- Teletrial DOH Internal Payment Protocol – Appendix to Supervision Plan – completed
- Addition of Site – CTRA Amendment proforma - completed

Victoria

The seven regional hubs across Victoria have been working independently to develop tools and infrastructure required within their operating areas. Work to date includes:

- Site specific Standard Operating Procedures updated, based on National Standard Operating for Clinical Trials including Tele-trials
- Adoption of ATP toolkit documents for jurisdiction and site-specific use
- SiteDocs software purchased for use with clinical trials.
- Source data plan and essential documentation guide developed
- Trial feasibility, start-up flowchart and start up metrics developed
- Purchase of trial specific pathology equipment (-20oC freezer, -80oC freezer centrifuge and fridge)
- Developed process for converting clinical trials into teletrials
- Development of other site-specific documents:
    - Updated Site CV
    - Site structure fee
    - Trial one page summary
    - Risk Assessment Matrix (still in development)
- Establishment of clinical trials webpage on the intranet, with relevant links
- Establishment of Clinical trials office
- Execution of a Master Confidentiality Disclosure Agreement with a contract research organisation, to streamline site preparations

Western Australia

The Teletrials Toolkit has been adapted for Western Australia, including the following:

- Teletrial Eligibility Framework
- Satellite Site Checklist
- Equipment/facilities checklist for Satellite Sites
- Supervision Plan

Two online education platforms have been identified as either essential or best practice training existing and future clinical trial health professionals:

- For training in Good Clinical Practice (GCP) health professionals have access to training via the WA Health Translation Network.
- For further expertise in clinical trial delivery, WA Country Health Service (WACHS) regional staff can now access professional development training, with the announcement of a new training partnership with the Australian Clinical Trial Education Centre (A-CTEC).

Pharmacy guidelines and templates have been developed and embedded into existing processes:

- Creation of adapted teletrial pharmacy procedure templates for program wide use
- Virtual IMP temperature reporting process to central pharmacy
- iPharmacy (dispensing software) Business Rules updated to include teletrials
- Build of clinical trials sites into all regional, rural and remote iPharmacy sites

The ATP-WA Senior Pharmacist also submitted a Clinical Workbench eMedicine Clinical Trial evaluation report v2.0 to state-wide Chief Pharmacist Forum

A physical central Pharmacy, co-located with another public hospital, is to be the central infrastructure point to virtually oversee the distribution of investigational products used in the Teletrial Program.

1.12: Please provide a reference list of conference presentations, publications, citations, mentions in social media, workshops, etc. generated to date in relation to the project and the implementation of the teletrial model as part of this Program.

Northern Territory

Ongoing program promotion and stakeholder engagement across the NT through multiple networks below:

- NT Teletrials Advisory Committee (Nov 2022)
- Top End, Big Rivers and East Arnhem Clinical Innovation and Research Committee (ongoing)
- RDPH Division of Medicine Research Committee (ongoing)
- RDPH Division of Surgery and Critical Care Research Committee (ongoing)
- RDPH Cancer Trials Unit Committee (ongoing)
- NT Health Research Coordinators peer support group (ongoing)
- Population and Primary health Care Senior Leadership Committee – Oct 2022
- East Arnhem Regional Leadership Committee – Oct 2022
- Big Rivers Senior Leadership Committee – Nov 2022
- Top End Regions Aboriginal Health Partnership Committee – Oct 2022
- Central Australian Academic Health Science Network – Oct 2022

Top End Renal Indigenous Consumers Reference Group – Nov 2022 NT sites visits:

- Katherine Hospital with Director of ATP – October 2022
- Gove District Hospital – October 2022 and planned for May 2023
- Alice Springs Hospital – Nov 2022 and planned for April 2023
- Plan for Tenant Creek Hospital – April 2023

National conferences:

- #2 ATP National Steering Committee Workshop (Oct 2022)
- ACTA Annual Scientific Meeting (Nov 2022) ATP National Sponsors Workshop (March 2023)
- Plan for ARCS Conference (June 2023)

Website Update: Teletrial section including A-CTEC support

#1 NT Health Clinical Innovation and Research Business Unit Update – March 2023 with a section dedicated to the ATP-NT progress update

Queensland

- Education Sessions (fortnightly) continued and until December 2022 and recommenced monthly from March 2023, available in Office 365 Stream.
- Presentation at Brisbane Cancer Conference, November 2023 (Plenary Speaker).
- Panel member at Brisbane Cancer Conference, November 2023.
- Presentation at the Victorian 7 Regional Hub Workshop, 17th March 2023.
- QRCCC Workshop presented and facilitated in Brisbane, 21st March 2023.
- Presentations at ANZGOG annual meeting, 22nd Brisbane 2023.
- Presentation at ATP Workshop, Brisbane, 23rd March 2023.

South Australia

Presentations have been given to the following stakeholder groups:

- Health Advisory Council Eyre and Far North Local Health Network
- MSD
- Roche

- SANOFI
- Royal Adelaide Hospital Haematology Clinical Trials Unit
- Director of Mental Health, Flinders Upper Norther Local Health Network
- UniSA Department of Rural Health
- Department of Correction Services
- SA Pharmacy
- Rural Support Services
- Research Governance Officer
- Manager Clinical Services
- Pharmacy
- Cancer Research SA
- CMAX
- SAHMRI
- Genesis Care
- Trans Tasman Radiation Oncology Group (TROG)
- Eli Lily
- Gilead Sciences
- Australasian Gastro-Intestinal Cancer Trials Group (AGITG)
- Bellberry
- Neuroendocrine Cancer Australia
- University of Melbourne
- Servier Australia

Conference Attendance:

- British Oncology Pharmacy Association 7 – 10 October 2022
- SA Vaccinology Conference 4 November 2022
- Australian Clinical Trials Alliance 7 – 8 November 2022
- Society of Hospital Pharmacist Association 1 – 3 December 2022
- V-CTEC 2 – 3 March 2023

Site Visits:

- Whyalla 22 – 24 November 2022
- SA Clinical Trials Pharmacy 9 February 2023
- Whyalla/Port Augusta 8 – 9 March 2023
  - Port Augusta Corrections Facility
  - Uni SA Whyalla Campus
  - Whyalla Hospital
- Department of Nuclear Medicine, The Queen Elizabeth Hospital

Tasmania

N/A – Nil Teletrials established yet.

Victoria

Presentation of the CTRSS-ATP project to:

- Director of Research at Barwon Health
- Research Operations Committee including representatives of all clinical research units across Barwon Health and Deakin University.

Conference presentation by the Barwon Health governance office at the *Regional Victoria Clinical Trials & Research* Meeting.

CTRSS ATP workshop – March 17th Melbourne (face to face)

NHW presentation to Nursing Graduate Students with discussion on CTRSS roles, general trials information and Career Pathways 30/03/2023

Attendance and presentations at Research Lunch

Involvement in planning for South-West Healthcare Research Day (May 2023)

VCCC Alliance Newsletters:

- October 2022: link to NHW success with skilled internship Read more ›
- March 2023: link to NHW new interns and interview with previous NHW intern Read more

Linked In comment to a post re MRFF funding grant for a phase 3 trial that CTRSS was involved in pilot 28/03/2023
https://www.linkedin.com/posts/theroyalmelbournehospital_rmh-led-study-to-look-at-improving-recovery-activity-7044503022382587904-3ukG?utm_source=share&utm_medium=member_desktop

Publication:

A capability framework to inform the fundamental requirements for clinical trial unit development, growth and long term success in outer metropolitan and rural areas. Woollett, A., Duncan, J., Voskoboynik, M., Shackleton, M., Dooley, M., Blum, R., McPhee, N., Wright, T., Wong, Z. W., Dixon, J., & Jane, S. M. (2023).

Contemporary Clinical Trials Communications, 32, 101072–101072.
https://doi.org/10.1016/j.conctc.2023.101072

Western Australia

Workshops

- WA Teletrial Research & Ethics Governance Working Group, Curtin University, Feb 2023
- Teletrial model in the context of medication management, Virtual, Feb 2023

Presentations

- WA Health Research Contracts Working Group, Oct 2022
- RGO Community of Practice Meeting, Oct 2022
- Fiona Stanley Hospital Clinical Trials Pharmacy, Nov 2022
- Regional Pharmacy Leadership Group, Nov 2022
- East Metropolitan Health Service Research Advisory Group, Dec 2022
- North Metropolitan Health Service Research Governance Team, Feb 2023
- Fiona Stanley Hospital Clinical Trials Unit Cancer Centre, Feb 2023
- WACH District Health Advisory Council Chairs, Feb 2023
- Curtin Health Innovation Research Institute, Mar 2023
- Curtin Centre for Clinical Research and Education, Mar 2023

Reports

- WA Country Health Service Annual Report 2021-2022

Measure Six: Health professionals adopt best practices faster

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or establishes best practices
- assesses the speed at which best practices are communicated to clinicians and health service administrators
- identifies how best practices are understood and adopted

1.13 Where applicable, how well were the best practices[4] understood and adopted and how was/will this (be) evaluated?

[4] *WHO defines Best Practices as "exemplary public health practices that have achieved results, and which need to be scaled up so as to benefit more people".*

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

Northern Territory

N/A- nil established clinical trials / teletrials to date

Queensland

Mandatory training for GCP including GCP for Devices. 51 staff trained since last report. 19 in house education sessions completed.

South Australia

Not applicable

Tasmania

N/A – Nil Teletrials established yet

Victoria

Across the seven regional hubs in Victoria, the following actions took place to implement best practice in the clinical trials environment:

- Good clinical Practice (GCP) certification. 10 staff completed GCP training. A total of 160 staff are GCP certified and GCP training and certification is actively promoted
- Training in understanding the *National Standard Operating Procedures for Clinical Trials including Teletrials*
- Other training and educational activities including
  - Promotion of education, and training opportunities from Dept of Health, Victorian Comprehensive Cancer Centre (VCCC), and Victorian Clinical Trials Education Centre (V-CTEC)
  - involvement in the Research Directors, and Victorian Rural and Regional Ethics and Governance Network (VRREGN) forums for discussion
  - incorporation of the *National Clinical Trial Governance Framework* to shape site specific research practices
  - inclusion of clinical trials related material in institutional Best Practice Clinical Learning Environment documents

Western Australia

Not applicable for this reporting period

1.14 How were the community members and consumers engaged in prioritising, designing and conducting research through means such as public consultations? For example, have any state committees or advisory groups been established? What engagement has been undertaken in your state?

Northern Territory

NT Teletrials Advisory Committee was established in 2022 and the inaugural meeting was held in November 2022. There are s47F consumer representatives including s47F First Nations consumers.

Ongoing discussion and consultation to potentially establish NT Health clinical research consumer advisory group as a resource for clinical research/trials team to co-design and include consumers at all stages of the proposed study.

ATP-NT team is also planning a consumer yarning session to develop culturally and linguistically appropriate educational tools to build on health professionals and public health literacy on research and clinical trials. This will hopefully promote consumers involvements in all phases of clinical trials including trials design and also increase recruitment numbers and retention rates into these trials.

Queensland

Teletrials Steering Committee OLD continues to meet regularly and includes consumer representatives. QRCCC currently recruiting 3 to 5 consumers - two of whom will be on the Steering Committee and collectively they will form a working group with the QRCCC.

South Australia

ATP-SA has established the SA Teletrials Advisory Committee with the inaugural meeting held on Thursday 10 November 2022. This committee has s47F consumer representatives from regional South Australia and a representative from the Aboriginal Health Council of SA.

Engagement activities have occurred with a broad range of stakeholders including investigators, universities, private research organisations, ethics committees, sponsors and consumer advocacy groups, and the SA Health Media and Communications team.

Tasmania

N/A – Nil Teletrials established.

Victoria

The Victorian Department of Health has proposed a state-wide clinical trials advisory group with consumer representation. Nominations to this committee have been requested.

Individual clinical trials institutions may consider also establishing similar committees.

Barwon Health:

- is conducting a Research Week which will involve consumer engagement activities
- SKILLED intern (funded by the CTRSS) will focus their site improvement project on the development and implementation of a consumer survey.

Latrobe Regional Hospital is developing a community engagement strategy, and local champions with lived clinical trial experience are encouraged to promote the positive aspects of clinical trial participation.

Northeast Health Wangaratta has appointed s47F consumer representatives to their Research Committee. Consumers recently reviewed our SOP's and provided feedback.
Consideration given in feasibility process for demonstration in protocol of Consumer Engagement or Committee Membership.

Western Australia

The WA Teletrials team are leveraging established avenues for community engagement across the State. WACHS has developed a Consumer and Community Engagement Strategy (2021–26) which aligns with the Teletrials community engagement plans.

Across the WA Country Health Service there are 21 District Health Advisory Councils (DHACs) with 167 members. In January 2023, the WA Teletrials team presented to the DHAC Chairs in preparation for closer engagement when all the infrastructure and contracts are established.

The community advisor on the Australian Teletrial Program has been invited to connect with the WA DHAC network to ensure that local issues and priorities are raised at a national level.

The SouthWest DHACs are currently working with the WA Teletrials team in relation to the first Teletrial involving the Albany Health Campus.

Part 2 – Commonwealth MRFF - Progress Report

1. Complete the following table for each milestone or objective.

The Comments field should summarise progress at the end of the reporting period towards completion of the agreed research activities relevant to each milestone/objective, and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective Northern Territory	**Agreed End Date**	**Actual / Anticipated End Date**	**Current % Complete**	**Comments**
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks and recruiting boosting activities	04 Oct 2023	04 Oct 2023	100%	Ongoing national collaboration
RCCC's deliver support in each jurisdiction to embed teletrial in RRR locations	04 Oct 2023	04 Oct 2023	60%	Ongoing recruitment for regional study coordinators
Evaluation Program continues	04 Oct 2023	04 Oct 2023	20%	Deed of variation is now fully executed. Nil eligible clinical trials/teletrials to date
Milestone/Objective Queensland	**Agreed End Date**	**Actual / Anticipated End Date**	**Current % Complete**	**Comments**
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks and recruiting boosting activities	04 Oct 2023	04 Oct 2023	50%	Majority of CT staff working in TT now have GCP training. QRCCC has an agenda item on each of the 20 clinical networks in QLD. QRCCC is actively promoting the set up of state wide cluster for state-wide services.
RCCC's deliver support in each jurisdiction to embed teletrial in RRR locations	04 Oct 2023	04 Oct 2023	60%	90% of the HHSs in OLD are ready with a CRC TT in place to take part in a TT

Evaluation Program continues	04 Oct 2023	04 Oct 2023	40%	Evaluation program continues with visits from JCU / QUT
Milestone/Objective South Australia	**Agreed End Date**	**Actual / Anticipated End Date**	**Current % Complete**	**Comments**
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks and recruiting boosting activities	04 Oct 2023	04 Oct 2023	100	ATP-SA involvement in National RCCC meetings including facilitation of meeting focused on Management of Investigational Product.
RCCC's deliver support in each jurisdiction to embed teletrial in RRR locations	04 Oct 2023	04 Oct 2023	100	The SA/NT RCCC was established on 30 May 2022. Additional roles have been recruited in early 2023. Rebranding is currently underway to change from SA/NT RCCC to ATP-SA.
Evaluation Program continues	04 Oct 2023	04 Oct 2023	100	Eligibility for the Teletrial Support Program has been finalised and communicated to SA stakeholders as part of engagement activities.
Milestone/Objective Tasmania	**Agreed End Date**	**Actual / Anticipated End Date**	**Current % Complete**	**Comments**
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks and recruiting boosting activities	04 Oct 2023	04 Oct 2023	100	
RCCC's deliver support in each jurisdiction to embed teletrial in RRR locations	04 Oct 2023	04 Oct 2023	**50**	In progress.
Evaluation Program continues	04 Oct 2023	04 Oct 2023		

Milestone/Objective Victoria	Agreed End Date	Actual / Anticipated End Date	Current % Complete	Comments
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks and recruiting boosting activities	04 Oct 2023	04 Oct 2023		Governance of the ATP-VIC program includes an Operations Advisory Group ('hub' clinical trial coordinators and interns) meeting monthly, Industry Engagement Group meeting quarterly and a recently established Consumer Engagement Group meeting quarterly. There is integrated sponsor engagement across all governance groups and a drive to assist industry to pivot to teletrials
RCCC's deliver support in each jurisdiction to embed teletrial in RRR locations	04 Oct 2023	04 Oct 2023		Two RCCC positions funded by ATP operating as start-up specialists: one located in the north-east (servicing 3 regional 'hubs') and one in central west (servicing four regional 'hubs').
Evaluation Program continues	04 Oct 2023	04 Oct 2023		Evaluation program continues with visits from JCU / QUT Active data entry into the ATP database.
Milestone/Objective Western Australia	**Agreed End Date**	**Actual / Anticipated End Date**	**Current % Complete**	**Comments**
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities	04 Oct 2023	04 Oct 2023	50	In 2022, ATP-WA conducted a comprehensive review of clinical training and competency assessment options and initiated negotiations with the Victoria Clinical Trial Education Centre (V-CTEC) on behalf of the ATP. This training platform has since been opened to all of Australia and renamed to A-CTEC
RCCCs deliver support in each jurisdiction to embed teletrials in rural, regional and remote locations	04 Oct 2023	04 Oct 2023	50	ATP-WA has focused on the development and approval of critical legal agreements and governance processes to enable Teletrials in WA.

				Key support and health services across the WA Health have also been supported to accept and approve Teletrials.
Evaluation program continues	04 Oct 2023	04 Oct 2023		Western Australian research governance authorisation has been granted for evaluation activities.

2. **Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during the reporting period.**

Northern Territory

Aligned with risk registry provided to National Office. See National Office Risk Registry (attached)

Queensland

Increased engagement with all the sites across QLD to offer support and training.

South Australia

ATP-SA has developed a risk registry that is reviewed at the end of each reporting period. There have been no changes to this document, all risks are still current.

Tasmania

Tasmania's progress was greatly impacted by staff shortages. A Teletrial coordinator was recruited for a short amount of time in November 2022 until the person returned to clinical work. As a result, the position was then vacant and little progress was made on the program until March 2023, when the current Teletrial coordinator commenced. The current coordinator is 0.6FTE, and a contract of offer for the remaining 0.4 FTE is awaiting final approval by Human Resources.

Victoria

- Year 2 performance against metrics is below target in some metrics and expenditure of funds due to contracts being delayed in year 1 (2021-22) with final signed contract with regional health services ((31 January 2022 in Victoria). **Risk mitigation**: funds were carried over into year 2 and will be used to increase staff positions (fixed term) to meet metrics.
- Risk of trials not planned or converting to teletrials is evident as companies cannot pivot to methodology quickly. Investigators similarly are slow to engage due to being time poor. Collaborative groups are approaching us and interested in taking up teletrials, this may be driven by the Teletrial Support Payment (funds not yet received). **Risk mitigation**: A series of Forums/workshops are planned in next reporting period to engage key decision makers and promote communications for change management to adopt teletrials.
- The risk of a fluid workforce environment, retaining and recruiting skilled staff in regional areas. **Risk mitigation**: Health services have up-skilled current nursing staff and retained SKILLED interns.
- Risk of not attracting more commercially sponsored clinical trials/teletrials for sustainability into the future. **Risk mitigation**: governance structure has an Industry Engagement Group for the Victorian program. A Forum with Industry in April 2023 will bring sponsors together with the 7 regional sites to learn how to work with commercial sponsors, developed collaboratively with BMS and Cth R&D Task Force.

- Risk of low recruitment to trials/teletrials is a focus. **Risk mitigation**: Community Engagement Group is established with consumer organisations to promote awareness of the ATP and access to trials/teletrials throughout Victorian networks.

Western Australia

Key risks are outlined below in overall progress report

3. **Complete the following table for all variation requests approved, submitted (pending approval) or in draft (pending submission) for this grant to date**

Description of Variation	Current Status (Approved/Submitted/In Draft)
Deed of Variation No.1	Fully Executed 29/03/2023 (NT)
MMM 2 variation	Submitted (Qld)
Variation to Funding Sub-contract: Commonwealth Grant for the Australian Teletrial Program	Signed by The Minister for Health and Wellbeing through SA Health 6 January 2023 Returned to ATP National Office 24 January 2023 (SA)
Deed of Variation – Incentive Program	The deed has been reviewed by our legal team and is with CFO for review prior to CEO approval. (WA)
Variation of Schedule 1, item 2 'Subcontracted Activities', Schedule 1, item 3 'Payment Schedule' and Schedule 1, item 7 'Contact Officer'	Approved, effective 4 October 2022 (Tas)

4. Provide a statement on your <u>overall</u> progress towards completion of the Program Activities by the agreed end date. If the Program Activity is not on track, describe the extent of the overall delay

Northern Territory

Establishment of ATP-NT RCCC: 4 fulltime positions have been recruited. Currently recruiting for regional study coordinators.

Governance: Robust governance structure was established including NT Teletrials Advisory Committee. NT representation on the ATP National Executive Committee, Steering Committee, Working Group and National RCCC group

Education and training: 93 people trained to date. GCP was conducted in Nov 2022 at Alice Springs Hospital, NT. Planning is underway to conduct face-to-face GCP and AIRSAFE Dangerous Goods training in May 2023 at Royal Darwin Hospital. As of 1st March 2023, A-CTEC is live and accessible at no cost to the end user – 17 people registered as of 31st May 2023

Stakeholder engagement: ongoing extensive consultations internally and externally, including but not limited to health executives, senior leaders, clinicians, researchers, key/partner institutions, industry sponsors, universities and research institutes, and consumers

Barrier analysis: currently being undertaken across all five regions within NT Health: Top End Regional Health Service, Big Rivers Regional Health Service, East Arnhem Regional Health Service, Central Australian Regional Health Service and Barkly Regional Health Service (6 public hospitals across 5 regional health services and primary health care clinics) to identify opportunities for further refinement and provide recommendations for sustainability planning to ensure benefits continue beyond the program period.

Inclusion and diversity: planning underway for a consumer yarning session to develop culturally and linguistically appropriate educational tools to build on health professionals and public health literacy on research and clinical trials. There is ongoing discussion and consultation to potentially establish NT Health clinical research consumer advisory group as a resource for clinical research/trials team to co-design and include consumers at all stages of the study.

Queensland

The QRCCC is making in signification progress with working towards our targets, we are on track to achieve the milestones and targets for the reporting period. Working towards final targets 04/10/2026.

- Participants 66 of 1750 (4%)
- New Satellite Sites 29 of 851 (3%)
- Improved Clinical trial Sites (PS) 24 of 283 (8%)
- Number of people trained 474 of 834 (57%)

South Australia

The major focus for ATP-SA continues to be capacity and capability building and stakeholder engagement. The third and final recruitment phase of ATP-SA team members is almost complete. Two out of three Registered Nurse Clinical Research Coordinators based in regional SA have now commenced which is a significant achievement as part of the capacity and capability building in regional SA.

The three Registered Nurse Clinical Research Coordinator positions are a result of partnerships between ATP-SA, Flinders University, University of South Australia and Riverland Mallee Coorong Local Health Network. Establishing partnerships such as this is extremely important in these early stages to build trust and relationships with key stakeholders.

Regional site visits are occurring as required to assess the capacity and capability at regional sites. To further support the capacity and capability of clinical trials in regional SA, Rural Support Services has recently employed a full time Medical Oncologist to focus on clinical trials in s47F where s47F of the Nurses is located.

Two internal planning workshops have been held in 2023 as new ATP-SA team members have commenced. A Communications Plan is being developed in consultation with Department for Health and Wellbeing Corporate Communications to further promote and market teletrials and clinical trials and the ATP-SA brand across South Australia.

A focus in 2023 has been engagement with commercial sponsors to promote the SA value proposition of opening up regional South Australian sites. A process for reviewing and executing Confidentiality Disclosure Agreements has been implemented to enable discussions to progress with sponsors around specific protocols. It has become evident that residents living in rural regional and remote South Australia have been missing out on accessing clinical trials due to the inability to identify current clinical trials with regional SA participants to convert to teletrials. Despite this, the team is currently in the process of setting up six teletrials with two of these being cross jurisdictional teletrials with a primary SA site and a NT satellite site. It is important to ensure the success of these early teletrials to develop the proof of concept and good news stories that can build the number of future teletrials across SA and NT. Additionally, there are a number of protocols being developed in regional SA for regional SA participants. While the team is continuing to engage and maintain relationships to progress these teletrials, there is only so much influence the team can have and delays in establishing the first teletrial are a result of sponsor processes.

The recruitment of the Training and Development Officer in early 2023 has supported the training pillar with training plans being developed for the Registered Nurse Clinical Research Coordinators based in regional SA and will be shared with ATP-NT upon completion. A face to face GCP training session was conducted at Southern Adelaide Local Health Network and uptake of the A-CTEC platform within South Australia has continued to increase after SA was the first jurisdiction to gain access as a pilot on 26 September 2022. This pilot has supported the rebranding of V-CTEC to A-CTEC in March 2023 and becoming a national training platform.

Collaboration with NT to support clinical trials and teletrials is continuing. Weekly team meetings have occurred between ATP-SA and ATP-NT team members since early 2022. Additional meetings have been scheduled as required to discuss specific items as they arise including clinical trial protocols. The ATP-SA team has openly

shared with ATP-NT newly developed resources including the SA protocol review process flowchart, all checklists and additional templates created for submitting teletrial applications to research offices.

Due to confidentially and legal reasons it is difficult to include external people in protocol review sessions for SA clinical trials however assistance has been offered in reviewing protocols for NT only teletrials. Ongoing support is provided to ATP-NT in completing teletrial specific documents for NT only teletrials and active involvement has occurred in reviewing Teletrial specific documentation for NT only teletrials. An appropriate level of engagement and communication is occurring from the ATP-SA team to support the uptake of clinical trials and teletrials in the NT.

Additionally, the ATP-SA Medical Director is continuing to support ATP-NT by providing ongoing in-kind strategic advice as the ATP-NT Medical Director and as is Chair of the NT Teletrials Advisory Committee.

This is an important program that is creating cultural change across South Australia. Setting up capacity and capability in regional South Australia has been a focus to ensure there are key positions on the ground to do the work in regional SA. As a result, there are definitely challenges in the uptake of the teletrial model. The team is heavily focused on building strong relationships to ensure the first teletrial is a success and can be used as a proof of concept to attract more clinical trials and teletrials to regional SA to make this a sustainable program.

Tasmania

Overall progress has been significantly delayed due to vacancies within the team. However, Tasmania has recently engaged a Research Governance Coordinator (1 FTE) and a Teletrial Coordinator (0.6 FTE) with another Teletrial Coordinator (0.4 FTE) expected to be onboarded in the coming weeks. Work on this program has therefore recently resumed, with a number of educational and training sessions planned for the next reporting period. We have also identified a number of trials with potential for inclusion in the Teletrial program and have begun working with researchers and support staff from these trials. In addition, the new team members have been engaging with inter-jurisdictional colleagues, other RCCCs and partner organisations. Further, we have established a centralised Teletrial email address to enable researchers and sponsors the ability to ask questions or get advice.

Victoria

Victoria is on track.

The effect of change management barriers in year 2 is being addressed through strategic governance, sector engagement and promotion through networks.

Regional health services are trial-ready and investing resources in starting teletrials

Teletrial website tile with information and guidance (from ATP-QLD RCCC) to promote teletrials to the sector (https://www.clinicaltrialsandresearch.vic.gov.au/). A regular e-bulletin is used to highlight new web information and other sector news.

Western Australia

Within 18 months, the ATP-WA team has:

- Established positions and recruited expertise into the coordinating team
- Selected first regional satellite site and undertook site visit to understand infrastructure and skill needs to support Teletrials
- Created new ethics governance documents including revised CTRA and patient consent forms and adapted the Teletrials Toolkit for WA
- Reviewed 18 trials for Teletrial conversion and selected the first Teletrial for WA – VITAFOOT.

Critical items affecting progress for WA include:

- Cross HSP governance issues which affect the ability to achieve governance reviews in a timely manner. HSPs in WA often have different governance requirements which can slow down review timeframes for trials that go across HSPs. The Department of Health is leading a review of governance policy across HSPs to streamline these processes.
- Regulatory requirements for infusional medicines. Currently, these clinical trial infusions are manufactured in public tertiary hospitals only. WACHS contracts Baxter for the provision of non-clinical

trial infusions and is seeking an extension of this contract to include the manufacture of clinical trial infusions. s47G(1)(b)

- WA is the only state in which the national Medicines Australia Clinical Trial Research Agreement Teletrials Sub-contract is currently not accepted within the state legal framework. The Health Services Act 2016 prohibits WA Health Service Providers (HSP) from entering into arrangements on behalf of other entities with respect to indemnity provisions, essential for the Teletrial Model. The ATP-WA has worked closely with the Department of Health and State Solicitors Office to ensure clinical trial research agreements can be used between WA Health Service Providers.

Part 3 – Commonwealth MRFF - Working with Children – Statement of Compliance

3.1 Complete the following table

Northern Territory

1	Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ **Yes** ☐ **No** ☒ **N/A**
2	Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**
3	Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☒ **N/A**
4	Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ **Yes** ☐ **No** ☒ **N/A**

Queensland

1	Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation? **Response:** **We are working with Children's' Hospital Queensland who are all fully compliant**	☐ **Yes** ☐ **No** ☒ **N/A**

2 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**
3 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☒ **N/A**
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ **Yes** ☐ **No** ☒ **N/A** **All clinical staff have child safety training**

South Australia

1 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ **Yes** ☐ **No** ☒ **N/A**
2 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**
3 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☒ **N/A**
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ **Yes** ☐ **No** ☒ **N/A**

Tasmania

4 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ **Yes** ☐ **No** ☒ **N/A**
5 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**

6 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ Yes ☐ No ☒ N/A
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ Yes ☐ No ☒ N/A

Victoria

7 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ Yes ☐ No ☒ N/A
8 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ Yes ☐ No ☒ N/A
9 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ Yes ☐ No ☒ N/A
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ Yes ☐ No ☒ N/A

Western Australia

10 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ Yes ☐ No ☒ N/A
11 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ Yes ☐ No ☒ N/A
12 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ Yes ☐ No ☒ N/A
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with:	☐ Yes ☐ No ☒ N/A

• the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	

Part 4 - Financial Report

3.1 Please complete the financial acquittal attached (Excel document) detailing budget and actual expenditure for the current reporting period and forecast expenditure for the next reporting period as per the 'Head of Expenditure' categories in the grant agreement budget. These categories include: Labour (excluding on-costs), Labour on-costs, Travel, Equipment, Contract, Other eligible expenditure, Minor Capital Works (none in original budget), Materials for Construction (none in original budget).

A detailed description of these expenditure categories can be found in the grant guidelines. Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?

A summary is provided as an overall statement of financial status as compiled and supported by the ATP National Office.

Northern Territory	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Queensland	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
South Australia	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Tasmania	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Victoria	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Western Australia	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	

Australian Teletrial Program

RISK REGISTER - Australian Teletrial Program

							Current risk assessment									Projected risk assessment				
Log #	Project Reg # *if app.*	Type of Risk	Description of risk	Risk location	Date identified	Risk owner	Current controls identify each step as C1, C2, C3 etc	Current project consequence	Current likelihood	Current rating	Current Risk score	Response protocol	Treatments identify steps as T1, T2, T3	Treatment due date	Treatement status	Projected consequence	Projected likelihood	Projected rating	Projected source	Review comments
		Financial	Adequate insurance coverage in line with Legal advice.	Qld Health	May-21	ATP / ORI	Qld Health Legal review and Qld Health unlimited liability insurance policy	Moderate	Rare	Low (5)	5	Treat	T1 - Maintain Qld Health insurance cover and risk register. T2 - Advise Qld Health Legal of significant changes to ATP activities/deliverables and grant agreement.							Link to Legal email regarding insurance
		Financial	Deferral requests with Qld Treasury	Qld Health	Jun-22	ATP / ORI	All deferral requests have been approved so far. Qld Treasury has provided a re-cashflowing solution. If activity levels increase and funds are expensed completly each financial year, there won't be a need for additional future deferral requests.	Moderate	Rare	Low (5)	5	Tolerate	Submission of deferral request by 10 January/ at the beginning of the year as suggested by Qld treasury/CPSS business services.							The reliance on deferral approval from Qld Treasury for funds that are for a specific purpose creates an unnecessary risk to the project. Failure to comply will result in a liability to the Commonwealth.
		Financial	Financial control of equipment expenditure	National	Jun-22	ATP/ORI	C1. The Grantee agrees to obtain the Commonwealth's prior written approval to use the Grant to purchase any item of equipment or Asset more than $20,000 (including GST). C2. Financial acquittals certifying that expenditure is in accordance with the grant agreement and guidelines.	Minor	Possible	Medium (9)	9	Treat	T1- Building the ATP (RedCap) database which is centralised and records information from all jurisdictions. Information in RedCap can be viewed and audited by the ATP National Office to ensure they are in line with the grant agreement and guidelines.							
		Financial	Independent external audit requirement and financial acquittals	National	Jun-22	ATP / ORI	C1. Financial acquittals certifying that expenditure is in accordance with the grant agreement and guidelines. C2. Provision of support to ATP program participants by an experienced accountant.	Major	Almost certain	Very High (23)	23	Treat	Implement financial acquittals with certifications in accordance with the grant agreement/guidelines and 6 monthly reporting schedule.							See s47F for clarification of independent external audit certifications and an example of a Management Representation Letter for a government grant.
		Financial	Inflation eroding the value of the funding program by the end of the program lifecycle	National	Jun-22	ATP / ORI	Qld Treasury are managing the surplus funds. Interest is not currently being earned on the grant proceeds. Further controls to be discussed.	Negligible	Almost certain	Medium (7)	7	Tolerate	Detailed business model to be developed by the end of year 3 of the program.	30-Nov-24	Open					
		Financial	Underspend of funding allocated inception to date (ITD)	National	Jun-22	ATP / ORI	C1. Financial acquittals C2. Financial reporting / budget development / monitoring.	Moderate	Possible	High (15)	15	Treat	T1- Aquittal reporting keeps accurate record of underspend		Ongoing					
		Legal	Risk of contracts not delivering on contract obligations (contract terms risk where contractual obligations don't align with the contract reality).	National	Perpetual	ATP / ORI	C1. Ramping up activity levels C2. Actual performance and processes setting a precident for contractual obligations (ie substantiation).	Major	Unlikely	Medium (14)	14	Treat	T1-Monthly status reports T2 payments on receipt of deliverbles achieved.		Ongoing					
		Operational	Attracting and retaining appropriately skilled RCCC staff	National		Jurisdiitons	C1. Only experienced clinical research coordinators to be engaged	Moderate	Possible	High (15)	15		T1-Ensure reruitment and retention strategies in place in each jursdciton T2 Provide appropriate eduction and support through DoH and RCCC set ups		Ongoing					
		Operational	Delayed launch of Program resulting in reduced opportunities for national communication of ATP	National		ATP / ORI	C1. Ongoing communication with strategic communication and submission of Ministerial date claimer request C2. Supporting documentation C3. Escalation to DG	Major	Likely	High (20)	20	Treat	T1. Regular communication with Coms regarding urgency . T2. Brief DG to escalate urgency and reputational risk to QLD as project	05-Nov-22	Closed					Comms plan implemented Escalatdon 26/07/2022 as per S/C 25/06/2022 action
		Operational	Delays to reporting to Commonwealth due to delays in jurisdictions reporting to the ATP National Office	National		ATP/ORI/Jurisdcitions	C1. Preparation and dissemination of reporting templates to partners allowing them enough time to prepare and return reports to national office for national office to consolidate and report back to Commonwealth	Moderate	Possible	High (15)	15	Treat	T1. Preparation and dissemination of reporting templates to partners allowing them enough time to prepare and return reports to national office for national office to consolidate and report back to Commonwealth	Ongoing						
		Operational	Delays to Teletrial Support Program rollout	National		ATP/Jurisdictions	C1. Business planning to establish the TSP is in progress	Major	Likely	High (20)	20	Treat	T1. Identifying barriers and working within the system to establish the teletrial support program T2.Variations to contracts secured	May-23						
		Operational	Governance framework implementation across jurisdictions with smaller population and work force	National		ATP/Jurisdictions	C1. Targets are being updated to reflect equitable representation of population and work force in all jurisdictions	Moderate	Possible	High (15)	15	Treat	T1. Monitoring as per report period. T2 National governance revision to support all jurisdictions	Dec-23						
		Operational	Inaccurate or incomplete data provided by RCCCs through REDCap data collection	National		Jurisdictions	C1. REDCap training is being provided as we go	Moderate	Possible	High (15)	15	Treat								
		Operational	Inter-departmental reliance at DoH (Bus. Services, Finance & Legal advice requests)	Qld Health	Jun-22	ATP / ORI	C1. Relying on Business Services.	Moderate	Likely	High (16)	16	Tolerate								Reducing reliance on DoH departments and resourcing an ATP accountant with access to QLD Health finance and legal colleagues with Commonwealth project experience. Ill-considered advice has been detrimental to the ATP project since inception.
		Operational	Lack of engagement with stakeholder	Qld Health	Jun-22	ATP / ORI	C1. ACTA proposal is finalised who will be working to engage clinical research networks C2. Feedback from advisory groups and IQVIA to	Moderate	Unlikely	Medium (12)	12	Treat	T1. Reaching out to and presenting to clinical networks T2. Uninterrupted communication with jurisdictional partners							
		Operational	Non-streamlined/consistent communications	Qld Health	Jun-22	ATP / ORI	C1. Monthly catch up with jurisdictional partners	Major	Possible	High (18)	18	Treat								
		Operational	RCCC staff do not follow agreed workflows or guidelines	National	Jun-22	ATP / ORI	C1. Only experienced clinical research coordinators to be engaged C2. Employ CRCs from a range of clinical trials backgrounds	Moderate	Unlikely	Medium (12)	12	Tolerate	T1.NO support development of processes and education							
		Operational	Supply chain disruptions caused by global pandemic affecting establishment of clinical trial sites.	National	Jun-22	ATP / ORI	Risk transferred to jurisdiction state partners, however this risk is systemic project risk.	Minor	Unlikely	Medium (8)	8	Tolerate								
		Social	Lack of consumer engagement	National	Jun-22	ATP / ORI	C1. CHF has finalised the consumer engagement strategy C2. Consumer Engagement starategy has been finalised and discussion to integrate ATSI community engagement strategy is underway.	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Clinical and consumer health forum and consumer engagement strategy from Consumer Health Forum (CHF) T2. Consumer Engagement Strategy to be implemented including special attention to ATSI community engagement	30-Apr-23	Ongoing					
		Social	Risk to not representing the diversity of partner jurisdictions' populations	National	Jun-22	ATP / ORI	C1. CHF has finalised the consumer engagement strategy which has been reviewed by C&C Advisory group	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Clinical and consumer health forum and consumer engagement strategy from Consumer Health Forum (CHF)T2. Employment of Lead communication Officer		Ongoing					
		Strategic	Classification and use of Modified Monash Model for the Teletrial Support Program (change from MM3-7 to MM2-7)	National	2021	ATP / ORI	C1. Jurisdictions to provide examples of MM2 activity which is disincentivised from participating in teletrials as it is currently excluded from the TSP eligibility guidelines (i.e. MM3-7) C2. ATP Executive Committee to be briefed	Moderate	Possible	High (15)	15	Treat	T1. Seek endorsement from ATP Executive Committee to raise with the Commonwealth T2. Discuss with the Commonwealth T3. Vary the head agreement with the Commonwealth from MM3-7 to MM2-7 T4. Amend TSP eligibility guidelines to be MM2-7	May-23						Action from 8/12/2022 ATP Executive Committee - ATP National Office to raise the MM2 issue with the Commonwealth.
		Strategic	Commercial sponsors not engaging with teletrials	National	Jun-22	ATP / ORI	C1. IQVIA is currently interviewing jurisdictional partners to identify barriers and challenges	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Sponsor Advisory group and IQVIA T2.National Workshop for sponsorre	Mar-23						
		Strategic	Integration with NSW and ACT	National	Jun-22	ATP / ORI	C1. 3-monthly meetings are being set-up with NSW and ATP	Minor	Possible	Medium (9)	9	Treat	T1-reular meetings T2 Sharing of documents and processes. T3.Include NSW in working groups icuements	30-Jun-23						
		Strategic	Lack of engagement with external stakeholder by clinicians	National	Jun-22	ATP / ORI	C1. Queensland is working on HSCE forum brief and will present to the forum C2. Seek for other jurisdictionals plans to engage their clinical and research networks	Moderate	Possible	High (15)	15	Treat	T1. Engage with and present to clinical networks							
		Strategic	Large investment in this Program not meeting outcomes; KPIs/milestones not being met	National	Jun-22	ATP / ORI	C1.RCCC set up	Major	Possible		18	Treat	T1. Extensive engagement with all stakeholder T2. Promoting the program and model through site visits and through atending conferences and seminars							
		Strategic	RCCCs/Primary site paying Teletrial support Program funds to ineligible primary and satellite sites	National	Jan-23	ATP / RCCCs	C1. Eligible trials reporting through REDCap	Minor	Possible		9	Treat	T1. For QRCCC each memo will include timeline for that trial and will be accompanied by REDCap reporting							
		Strategic	Risk to harmonisation: * inconsistency of RCCC situated within jurisdiction, * sites operating outside of program model, * misalignment with operating processes and policies between states	National	Jun-22	ATP / ORI	C1. Detailed implementation plan template is prepared for jurisdictional partners	Major	Possible	High (18)	18	Treat	T1. Monthly catch up with jurisdictional partners T2. Detailed implementation plan from jurisdictional partners T3. Restructuring the executive committee to have representation from high-enough policy makers/influencers from jurisdictional partners							

NT Regional Clinical Trial Coordinating Centre - Education and Training Record

Module name	Brief summary of module	Provider Name	Delivery mode (face to face, virtual, hybrid)	Location (if delivered face to face)	Date/s delivered	Duration (how many hours/days)	How many people attended/completed?	How many of those who attended/completed were from MM3-7 category locations?	Comments
Project Management Fundamentals for Research and Clinical Trials	The key elements of what it takes to manage projects successfully and methodically in research and clinical trials by applying established and recognised methodologies	PRAXIS Australia	Virtual	N/A	13/07/2022	4h	s47F	0	
Conducting Clinical Research - Essential Good Clinical Practice Training for New Coordinators & Researchers E6 (R2)	GCP principals across design, conduct, management, recording, analysis, &/or reporting of clinical trials.	ARCS Australia	F2F	Menzies Auditorium, RDH Grounds	19-20/09/2022	2d	44	s47F	
Essential Good Clinical Practice Training for Clinical Investigational Sites E6 (R2)	Overview of GCP, the principles of ICH-GCP, and investigator responsibilities.	ARCS Australia	F2F	Menzies Auditorium, RDH Grounds	21/09/2022	4h	27	0	
Essential Good Clinical Practice Training for Clinical Investigational Sites E6 (R2)	Overview of GCP, the principles of ICH-GCP, and investigator responsibilities.	ARCS Australia	F2F / Virtual	John Hawkins Lecture Theatre, ASH	17/11/2022	4.5h	20	15	
Trials Essentials for Research Support Team	TransCelerate meeting the minimum requirement of ICH E6 (R2) GCP; Introduction to Clinical Trials, Running a Clinical Trial from Start to Finish, The Regulatory Environment of Clinical Trials, Ethics & Governance Application Process, Safety Reporting in Clinical Trials, Monitoring and Auditing Clinical Trials	A-CTEC	Virtual	N/A	9/03/2023	10	s47F	0	

Queensland

Module name	Brief summary of module	Provider Name	Delivery mode (face to face, virtual, hybrid)	Location (if delivered face to face)	Date/s delivered	Duration (how many hours/days)	How many people attended/completed?	How many of those who attended/completed were from MM3-7 category locations?	Comments
Principles of GCP (CS.01)	Good Clinical Practice standards (E6 R2)	PRAXIS	Online		Various	2-4 hours	49	8	
GCP for Devices (CS.OS)	Good Clinical Practice for Devices Module	PRAXIS	Online		Various	4-6 hours	s47F	0	
Education Session	ATP database	ATP National Office	Online		12/10/2022	1/2 hour	12	0	
Education Session	Cancer Nusing Society of Australia	QRCCC	Online		26/10/2022	1/2 hour	6	s47F	
Education Session	Training on site at QRCCC	QRCCC	Face to face	QRCCC Office Townsville	10/11 - 11/11/2022	1/2 hour	6	0	
Education Session	PARTNER Project -s47F	QRCCC	Online		23/11/2022	1/2 hour	8	s47F	
Education Session	Infonetica -ERM -s47F	QRCCC	Online		7/12/2022	1/2 hour	10		
QRCCC Training	Information regarding TT Roles	QRCCC	Online		12/10/2022	1 hour	s47F		
Research in Childrens		PRAXIS	Online		8/11/2022	4-6 hours		0	
QRCCC Information booklets	QRCCC Information booklets created for Sponsors, New Sites, New PI and SI, New CRC's, HHS Executives, Finance Department, Ethics and Governance and supporting Departments	QRCCC	Online		Various	Various		0	
QRCCC Workshop	Workshop 2023 - Understand the Teletrial model, the functions and Processes	QRCCC	Oneline and Face-to-Face	Brisbane	21-Mar-23	2 hours	68	3	

South Australia

Progress Report - Part 1.5 Education and Training

Reporting Period 1 October 2022 to 31 March 2023

Module name	Brief summary of module	Provider Name	Delivery mode (face to face, virtual, hybrid)	Location (if delivered face to face)	Date/s delivered	Duration (how many hours/days)	How many people attended/completed?	How many of those who attended/completed were from MM6-7 category locations?	Comments
Total							150	17	
IATA Training	Safe transport of infectious substances by air shipper trainine	Syneos Health	Virtual	N/A	12/07/2023	3 hours	S47F	0	Attended by cluster start-up specialist
GCP Training	Covers origins, rational, principles and relevant guidelines of GCP, roles and responsabilities of research, data/record management, research ethics and governance	Praxis, SALHN, ATP SA	In-person	SALHN	7/10/2023	6 hours	27	S47F	Attended by various SA research professionals
GCP Training	12 modules, each discusses a specific GCP standard. General conduct of research standards are also presented.	National Drue Abuse Tr	Virtual	N/A	14/02/2023	8 hours	S47F	0	Attended by training and development officer
GCP Training	Covers origins, rational, principles and relevant guidelines of GCP, roles and responsabilities of research, data/record management, research ethics and governance	Syneos Health	Virtual	N/A	27/02/2023	5 hours		0	Attended by training and development officer
CALHN Pharmacy Training	Overview of CALHN pharmacy facilities and proceedures	CALHN	In-person	RAH Pharmacy. Adelaide. SA	27/02/2023	8 hours		S47F	Attended by liason officer and cluster start-up specialist
The National Clinical Trials Governance Framework – what to expect	Overview of NSQHS standards and assessment process that provide nationally consistent approach to clinical trial services governance across health service oraanizations	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	2/03/2023	1 hour			Attended by liason officer, training and development officer, Manager and cluster-start up specialist
Trial Quality/Quantity...What does this mean?	Importance of both quality and quantity in clinical trials	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	2/03/2023	1 hour			Attended by liason officer, trainine and development officer, Manager and cluster-start up specialist
The significance of risk assessments	Expectations between sponsor and CRO, Site Visit Selection, IP risk and manifacturine. supportine documents	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	3/03/2023	45 mins			Attended by liason officer, training and development officer, Manager and cluster-start up specialist
Consumer's Needs: First & Foremost	Importance of considering consumer needs, how to meaningfullly implement consumer feedback	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	3/03/2023	45 mins			Attended by liason officer, training and development officer, Manager and cluster-start up specialist
Improving recruitment through Consent	Exploration of current PICF fomat, InFORMed approach to improve consumer comprehension	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	3/03/2023	45 mins			Attended by liason officer, training and development officer, Manager and cluster-start up specialist
Diversity, Equity and Inclusion in Clinical Trials	How current landscape of clinical trials affects DEI and importance of implementing improvements, overview of successful cases	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	3/03/2023	45 mins			Attended by liason officer, training and development officer, Manager and cluster-start up specialist
Measuring trial complexity meaningfully	Measurine trial complexity throuah workload calculation	A-CTEC	In-person, online	Deakin Downtown. Melbourne. VIC	3/03/2023	30 mins			Attended by liason officer. trainine and development officer. Manaeer and cluster-start uo specialist
The power of sponsor metrics	Data svstems used by sponsors. use metrics to improve reportine	A-CTEC	In-person. online	Deakin Downtown. Melbourne. VIC	3/03/2023	30 mins			Attended by liason officer. trainine and development officer. Manaeer and cluster-start uo specialist
Facing new emerging science	Current emerging science and clinical trials implications	A-CTEC	In-person, online	Deakin Downtown, Melbourne, VIC	3/03/2023	30 mins			Attended by liason officer, training and development officer, Manager and cluster-start up specialist
Foundations of Oncology	Introduction to oncoloav. core topics in cancer therapeutics	SHPA	Online	N/A	18/03/2023	10 hours			Attended by liason officer
Introduction to ATP	Introduction to Australian Teleirial Proeram and ATP SA	ATP SA	Virtual	N/A	24/03/2023	1 hour		0	Attended by reeional nurse
Overview of Ethics and Governance	Foundation guidelines for the ethical review of research, ethics committee and applications. SA Health policies	SALHN Ethics and Gove	Virtual	N/A	28/03/2023	3 hours			Attended by training and development officer
April Webinar: Preparing for NCTGF Accreditation assessment	The phases, roles and information required of an accreditation	A-CTEC	Virtual	N/A	6/04/2023	1 hour		S47F	Attended by regional nurses, training and development officer, cluster start-up specialist
A-CTEC MODULES									
Safety Monitoring and Reporting in Trials	Course covers safety reporting requirements for investigational products in accordance with: NHMRC EtHS9 guidance on safety monitoring and reporting in clinical trials involving therapeutic goods 2016; the safety reporting responsibilities of sponsors and principal investigators in therapeutic goods clinical trials; PI oversight in safety management of their trial participants	A-CTEC	Virtual	N/A	30/10/2022	2 hours	S47F	0	
Trial Regulatory Requirements in Australia	Course covers the Australian regulatory requirements governing clinical trials; the impact of overseas regulatory agencies on trials conducted in Australia; the roles of Human Research Ethics committees and Research Governance Offices in reviewing clinical trials in Australia; the Australian research ethical values and the ethical conduct of clinical trials; the Australian national legislation impacting the conduct of a clinical trial in Australia; the different application forms used in submitting a clinical trial to ethics and governance; the research application and sites coordination process in Australia	A-CTEC	Virtual	N/A	30/11/2022	2 hours		0	
PI Oversight and Trial Management	Course covers roles and responsibilities of PI's research support team; importance of delegation of trained staff; PI oversight during the trial management; role of PI in recruitment and requirements of informed consent; difference between monitoring, auditing and inspection; the auditine process and PI oversight	A-CTEC	Virtual	N/A	28/02/2023	1 hour		0	
Protocol Compliance & Serious Breaches	Course covers PI responsibility in overseeing protocol compliance; the reporting responsibilities of PI & sponsor when serious breaches occur in trials: protocol deviations and serious breaches in trials	A-CTEC	Virtual	N/A	03/04/2023	1.5 hours		0	
Writing in Plain Language for Research Participants	Course covers what is plain language, the National Statement requirements when writing PICF, participants needs, principles of plain lanauaae writine. and writine tips for PICF	A-CTEC	Virtual	N/A	05/04/2023	2 hours		0	
Ethics and Governance Application Process	Course covers the different application forms used in submitting a clinical trial to ethics and governance; the research application and sites coordination process in Australia; the documents required for ethics and governance review and approval, the post-authorisation reports required to be submitted during the lifetime of a clinical trial	A-CTEC	Virtual	N/A	1 Oct - 31 March	2.5 hours	6	0	
Introduction to Clinical Trials	Course covers the development process of a new investigation product; the different clinical trials phases and common trial design terminology; the main players involved in clinical trials; high level overview of the steps involved in running and manaaina clinical trials	A-CTEC	Virtual	N/A	1 Oct - 31 March	1.5 hours	16	0	
Monitoring and auditing clinical trials	Course covers the difference between monitoring, auditing and inspection; the role of monitors (CRAs) in clinical trials; different monitoring approaches in a clinical trial; the auditing process and its relation to the quality management of a clinical trial; concepts of root cause analysis and corrective and preventive actions for trials audit/inspection findings; guiding tools and checklists to prepare for site audit/inspection visits	A-CTEC	Virtual	N/A	1 Oct - 31 March	2 hours	S47F	0	
Running a Clinical Trial from Start to Finish	Course covers different stages involved in running clinical trials; the role of sponsor and site in the feasibility and start-up stage; the clinical trial essential documents required to be retained at the site; the process of enrolling participants in a clinical trial, including informed consent and required documentation; the process of clinical trial data management; the requirements for study closure and archivine	A-CTEC	Virtual	N/A	1 Oct - 31 March	3 hours	0	0	
Safety reporting in clinical trials	Course covers the different safety terminologies used in clinical trials; the safety reporting responsibilities of sponsors and principal investigators; the safety reporting requirements for investigational products in accordance with the NHMRC auidelines 2016	A-CTEC	Virtual	N/A	1 Oct - 31 March	1.5 hours	7	0	
The regulatory environment of clinical trials	Course covers the Australian regulatory requirements governing clinical trials; the impact of overseas regulatory agencies on trials conducted in Australia; the roles of Human Research Ethics committees and Research Governance Offices in reviewing clinical trials in Australia; the Australian research ethical values and criticise the ethical conduct of clinical trials; the Australian national legislation impacting the conduct of a clinical trial in Australia	A-CTEC	Virtual	N/A	1 Oct - 31 March	3 hours		0	
Trial Feasibility & Start-up Process	Course covers site enablers to run effective trials; core components of trial feasibility assessment; standard of Care (SOC) and Above SOC trial procedures and the impact on trial budgeting; process, components and responsibilities of trial budgeting and contracting; core elements of study start-up & initiation	A-CTEC	Virtual	N/A	1 Oct - 31 March	1.5 hours	S47F	0	
Trials Essentials for Investigators	Introductory package consists of 5 separate courses and equips the investigators with foundational knowledge about running clinical trials in Australia, including trial regulatory requirements in Australia, trial feasibility & start-up process, safety monitoring and reporting in trials, protocol compliance and serious breaches, PI oversight and trial manaement.	A-CTEC	Virtual	N/A	1 Oct - 31 March	10 hours		0	
Trials Essentials for Research Support Team	Introductory package consists of 6 courses and equips the research support team with foundational knowledge about running clinical trials in Australia, including introduction to clinical trials, running clinical trials from start to finish, the regulatory environment of clinical trials, ethics and governance application process, safety and reporting in clinical trials, monitorine and auditine clinical trials	A-CTEC	Virtual	N/A	1 Oct - 31 March	15 hours	16	S47F	

Tasmania

Module name	Brief summary of module	Provider Name	Delivery mode (face to face, virtual, hybrid)	Location (if delivered face to face)	Date/s delivered	Duration (how many hours/days)	How many people attended/completed?	How many of those who attended/completed were from MM3-7 category locations?	Comments
ATP Basics	Introduction to the Teletrial model for Clinical Trial Staff/Researchers	s47F	Face to Face	Launceston General Hospital	22/11/2022	1hr	s47F	0	
ATP Basics	Introduction to the Teletrial model for Clinical Trial Staff/Researchers		Face to Face	Launceston General Hospital	16/01/2023	1hr		0	
ATP Basics	Introduction to the Teletrial model for Clinical Trial Staff/Researchers		Face to Face	Launceston General Hospital	15/02/2023	1hr		0	
ATP Basics	Introduction to the Teletrial model for Clinical Trial Staff/Researchers		Online	Online	9/11/2022	30mins	18	0	

Victoria

Progress Report - Part 1.5 Education and Training

Reporting Period 1 October 2022 to 31 March 2023

Module name	Brief summary of module	Provider Name	Delivery mode (face to face, virtual, hybrid)	Location (if delivered face to face)	Date/s delivered	Duration (how many hours/days)	How many people attended/completed?	How many of those who attended/completed were from MM3-7 category locations?	Comments
Alfred Health TrialHub – Clinical Trials Pharmacist Credentialing		Alfred Health	Virtual			6 hours	s47F		
Biological Specimen Transport		Dangerous Goods Training	Virtual		9/03/2023	1 day			
Clinibase Training		CTA	Virtual		18/10/2022	1 hour			
Clinibase Training		CTA	Virtual		8/11/2022	1 hour			
Clinical Trial Design		VCCC	Virtual		6/10/2022	full day			
Clinical Trial Risk Mitigation Plan		Alfred Trial Hub	Virtual		15/11/2022	1 hour			
Clinical Trials Fundamentals		Monash University	Virtual		3/3, 17/3 and 31/3/23	3 days			3 days, 8 hours a day
Closing the Gap	Improving ATSI health outcomes	LRH	in person	LRH	16/3/2023	1 hour			
Competency Framework Education		Alfred Trial Hub	Virtual		20/10/2022	1 hour			
Consumer Engagement		VCCC	Virtual		10/03/2023	1 hour			
Consumer Engagement in Research	as titled	Telethon Kids/Life Course Centre	virtual		Feb 23 - March 23	5 hours			non paid
Consumers as active partners in research		VCCC	Virtual		23/02/2023	2 hours			
Conversations Matter: Communication Skills for Health Behaviour Change 2	as titled	VCCC	virtual		09/11/2022	2 hours			
Digital Health Informatics	Unit of Masters of Public Health	Torrens Universtiy Australai	virtual		21 Feb 2023 - 9 May 2023	60 hours			non paid
Education Session		Alfred Trial Hub	Virtual		27/02/2023	1 hour			
Electronic Records Management		VCCC	Virtual		28/02/2023	1.5 hours			
Emerging Changes in Clinical Trials Practices		University of Melbourne	Virtual		21/10/2022	5 hours			
GCP Training		VCCC	Virtual		24/03/2023	1 hour			
Health Privacy & Health Records Act and Australian Privacy Principles		Online course by health compliance commissioner	Virtual		6/03/2023				
IATA safe shipping and Handling of infectious substances		Civil Aviation Australia	Virtual		2/03/2023				
In House Team Communication		TrialHub	In person	LRH - Monash	31/01/2023	1.5 hours	7		
Introduction to ERM Applications		Infonetica	Virtual		14/02/2023	1 hour			
Mentorship program		VCCC	Virtual		1/02/2023	1 hour	s47F		
Mentorship program		VCCC	Virtual		15/02/2023	1 hour			
Research Integrity Showcase	as titled	HTQ	virtual		16/03/2023	1 hour			
Research Translation - virtual event	various health translation activities	HNHMRC	virtual		21 & 22 Nov 2022	8 hours			
shadowing visit to Alfred Health Clinical Trial Unit	as titled	Alfred Trial Hub	in person	Alfred	8/12/2022	8 hours			
SiteDocs Training		SiteDocs	Virtual		22/02/2023	1 hour			
SiteDocs Training		SiteDocs	Virtual		11/01/2023	1 hour			
Strengthening Support for Aboriginal & Torres Strait Islander Parents Experiencing Complex Trauma in the Perinatal Period Information Session		Vic Aboriginal Corporation Association	In person	LRH	6/02/2023	45mn			
Strengthening Support for Aboriginal & Torres Strait Islander Parents Experiencing Complex Trauma in the Perinatal Period Information Session	as titled	Vic Aboriginal Corporation Association	in person	LRH	08/02/2023	1 hour			
Trial Essentials for Research for Support Team	as titled	VCCC	virtual		Oct 22-March 23	15 hours			
V-CTEC essential courses for research support team		V-CTEC	Virtual		6/03/2023				
weekly Clinical Trial Coordinator sessions	different aspect of CTC role	Alfred Trial Hub	virtual		1 Dec - 16 Mar	18 hours			weekly 1.5 hours (12 weeks)
Clinibase Training		CTA	Virtual		28/03/2023	1 hour			
CTRSS Workshop		CTRSS	in person	Melbourne	17/03/2023	1 day			
VCTEC Conference		VCTEC	in person	Melbourne	2 and 3/03/2023	2 days			
Ethics Review Manager training	Training researchers on the basic applications of ERM	Department of Jobs Precints and Regions	Virtual	N/A	1Oct22-31Mar23 (Intro to ERM)	2 hour session			
Ethics Review Manager training	Training reseachers on how to prepare and submit for ethics approval and for Site Specific Assessment (SSA)/research governance	Department of Jobs Precints and Regions	Virtual	N/A	1Oct22-31Mar23 (SSA Application)	2 hour session			
Ethics Review Manager training	Training reseachers on how to prepare and submit for post ethics approval and for post governance applications	Department of Jobs Precints and Regions	Virtual	N/A	1Oct22-31Mar23 (Post Approval/Post Authorisation)	2 hour session	6		
SKILLED	Clincial trials training program, online and on-the-job	Victorian Comprehensive Cancer Centre (VCCC)	Hybrid	VCCC	01 October - 02 Dec 2022 intern for 2022 20 February and continuing for 2023 intern	40 weeks combined on job experince and formal training days	s47F		Funded program by Department of Jobs Precincts Regions
Australian Privacy Principles	Training provided by VCCC for SKILLED Internship Program	Office of the Australian Information Commissioner	Virtual		1/03/2023 15/03/2023	1 day			
Site Docs	Onboarding session	TrialDocs	Virtual		5/10/2023	1 hour			
Site Docs	Introductory training session	TrialDocs	Virtual		15/03/2023	1 hour			
Health Records Act	Training provided for understanding or Health Records Act	Health Complaints Commissioner	Virtual		27/02/2023 15/03/2023	1 hour			
Safe Transport of Infectious Substances By Air	Certification to enable shipping biological samples	Civil Aviation Academy	Virtual		7/03/2023	1 day			
V-CTEC	Trials Essentials for Research Support Team	V-CTEC	Virtual		28/02/2023 15/03/2023	15 hours			
Good Clinical Practice	Certification to enable working in trials	Peter MacCallum Cancer Centre	Face to Face	VCCC	1/03/2023	1 day			
Good Clinical Practice	Certification to enable working in trials	NIDA	Virtual		22/03/2023 13/02/2023 17/01/2023 05/12/2022	3 hours			
Good Clinical Practice	Certification to enable working in trials	Genesis Research Services	Virtual		29/11/2022	3 hours			
GCP for Medical Devices	Training for trials in Medical Devices	Praxis	Virtual		18/01/2023	4 hours			
Data Safety and Monitoring Boards for Clinical Trials	General training for DSMB	The Global Health Network	Virtual		20/03/2023	1 hour			
Introduction to Clinical Research	General training for trials	The Global Health Network	Virtual		19/03/2023	1 hour			
Introduction to Collecting and Reporting AE's in clincial research	General training for trials	The Global Health Network	Virtual		16/03/2023	1 hour			
Introduction to Data Management for Clinical Research Studies	General training for trials	The Global Health Network	Virtual		19/03/2023	1 hour			
Introduction to Data Management	General training for trials	The Global Health Network	Virtual		20/03/2023	1 hour			
Introduction to Good Clinical Laboratory Practice	General training for trials	The Global Health Network	Virtual		20/03/2023	1 hour			
Mental Health Wellbeing	Presentation on Grit and Resilience and progressing mental wellness in the community	Grit and Resilience	Virtual		13/10/2022	1 hour			
Emerging Changes in trial practice	Webinar on changes in trial design and management	University of Melbourne	Virtual		21/10/2022	1 hour			
Towards Greater Equity in Palliative Care	Webinar presentation	University of Melbourne	Virtual		26/10/2022	1 hour			
National HREC Conference	3 day HREC conference with a broad agenda for HREC members and researchers	Queensland Health	Virtual		23/11/22 - 25/11/22	3 days			
Unconscious Bias	Webinar discussing unconscious bias, diversity and inclusion	Northeast Health Wangaratta	Virtual		30/11/2023	1 hour			
Patient reported outcomes in clinical trials	Monthly webinar discussing the value of PROMS ? More than just a survey	V-CTEC	Virtual		1/12/2023	1 hour			
Clinical Research Nurse Professional Standards	Discussion of new Research Nurse Professional Standards	ANZ College of Anaesthetists CTN	Virtual		6/12/2023	1 hour			
World Cancer Day	Monday Live Lunch Series	VCCC	Virtual		6/02/2023	1 hour			
Insights into Stroke: Big Data, epidemiology and prevention	Webinar for stroke programs	NHMRC	Virtual		9/02/2023	1 hour			
Risk adapted breast screening	Public Seminar	VCCC and Florey Institute	Virtual		21/03/2023 22/03/2023	3 hours			
Building the Waratah Vaccine Trials Network	Webinar presenting the creation of a vaccine CTC in NSW	NHMRC	Virtual		29/03/2023	1 hour			
Annual Conference	2 day conference covering NCTGF, teletrials etc	V-CTEC	Hybrid		02/03/203 03/03/2023	2 days			
Regional Victorial Halth Services Clinical Trials and Research Meeting	Meeting with all CTRSS sites	DH	Face to Face		21/03/2023	1 day			
Working with Interpreters	Training to communicate with the use of an interpreter	Northeast Health Wangaratta	Virtual		16/03/2023	1 hour			
SKILLED	Clincial trials training program, online and on-the-job	Victorian Comprehensive Cancer Centre (VCCC)	Hybrid	Peter Mac, Melbourne	February 2023 Ongoin	6			
GCP	Good Clinical Practice training	Global Health	Virtual	N/A	Various	1	6	s47F	

V-CTEC	Comprehensive Course Package	V-VTEC	Online	N/A	Various	15	6	s47F	
Good Clinical Practice	This short course aims to provide the researcher with the basic principles of GCP and how these principles can be applied practically in the research setting.	Global health training centre/ genesis training	virtual		self led so no specific date	1	18	unknown	
Running a trial start to finish	introduction to research support staff on how to run a Clinical trial start to finish	A-CTEC	virtual		self led so no specific date	3	s47F	unknown	
Safety Reporting in Clinical Trials	Introduction into safety reporting responsabilites and requirements	A-CTEC	virtual		self led so no specific date	1.5		unknown	
Ethics Review Manager training	Training researchers on how to prepare and submit Site notifications and amendments	CTRSS-ATP Project Lead	Face to face	Barwon Health	23Jan23 & 3Feb23	2*2 hour sessions		s47F	
Lab Operations, shipping of dangerous goods	Self-paced online training and certification for safe collection, handling, packaging, and shipment of specimens.	Mayo Clinic	Virtual	N/A	8-Feb-23 & 16-Feb-2023	2 hour session		0	
New Staff orientation	Discussion reg. project and how CTRSS-ATP can provide assistance/support.	CTRSS-ATP Project Lead	Face to face	Barwon Health	15-Feb-23	1 hour session		0	
Basic Life support Traning	Basic Life support Traning	Barwon Health	Virtual	Barwon Health	21-Feb-23	2 hour session	10	not collected	Online module is follwed by
Basic Life support Traning	Basic Life support Traning	Barwon Health	Face to face	Barwon Health	21-Feb-23	2 hour session			
New Staff orientation	New Staff orientation - Research website & basic information on the research at BH	CTRSS-ATP Project Lead	Face to face	Barwon Health	22-Feb-23	1 hour session			
New Staff orientation	VCTEC webisite & GCP suite, new starter BH trial coordinator checklist provided to track progress	CTRSS-ATP Project Lead	Face to face	Barwon Health	08-Mar-23	1 hour session		s47F	
GCP	GCP course for investigators/sub investigators. Understand the requirements for trial documentation, protocol amendments, requirements such as indemnity, reporting lines for adverse events and provision of medical care for trial participants.	Global health GCP traning	Virtual	N/A	24-Feb-23	2 hour session	s47F	not collected	
SKILLED-VCCCA Intern	A 40 week on-site supervised internship that is designed to help the intern develop a study coordinator skill-set. The program is monitored through a tailored competency framework based learning sytem, with a quantitative assessment grading system.	VCCA-SKILLED (regional intern funded by CTRSS)	Face to face	Barwon Health	27-Feb-23	39 weeks	s47F	0	
VCTEC	VCTEC Annual Conference - Quality versus quantity in clinical trials	VCTEC	Hybrid	Deakin Downtown Campus, Melbourne	2-Mar-2023, 3-Mar-23	1.5 days	7	s47F	
Regional Victoria Clinical Trials & research meeting	Focus of meeting is the NCTGF accreditation, and a networking event	ATP/Bendigo Health	Face to face	Clocktower Cnetre, Moonee Ponds	17-Mar-23	1 day	6		
Trial Essentials for Research Support		VCTEC	Online		Jan-23	10hrs			
GCP training		Global Health Network	Online		Jan - Feb 2023	4hrs			
Skilled intern program		VCCC	Face to face	305 Grattan St, Melbourne VIC 3000	20 - 24 Feb 2023	4 days			
ERM training		Victorian Government	Online		Feb-23	2hrs			
GCP training		VCCC	Online		Feb-23	4hrs			
Regional Victoria Health Services Clinical Trials & Research Meeting		Bendigo Health	Face-to-face	Clock Tower Centre, 750 Mount Alexander Road, Moonee Ponds, VIC 3039	17th March 2023	6hrs			
GCP	Global Health Network ICH Good Clinical	Global Health Network	Virtual	N/A	N/A	1hr approx	10	10	
V-CTEC ISF training	ISF training for trial coordinators	V-CTEC	Virtual	Virtual	Various dates	1day			
VCCC Clinical Trials in Practice		VCCC	Virtual	N/A	N/A	N/A			
Regional Research Meeting		CTRSS-ATP	face to face	Moonee Ponds	17-Mar	1day			
NCTGF Workshops	Workshop for implementation of NCTGF	The Commision	Virtual	N/A	Various dates	1.5hrs			
SKILLED intern	VCCC Skilled internship	VCCC	face to face	GVH	Ongoing	10 months			
Study specific training	SIV, study specific modules	Sponsors	face to face/virtual	GVH / online	Various dates	Various	26	26	
V-CTEC Annual Conference	V-CTEC Annual Conference	V-CTEC	face to face/virtual	online/Melb	Mar-23	1 day	s47F		
						Total	**262**		

Western Australia

Progress Report - Part 1.5 Education and Training

Reporting Period 1 October 2022 to 31 March 2023

Module name	Brief summary of module	Provider Name	Delivery mode (face to face, virtual, hybrid)	Location (if delivered face to face)	Date/s delivered	Duration (how many hours/days)	How many people attended/completed ?	How many of those who attended/completed were from MM3-7 category locations?	Comments
Good Clinical Practice (GCP) in Australia	ICH-GCP (E6 R2) - Tanscelerate Approved. Comprehensive course designed by WAHTN including Australian and Western Australian specific guidance	WAHTN	Online course facilated by face to face WA RCCC staff.	Virtual	22/10/2022	5.5 hours	s47F		
FSH clinical trials pharmacy	Education on the teletrial model in the context of medication management	WARCCC	Virtual presentation	Virtual	16/11/2022	30 minutes	s47F	0	
Regional Pharmacy Leadership Group education	Education on the teletrial model in the context of medication management	WARCCC	Virtual presentation	Virtual	22/11/2022	1 hour	10	s47F	
AHC pharmacy trials training	Education on the teletrial model and VITAFOOT	WARCCC	Virtual presentation	Virtual	13/12/2022	30 minutes	s47F		
Good Clinical Practice (GCP) in Australia	ICH-GCP (E6 R2) - Tanscelerate Approved. Comprehensive course designed by WAHTN including Australian and Western Australian specific guidance	WAHTN	Online course facilated by face to face WA RCCC staff.	AHC	15/12/2022	5.5 hours			
Good Clinical Practice (GCP) in Australia	ICH-GCP (E6 R2) - Tanscelerate Approved. Comprehensive course designed by WAHTN including Australian and Western Australian specific guidance	WAHTN	Online course facilated by face to face WA RCCC staff.	AHC	12/01/2023	5.5 hours			
Teletrial Model and Implementation in WA	Clinical Trial Education plus application of the ATP to the WA context	WARCCC	Teams Meeting	EMHS Research Advisory Group	14/12/2022	2 hours	15	MM2 plus Regional Outreach	
Teletrial Model and Implementation in WA	Clinical Trial Education plus application of the ATP to the WA context	WARCCC	Teams Meeting	AKMH	16/12/2022	2 hours	s47F	MM2 plus Regional Outreach	
Teletrial Model and Implementation in WA	Clinical Trial Education plus application of the ATP to the WA pharmacy context	WARCCC	Teams Meeting	Virtual	1/02/2023	25 minutes	55	28	
Teletrial Model and Implementation in WA	Detailed review of ethics and governance considerations around TT	WARCCC	FTF	Curtin University	23/02/2023	3 hours	6	nil	
Good Clinical Practice (GCP) in Australia	ICH-GCP (E6 R2) - Tanscelerate Approved. Comprehensive course designed by WAHTN including Australian and Western Australian specific guidance	WATHN	Online Course	Virtual	1/03/2023	3 hours	s47F	nil	
Good Clinical Practice (GCP) in Australia	ICH-GCP (E6 R2) - Tanscelerate Approved. Comprehensive course designed by WAHTN including Australian and Western Australian specific guidance	WATHN	Online Course	Virtual	6/03/2023	3 hours		nil	
								97	

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Progress Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through progress reports. For varying your grant and grant agreement please refer to the MRFF Grant Variation Policy.

Please ensure that you are using the latest version of the Progress Report template. You must submit your report on the business.gov.au portal. You can enter the required information in stages and submit when it is complete.

Project Information

Grant ID	MRFRR000005
Grant Opportunity Name	Medical Research Future fund – National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant
Administering Organisation	The State of Queensland acting through Queensland Health
Chief Investigator A / Project Lead	Kaye Hewson
Grant Title	Australian Teletrials Program
Grant Agreement Start and End Dates	19/09/2021 - 04/10/2026
Research Activity Start and End Dates	5/10/2021 - 30/09/2026
Australia New Zealand Clinical Trials Registry Trial ID (where relevant)	
Reporting Period	01/04/2023 - 31/09/2023
If the Commonwealth Commercialisation Clauses apply to this project, have there been any changes to the Commercialisation Plan?	No
Do you plan to execute any new agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	N/A

Project Progress

Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement.

The comments field should clearly summarise progress at the end of this reporting period towards completion of the agreed research activities relevant to each milestone/objective and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Continue delivery of national components including education and training, promotion and awareness, engagement with clinical network, and recruitment boosting activities.	04/10/2023	04/10/2023	100%

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Comments:

Harmonisation – The ATP policy harmonisation team has been undertaking significant developments across the key areas of contract/agreement standardisation and supporting guidance materials.

1) **National Confidential/Non-Disclosure Agreement (CDA) development**
Jurisdictions reported issues with inconsistent and multiple variations of non-disclosure requirements between health organisations and sponsors who conduct clinical trials. To address this, in collaboration with New South Wales Ministry of Health, ATP is leading the development of a standardised CDA with nationally accepted terms and conditions. The benefits of a nationally accepted agreement template are wide-reaching across the clinical trial industry, including improving the uptake of the Teletrial model.

2) **Clinical Trial Research Agreement (CTRA) for Investigator-Initiated Teletrials**
The legal arrangements for the Teletrial model currently rely upon a head agreement between a sponsor and a primary site, under which the subcontract operates. The model is now being taken up by several investigator-led clinical trials, whereby the investigator's organisation is often both the sponsor and the primary site. As such, ATP has developed an investigator-initiated teletrial CTRA for use in these circumstances. The new agreement will be piloted in Queensland and shared with jurisdictions for state-based legal review. ATP will seek to have this CTRA added to the suite of Medicines Australia agreements, once all jurisdictions have completed their reviews.

3) **Teletrial Supervision Plan**
Collaborating with the Alfred Trial Hub, VCCC Alliance and New South Wales Ministry of Health, the ATP facilitated an extensive review of the Teletrial National Supervision Plan to achieve a nationally accepted document. This arose after different iterations emerged across the jurisdictions and increased requests for more information were made from Research Governance Officers and Certified Human Research Ethics Committees (HRECs) on the content of Supervision Plans. The consultation process encompassed various stakeholders who manage and undertake Clinical Trials and Teletrials, including Research Governance Officers, Certified HRECs, and Clinical Trial Sites with and without Teletrial experience. The revised National Supervision Plan is grouped by key topics for quick completion and directs the reviewing bodies to information relevant to them, including an accompanying information sheet specifically for HRECs. The ATP is now exploring digital application options of the Supervision Plan, to support ease of use and optimal user experience.

4) **Sponsor Guidance document**
ATP received feedback from clinical trial sponsors requesting sponsor-specific information to implement the Teletrial model. In response, ATP developed a three-page short summary directly relevant for sponsors and are drafting a more detailed sponsors and sites guidance document. The summary with resource links is the first stage of a sponsor package being co-designed in consultation with commercial sponsors and jurisdictions, to assist in future plans to increase the commercialisation of health research outcomes.

5) **Current review of National Teletrial Compendium**
The Clinical Trials Project Reference Group recently invited input into the 2023 review of the National Teletrials Compendium, including the National Principles for Teletrials in Australia and the National Standard Operating Procedures for Clinical Trials. ATP is providing formal consultation coordination across six jurisdictions on amendments related to teletrials.

Education and training- All six Jurisdictions now have agreements in place with the Australian-Clinical Trial Education Centre (A-CTEC) giving free access to Clinical Trial education. A review of online modules is in progress. All jurisdictions are represented on the A-CTEC Stakeholder Committee.

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete

Recruitment boosting activities- Approval of the submission by ATP NO for Inclusion of MM2 sites in the Teletrial Support Payment Guidelines being updated. No deed of variation has been advised as necessary. Queensland and Victoria are now able to provide those payments to MM2 sites backdated to the commencement of ATP. Guidelines once endorsed by the Executive Committee will be provided on the ATP website.

Promotion and awareness The National Office now have a dedicated Communication Leads Officer. An accessibility and readability review has been conducted, leading to the revision of brand assets including the ATP logo, branding, fonts, and colour. All communication material will be held to international readability benchmarks to ensure messages are easily understood and memorable.

The Communication and Engagement Strategy including a comprehensive consumer engagement plan is being updated following market analysis in each jurisdiction. This has been benchmarked to understand audience awareness, perception, and attitudes towards Clinical Trials and Teletrials. In development is a communication and engagement toolkit for all jurisdictions, to standardise and bring consistency to all materials, including documents and presentations. A Teletrial Consumer brochure developed in partnership with Alfred Trial Hub and Cancer Council Victoria is now available across Australia to explain the teletrial model and value of being on a Clinical Trial- “developed by consumers for consumers”.

The National Office continues to present at Conferences and Scientific meetings.

- **National Telehealth Conference** 27-28 April 2023, Sydney
- **ARCS conference** 6-8 June 2023, Sydney
- **MEDIFEST** - Equity in Health care -Breakfast panel July 2023
- **Rural and Remote Health Symposium** 21-22 June 2023, Canberra
- **SCRS ANZ Site Solutions Summit** 18-19 July 2023, Melbourne
- **National Nursing Forum** 9-11 August 2023, Adelaide

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
RCCCs deliver support in each jurisdiction to embed teletrials in rural, regional, and remote locations	4/10/2023	30/09/20223	100%

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Comments:

Establishing the role of RCCCs and communicating their value proposition as part of their place in the major infrastructure investment for South Australia, Queensland, Western Australia, Victoria, Tasmania, and the Northern Territory. Victoria is a more dispersed model with seven trial Hubs acting independently with the same reporting requirements at sites. This reporting period includes all Hubs into the RCCC network for peer support and shared learning opportunities.

South Australia (SA RCCC)-

Three Clinical trial Nurses are now employed at three regional health networks as joint appointments with the University of Flinders and the University of South Australia, (see SA jurisdiction ATP impact report). These Clinical Trial Nurse Coordinators continue stakeholder mapping within their LHN across clinical specialities for Primary Investigator, and Associate Investigator interest.

The first across jurisdictional Teletrial has been approved and is open for patient recruitment between Adelaide and Darwin. This trial was delayed and is progressing now that the Northern Territory clinician has returned from leave and agreement that FMC CTC will conduct visits remotely.

The SA RCCC continue to build stakeholder relationships across the state. The RCCC is working with Limestone Coast Local Health Network (LC LHN) and Riverland Malee Coorong Local Health Network (RMCLHN) as they develop their research strategy and LHN research governance processes.

The Clinical Trial Liaison Officer gave a short presentation on ATP-SA to a group of sponsors that has provided some encouraging leads at the opening of The Cancer Research South Australia's new purpose-built clinical trial facility in Adelaide 19 September 2023. The RCCC attended the Spring into Clinical Trial Week 15th September, networking resulted in several more clinical trial inquiries.

Queensland (QRCCC (Qld Regional Clinical Trial Coordinating Centre))

The QRCCC has added to its core workforce by including a part-time Research Governance Officer and two part-time Clinical Research Managers, located in Central Queensland and s47F All staff in QRCCC travel around the state providing onsite support, education, and more recently backfill to clinical trial nurses for patient recruitment to support start-ups and ensure continuity of clinical trial activity across primary/satellite sites. As each HHS is visited, a detailed action plan for ongoing engagement is also developed. This includes purchasing equipment and/or assisting with developing business modelling for their clinical trial units. Visiting Cape and Torres Strait in July resulted in Aboriginal and Torres Strait Islander engagement. It proved to be an important reminder that a different approach with community and elder leadership is required for First Nations Queenslanders.

The QRCCC completed a site review across Hospital and Health services facilities for capacity and capability. This included where clinical trials have been conducted across all clinical specialities and where resources in the form of Teletrial Coordination Nurses have been deployed. This onsite experience has led to several across jurisdictional border opportunities being offered by QRCCC and the informal mentoring of other Start-Up specialists and broader research teams within RCCCs.

The QRCCC including the Clinical Director have an extensive portfolio of presentations both from abstract submitted to conferences and being invited keynote speakers. International recognition of the Pilot in Queensland in partnership with the Clinical Oncology Society of Australia is now being expanded through the Australian Teletrial Program implementation.

QRCCC have almost met their target number of people trained and have conducted a gap analysis of the A-CTEC modules for future development. The two educators provide regular training sessions across the state and through a network of Teletrial Coordinators.

Northern Territory (NT RCCC)

The NT RCCC has added to its workforce with a Senior Clinical Trial Pharmacist and a new Program Manager has recently joined the team. There are ongoing challenges to recruiting full-time Alice Springs and Katherine Hospital Nurse Research Coordinators.

Three teletrials have now been activated in three different specialties: Oncology (SA/NT cluster), a drug testing for metastatic pancreatic ductal adenocarcinoma, Central Australia/Barkly Region, a medical device using AI-guided echocardiography and in the same region as well as the Top End, an innovative digital health trial looking at the effects of a mobile app on serum phosphate control in dialysis patients.

There was an Onsite advisory committee meeting in July 2023 with SA/NT s47F onsite.

The RCCC has completed a teletrial Barrier Analysis study including its report and presentation of findings to key stakeholders which has resulted in a comprehensive understanding of site capability. Development of resources such as Credential 2x clinical trials pharmacists in collaboration with Alfred Health Trial Hub and development of NT Health Clinical Trials Handbook

The ATP-NT Team is working to establish a research career pathway for NT Health nurses (Nurse 4 – Nurse 7) in collaboration with NT Health Chief Nurse and Midwifery Office (see ATP- NT Impact statement).

The A-CTEC online learning open to all NT interested parties, was launched at the NT Health Research Symposium. The team has facilitated the conduction of the 3rd F2F GCP training and conducted Dangerous Goods by Air - Transporting Infectious Substances training.

Site visits have been conducted to:

- Gove District Hospital and conducted research capacity building workshop with Miwatj Health; and
- Alice Springs Hospital to assess pharmacy capability for IMP management

Active engagement with local investigators to build interest and confidence to take on clinical trials portfolio, i.e., planning for a PI workshop

Ongoing engagement with regional executive leadership teams to promote clinical trials and teletrials.

The team has recently secured approval for purchasing a refrigerated centrifuge and pharmacy setup for the Royal Darwin Hospital Clinical Trials Unit.

Tasmania (Tas RCCC)

The team in the Tas RCCC now consists of one full-time equivalent across two Teletrial Coordinators and One Start-Up specialist. The Start-Up Specialist is based in s47F

Additionally, the Tasmania Research office has invested in an ethics officer and combined with the investment in the electronic Research Ethic Management system REGIS provides a central place for research governance and ethics seen as a major drawcard for commercial sponsors. RCCC is also promoting the use of SiteDocs for Cancer Services to conduct first teletrials

The RCCC is working with Hobart and Launceston currently for two oncology studies which have progressed to the approval stage.

The launch of A-CTEC modules has resulted in 74 people accessed training whilst the Start Up specialist also provides onsite training and mentoring.

Western Australia WARCCC (WA Regional Clinical Trial Coordinating Centre))

Additional staff employed in this reporting period are two research staff and a Business Support role joining the RCCC team.

WA Country RCCC has also conducted and concluded their first teletrial Vitafoot- diabetic foot trial complete (see jurisdiction Impact statement).

ATP-WA Country established the WA Teletrial Clinical Advisory Group as part of their developing governance. The team has also undertaken a Scenario Mapping Workshop in planning for teletrials across RRR WA with the outcome to look at the following clinical trial characteristics: sponsor, trial type, funder, participant type, category condition, participant types, and primary and satellite sites.

ATP-WA Country officially launched their program in July and with it developed a promotional video. Site visits have occurred to Geraldton and Mid-West, and they have participated in the Kimberley Aboriginal Research Health Forum.

In managing the practical operational aspects of teletrials, WARCCC convened a Western Australia Country Health Service (WACHS) and National Safety and Quality Health Services (NSQHS) Clinical Trial Governance Framework Working Group to develop a WA Teletrial Governance Guide.

WA Country has a proactive digital program and has obtained pre-conceptual approval for two digital software platforms.

Management and storage of IMP have been a challenge. WA Country has now secured a co-located WACHS Teletrial Pharmacy storage facility at Fremantle Hospital.

WA Country RCCC has reported 181 education participants, launching the A-CTEC modules and conducting sessions for Clinical Trial Pharmacists, facilitating GCP training and onsite information sharing sessions.

Planned activities for increasing research capacity and readiness are:

- Start-up support for the 2nd Teletrial (diabetic app intervention)
- Conduct site feasibility for 3rd Teletrial (expected to be paediatric allergy study)
- Continue review of 6 more potential trials
- New Clinical Trial Coordinators and Research Nurses to join WARCCC in October & November

Preparation is in place for the WA Community Reference Group

Victoria RCCC-VIC

Study start-up and investigator support

After vacancies in these positions, RCCC-VIC has recruited and will work with two regional Study-Start-up Specialists and a Medical Officer to provide 'on-site' support to establish teletrials in rural and regional Victoria.

These two start-up specialists (SSS) operate across the 7 Clinical Trial Hubs and work directly with sites to support them in trial and teletrial start-up.: Goulburn Valley, La Trobe Regional Health, Northeast Wangaratta, Bendigo, Barwon Health, Warrnambool, Grampian Health. The RCCC works with SSS on projects and has close contact regarding developing the teletrial training modules.

Sector engagement and policy development to implement teletrials

To foster knowledge exchange and collaboration, the RCCC-VIC hosts events tailored to the specific needs of relevant stakeholders to implement the teletrial model.

These events bring together Victorian HREC managers, research governance officers (RGOs), rural health service representatives, and commercial sponsors to engage in discussions and networking. These forums play a pivotal role in advocating and identifying potential location of teletrials in regional, rural, and remote areas of Victoria. Furthermore, they provide regional sites with an opportunity to raise awareness about teletrials in rural and regional communities.

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Teletrial training and resources The RCCC-VIC assists Victorian sites to link into existing training resources and advises on additional training and education opportunities. The team is currently developing teletrial training sessions. These will address an overview of teletrials, setting up a teletrial, research governance and ethics requirements, monitoring, and reporting requirements in teletrials. The sessions will cover the teletrial life cycle, and modules developed to focus on specific aspects of teletrials. Online sessions will be instructor-led. The seven hubs are now reporting a greater emphasis on the teletrial cluster opportunities and converting Clinical Trials into Teletrials for a broader reach of clinical trials, particularly in non-oncology specialties. In Barwon Health for example a current TT being explored is for Aboriginal and Torres Strait Islanders for Diabetic monitoring as a Teletrial across outpatient at Geelong to a Primary Health Centre. These regional sites are all working to achieve accreditation under National Clinical Trial Governance Framework (NCTGF). s47G , a MM1 site has achieved a 2.6/3 score in their recent review. Hubs report working on a variety of enablers for TTs. These include a schedule of fees for commercial sponsors, working on Standard Operating Procedures and other documentation, confirming the need for central coordination and consultation for harmonisation activities, and developing a TT toolkit for implementation. All Hubs are active in providing education and training, and two Hubs report making GMP training available through Learning Management System (LMS) sites. Education activities include ERM training, laboratory operations, and Aboriginal and Torres Strait Islander Cultural training. All Hubs have access to A-CTEC online modules and VCCC resources. All Hubs are active in communications through newsletters, research symposiums, and grant rounds and strongly focus on consumer engagement and building resources. Risks: Hubs note the focus is on the activities of working toward the National Clinical Trial Governance Framework.			

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Y2 Evaluation program continues - JCU/AusHSI report summarised	04/10/2023	04/10/2023	80%

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Comments Activities and progress Embedded Customer Data Collection and Operations Evaluation Report – Interim analysis of evaluation study for impact and sustainability planning **Stage 2 ethics:** approval received. **Stage 2 Governance approvals:** 40 governance approvals are required in 6 jurisdictions for interviews and stakeholder activities. Status: *Victoria:* 7 required, all in process *SA:* 7 required, 1 complete, 6 in process Qld: 17 required, 1 complete, lead RGO SSA pending approval *WA:* 7 required, still negotiating process *Tas:* 1 required, negotiating new agreement with Tasmania Health Service, which requires sharing of QUT, JCU, and QH Service Agreement *NT:* 1 required, in process **Stage 2 RCCC monitoring activities:** Commenced in Qld and Victoria, awaiting governance approvals in other jurisdictions. Met with all jurisdictions face-to-face in May 2023. Regular contact channels are well established. **Stage 2 QH REDCap data transfer:** One data extract (July 23). Data set reviewed; some clarifications sought, and recommendations were made for future. Data to be extracted and transferred to QUT three monthly, at the end of each quarter, commencing Oct 23. Established process and team responsibilities for filing and monitoring of the REDCap data extracts. **Stage 2 QH ATP activity reports:** QH ATP National Office to provide these 6-monthly commencing Oct 2023.Established process and team responsibilities for filing and monitoring of the RCCC/ATP activity reports. **Stage 2 RCCC, stakeholder and trial participant interviews:** Process planning commenced for these in February – May 2024. Piloting of tools planned for late 2023. No significant risk to the progress in this reporting period. Noting also that the currently experienced delays in governance approvals should be resolved by January2024, allowing qualitative data collection activities as planned in Q1 and Q2 2024 **Publications and conference presentations** Final draft manuscript, provisional title: The Australian Clinical Trial Landscape: Perception of rural, regional and remote health service capacity and capability Conference presentation 9th Rural and Remote Health Scientific Symposium Canberra 21 June 2023 Title: The Australian rural, regional and remote clinical trial landscape and teletrial readiness Jurisdictional RCCC/ATP team workshops May 2023 Attendance: Victoria, Western Australia, South Australia, Queensland, Northern Territory, Tasmania.			

Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)

ATP National Office (ATP NO) has responded to the recommendations in the IQVIA Sponsor report and subsequent workshop. In August ATP NO convened a webinar to provide an information platform for sponsors. Over 100 people participated with 80% of those surveyed indicating they would consider running or converting a Clinical Trial to a Teletrial. The intent of these webinars is to provide a continuous platform for information sharing and build the influence across industry for the uptake of TTs.

A broader group of consumers has been recruited to help co-design resources. Together, working with ATP NO, Alfred Trial Hub and Cancer Council Victoria, this group developed a Consumer Teletrial brochure that has been widely distributed to stakeholder, with positive feedback received from consumers and clinicians alike.

ATP NO commenced a market analysis of public perceptions of clinical trials and teletrials to inform the Communication and Stakeholder Engagement strategy. This will form the basis of upcoming communication campaigns.

ATP NO holds a monthly RCCC network meeting and recently expanded this to include all seven hubs in Victoria. This acts as an education and information-sharing platform. The RCCC have all received training in the ATP Data base and engaged in quality and monitoring functions of RCCCs for Teletrials once up and recruiting patients.

Complete the following table for all variation requests under the MRFF Grant Variation Policy approved, submitted (pending approval) or in draft (pending submission) for this grant to date.

Type of Variation	Description of Variation	Current Status
Change to grant activity	Inclusion of MM2 in Teletrial Support Program for satellite site payments per patient based on postcode. N.B advice is request approved however does not require Deed of variation as still consistent with terms of Heads Agreement	Approved

Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)

1.The monthly alignment meeting of VRCCC, Alfred trial Hub, ReVitalise and NSW/ACT RRR Program have endorsed the need for a national approach. This will result in increased collaboration, knowledge sharing and a work program for sustainability of clinical trials in RRRs.

- ATP National Office has now convened a national meeting for reform of research governance for supporting teletrial uptake-Adelaide 14th November 2023.

2.Uptake of the model for sustainability requires commercial sponsor use and acceptance.

- National Office has commenced Sponsor awareness and education webinars targeting new companies and Contract Research Organisations (CROs).
- We continue to ensure an ATP presence at relevant meetings and conferences to increase awareness of the program with key stakeholders, including clinicians and primary health networks.

3. Transient and temporary nature of Clinical Trial workforce affects recruitment and retention.

- RCCC act as onsite support and provide additional workforce when required to start up teletrials.
- ATP NO is conducting an environmental scan of documents and resources currently being used across jurisdictions, to standardise these, update as required and review considering readability and accessibility and with specific target audiences in mind.

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4. Low collection of demographic data for evaluation.

- Communication to jurisdictions and collateral development including patient facing FAQs and information on the value of including consent for demographic data is currently underway.
- JCU/AusHSI Evaluation team proving information at Steering Committee meeting in Adelaide November 13th, 2023.

Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)

The ATP program continues to grow in movement and momentum. More requests and acceptance at engagement activities and keynote opportunities, including a joint trade ARCS display for all jurisdictions and an oral presentation.

The REDCAP database has been enhanced to capture why clinical trials may not progress to a Teletrial. Specific to Victoria, it also records the number of oncology/non-oncology which are "closer to home" and not part of this MRFF infrastructure grant. Training is provided regularly to jurisdictions with quality assurance conducted by NO. The recent purchase of Power BI means analytics and trends can be visualised once it is fully functional.

Delays to implementation of TTs in jurisdictions is further outlined in Appendix 1 Monitoring Indicators. IQVIA are undertaking an analysis of recent TT negotiations which have not progressed with Commercial sponsors. In addition, ATP NO have convened a national workshop in November to "tackle" delays to research governance which are impacting on the uptake of TTs. ReVitalise and NSW/ACT RRR program are participating.

S47G

Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)

Key enablers and barriers that inform our national work program

Barriers:

- Lack of capacity and capability for management of Investigation Management Product (IMP) specifically regional IMP transport guidelines and development of an educational framework for Clinical Pharmacists. A Working Group has been convened and led by ATP - WA Country with Transport Guidelines to be published by March 2024.
- Developing capacity and capability of Pathology services in rural settings, specifically timely transport of samples and laboratory capacity issues at smaller rural sites. Exploring current courier and transport options and training at sites for specific samples are being explored.

- Lack of consistency in site fees and management by primary sites for satellites. A review of site fee schedules to assist with clinical trials/teletrials budget negotiations is planned.
- Workforce recruitment into RCCC at remote locations are identified. SA and NT have provided some workforce development options (see Monitoring indicators, measure one).
- Digital Platforms for site files and pharmacy management of investigational products continue to be a high priority impacted by delayed approvals

Key enablers:

- Involvement in Clinical Trials where travel is involved (particularly collaborative CTs) do not include access to Travel Subsidy Schemes. Sponsors will sometimes cover. ATP aims to reduce travel where possible, however in some instances travel is required. ATP NO will work with partners to advocate for a change in jurisdiction policy.
- A Master National Supervision Plan developed through national consultation led by ATP is seen as a key document for the uptake of TTs. It includes key roles and responsibilities across clusters and is as an education tool for HRECS.
- National Confidentiality Agreement – for mutual acceptance across primary/ satellite sites will reduce duplication and legal review and assist TT implementation across multiple jurisdictions.
- Technology -several jurisdictions are reviewing inclusion to enhance site capability and enhance communications across sites. ATP- WACH is developing a digital strategy.

Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.

This question applies only to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
Melbourne University	PARTNER Network	s47G	s47F	To date s47(1)(b)	1/04//2023 - 30/09/2023	20%
Australian Clinical Trial Alliance (ACTA)	ACTA	ACTA has now appointed a Clinical Trial Specialist to lead activities for ATP schedule of work.	s47F	s47(1)(b)	30/06/2023 - 30/04/2024	10%

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		A Working Group have been convened to provide advice on Clinical Trial Networks participation in TTs established and new.				

Project Expenditure

Provide details of all expenditure incurred using MRFF funding during this reporting period and the estimated expenditure for the next reporting period.

Expenditure should be divided into the same categories as the budget in your grant agreement.

The table should indicate for each expenditure item (A), the approved budget (B) and the total expenditure: in this period (C), to date for the budget item (D) and estimated for next period (E). The comments field (F) should justify any differences between the budgeted and actual expenditure for the current reporting period, including any details of anticipated expenditure or any downstream effects of these differences.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact mrff@industry.gov.au.

(A) Expenditure Item	(B) Approved Budget (AUD)	(C) Actual expenditure for this period (AUD)	(D) Total expenditure to date (AUD)	(E) Estimated expenditure for next period (AUD)	(F) Comments
Minor Capital Works					
Materials for Construction					
Equipment					
Labour *(Excluding On-costs)*					
On-costs (capped at 30% of Labour costs)					
Contract					
Travel					
Other eligible expenditure					
TOTAL					

s47G

Comments:

i. Expenditure on equipment was approximately 87% under budget in the current reporting period. Although the expenditure was expected to increase significantly in the current reporting period, the delay in recruitment as well as the delay in commencement and/or increase in teletrial activities across partner jurisdictions have led to the shortfall in expenditure on equipment. With the trials in pipeline and more trials anticipated by partner jurisdictions, much of the fund under this heading is expected to be used in calendar year 2024 and onwards. This category also includes logistics with some TTs to be assisted with courier costs until longer term transport solutions have been negotiated. WA for example have been negotiating with Baxter to service regional sites with IMP.

ii. As forecasted in the previous progress report, labour expenses (excluding on-costs) increased by approximately 18% in the current reporting period and was broadly in line with the budget for the period. The increasing trend in labour expenses is expected to continue further as recruitments are still progressing across different jurisdictions.

iii. Similar to the previous reporting period, expenditure relating to On-costs was limited to 21% of the labour cost in the current reporting period.

iv. Expenditure under "Contract" primarily includes subcontracting expenses and was originally budgeted under "Other eligible expenditure". Expenditure under this item accrues as per the payment terms under the contract with different sub-contractors. This expenditure item has been added to "Other eligible expenditure" for the purpose of calculating variance against the budget.

v. Travel expense was 26% above budget for the current reporting period which marginally offsets the variance/underspent of previous reporting periods. ATP national office has led and encouraged intense teletrial awareness campaigns across all partner jurisdictions as well as increased attendance to various conferences and meetings relating to clinical trials. The increase in such activities drives the increase in travel expenses.

vi. "Other eligible expenditure" also includes payments against the TSP (Site set-up Payment for Primary sites and Per-patient payments for Satellite sites). Other eligible expenditure, after including expenditure against "Contract" (as per point no. iv above) and the TSP was short by approximately 81% compared to the budget for the current reporting period. The variance is primarily impacted by the delay in teletrial activities. We note that some partner jurisdictions have reported a good pipeline of teletrials which will increase the TSP payments and reduce the variance in 2024.Payment schedule with a subcontractor was also amended by ATP National Office which reduced the expenditure against contract in the current reporting period further adding to the variance under this category.

vii. During the current reporting period, total expenditure was under budget by approximately 42%. This was primarily due to underspent TSP funds resulting from smaller number of teletrial activities across partner jurisdictions during the current reporting period. As the teletrial activities increase in future reporting periods, this will result in an increase in expenditure across all headings thereby reducing the total gap between budget and actual expenditure. Including MM2 in site eligibility for satellites sites mean existing TTs will receive payments per patient recruited in this next reporting period.

Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)

All expenditure incurred during the reporting period is eligible under the scheme Guidelines s47G

Provide details of any partner contributions received during this reporting period and indicate whether each contribution has been made as expected. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.

If a contribution has not been made as expected, describe the impact of any delays or changes to the delivery of the Research Activity. If the project does not have partners that committed to make cash or in-kind contributions, select N/A in the table below.

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Name of Partner	Type of Contribution	Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
enter name of partner organisation	Select	enter amount in $AUD	enter amount in $AUD	enter comments describing the impact of any delays or changes to the delivery of the Research Activity
N/A	N/A	N/A	N/A	

Project Evaluation

Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the MRFF Monitoring, Evaluation and Learning Strategy (November 2020) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were required to be submitted with the application, select N/A in the first row of the table below.

For each Measure of Success applicable to your project:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.)
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

Add rows as necessary.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress
Select	enter outcome/result from application	enter comments summarising anticipated progress	enter comments summarising actual progress to date
More Australians access clinical trials	5000		52
New clinical Trial sites	2430		33
Improved clinical trial sites	810		31
New clinical trials	203		42
No of people educated	5000		2016

Figures in this reporting period do not corelate to the figures in previous reporting periods due to the following reasons:

- *ATP National Office has, in this reporting period, implemented REDCap database as the single source of truth for all information relating to trials, sites and participants. Any information that has not been entered into the database or entry of incorrect or incomplete data has been excluded in the count.*
- *RCCCs were manually providing such data in the previous reporting periods where the count also included anticipated trials as well as registered trials which did not later convert to teletrials.*

The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)

Note that your response may be used in public communications about the MRFF, and that you may be contacted to expand on your response below. Please indicate whether any of the information you provide is commercial in confidence.

The Regional Clinical Trial Centres are now fully operational and provide expertise and experienced clinical trialists working across all jurisdiction's public/ private and primary health care health services. They provide support to the start-up of clinical trials from protocol development through to commencing patient recruitment. They provide education and training onsite for workforce development supplemented by unrestricted access to the Australia-Clinical Trial Education Centre (A-CTEC) online modules.

Feedback form Commercial Sponsors is the information supplied by RCCC provides much needed and rich information to bring CTs to regional, rural, and remote areas of Australia. RCCC have conducted environmental scans for capacity and capability across sites to be able to deploy additional staff, equipment, and support for GCP training to conduct clinical Trials. This combined with a Teletrial Support Payment means Primary Sites now can receive a payment to support them coordinating the CT across satellite (local sites) with each satellite site able to receive a payment for patients if they live in regional, rural, and remote areas. Ongoing work is in now developing a standardised suite of tools to ensure the streamlined and efficient implementation of Teletrials.

Attachments

Attach any agreed evidence required above (e.g. updated risk management plan).
Attachment 1: Risk Management Plan

Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the Criminal Code 1995 (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Jurisdiction	All partner jurisdictions
Reporting Period	1 April to 30 September

Part 1 – Commonwealth MRFF Monitoring Indicators

Measure One: Increased focus of research on areas of unmet need

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies areas of unmet need and facilitates more research into these areas
- leads to new health treatments, drugs, interventions, devices and diagnostics
- embeds such approaches into clinical practice

1	**What approaches have been employed to ensure key areas of unmet need (as identified by the Grantee) are being met?**

Northern Territory

Improving Clinical Trials Access in Central Australia through Teletrials

Before ATP NT Health had approximately 50 clinical trials primarily centred in the Top End/Royal Darwin Hospital. Patients had to either travel to Darwin to participate in trials, or trial staff travelled to remote areas to conduct trial activities and recruit participants. This resulted in disparity in access and rural and remote patients significantly underrepresented in clinical trials and clinicians lacking essential support.

May 2022 – focus on establishing governance, stakeholder engagement, staff recruitment, education, and training in order to extend TT's to NT regions including Big Rivers, East Arnhem, Central Australia and Barkly. This meant a cultural shift to emphasise why clinical trials are important and promote teletrials as a new approach to conducting trials closer to home and being integrated into routine healthcare services.

July 2022 – launch of three TTs (refer to Project Progress comments)

Interestingly, two out of the three trials designated Alice Springs Hospital as their primary site, highlighting the region's highly capable healthcare workforce. While the clinicians demonstrated capability, they needed support to establish and run the clinical trial and Teletrial. Local recruitment for a research coordinator wasn't feasible but ATP-NT still closely collaborated with the trial teams, offering remote support, advocating for teletrials, assisted with research and ethics applications, provided comprehensive education and training, ensured Good Clinical Practice (GCP) compliance (including face-to-face training and access to online A-CTEC) and maintained constant communication to ensure the team felt supported.

ATP-NT's introduction of teletrials is transforming clinical trial accessibility in Central Australia, bridging gaps, empowering local healthcare professionals, and redefining the integration of trials into routine healthcare operations. Further efforts will continue to build on these achievements and increase access to clinical trials across the NT.

Capacity building in South Australia

Prior to the implementation of the Australian Teletrial Program into South Australia, none of 254 clinical trials occurred outside metropolitan Adelaide and clinical trials were not recognised as an important priority for the six regional Local Health Networks.

As a first for South Australia, in May 2023 three new Nurse Consultant – Clinical Research Coordinator positions started in three regional locations. These permanent positions are possible because of co-funding arrangements between Riverland Mallee Coorong Local Health Network, Australian Teletrial Program – South Australia, Flinders University and University of South Australia. In two of out the three Local Health Networks (LHNs) where the nurses are based, no similar positions have previously existed, and no clinical trials have been conducted.

As a result of these positions, and the implementation of the National Clinical Trials Governance Framework, there is now more awareness about research and clinical trial activity. The regional LHNs are establishing research processes to build research capacity and capability. This includes for two of the LHNs, the development of a research strategy, progress towards establishing their own local research office and allocating resourcing to research with onsite research support staff.

While these are all positive changes the ATP Cluster Start-up Specialists have encountered difficulties in obtaining all the required documentation for the research governance approvals to set up Teletrial clusters in regional SA. As the structure currently works, the Rural Support Services (a centralised business unit supporting the six regional LHNs across South Australia) conducts Site Specific Assessments on behalf of the six regional LHNs. This means the regional LHNs are implementing a separate approval process prior to research governance approval, in the form of clinical governance approval. These clinical governance approvals are required prior to the SSA submission and add significant workload and time. For example, to set up a teletrial with a primary site and two satellite sites based in three regional LHNs, there are four separate clinical governance approvals required, all with differing, and at times, unclear and changing processes for approval.

Identifying the processes for approval has been a particular challenge as clinical trials and teletrials are new to these regions. Another example of an obstacle the ATP-SA team has encountered in one regional LHN, this organisation employed a Research Support Officer to develop a research strategy and define a clear clinical governance approval process which was making significant progress until the Research Support Officer went on unexpected, indefinite leave. Consequently, this has resulted in a clinical governance approval sitting for more than six weeks waiting for a response, but also no clear direction on how to progress the approval.

The ATP-SA team is continually following up on requested approvals and work with regional LHNs to clarify processes, but this takes significant time and effort due to lack of workforce and resourcing. This is just one example of the many obstacles the ATP-SA team faces.

QRCCC identifies the need for a nationally agreed Confidential Disclosure Agreements (CDA) template.

Current CDAs and other contracting arrangements for the Teletrial model are all different, and without a national template, patients from accessing clinical trials. After getting legal advice from the Department of Health (DoH), the QRCCC needs to seek legal advice at each participating Hospital and Health Service (HHS). This takes up to four months per CDA at the Department, and up to three months for each HHS involved. Having a nationally agreed CDA template without the need to include additional clauses, will improve efficiency and reduce the cost and time to get patients into trials. Current delays are creating a significant issue for Sponsors and is stopping them from offering clinical trials in regional, rural and remote areas. Trials sites report their frustration at these processes because it results in patients being denied access to participate. Teletrials on by the QRCCC have been unable to progress as the recruitment times have passed by the time CDAs are executed and the number of CDAs required to build clusters in the Teletrial model.

To solve this, the rapid governance framework used to consult and collaborate across Australia and develop an agreed National Supervision Plan, will be used to design a standardised national CDA. An effective and efficient CDA process will remove existing barriers for clinical trial site to run Teletrials.

Coordination between Launceston General Hospital (LGH), Northwest Regional Hospital (NWRH) and the Royal Hobart Hospital (RHH).

The benefit of having the Tasmanian Health Service (THS) under one legal entity and one Research Governance Office is that each health service has access to all patient-related data and records, streamlining the conduct of general medical services and clinical trial activity. Furthermore, restrictions placed on sites that want to establish Teletrials between the North and the South of the state are reduced as there is only one RGO to approve these activities. Despite these advantages, coordination between the Northern regions of the state (comprised of the LGH and NWRH) and the South (primarily the RHH) remains disjointed. Despite being under one health service, they have, historically conducted their business independently, with little consultation and entirely different site-specific procedures.

Though small, Tasmania has a unique context with an interesting historical North/South geographical and political divide. This manifests in tensions between regions who perceive unfair distribution of funding and resourcing. In reality, staff are under-resourced in all departments conducting clinical trials which is an ongoing barrier against the full implementation of the ATP. There is an extreme shortage of experienced staff to ensure the successful start-up and ongoing maintenance of Teletrials as well as the usual clinical trials workload not only in distant and remote areas of the state, but also in MM2 cities like Launceston and Hobart. This is preventing Tasmania from being able to establish Teletrials.

Despite these barriers, the Tasmanian RCCC is determined to build a collaborative relationship and ensure a joint

effort to improve access for Tasmanians to clinical trials. They have adopted several strategies to encourage stakeholders to adopt the Teletrial model for the benefit of their patients.

1. Regular departmental meetings for Cancer Services at RHH and LGH. This concept/model will be adapted to other departments once relationships between the sites are established. This regular meeting is where key stakeholders from each hospital's cancer clinical trial units are invited to participate and discuss new/existing clinical trials that may be suitable to be conducted as a Teletrial. Invitations are extended to the Pharmacy and Pathology departments at both sites. Encouraging input from these supporting departments has increased collaboration between the clinical trials unit as they feel more included and engaged when negotiating trials being conducted.
2. Key stakeholders from the North and South have contributed and collaborated to develop local standard operating procedures, the National Supervision Plan, and the Tasmanian site CV.
3. The RCCC is helping the South recruit a Research Director, like the one recently filled in the North. The RCCC will then help coordinate regular meetings and collaboration between them to align and streamline research -including Teletrials- across the two regions.

This has resulted in each region acknowledging a shared responsibility to offer patients in Tasmania equitable access to clinical trials, and an agreement between the RHH and LGH to convert two current active clinical trials to Teletrials. Each site will act as a Primary Site and a Satellite Site for a study, respectively. Additionally, the clinical trials unit has agreed to coordinate and collaborate if they are contacted by a Sponsor.

ATP-VIC hosted a Teletrials-Ethics, site governance, and start-up workshop for stakeholders.
The workshop provided a chance to exchange important information and increase awareness and understanding of Teletrial requirements and processes. It achieved a shared understanding of the workflow and process to advance Teletrial policy development with Victorian HREC Managers, Research Governance Officers (RGOs), commercial sponsors, and regional health service representatives.

There have been several targeted events providing opportunities for discussion and networking to develop clinical trials and Teletrials in regional health services. The most recent workshop provided a unique opportunity to bring four sectors together, workshop ideas and challenges and to inform future direction. In total, 96 representatives from the seven regional hubs, twenty-one health service HRECs and RGOs and sponsors and industry representatives attended and participated in the workshop.

Topics presented included sponsor perspectives, Teletrial experience at a regional site and HREC and Governance requirements. During the workshop, opportunity was given for troubleshooting main pain points, scenario discussions and networking opportunities.
Panels of experts from the four sectors were set up to discuss challenges and special considerations relating to Teletrials raised by various stakeholders. An interactive format enabled attendees to respond to pre-determined questions, provide viable solutions and consult with the panel of experts. Open discussion and networking opportunities were also provided.

The insights gained from the workshop led to the development of a Teletrial action plan that was shared to attendees. It highlights the main tasks to focus on, including the rollout of targeted training sessions for Teletrials.

Measure Two: More Australians access clinical trials

This measure considers the extent to which outcomes of MRFF-funded research:

- create better opportunities for Australians to access clinical trials by funding activities that support research to progress to the clinical trial stage, and directly supporting additional clinical trial activity
- builds Australia's clinical trial capability and leadership at the national and international level

1.2 Please complete the tables on the following pages for your jurisdiction only to record:

1) the number of **new** (satellite site per protocol count) or **improved** (primary site per protocol count) clinical trial sites (TABLE 1),

2) the number of new clinical trial participants (TABLE 2), and

3) the number of new clinical trials (primary site per protocol count) (TABLE 3); directly linked to your project activities.

TABLE 1: Number of new or improved[1] clinical trial sites by state or territory and MMM Code *

State/ Territory		Target for achievement by Project Completion	Actual number of new or improved sites (cumulative total, project to date)							
			MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
NT	New Sites	32	0	0	0	0	0	0	0	**0**
	Improved Sites	11	0	1	0	0	0	0	0	**1**
QLD	New Sites	851	3	17	4	3	0	0	1	**28**
	Improved Sites	283	11	11	0	0	0	0	0	**22**
SA	New Sites	332	0	0	0	0	0	0	0	**0**
	Improved Sites	111	0	0	0	0	0	0	0	**0**
TAS	New Sites	32	0	0	0	0	0	0	0	**0**
	Improved Sites	11	0	0	0	0	0	0	0	**0**
VIC	New Sites	972	0	0	5	0	0	0	0	**5**
	Improved Sites	324	6	1	0	0	0	0	0	**7**
WA	New Sites	211	0	0	0	0	0	0	0	**0**
	Improved Sites	70	1	0	0	0	0	0	0	**1**
Total	**New Sites**	**2430**	**3**	**17**	**9**	**3**	**0**	**0**	**1**	**33**
	Improved Sites	**810**	**18**	**13**	**0**	**0**	**0**	**0**	**0**	**31**

TABLE 2: Number of clinical trial participants by state or territory and MMM Code *

State/ Territory	Target for achievement by Project Completion	Actual number of new clinical trial participants (cumulative total, project to date)							
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
NT	68	S47F							
QLD	1750								
SA	682								
TAS	68								
VIC	2000								
WA	432								
Total	**5000**	s47F							**52**

TABLE 3: Number of new clinical trials by state or territory and MMM Code *

State/ Territory	Target for achievement by project completion	Actual number of new clinical trials (cumulative total, project to date)							
		MM1	MM2	MM3	MM4	MM5	MM6	MM7	Total
NT	3	S47F							
QLD	71								
SA	28								
TAS	3								
VIC	81								
WA	17								
Total	**203**	S47F							**42**

* Figures in this reporting period do not corelate to the figures in previous reporting periods due to the following reasons:

- ATP National Office has, in this reporting period, implemented REDCap database as the single source of truth for all information relating to trials, sites and participants. Any information that has not been entered into the database or entry of incorrect or incomplete data has been excluded in the count.
- RCCCs were manually providing such data in the previous reporting periods which included anticipated trials as well as registered trials which did not later convert to teletrials.

1.3 For new clinical trials generated by your jurisdiction's project activities, please provide the number of clinical trials by:

- Demographics of population (e.g. ATSI, CALD)
- Age group of target population (i.e. youth/paediatric; adult; older people)
- Disease type (e.g. oncology)
- Sponsor type (i.e. investigator initiated, commercial, etc.)

You may either provide the information below or attach it to this report. If you attach a document, please provide the name of the document below.

Pendng requiring consent form to be abl to collect this data

1.4 Describe the progress towards target recruitment numbers and the retention rate for clinical trials.

See jurisdiction impact statements in Measure 1

All jurisdictions continue with activities from last reporting period.

s47G

s47G

1.5 Education and training –

Please complete the table below and the spreadsheet provided for education and training details

How many staff have been trained on clinical trial related methodology?	Target	Actual to date Progress against target
Northern Territory	833	157
Queensland	834	801
South Australia	833	226
Tasmania	833	74
Victoria	2000	567
Western Australia	833	191

N.B By next report an impact analysis of educational activities will be reported including a breakdown of professions and postcodes accessing online training modules accessed through A-CTEC.

Measure Three: New health technologies are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health technologies, including precision medicine
- measures the awareness of new health technologies among clinicians and patients
- embeds new health technologies into clinical practice

1.6 Where applicable, are new and emerging health technologies[2] being embraced by clinicians and patients involved in the clinical trials funded through this project? If so, how?

[2]*A health technology is defined by the World Health Organisation as "the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives."*

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
For example, can you please provide a case study of a clinical trial conducted as a teletrial under this Program?

Northern Territory
Two Technologies currently approved for clinical trials in remote areas of Northern territory

1. Agile ECHO Teletrials: The teletrial utilises a medical device AI echocardiography involving two primary sites in Central Queensland and (TiTree and Hermannsburg) and satellite in Barkly regions
2. Telekinesis Teletrial: utilises an innovative digital health trial examining the effects of a mobile app on serum phosphate control in dialysis patients led by allied health patients

Western Australia – Vitafoot (profile din previous report. See case study below)

A digital three-dimensional wound imaging system was installed at Albany Health Campus and used by local clinicians over the course of the trial. The camera continues to be used to improve standard of care service delivery.

Measure Four: New health interventions are embedded in health practice
This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or validates new health interventions
- measures the awareness of new health interventions among clinicians and patients
- embeds new health interventions into clinical practice

1.7 Where applicable, how are the health interventions[3] changing health practice amongst medical practitioners involved in the clinical trials?

A health intervention is defined by the World Health Organisation as an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.
For example, can you please provide a case study of a clinical trial conducted as a teletrial under this Program?

Queensland has solved a travel issue that can be replicated and scaled to give better opportunities to patients living in remote areas.

The QRCCC identified a patient already travelling to participate in clinical trials and proactively established a new Primary Site and Sponsor. The patient no longer has to travel over 2,600 kilometres to a metropolitan site.

Providing care close to home improves patient outcomes because it keeps them close to home and family support and helps retain them on the trial. These patients are also unable to access patient Travel Subsidy Scheme which is a disadvantage in accessing clinical trials and out of pocket expense to patients in time and money. This approach will now be replicated to give more patients access to clinical trials closer to home.

Western Australia leverages technology in a trial designed to improve infrastructure in regions.

Clinical trials have traditionally been restricted to tertiary hospitals in urban areas, leading to disparities in access for rural patients and healthcare services. The limitations posed by travel, expenses, illness management, and social disruption have significantly reduced the participation of rural patients in clinical trials.

The WA Regional Clinical Trial Coordinating Centre (WARCCC) provides on-the-ground training, support and guidance in clinical trial conduct along with access to education services. These capacity-building activities address the critical need for training and mentoring clinical research professionals across regional health sites.

The first Teletrial began in mid-2023 at the Albany Health Campus, with rural-based patients welcomed into Fiona Stanley Hospital's VITAFOOT diabetic foot ulcer study. A digital three-dimensional wound imaging system was installed at Albany Health Campus and used by local clinicians over the course of the trial. The camera continues to be used to improve standard of care service delivery. Clinicians from the Albany High Risk Foot service team worked with lead researchers from Fiona Stanley Hospital's Multidisciplinary Diabetes Foot Ulcer team via videoconferencing technology.

The successful initiation of the first Australian Teletrial in Western Australia highlights the potential for regional hospitals to play a crucial role in addressing health inequity. By leveraging technology to implement measures that establish critical clinical trial infrastructure in the regions, the program has the potential to improve healthcare outcomes for rural patients. Furthermore, the use of telemedicine and digital imaging systems has paved the way for the enhancement of remote healthcare services, starting in the context of wound care management.

"We see Teletrials as being a really big opportunity for us. In one of our previous trials that we'd done for wound

healing, which was a trial of spray on skin, 40 percent of all eligible participants ineligible because they were from rural, remote and regional areas. The opportunity to start recruiting from WA regional sites is a huge opportunity." Professor Laurens Mannings, Fiona Stanley Hospital

"It really does give us an opportunity to provide an equitable platform for patients to access cutting-edge research processes in Albany" Tep Llewellyn, Albany Senior Podiatrist
"Participating in Teletrials was a positive experience for all pharmacy department staff involved and really helped us develop a new set of skills specific that we hope to continue to utilise in future Teletrials. It has also strengthened interprofessional collaboration"
Rheanna Fairhead, Albany Regional Clinical Pharmacist.

Victoria
Clinical Trials Case Study – IRiL Teletrial implementation

S47F

Measure Five: Research community has greater capacity and capability to undertake translational research. When answering all questions for this measure, please focus on positions within the Australian Teletrial Program teams, and the implementation of the Program and its activities and components (rather than the research teams and the specific trials under this Program)

This measure considers the extent to which outcomes of MRFF-funded research:

- increases researcher capacity
- improves the awareness of translational research within the research community
- supports capability development to undertake translational research

1.8 Please complete the table below

	Full Time	Part Time	Casual
Northern Territory			
Target number of positions to be created	7	4	0
Actual number of new positions created	4	0	0
Queensland			
QRCCC- recruited	4	6	0

Target number of positions to be created in HHS	5	21	0
Actual number of new positions created	9	17	0
South Australia			
Target number of positions to be created	9	1	0
Actual number of new positions created	6	4	0
Tasmania			
Target number of positions to be created	5	0	0
Actual number of new positions created	2	5	0
Victoria			
Target number of positions to be created	4	7	0
Actual number of new positions created	4	8	0
Western Australia			
Target number of positions to be created	7	3	0
Actual number of new positions created	4	3	0

1.9 Please provide details on the number and nature of the positions created.

This may include, but is not limited to, study coordinators, research nurses, pharmacists, clinicians, and researchers.

Northern Territory

Recruited to date:

- Program Manager 1.0 FTE commenced
- Program Support Officer 1.0 FTE vacant
- Study coordinator Top End Region 1.0 FTE commenced
- Senior Pharmacist 1.0 FTE – commenced

Recruitment in progress:

- Study coordinator Big Rivers Region 0.4 FTE
- Study Coordinator Central Australia Region 1.0 FTE

Recruitment in planning:

- Study Coordinator East Arnhem Region 0.4 FTE
- Study Coordinator Barkly Region 0.2 FTE
- Cluster Start-up Specialist 1.0 FTE
- Aboriginal Health Practitioner Top End Region 1.0 FTE
- Aboriginal Health Practitioner Central Australia Region 0.5 FTE

Queensland

QRCCC

1. Medical Director 0.2 FTE
2. Assistant Director of Nursing 1.0 FTE
3. Start Up specialist -2.0 FTE
4. Nurse Educators 1.2 FTE
5. Senior Project Officer 1.0FTE
6. RGO part-time position for 4 x RRR HHSs (Torres & Cape, Northwest, Southwest, Central West Health Services) has been created to provide assistance, support and leave coverage.
7. CRC (travelling) Full time position to provide assistance, support and leave coverage. Two 0.5 FTE.
8. 11x 0.5 FTE TT coordinator in Hospital and Health Services

South Australia

ATP-SA roles as at 31 March 2023:

1. Medical Director 0.2FTE
2. Project Manager 1FTE
3. Clinical Trial Liaison Officer 1FTE – located in s47F SA
4. Administrative Officer 1FTE
5. Cluster Start-up Specialist SA 1FTE
6. Cluster Start-up Specialist SA/NT 1FTE
7. Training and Development Officer 1FTE
8. Registered Nurse Clinical Research Coordinator – South East 0.8FTE
9. Registered Nurse Clinical Research Coordinator – Riverland 0.8FTE
10. Registered Nurse Clinical Research Coordinator – Whyalla/Port Augusta – 0.8FTE

Tasmania

The positions created are to establish baseline infrastructure:

- Project Coordinator
- Research Governance Officer
- Teletrial Project Officer
- Clinical Trials Liaison Officer
- ICT System Program Officer
- Clinical Director

Victoria

RCCC-VIC
1 x 1.0FTE Program Coordinator
1 x 0.8FTE Project Officer
Organisation 1 Goulburn Valley Health
1 x 0.9FTE Clinical Trial Coordinator ATP-VIC funded
1 x 0.1FTE Clinical Trial Coordinator ATP-VIC funded
Organisation 2 Barwon Health
1 Clinical Trials Coordinator ATP-VIC funded
Organisation 3 Latrobe Regional Hospital
Two part-time Clinical Trial Coordinators ATP-VIC funded
Organisation 4 Grampians Health
1 x 0.74FTE Project Officer ATP-VIC funded
1 x 0.2 6FTE Tele Trials Start Up Specialist/Clinical Coordinator ATP-VIC funded
Organisation 5 Northeast Health Wangaratta

s47F

Organisation 6-Southwest Healthcare
1 x 1.0FTE Clinical Trial Project Coordinator (new appointment Oct 23) ATP-VIC funded
Western Australia

- Medical Director 0.2FTE
- Project Lead Fulltime
- Senior Pharmacist Fulltime
- Clinical Trial Manager Fulltime
- Research Governance Officer 0.5FTE
- Research Officer 0.5FTE
- Business Support Officer Fulltime

1.10 For any research roles created by your project, please detail the career stage(s) of the researcher(s) (early, mid or established).

Northern Territory

- Program Manager – established career in research
- Program Support Officer - mid career in research
- Study coordinator - early career in research
- Senior Pharmacist – early/mid-career in research

Queensland

14 of the 16 Clinical Research Coordinators (for each individual HHS) have been recruited. The Clinical Director and Assistant Nursing Director are established senior researchers.

South Australia

The Registered Nurse Clinical Research Coordinator roles employed through the Riverland Mallee Coorong Local Health Network are joint appointments with Flinders University and University of South Australia. The South East and Riverland roles have commenced, and incumbents also hold university academic status. Both roles are early-stage researcher roles.

Tasmania

s47F

s47F

Victoria

Not applicable

Western Australia

Not applicable

1.11 Provide a catalogue of new infrastructure developed by the project to date and use of infrastructure by researchers in a collaborative manner. For example, new policies and processes for supporting teletrials in your state.

All sites have participated in harmonisation Activities including Working group to develop key pieces of documentation/templates, two examples:

WA and National Office led Supervision template development Working Group- key output nationally accepted Supervision template to guide, inform and educate cluster set up of Teletrials

WA Pharmacy Working group – intended key output Pharmacy Clinical Trial Educational module development, IMP transport Guidelines and credentialling framework

Victoria

Clinical Trials Case Study – IRiL Teletrial implementation

s47F

All states and territory are building on infrastructure reported in last reporting period

Northern Territory.

NT Health Research website update to include ATP
https://health.nt.gov.au/data-and- research/nt-health-research/teletrial-program
Ongoing update on NT Health clinical trials register
https://health.nt.gov.au/data-and- research/nt-health-research/nt-health-clinical-trials-register to ensure information is current and accurate
A-CTEC – now live and accessible to the NT at no cost to the end user (since 1st March 2023)
https://health.nt.gov.au/data-and-research/nt-health-research/good-clinical-practice- training#

Ongoing discussion with education team to embed research/clinical trials education into main learning system
Development of nursing career pathway for research (N4-N7)
Development of induction packages for new research staff
Recommendations for PATS travel guidelines update to include support for clinical trials activity
Development of NT Health Clinical Trial handbook

Queensland

Teletrial CRC Community of Practice established, meeting monthly and facilitated by the QRCCC.

Equipment being funded across hospital facilities includes centrifuges, fridges and office set up (Nambour and Gympie).

Onsite support for start-up activities for Teletrials including backfill for CT nurses in Mackay in September.

Queensland Clinical trial Portal is being reformed currently

South Australia

SA Health launched a new clinical trials portal on 20 March 2023 with a fresh new look and updated information: http://www.sahealth.sa.gov.au/saclinicaltrials

New documents and processes that have been developed by ATP-SA:

Developed and implemented a process for reviewing and executing Confidentiality Disclosure Agreements

Teletrials document checklist

Standard Operating Procedure for consenting via Telehealth

Proforma letters developed:

- Submission to HREC cover letter
- Principal Investigator agreement to oversee cluster
- Satellite Site agreement to participate in the cluster
- Sponsor agreement for trial to be run as a teletrial
- Clinical Governance Committee support

Tasmania

Teletrials Standard Operating Procedures (under development), in accordance with the National Teletrial Standard Operating Procedures.

Research Governance Streamlined Approval Process – underway

Teletrial Start Up Guide – Tasmania Specific - underway

Teletrial Conversion Steps – Tasmania Specific – underway

Teletrial DOH Internal Payment Protocol – Appendix to Supervision Plan – completed

Addition of Site – CTRA Amendment proforma - completed

Victoria

The seven regional hubs across Victoria have been working independently to develop tools and infrastructure required within their operating areas. Work to date includes:

Site specific Standard Operating Procedures updated, based on National Standard Operating for Clinical Trials including Tele-trials

Adoption of ATP toolkit documents for jurisdiction and site-specific use

SiteDocs software purchased for use with clinical trials.

Source data plan and essential documentation guide developed

Trial feasibility, start-up flowchart and start up metrics developed

Equipment not funded under ATP- Victoria however sites have purchased of trial specific pathology equipment (-20oC freezer, -80oC freezer centrifuge and fridge). Identified as a need across several sites.

Developed process for converting clinical trials into teletrials

Development of new processes for delivery of trials in surgery and in-patient units

Development of fee schedule for non-CTA managed trials

Development of other site-specific documents:

- Updated Site CV
- Site structure fee
- Trial one page summary
- Risk Assessment Matrix (still in development)

Establishment of clinical trials webpage on the intranet, with relevant links

Use of Microsoft 365 and utilisation of Sharepoint and apps to further build awareness and create efficiency across the organisation regarding practices, procedures and connections (working to breakdown culture of silos and teams when undertaking projects.

Establishment of Clinical trials office

Execution of a Master Confidentiality Disclosure Agreement with a contract research organisation, to streamline site preparations

Western Australia

The Teletrials Toolkit has been adapted for Western Australia, including the following:

Teletrial Eligibility Framework

Satellite Site Checklist

Equipment/facilities checklist for Satellite Sites

Supervision Plan

Equipment funded

- eISF for the WA Country Health Service approved and accessible for WARCCC and sites
- State-wide IMPS progressed through the IT approval system

Two online education platforms have been identified as either essential or best practice training existing and future clinical trial health professionals:

For training in Good Clinical Practice (GCP) health professionals have access to training via the WA Health Translation Network.

Governance Guide circulated to all Research Governance Units in WA (trialled for 4 months then revised before publicly published)

For further expertise in clinical trial delivery, WA Country Health Service (WACHS) regional staff can now access professional development training, with the announcement of a new training partnership with the Australian Clinical Trial Education Centre (A-CTEC).

Pharmacy guidelines and templates have been developed and embedded into existing processes:
Creation of adapted teletrial pharmacy procedure templates for program wide use
Virtual IMP temperature reporting process to central pharmacy
iPharmacy (dispensing software) Business Rules updated to include teletrials
Build of clinical trials sites into all regional, rural, and remote iPharmacy sites

The ATP-WA Senior Pharmacist also submitted a Clinical Workbench eMedicine Clinical Trial evaluation report v2.0 to state-wide Chief Pharmacist Forum

A physical central Pharmacy, co-located with another public hospital, is to be the central infrastructure point to virtually oversee the distribution of investigational products used in the Teletrial Program.

1.12: Please provide a reference list of conference presentations, publications, citations, mentions in

social media, workshops, etc. generated to date in relation to the project and the implementation of the teletrial model as part of this Program.
ATP- Western Australia Science on the Swan, Perth WA (booth and presentation) Royal Perth Hospital Grand Rounds WA Country Health Service Grand Rounds WA Teletrial Launch by Minister Dawson Kimberley Aboriginal Health Research Forum Showcase of first WA Teletrial in the WACHS Annual Report Participation in the Kimberley Aboriginal Research Health Forum **ATP-Queensland – period April to end of September** Rural and Remote Forum – Cairns ARCS – Sydney Information booth ATP Sponsor Workshop – Virtual QLD Clinical Trial Consortium Meeting -Virtual Presentation ACTA Teletrial WG- influence trial groups to insert "Teletrial model as a recruitment mechanism within protocols themselves" and encourage PIs to include satellites at feasibility stage VCCC alliance conference- Teletrials as part of health equity for RRR and Indigenous communities CNSA conference- Teletrials as part of health equity for RRR and Indigenous communities Qld Diabetes network- role of QRCCC in setting up clusters Qld Clinical Senate- Teletrials as part of networked clinical trial system PAH research symposium- Teletrials, clusters and health equity for RRR and Indigenous communities Canadian cancer trials network—workshop participant to advise on clusters and get buy in from global sponsors ASCO Breakthrough Japan- to get buy in from ASCO and global sponsors and PIs Setting up Qld medical oncology, palliative care and haematology trial networks using ATM Qld Neurology, children's, and respiratory champions for enabling RRR access for trials BHNQ proposal and media campaign to get two patients onto Teletrials Omico network- leveraging whole genomic sequencing program for ATP 2x ASCO education podcasts- Rural oncology practice and Teletrials ASCO daily news and ASCO connection articles on Teletrials Australian internal medicine research conference- Teletrials and clusters Connecting QRCCC with AGITG (New Zealand) and Mental Health trial network conferences COSA council to promote ATP as part of health equity **ATP-South Australia** Presentation to FUNLHN Nursing and Midwifery Leadership Council 18/8/2023 VCCC Presentation 14 August 2023 – Monday Lunch Live: New Trials Methodologies (presentation by ATP-SA Clinical Trial Liaison Officer and Cluster Start-up Specialist SA) Presentation to FUNLHN Nursing and Midwifery Leadership Council 18/8/2023 Spring Into Clinical Trials Event – 11 September 2023: valuable promotion and networking opportunities, with a result a number of new protocols to review. Attendance at SALHN Research Week, Monday 18 September – Friday 22 September 2023 including promotional presence in a booth/table on Monday 18 September. Attendance at the opening of Cancer Research South Australia's new purpose-built clinical trial facility in Adelaide 19 September 2023. Clinical Trial Liaison Officer gave a short presentation on ATP-SA to a group of sponsors that has provided some encouraging leads. Presentation to Whyalla Interagency Group (6 September 2023) to promote awareness of research and clinical trials to consumer groups in Whyalla region. **ATP-Northern Territory** Regular internal newsletter – 2nd edition ARCS Conference Booth - June 2023 Alfred Health Trial Hub Showcase Event - June 2023

Showcase Event for the 2023 International Clinical Trials Day – May 2023
Active coordination of NT Health Research Coordinators Peer Support Network – monthly meeting
ATP-Tasmania
Internal newsletter announcements i.e., REACH Tile. (quarterly)
Presentations to Clinical networks
ATP- Victoria
Regional Hubs
Presentation of Clinical Trials including Teletrials at NHW Grand Rounds for Research Week to boost PI awareness and recruitment.
Presentation to Victoria Teletrial Forum (attended by sites, sponsors, HRECs, RGOs).
Regional Victoria Clinical Trials & Research Meeting (17th March 2023)
A-CTEC conference (March 2023)
Alfred Trial hub Showcase (16 June 2023)
ATP _Victoria conference (21 July 2023)- panellists
Hosted information booths in the main hospital thoroughfare to promote and celebrate International Clinical Trials Day (May 2023) Doctors for Regional Innovation, Vision, Excellence, Research & Scholarship Drivers conference (23 September)

Measure Six: Health professionals adopt best practices faster

This measure considers the extent to which outcomes of MRFF-funded research:

- identifies or establishes best practices
- assesses the speed at which best practices are communicated to clinicians and health service administrators
- identifies how best practices are understood and adopted

1.13 Where applicable, how well were the best practices[4] understood and adopted and how was/will this (be) have evaluated?

[4] WHO defines Best Practices as "exemplary public health practices that have achieved results, and which need to be scaled up so as to benefit more people".

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

Best practice is established through national harmonisation activities detailed in the Progress Summary report.
Other supporting activities to ensure bast practice are:

- GMP - Mandatory training for Clinical Trial remains the gold standard for ensuring best practice. A-CTEC have developed a shorter course for PIs and Ais in appreciation of time poorness of clinicians
- Training in understanding the *National Standard Operating Procedures for Clinical Trials including Teletrials.*
- Most regional sites working towards National Clinical Trial Governance Framework. s47G recently received a 2.6 rating.

Measure Seven: The Community engages with and adopts new technologies and treatments

1.14 How were the community members and consumers engaged in prioritising, designing and conducting research through means such as public consultations? For example, have any state committees or advisory groups been established? What engagement has been undertaken in your state?

The ATP national office has commissioned a piece of market analysis to inform perceptions of Teletrials, Clinical Trials Telehealth. Initial review indicates our approach to consumer engagement and consultation needs to

change. ATP NO will provide a full analysis and Consumer engagement strategy in the next reporting period. The ATP NO also is secretariat to a National Clinical and Consumer Advisory Group. This group is cochaired by a Consumer and ACTA member. They have elected to meet quarterly with a face-to-face meeting next year planned.

All jurisdictions engagement with consumers was advised in the last reporting period.

Northern Territory

Ongoing- NT Teletrials Advisory Committee was established in 2022 and the inaugural meeting was held in November 2022. There are s47F consumer representatives including s47F First Nations consumers.

ATP-NT team held a consumer yarning session to develop culturally and linguistically appropriate educational tools to build on health professionals and public health literacy on research and clinical trials.

Queensland

Ongoing - Teletrials Steering Committee OLD continues to meet regularly and includes consumer representatives. QRCCC recruited s47F consumers - s47F of whom will be on the Steering Committee and collectively they will form a working group with the QRCCC. s47F of these consumers worked with other consumers through the ATP NO and Alfred Trial Hub and Victorian Cancer Council partnership to develop the Consumer Teletrial Brochure.

South Australia

Ongoing-ATP-SA has established the SA Teletrials Advisory Committee with the inaugural meeting held on Thursday 10 November 2022. This committee has s47F consumer representatives from regional South Australia and s47F from the Aboriginal Health Council of SA.

Tasmania

Currently involved in setting up first two TTs across

Victoria

Nominations to this committee have been requested.

Individual clinical trials institutions have provided information in their reporting activities with consumers may consider also establishing similar committees such as Northeast Heath Wangaratta. Other activities include:

- Latrobe have developed a Communications and community engagement strategic plan for research and named two clinical trial participants as “ambassadors”. Community engagement events are planned dot engage with GPs.
- Barwon Health -The Adrian Costa Clinical trials centre participate in Run4Geelong event in November 2023 to raise funds and awareness for clinical research.
- Southwest Healthcare – community engagement through attending local community hubs (RSL and library) information session.

Western Australia

Preparing for a WA Community Reference Group

The inclusion of consumer stories of First Teletrial in their Official Launch in July 2023 by Minister Dawson.

Part 3 – Commonwealth MRFF - Working with Children – Statement of Compliance

3.1 Complete the following table

Northern Territory

1	Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☒ **Yes** ☐ **No** ☐ **N/A**
2	Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☒ **Yes** ☐ **No** ☐ **N/A**
3	Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☒ **Yes** ☐ **No** ☐ **N/A**
4	Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☒ **Yes** ☐ **No** ☐ **N/A**

Queensland

1	Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation? **Response:** **We are working with Children's' Hospital Queensland who are all fully compliant**	☐ **Yes** ☐ **No** ☒ **N/A**
2	Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**
3	Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☒ **N/A**

4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ **Yes** ☐ **No** ☒ **N/A** **All clinical staff have child safety training**

South Australia

1 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ **Yes** ☐ **No** ☒ **N/A**
2 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**
3 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☒ **N/A**
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ **Yes** ☐ **No** ☒ **N/A**

Tasmania- Statement is pending for Tasmania as they work through internal processes. Noting they previously reported NA and have not registered an active TT yet

4 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ **Yes** ☐ **No** **N/A**
5 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☐ **N/A**
6 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☐ **N/A**
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above	☐ **Yes** ☐ **No** ☐ **N/A**

• relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	

Victoria

7 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation?	☐ **Yes** ☐ **No** ☒ **N/A**
8 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☐ **Yes** ☐ **No** ☒ **N/A**
9 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☐ **Yes** ☐ **No** ☒ **N/A**
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks • relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	☐ **Yes** ☐ **No** ☒ **N/A**

Western Australia

10 Is the organisation, and persons working with children on behalf of the organisation in relation to the Activity, compliant with Commonwealth, State or Territory legislation? Yes, Clinical Trial Coordinators and Research Nurses have current Working with Children (WWC) Checks, as required by the Western Australian Government.	☒ **Yes** ☐ **No** ☐ **N/A**
11 Has the organisation completed a risk assessment in relation to the Activity and all persons who may engage with children in association with the Activity?	☒ **Yes** ☐ **No** ☐ **N/A**
12 Has the organisation put in place an appropriate strategy to manage risks identified through the risk assessment?	☒ **Yes** ☐ **No** ☐ **N/A**
4 Has the organisation delivered training and established a compliance regime to ensure that all persons who may engage with children are aware of, and comply with: • the National Principles for Child Safe Organisations • the risk management strategy in item 3 above • relevant legislation relating to requirements for working with children, including working with children checks	☒ **Yes** ☐ **No** ☐ **N/A**

• relevant legislation relating to requirements for working with vulnerable people, including working with vulnerable people checks; and • relevant legislation relating to mandatory reporting of suspected child abuse or neglect however described?	

Part 4 - Financial Report

3.1 Please complete the financial acquittal attached (Excel document) detailing budget and actual expenditure for the current reporting period and forecast expenditure for the next reporting period as per the 'Head of Expenditure' categories in the grant agreement budget. These categories include: Labour (excluding on-costs), Labour on-costs, Travel, Equipment, Contract, Other eligible expenditure, Minor Capital Works (none in original budget), Materials for Construction (none in original budget).

A detailed description of these expenditure categories can be found in the grant guidelines. Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?

A summary is provided as an overall statement of financial status as compiled and supported by the ATP National Office.

Northern Territory	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Queensland	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
South Australia	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Tasmania	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Victoria	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	
Western Australia	
Is a financial acquittal being provided for this reporting period certifying that the expenditure incurred is in accordance with the grant agreement and guidelines?	Yes
if no, please explain why	

Australian Teletrial Program

RISK REGISTER - Australian Teletrial Program

								Current risk assessment								Projected risk assessment				
Log #	Project Reg # *if app.*	Type of Risk	Description of risk	Risk location	Date identified	Risk owner	Current controls identify each step as C1, C2, C3 etc	Current project consequence	Current likelihood	Current rating	Current Risk score	Response protocol	Treatments identify steps as T1, T2, T3	Treatment due date	Treatement status	Projected consequence	Projected likelihood	Projected rating	Projected source	Review comments
		Financial	Underspend of funding allocated inception to date (ITD)	National	Jun-22	ATP / ORI	C1. Financial acquittals C2. Financial reporting / budget development / monitoring.	Moderate	Possible	High (15)	15	Treat	T1- Aquittal reporting keeps accurate record of underspend		Ongoing					
		Legal	Risk of contracts not delivering on contract obligations (contract terms risk where contractual obligations don't align with the contract reality).	National	Perpetual	ATP / ORI	C1. Ramping up activity levels C2. Actual performance and processes setting a precident for contractual obligations (ie substantiation).	Major	Unlikely	Medium (14)	14	Treat	T1-Monthly status reports T2 payments on receipt of deliverbles achieved.		Ongoing					
		Operational	Attracting and retaining appropriately skilled RCCC staff	National		Jurisdiitons	C1. Only experienced clinical research coordinators to be engaged	Moderate	Possible	High (15)	15		T1-Ensure reruitment and retention strategies in place in each jursdciton T2 Provide appropriate eduction and support through DoH and RCCC set ups		Ongoing					
		Social	Lack of consumer engagement	National	Jun-22	ATP / ORI	C1. CHF has finalised the consumer engagement strategy C2. Consumer Engagement starategy has been finalised and discussion to integrate ATSI community engagement strategy is underway.	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Clinical and consumer health forum and consumer engagement strategy from Consumer Health Forum (CHF) T2. Consumer Engagement Strategy to be implemented including special attention to ATSI community engagement	30-Apr-23	Ongoing					
		Social	Risk to not representing the diversity of partner jurisdictions' populations	National	Jun-22	ATP / ORI	C1. CHF has finalised the consumer engagement strategy which has been reviewed by C&C Advisory group	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Clinical and consumer health forum and consumer engagement strategy from Consumer Health Forum (CHF)T2. Employment of Lead communication Officer		Ongoing					
		Strategic	Commercial sponsors not engaging with teletrials	National	Jun-22	ATP / ORI	C1. IQVIA is currently interviewing jurisdictional partners to identify barriers and challenges	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Sponsor Advisory group and IQVIA T2.National Workshop for sponsorre	Mar-23						
		Strategic	Integration with NSW and ACT	National	Jun-22	ATP / ORI	C1. 3-monthly meetings are being set-up with NSW and ATP	Minor	Possible	Medium (9)	9	Treat	T1-reular meetings T2 Sharing of documents and processes. T3.Include NSW in working groups icuements	30-Jun-23						
		Strategic	Lack of engagement with external stakeholder by clinicians	National	Jun-22	ATP / ORI	C1. Queensland is working on HSCE forum brief and will present to the forum C2. Seek for other jurisdictionals plans to engage their clinical and research netwroks	Moderate	Possible	High (15)	15	Treat	T1. Engage with and present to clinical networks							
		Strategic	Large investment in this Program not meeting outcomes; KPIs/milestones not being met	National	Jun-22	ATP / ORI	C1.RCCC set up	Major	Possible		18	Treat	T1. Extensive engagement with all stakeholder T2. Promoting the program and model through site visits and through attending conferences and seminars							
		Strategic	RCCCs/Primary site paying Teletrial support Program funds to ineligible primary and satellite sites	National	Jan-23	ATP / RCCCs	C1. Eligible trials reporting through REDCap	Minor	Possible		9	Treat	T1. For QRCCC each memo will include timeline for that trial and will be accompanied by REDCap reporting							
		Strategic	Risk to harmonisation: * inconsistency of RCCC situated within jurisdiction, * sites operating outside of program model, * misalignment with operating processes and policies between states	National	Jun-22	ATP / ORI	C1. Detailed implementation plan template is prepared for jurisdictional partners	Major	Possible	High (18)	18	Treat	T1. Monthly catch up with jurisdictional partners T2. Detailed implementation plan from jurisdictional partners T3. Restructuring the executive committee to have representation from high-enough policy makers/influencers from jurisdictional partners							
		Operational	Issues relating to REDCap data: - Mismatch of information manually provided and data entered in REDCap - Lack of information relating to participants demographics	National	Oct-23	ATP / ORI	C1. Reconiling data in REDCap with data manually provided by partner jursidictions. C2. No specific controls about demographic information of participants.	Minor	Possible	Medium (9)	9	Treat	T1. Identifying the bugs or issues in REDCap and making relevant changes to the database as necessary T2. Encouraging sites to get consent from participants to collect demographic information	Apr-24	Ongoing					

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Progress Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through progress reports. For varying your grant and grant agreement please refer to the MRFF Grant Variation Policy.

Please ensure that you are using the latest version of the Progress Report template. You must submit your report on the business.gov.au portal. You can enter the required information in stages and submit when it is complete.

Project Information

Grant ID	MRFRR000005
Grant Opportunity Name	Medical Research Future fund – National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant
Administering Organisation	The State of Queensland acting through Queensland Health
Chief Investigator A / Project Lead	Kaye Hewson
Grant Title	Australian Teletrials Program
Grant Agreement Start and End Dates	19/09/2021 - 04/10/2026
Research Activity Start and End Dates	5/10/2021 - 30/09/2026
Australia New Zealand Clinical Trials Registry Trial ID (where relevant)	N/A
Reporting Period	1/11/2023 -31/03/2024
If the Commonwealth Commercialisation Clauses apply to this project, have there been any changes to the Commercialisation Plan?	No
Do you plan to execute any new agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	N/A

Project Progress

1. *Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement.*

The comments field should clearly summarise progress at the end of this reporting period towards completion of the agreed research activities relevant to each milestone/objective and provide a justification for any changes or delays to milestones/objectives.

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Milestone 001 • Execute contracts • Convene Steering Committee and relevant Advisory Groups • Begin harmonisation activities • Establish the national project office • Establish RCCCs in OLD, VIC/TAS, WA, SNNT • Begin National Education and Promotion Program delivery • Local context mapping • Begin Teletrial Support Program • Finalise and socialise evaluation framework with all stakeholders	04 October 2022	As per previous report	
Milestone 002 •Continue delivery of national components including education and training, promotion and awareness, •engagement with clinical networks, and recruitment boosting activities •RCCCs deliver support in each jurisdiction to embed teletrials in rural, regional and remote locations •Evaluation program continues		As per previous report	

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Milestone 003 ***Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities*** **Comments:** *enter progress summary to date, justifications for changes or delays and strategies to rectify.* **National Teletrial Supervision Plan (NSP)** The template was endorsed by the Executive Committee in December 2024 and is on the ATP website and will soon be on the Medicines Australia site. The NSP is being piloted across several jurisdictions and is being communicated to users through industry e-newsletters, abstract posters and oral presentations. An online version with guidance and education modules are currently in development. **National Teletrial Compendium** ATP coordinated a national response to the request for Teletrial Compendium review. Recommendations provided include: - Clarification on the scope of the Compendium - Simplified definitions - Additional points to underpin purpose of the Teletrial model. - No feedback has been provided on this response at the time of this report. All teletrial documents are under review in consultation and co-design with relevant stakeholders. - User experience is being updated to ensure best user journey for content on the website, which will be the main source of "truth" for Teletrial documents. **National Research Governance Workshop** ATP coordinated a national workshop on research governance reform. The objectives of the workshop were to: - Identify opportunities for efficiency at all parts of start-up journey. - Identify solutions for an expedited approach for sites with potential trial participants. - Outcomes that are applicable nationally and relevant to teletrials. There were four high level recommendations of the workshop: - To achieve high quality and efficient governance processes institutions must provide a stable, supported, and genuine executive level investment in research governance and clinical trial operations. - The sector should seek opportunities for improved workflows (such as delegated authority, reduced number of approvers, notification versus approval, e.g., distributed authority model). - Development of enhanced site capability (infrastructure and workforce) and credentialing framework, enabling rapid patient and trial matching (development versus regulatory). - Development and roll out of standardised templates, guides, and harmonisation of processes incorporating teletrial methodology wherever possible. ATP is currently seeking Steering Committee endorsement of the report and plan for publication, however, there have been barriers relating to report content and intention that have hindered progress to date. ATP participating jurisdictions have been provided an opportunity to provide	**01/05/2024**	**01/12/2024**	**50%**

individual feedback, with all but one jurisdiction agreeing to endorse or provide in principle endorsement at the time of this report. ATP plans to consolidate all feedback provided to understand common themes and establish a way to publication.

Education and training

Two jurisdictions have achieved their target number for education and training. It is clear by having national access to online modules this provides a resource for Clinical trial/TT that has not occurred before and people are interested.

Whilst this is a great achievement this is not reflected in the number of active teletrials. In March 2024 an education working group was convened to look at how to achieve greater impact through education and training.

Onsite GCP training and onsite mentoring are two of the strategies currently being used. Workforce development and attracting and retaining staff through professional development and career progression will be a focus of this group once a scoping exercise of available resources within each jurisdiction is completed.

Audience Insight driven Communications Strategy to promote ATP

A market analysis of awareness and understanding was conducted across each jurisdiction, across metropolitan, regional, rural and remote (RRR) audiences for both healthcare workers (clinicians, GPs, nurses, allied health) and patients/consumers. There was no statistical variation between metro or RRR or state/territory.

- 15% of health care workers were aware of teletrials
- 0% of healthcare workers understood or were able to explain the model
- 6% of patients were aware of teletrials
- 0% of patients understood how teletrials worked
- 95% of healthcare workers believe in clinical trials as a crucial step in the development of new treatments and practices.
- When teletrials were explained nine in 10 healthcare workers supported the idea and four in five said they would recommend that their patients or someone they know participate
- Four in five patients support the idea of teletrials, with half considering participating
- For patients, the trusted source of healthcare information was Primary Health (GPs and practice nurses).

Based on these results, that patients want their trusted health workers to recommend the best care treatment, and knowing forced clinician adoption does not work, the communications strategy uses behavioural science theory to first target clinicians to increase awareness and understanding of teletrials from 15% to 25%. These clinicians will then encourage and seek out potential trials for their patients to participate in, and researchers will actively seek converting clinical trials to teletrials to include regional, rural and remote participants. The four priority areas being focused on are: improving the user experience, content and analytics capability on the ATP website, raising the profile of the Regional Clinical Trials Coordinating Centres (RCCC), launching a targeted communications campaign for healthcare workers and demonstrating patient benefits through lived experience. A suite of content is under development, and in parallel public relations work is being leveraged to promote ATP to targeted audiences. As the analytics capability improves, enquires and lead generation will be tracked and compared against teletrial pipeline development.

This approach has been endorsed by the Clinical and Consumer Advisory Group and Sponsor Advisory Group and aligns with the IQVIA report conducted in December 2022 and by the soon to be released academic

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paper 'The Australian clinical trial landscape: Perceptions of regional, rural and remote health service capability and capacity' by QUT/JCU. ATP has also been invited to present this Communications Strategy and approach at the NSW/ACT R3-CTEP Advisory Group meeting.

Engagement with clinical networks
Clinician champions continue to work with ATP and through national jurisdiction engagement new groups of clinicians across a broad range of specialities have become involved.

Promotion of ATP
- Keynote speech at the 25th ASM Annual Scientific Meeting in New Zealand
- AusBio Tech session with industry
- MAGNET Mental Health ASM and Cancer in Primary Care Conference
- MRFF Governance Workshop in collaboration with ACTA chaired by s47F and includes ATP NO Director Kaye Hewson
- The Northern Territory ATP program launched in Darwin leading to an ABC national radio interview
- ATP was invited to participate in the *'Equitable access to diagnosis and treatment for individuals with rare and less common cancers, including neuroendocrine cancer'* Senate Inquiry
- Rural Medicines Australia abstract poster, oral presentation and exhibition stand
- International Clinical Trials Symposium keynote speech and panel presentation from Kaye Hewson, joint exhibition stand with ACTA and abstract poster
- Cancer in Primary Care Conference
- COSA Conference presentation and abstract poster
- ATP content has been provided and published for the Clinical Oncology Society of Australia, Partyline Magazine for the National Health Rural Health Alliance and R&D Taskforce
- Promotion at Bendigo Medical Research Week
(Please see appendix for articles and posters)

Other activity
- All teletrial documents are under review in consultation and co-design with relevant stakeholders
- User experience is being updated to ensure best user journey for content on the website, which will be the main source of "truth" for Teletrial documents
- Content creation is underway to demonstrate patient demonstration through lived experience, with videos being planned for Townsville and Rockhampton (Qld), Darwin and Alice Springs (NT) and Warrnambool and La Trobe (Victoria).

Recruitment boosting activities.
1. Partner – please see appendix for full report for Primary Health care focus.
2. The Australian Clinical Trial Alliance (ACTA) -responding to a survey that was conducted across Clinical trial networks ACTA has provided the following deliverables.-convened an ACTA Teletrial Project Working Group
- Held an ACTA Teletrial Webinar featured speakers from oncology and non-oncology Clinical Trial Networks (CTNs) / Coordinating Centres (CCs) who shared their experiences and insights on the challenges, hurdles and successes of setting up and running Teletrials within investigator-initiated trial networks.139 people attended. Recoding available at https://clinicaltrialsalliance.org.au/australian-teletrial-program-atp-project/

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-Engagement with ACTA clinical Trial Networks and coordinating centres. Booth and trade tables at several –promotion through trade tables of ATP at conferences. 3. Teletrial Support Payments- active now in South Australia (SA), Victoria (VIC), Queensland, (QLD) Western Australia (WA), and Northern Territory (NT). Inclusion of MM2 locations in payments has meant reconciliation activities in Victoria and Queensland. The Redcap data base now shows activity in MM2-and small number of MM7 participants. 4.Workshop for "Changing landscape of CTs in the era of COVID-19" with all the ATP jurisdiction and service providers, consumers and Advisory Committee Chairs in November 2019 informed activities and focus for 204/205. These included National Policy for CTs, Consumer awareness and engagement, Data and digital platforms (identified as biggest change), workforce, service /site for logistics.			
Interim analysis of evaluation study **Comments:** *enter progress summary to date, justifications for changes or delays and strategies to rectify.* **Embedded Customer Data collection and operations evaluation Report – Interim analysis of evaluation study for impact and sustainability planning -** On track for completion September 2024. **<u>Stage 2 Governance approvals</u>** 40 governance approvals required in six jurisdictions for interviews and stakeholder activities. <u>Status</u>: *Victoria:* 4 achieved; 3 to be progressed for 2026 data collection *SA:* 7 required, 1 achieved, 6 to be progressed for 2026 data collection *Qld:* 16 required, 5 approvals achieved, 3 likely to enable 2024 data collection, 8 to be progressed for 2026 data collection *WA:* 7 required, 1 to be progressed to enable participation in 2024 data collection, 6 to be progressed for 2026 data collection *Tas:* Achieved *NT:* Achieved. **<u>Stage 2 RCCC monitoring activities</u>** Ongoing in Qld, SA, and Vic, NT. Recently commenced in Tas. WA to commence once approval has been obtained. **<u>Stage 2 QH REDCap data transfer</u>** Extracts received from October 2023 and January 2024. Review by QUT and JCU of essential items for the evaluation. As previously advised, missing data continues to be a major issue and will limit the quality and quantity of evaluation reporting. **<u>Stage 2 QH ATP activity reports</u>** QH provided an initial collation of report items in Jan 2024. Established process and team responsibilities for filing and monitoring of the RCCC/ATP activity reports. Missing data is an issue and will limit the depth and quality of evaluation of RCCC activity. **<u>Stage 2 RCCC, stakeholder and trial participant interviews</u>** Process established for recruitment of participants and scheduling of interviews. Piloting of tools implemented in February 2024.Recruitment commenced in February 2024.Nineteen interviews conducted as of 31/03/24. **<u>Delays and risks</u>** **Lack of data** The key risk to achieving KPIs 3 and 4 are the ongoing issues with lack of evaluation data. This relates mainly to:	**04/10/2022**	**04/10/2024**	**50%**

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1. The unwillingness of jurisdictions to provide deidentified demographic data without additional individual patient consent. This limits the data extracts provided by Queensland Health to the study team, which will reduce the accuracy and quality of the evaluation reporting (particularly distance from the primary site).
2. The large amount of missing data generally in those extracts. Some of this is due to the very low/nil level of teletrial activity in several jurisdictions.
3. The evaluation team raised concerns about lack of data with ATP national team in October 2023. Mitigation activities include a monthly data meeting with the QH ATP team and ongoing review and mapping of required information against provided and potentially available information/data.

Strategies to rectify

ATP National office has convened a Data and Digital working group with representatives from all jurisdiction's participating, with an emphasis on data quality, requirements for the program and end user experience. Dr s47F will join the ATP Data group as the evaluation representative in April 2024. ATP NO has confirmed that there should be no research ethics or governance problem with jurisdictions providing the information as requested without an additional layer of consent.

To raise awareness of the importance of program data (including participant data) for the evaluation, s47F presented at the ATP steering committee meeting in November 2023 and Communications leveraged and edited materials in the ACTA Consumer Engagement Toolkit for each jurisdiction to promote locally. This built on the May 2023 evaluation team visits to each jurisdiction that included a presentation on the evaluation purpose, outcomes, and the role of the RCCC in supporting and taking part in the evaluation.

Governance delays

Delays in obtaining governance approvals are ongoing. We have ordered and prioritised approvals in the last 3 months so that all jurisdictions have at least one approval and are able to participate in the interim evaluation activities for KPI3. We prioritised health districts for governance approval completion where there is current teletrial activity. We will continue to progress all approvals to enable full participation in the 2026 data collection activities for KPI4.

Priorities

The next progress report is due on 15 October 2024. The team's focus in the next reporting period will be on completing the data collection and analysis for the Deliverable 3 interim analysis report, due 04/09/24. This includes completing the remainder of visits to each jurisdiction in April and May to meet with the RCCC teams and conduct face-to-face interviews. Online interviews will be conducted up to the end of May 2024.

s47G

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Strategic targeting of global biopharma to attract commercial clinical trials to teletrials sites **Comments:** ATP is committed to creating pathways and leveraging investment opportunities from commercial sponsors that will help build a sustainable model in the future. ATP has a Sponsor Advisory Committee whose members represent the top twenty global pharmaceutical companies and meet quarterly. Their role is to advise, and co-design/collaborate/review documents supporting implementation of ATP and then share to internal and external networks. A Sponsor workshop was held in March 2023 and followed up with two further webinars after feedback and survey results from the webinar. Sponsors have indicated through the IQVIA report and through ATP surveys that they want regular and UpToDate information on Teletrials, working examples of set up procedures and opportunities to understand progress across harmonisation. - August 2023- *'Teletrials – Start Up – How to?*' – nearly 100 attendees, 100% found the event extremely useful or useful, 100% said they would attend the next event and 80% indicated they were likely to consider converting to a teletrial or running a teletrial. - December 2023 '*Update on Teletrial landscape, FAQs'* - 86 registered participants, 60 attendees. Video of webinar emailed post event to all participants. - Five global sponsors have been consulted for the IMP Transport Guideline project looking at the rapid narrative review which will inform the guideline, which the TGA and Commission have agreed to sponsor onto IGPRG who will publish the final guide. - Meetings have been secured with Contract Research Organisations (CRO) for engagement and education in their internal meetings. - A suite of guidance documents debunking teletrial myths and promoting industry harmonisation are being co-designed with sponsors. - Sponsors have asked to co-author a letter recommending one National program to improve equitable access to clinical trials, this being the ATP model. Further to this, strategic targeting of global biopharma has extended to med tech, preventative healthcare, models of care and non-drug interventions to attract a broader range of commercial clinical trials to teletrials, with an approach underway to national peak bodies for partnership and promotion of the model across key stakeholder groups. **<u>New sponsor trials in QLD, NT, SA achieved</u>** A major project has commenced in Queensland on the back of new manufacturing plant being developed for MRNA vaccine development for infectious diseases. The previously mentioned IQVIA report recommendations are all being addressed, including raising the profile of RCCCs, addressing ways to streamline and harmonise timelines for research governance. ATP has responded with major profile piece in the R&D Taskforce paper, Clinical Oncology Society of Australia and in the National Rural Health Alliance peak body online magazine (going out to 17,000 subscribers). The National Supervision Plan was identified by stakeholders as a high priority, as since the inception of teletrials the model expanded across	**04/10/2026 time (ongoing across life of program)**	**04/10/2024**	**50%**

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Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete
jurisdictions, interventions and specialities resulting in the development of multiple varied supervision plan templates. Following rigorous consultation and collaboration with all jurisdictional partners as well as NSW/ACT R3-CTEP and Alfred trial Hub and ReVitalise. to create a simple and adaptable template suitable for all trial types to facilitate research governance submission and review, minimise governance amendments, and inform the completion of Teletrial sub-contracts.			
Milestone 004 •Continue delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities •Establish RCCCs in TAS and NT	04 October 2025	Yet to start	0%
Milestone 005 •Finalisation of data collection for evaluation •Finalise delivery of national components including education and training, promotion and awareness, engagement with clinical networks, and recruitment boosting activities •Final impact analysis	04 October 2026	Yet to start	0%

2. *Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)*

ATP partners continue to undertake capacity building activities to enhance the landscape for the introduction of Teletrials in RRR locations by knowledge building within their own teams, providing leadership in the implementation of the ATM, valuing communities working with in and for them, and network building increasing the momentum and support for the program.
In February 2024 Clinician and Consumer Advisory met face to face providing advice on the development of the Communication Strategy materials (as approved in November 2023 by the group). Together key messages, the ATP story and activities to engage with a broad group of clinicians was confirmed.

ATP National Office Director Kaye Hewson was called as a witness to Senate Community Affairs enquiry into equitable treatment and diagnosis of rare and less common cancers in Canberra on March 1, 2024. Parliament was attended by Kaye Hewson and Professor Julie White, Chair of ATP Executive Committee, Dr Wei San Lam Clinical Director ATP-WA Country. The session went extremely well with the Senators impressed with the ATP model both with how it is helping to harmonise clinical trials broadly and increase equity of health access. Senator Askew said, “this is the solution to the problem we have been looking for”.

All Senators agreed and noted that the program could be a lever to attract and retain healthcare workforce to RRR areas and provide additional career pathways along with increased job satisfaction. They asked if working as a national body would be a stronger force to then seek additional funding in the future and agreed that a five-year program may not embed ATP across multiple and very different jurisdictional health services. Senator Askew will be meeting with the Tasmanian team to see if any assistance can be provided to scale ATP in that region, and a question on notice from Senator Pratt included a request on what ATP would like the Senate to recommend to recognise and support the Regional Clinical Trial Coordinating Centres, which have been the major infrastructure build from the MMRF grand funds, and are the critical piece of ongoing infrastructure required for future program sustainability.

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3. *Complete the following table for all variation requests under the MRFF Grant Variation Policy approved, submitted (pending approval) or in draft (pending submission) for this grant to date.*

Type of Variation	Description of Variation	Current Status
Select	N/A in this reporting period	Select

4. *Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)*

Inclusion of demographic data from jurisdictions
The National Office is addressing this by working with jurisdictions to understand their concerns and provide advice on consent avenues. The Evaluation Team attended the National Steering Committee meeting November 2023 to raise issue and discuss concerns.

National implementation of National Clinical Trial Governance Framework (NCTGF) rollout has resulted in some delays due to timing of this release and roll out of ATP. Through the Executive Committee cross membership of the Interjurisdictional Policy Reform Group this had been raised and a commitment by the Commonwealth to provide additional educational support to regional and rural areas for NCTGF implementation. In kind support from RCCCs to understand gaps and opportunities has been acknowledged.

Targets have no linear correlation, and this requires revision based on actual experience and site knowledge
Large labour component not acknowledged in RCCC Clinical Trial work particularly in conversion to Teletrials or not supported through model. (See table in Measuring Milestone Jurisdictional reports). Activities build infrastructure through experience gained in negotiation and stakeholder engagement, building knowledge of processes and familiarity with documentation. Negotiation of targets set to be presented to the MRFF executive with a discussion paper for consideration of experience gained to date and lived experience of RCCCs gaining knowledge of their workforce, legal, regularity processes and labour component of setting up TTs.

Workforce shortage and jurisdictional competition for regional, rural and remote experienced workforce.
Short term contracts and lack of permanency in clinical trial and teletrial positions inhibits ability to see beyond the number of trials in the pipeline. An Education and Workforce Development working jurisdictional group has been convened by ATP NO to provide advice to Executive leadership groups. The Queensland Regional Clinical Trial Coordinating Centre (QRCCC) has started business modelling and provided a Chief Executive Forum with a clear strategy that sees a return on investment for investing in workforce from commercial sponsor opportunities. This has been well received and there is more understanding and support and has moved closer to agreement for future sustainability.

5. *Provide a statement on your <u>overall</u> progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)*

All jurisdictions now have a pipeline of teletrials which includes interjurisdictional teletrials. Significantly there are many non-oncology and multidisciplinary clinician teams involved. Thus, proving the Australasian Teletrial model has transcended the pilot outcomes and can be applied across most clinical disciplines. We are seeing community benefit from Teletrials and appetite from the commercial sector to collaborate in trials that solve real world problems and concerns.

Cultural safety is not considered to be high across the jurisdictions, particularly Northern Territory and Western Australia. Structural marginalisation of Aboriginal and Torres Strait Islander people has continued within a colonial structure perpetuating the norms of colonialism. Structural change is required in all health services operating under this system. ATP NO has started work on the co-creation and design of a culturally safe platform for Aboriginal and Torres Strait Islander people to lead and participate in clinical trials under international rights protected and ratified by Australia. The standards of the *United Nations Declaration on the Rights of Indigenous People* and the *International Convention on the*

Elimination of All Forms of Racial Discrimination will be followed, particularly protections and standards around self-determination and consent.

As well as this, inclusion of First Nations people in the program is already being realised with three major teletrials that are working with and working for Australian Indigenous communities. Three examples are: the Victoria – Flash – Diabetes –continuous blood glucose monitoring versus regular finder prick crossover clinical trial, Northern Territory – Agile Echo- AI guided echocardiography to assist cardiovascular patient management and Agile Queensland -Deadly ear program paediatric – Drumbeat, an AI project-AI to identify Otitis media from images of the eardrum taken from video otoscope (NSW, QLD and NT collaboration).

Collaboration across jurisdictions is increasing and includes the REVitalise and NSW/ACT R3-CTEP which are looking to ATP for leadership in national harmonisation activities. The more experience jurisdictions have with teletrials the greater the momentum for harmonisation activities to implement the program successfully.

The risk management registry identifies and describes the considerable challenges the program faces to embed into each jurisdiction. The deliverables in terms of targets are not on track and will be a subject of renegotiation as suggested by the MRFF executive. Based on our experience of capacity and capability building, the infrastructure components are described within this report and on track to be completed by the project end date of 04/10/2026.

6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)*

The national policy environment is both an enabler and barrier for the progress of the ATP implementation of Teletrials. There is an opportunity to raise awareness and provide input into national policy that recognises the value and the complexities of the program across RRR locations. Barriers are faced when considering the perceived and actual nuances of jurisdictions and focus of this in regions.

Enablers
There has been recognition that a statewide team of experts in Regional Clinical Trial Coordination Centres (RCCCs) is the major enabler infrastructure investment. The role of the study start-up specialist (called Clinical Trial Coordinators in WA) is evolving as an essential conduit between commercial sponsors, researchers, and trial sites. They are first point of contact and work alongside Trial Coordinators to train and implement teletrials in non-metro areas and build capacity, capability and confidence in the team and the health service it operates under.

National representation of jurisdictions on Intergovernmental Government Policy Reform Group (IGPRG) now has as standing agenda item on advisory committees to review ATP progress and impact of NCTGF in regional settings. This has also provided a focus on clinical trials and systems required to have appropriate resources. The Communication Strategy deliverables will increase awareness and understanding of teletrials by raising the profile of the RCCCs, through a healthcare worker communications campaign and demonstrating patient benefits through real stories and case studies.

Barriers
Research Governance – inconsistencies and duplication of processes across interjurisdictional and intra-jurisdictional sites delays approval and deters commercial sponsors. National Workshop has provided several recommendations including streamlined approval from Primary sites extending to satellite sites. ATP representatives have been invited to participate in a RGO reform pilot being conducted in North Queensland, with the hopes these learnings can inform the broader program. Any streamlined model of RGO review will need to take into consideration the legal and fiduciary responsibilities of sites and consider the reluctance of jurisdictions to move to a new approval model which is a significant barrier to RGO streamlining.

Lack of knowledge of model by HRECs
Education of HRECs on the model and use of the National Supervision Plan to demonstrate role of sites and stakeholder is planned. Different data confidentiality laws and access to digital technology across jurisdictions.

7. *Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.*

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

This question applies only to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
Melbourne University	Partner	Mai purpose to engage and implement Clinical Trials/teletrials into primary health care. Please see attachment Partner report providing progress on Four deliverables: Recruitment of Statewide coordinators Number of GP practices recruited. Development of educational and training resources for GP Number of clinical trials commenced	s47F	s47(1)(b)	01/05/2022	40%
Australian Clinical Trial Alliance (ACTA)	ACTA ATP Teletrial Project	ACTA have been contracted to deliver engagement activities with clinical trial networks (CTNs) in Australia to deliver a foundations program for clinicians with a collaborative trial focus to expand teletrials to therapeutic areas. Activities are described under Teletrial Boosting Tools- milestone 1 of the progress summary report. ACTA are currently in negotiation with ATP NO to revise the next phase of contract based on advice from the Project Working Group and further feedback and consultation with the jurisdictional partners.	s47F	s47(1)(b)	1/11/2022	55%

Project Expenditure

8. *Provide details of all expenditure incurred using MRFF funding during this reporting period and the estimated expenditure for the next reporting period.*

Expenditure should be divided into the same categories as the budget in your grant agreement.

The table should indicate for each expenditure item (A), the approved budget (B) and the total expenditure: in this period (C), to date for the budget item (D) and estimated for next period (E). The comments field (F) should justify any differences between the budgeted and actual expenditure for the current reporting period, including any details of anticipated expenditure or any downstream effects of these differences.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact mrff@industry.gov.au.

(A) Expenditure Item	(B) Approved Budget (AUD)	(C) Actual expenditure for this period (AUD)	(D) Total expenditure to date (AUD)	(E) Estimated expenditure for next period (AUD)	(F) Comments
Minor Capital Works	s47G				
Materials for Construction					
Equipment					
Labour *(Excluding On-costs)*					
On-costs (capped at 30% of Labour costs)					
Contract					
Travel					
Other eligible expenditure					
TOTAL					

Comments:

i. Compared to the previous reporting period, expenditure on equipment has remained broadly stable at 90% of the budget in this reporting period. With the pipeline of trials starting to be reviewed and converted to actual trial activity, the jurisdictions will require more infrastructure support in the next reporting period(s). Accordingly, the jurisdictions have advised their plans to purchase additional equipment in next reporting period. NT for example is having ongoing discussions for purchase of additional equipment and is also locating suitable space for it while WA has forecasted expenditure relating to medication logistics and digital infrastructure in the next reporting period and is awaiting internal approval.

ii. Labour expenses (excluding on-costs) increased by approximately 14% in the current reporting which was approximately 14% over the budget for the period. The underspent amount for labour in prior reporting periods was utilised to fund the labour expenses over its budget in this reporting period.

iii. Similar to the previous reporting period, expenditure on labour on-costs continued to remain at 21% of the labour cost (excluding on-costs) in the current reporting period.

iv. Expenditure under "Contract" primarily includes subcontracting expenses and was originally budgeted under "Other eligible expenditure". Expenditure under this item accrues as per the payment terms under the contract with different sub-contractors. Payment of approximately $1.4M to two sub-contractors that was originally due in the current reporting period was agreed to be deferred to the next reporting period due to the delay in delivery. Hence, there is only nominal expense under this heading in the current reporting period. This expenditure item is added to "Other eligible expenditure" for the purpose of calculating variance against the budget.

v. Travel expense was 69% above budget for the current reporting period and has helped to offset the variance/underspent of previous reporting periods. Cumulative travel expenses now stand at 13% below its cumulative budget till the current reporting period. With the appointment of the Communications Lead at the ATP national office, the number and frequency of teletrial promotion and awareness campaigns have increased significantly and involves frequent travel to multiple jurisdictions which justifies the increase in travel expenses.

vi. "Other eligible expenditure" also includes payments against the TSP (Site set-up Payment for Primary sites and Per-patient payments for Satellite sites). Other eligible expenditure, after including expenditure against "Contract" (as per point no. iv above) and the TSP was short by approximately 86% compared to the budget for the current reporting period. The cumulative total expenditure of TSP till the current reporting period has remained nominal at $0.07M against a cumulative budget of $7.17M which is the key contributor for the significant variance in 'other eligible expenditure'. The lower than forecasted number of teletrial participants and the slower than anticipated

time for commencing teletrial activities in new sites has led to the increasing variance in TSP over the reporting periods.

vii. During the current reporting period, total expenditure was under budget by approximately 36%. This was primarily due to underspent TSP funds resulting from smaller number of teletrial participants across all jurisdictions during the current reporting period. As the teletrial activities increase in future reporting periods, this will result in an increase in expenditure across all headings thereby reducing the total gap between budget and actual expenditure.

9. *Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)*

All expenditure incurred during the reporting period is eligible under the scheme Guidelines.

As indicated in the previous progress report, a total sum of $1,276 relating to recruitment expenses for ATP National Office, incurred during prior reporting periods, is ineligible under the scheme Guidelines. Entries relating to ineligible expenses were incorrectly posted however, the entries could not be reversed due to identification of the entries after the expiry of the accounting cut-off date for the financial year. Following identification of the ineligible expenses, ATP National Office has undertaken following actions:

- Given that the ineligible expenditure incorrectly allocated against the cost centre of the program could not be reversed, ATP National Office has developed a plan whereby Queensland Health will reimburse an expenditure relating to the project valued at not less than $1,276. The expenditure reimbursement journal will be entered by 30th June 2024 and will be reflected in the progress report for the reporting period 01 April 2024 to 30 September 2024
- To prevent reoccurrence of such errors, ATP National Office has set up a system to review all project related financial transactions reflected in its books at the end of each month. Such month-end reviews not only identify incorrect entries, the early identification means any incorrect entries can also be reversed.

The risk of such errors has been acknowledged, assessed, and entered in the risk register along with the action plans. The risk register will be reviewed, and the risk of such errors will be assessed against the action plans on an ongoing basis.

10. *Provide details of any partner contributions received during this reporting period and indicate whether each contribution has been made as expected. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.*

If a contribution has not been made as expected, describe the impact of any delays or changes to the delivery of the Research Activity. If the project does not have partners that committed to make cash or in-kind contributions, select N/A in the table below.

Name of Partner	Type of Contribution	Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
enter name of partner organisation	Select	enter amount in $AUD	enter amount in $AUD	enter comments describing the impact of any delays or changes to the delivery of the Research Activity

Project Evaluation

11. *Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the MRFF Monitoring, Evaluation*

and Learning Strategy (November 2020) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were required to be submitted with the application, select N/A in the first row of the table below.

For each Measure of Success applicable to your project:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.)
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

Add rows as necessary.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress
Select	enter outcome/result from application	enter comments summarising anticipated progress	enter comments summarising actual progress to date
More Australians access clinical trials	5000		127
New clinical Trial sites	2430		47
Improved clinical trial sites	810		37
New clinical trials	203		43
No of people educated	5000		3312

12. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)

Appetite for teletrials and momentum for the Australian Teletrial Program is increasing across Victoria, Queensland, South Australia, Western Australia, Tasmania, and the Northern Territory. Tangible community benefits from teletrials are being recognised within clinical and research networks, with large numbers of patients being recruited for non-oncology studies such as the first ever sexual diseases teletrial in Central Queensland. The use of AI to detect Rheumatic heart disease in the Agile Echo TT helps reduce the number of First Nations people living in and around Alice Springs from travelling off-country to Adelaide for investigation. Patients accessing dermatology teletrials in the La Trobe region now have access to a service not offered outside of inner Melbourne. Multidisciplinary clinicians are receiving specialist training providing professional development and care opportunities through these TTs. Upcoming trials include a fragility study that will directly benefit a community with growing elderly population that is struggling to recruit and retain allied and primary health workers post Covid, a multi-site gynaecology teletrial to improve the health of First Nations women living in remote areas, as well as practical and useful alternative diabetes models of care.

The six Regional Clinical Trial Coordination Centres are working collaboratively to identify sites for “clusters” of multi-jurisdictional teletrials having gained in-depth knowledge of sites and working with them to build their capacity and capability to participate and or lead a teletrial. In the rare cancer space across jurisdictional collaboration for teletrials gives greater access and recruited numbers for new treatments in paediatrics and adults. This means evidence builds quicker for greater universal access in Australia treatments.

Your response may be used in public communications about the MRFF, and that you may be contacted to expand on your response below. Please indicate whether any of the information you provide is commercial in confidence.

Attachments

Attach any agreed evidence required above (e.g. updated risk management plan).

- Monitoring Indicators Jurisdictional Report
- Partner Network Report
- Risk Registry

- Promotion Awareness Appendix

Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Appendix 2

Medical Research Future Fund National Critical Infrastructure Initiative – 2019 Rural, Regional and Remote (RRR) Clinical Trial Enabling Infrastructure grant opportunity: monitoring indicators progress report.

Measure One: Increased focus of research on areas of unmet need

This measure considers the extent to which outcomes of MRFF-funded research:

- *identifies areas of unmet need and facilitates more research into these areas*
- *leads to new health treatments, drugs, interventions, devices and diagnostics*
- *embeds such approaches into clinical practice*

Please note that this report is consolidated from the responses from six partner jurisdictions therefore, for each milestone measure, we have provided a response from our partner jurisdiction under their own headings.

What approaches have been employed to ensure key areas of unmet need (as identified by the Grantee) are being met?

Each ATP partner jurisdiction has now have had critical insight into their political, social and cultural environment. Taking these into consideration they have provided their response on the identification of areas of unmet need below.

Northern Territory:

Implementation of the pre-ANVU Teletrial in Darwin, Northern Territory as a cross-jurisdictional Teletrial with Queensland, Tasmania, and South Australia

The Queensland Centre for Gynaecological Cancer Research (QCGC) contacted the Northern Territory branch of the Australian Teletrial Program (ATP-NT) in December 2023 after the Alan Walker Cancer Care Centre in the Northern Territory (NT) was unable to provide medical oncology support for the pre-ANVU clinical trial (CT) due to workforce shortages. QCGC had discussed the trial with an NT based s47F who was eager to be involved but lacked capacity to progress this CT through the submission and startup process due to an overburdened surgical workload and no dedicated research support staff. The ATP-NT team met with the Principal Investigator associated with the trial, the NT surgical oncologist and QCGC research coordinators to discuss the feasibility of establishing the pre-ANVU trial as a Teletrial. Initial meetings identified the opportunity for this CT to be run as a cross-jurisdictional Teletrial with in collaboration with the Queensland ATP team, with Darwin acting as a satellite site to a Queensland primary site. This case study explores the implementation of the pre-ANVU vulvar cancer trial as a cross-jurisdictional CT under the Australian Teletrial Program model.

About the trial: The pre-ANVU trial is a prospective, experimental, non-randomised study to assess the feasibility of groin ultrasound to predict lymph node involvement with histologically proven vulvar cancer with an overall aim to evaluate the use of less invasive approaches such as ultrasound to accurately diagnose vulva cancer and detect lymph node involvement (1).

Establishing the Teletrial Cluster: The ATP-NT contacted ATP-QLD personnel to explore the suitability of establishing the pre-ANVU trial as a cross-jurisdictional Teletrial and to introduce the sponsor to the Queensland team. All those involved in these conversations agreed that setting up pre-ANVU as a cross jurisdictional Teletrial was fitting with the vision and objectives of the ATP to create an interconnected clinical trials system that would enable all Australians equal access to clinical trials, which was further bolstered when the sponsor requested the inclusion of South Australia and Tasmania to the trial. While pre-ANVU has received Ethics approval in Queensland, the trial has not yet finalised some components of the Teletrial model, such as sub-contracts and a supervision plan, however this is expected to occur in the coming months, with a goal to commence enrolling patients by mid-2024. Presently, there are four states included in this Teletrial cluster, with the primary site located in Queensland, and satellite sites in Queensland, South Australia, Tasmania, and the Northern Territory, covering more than 8,000 kilometres.

Observed benefits: Despite being a rare cancer with an incidence of 2.5/100,000, equating to 400 Australians diagnosed every year, vulvar cancer and its associated treatments cause significant morbidity (1). Moreover, the Northern Territory experiences higher rates of vulvar cancer than the rest of Australia, particularly in First Nations populations. Indeed, a report published by the Menzies School of Health Research in 2017 cited studies identifying the incidence rate of vulvar cancer in East Arnhem in the NT at over 50 times the national Australian rate, and the highest identified anywhere in the world (2). Due to the rarity of the disease, enrolling enough participants to a CT remains difficult, facilitating the need to cast a wide geographical net to ensure recruitment targets are met, allowing for statistically significant results which may inform future practice. Patients living in RRR areas of Australia often miss the opportunity to be enrolled in CTs such like pre-ANVU as those who meet inclusion criteria may only number one or two, and the additional workload placed on clinicians for involvement in CTs can

overburden already stretched-thin clinics and staff. The ATP in this instance offered a way for clients and clinicians living in RRR areas to participate in CTs by enabling less experienced or smaller Satellite Sites (SS) to be added as trial sites under the supervision of a Primary Site. Though this case study does not involve a formal evaluation, using the Teletrial model increased equity in trial accessibility by affording patients diagnosed with rare vulvar cancer, including those living in MM7 Modified Monash Model classified regions of the NT, the opportunity to participate in a CT that they would likely have been excluded from in standard trial models (3). On top of the importance of providing equitable access to CTs, the value of diversifying trials by including those living in RRR areas, First Nations people, culturally and linguistically diverse (CALD) populations, and participants from a variety of socioeconomic backgrounds cannot be underestimated, where a lack of representation may lead to less effective medical interventions (4). Finally, the NT-based surgical oncologist involved in this CT stated that taking on the trial without logistical support from the ATP-NT would have been very difficult due to a demanding work schedule and limited research coordination support.

Enablers and challenges: Having previously conducted several Teletrials in the Northern Territory, including a cross jurisdictional trial with South Australia, the ATP-NT had experience in engaging with other jurisdictions, simplifying the process of establishing this Teletrial as interstate relationships were 3 already formed, and start-up procedures well-defined. The benefit of identifying a Queensland location as being the Primary Site for the trial meant the inclusion of the very experienced ATPQLD team as collaborators on this Teletrial, which allowed for additional logistical support and mentoring for the ATP-NT team. The sponsor, trial PI in QLD and AI in NT were all experienced in conducting trials and had existing relationships with each other due to their work in the field gynaecological cancer, with this familiarity streamlining meetings in the establishment of the trial and delegation of duties. As the trial sites were in different states, clear communication regarding the different requirements in each jurisdiction was essential, both with the sponsor and between the primary and satellite sites, while regular check-ins between sites ensured submission processes were as streamlined as possible. One challenge of the trial was arranging online meetings between the sponsor, PIs, AIs and ATP staff which suited everyone's work schedules and other commitments, while taking into consideration different time-zones. Telecommunication and online calendars/scheduling made this possible and is demonstrative of the value of such technologies in the clinical trial space.

Recommendations/Future directions: This case study underscores the value in establishing cross-jurisdictional trials to meet areas of unmet need - such as research around rare cancers - by linking sponsors and sites in different states under the Teletrial model, allowing for more diversity in trial participants, greater access to clinical trials for those living in RRR areas, and increased patient enrolment. As such, opportunities to establish cross-jurisdictional Teletrials should always be considered in early discussions with sponsors and clinicians active in the clinical trials space.

References:

1. University of Queensland. Feasibility of Groin Ultrasound to Predict Groin Lymph Node Involvement in Patients with Histologically Proven Vulvar Cancer and Feasibility of Biomarker Discovery in the Differential Diagnosis of VIN versus Invasive Vulvar Cancer Pre-ANVU (Australian National Vulvar Cancer Trial) Establishing a Novel Pathway to Best Practice Treatment in Vulvar Cancer. 2024 Jan.

2. Condon J. A Vulvar Cancer Cluster in Indigenous Women in Arnhem Land: Report 2017. Menzies School of Health Research [Internet]. 2017 [cited 2024 Apr 18];Version 1.2. Available from: https://www.menzies.edu.au/content/Document/Report2017_v1_2.pdf

3. Australian Government Department of Health and Aged Care. Modified Monash Model [Internet]. Australian Government Department of Health and Aged Care. 2019. Available from: **https://www.health.gov.au/topics/rural-health-workforce/classifications/mmm**

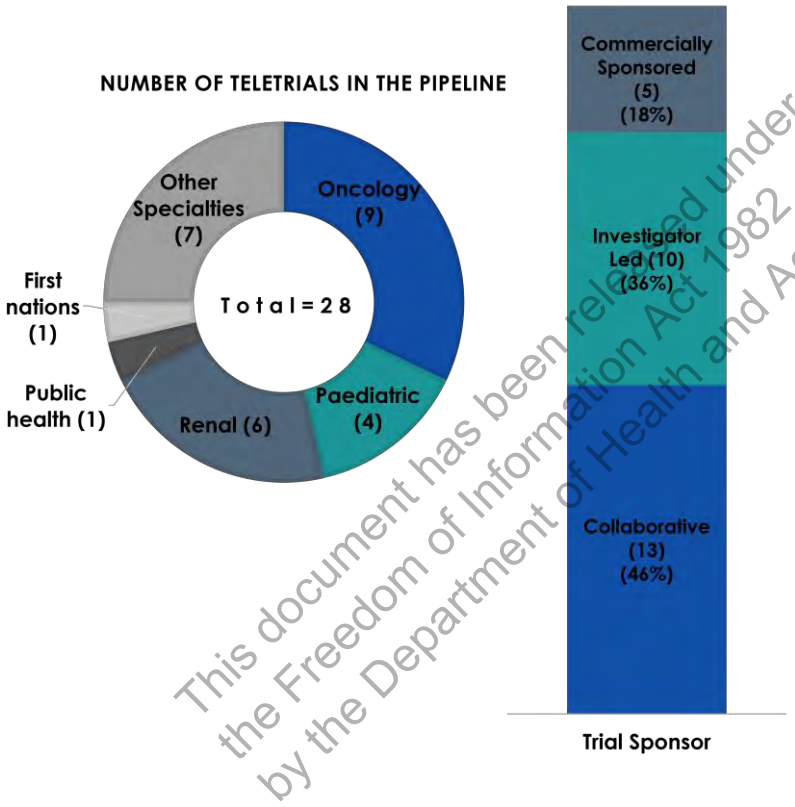
4. Straiton N. Clinical Trial Awareness and Access Amongst Culturally and Linguistically Diverse (CALD) populations: Environmental Scan. 2020.

Queensland:

Queensland has identified and attracted key commercial sponsors for a trial in sexually transmitted disease which is an area of unmet need.

Queensland have supported a Regional Public Health Unit site in regional QLD to be trained and ready to undertake a clinical trial as a teletrial. Setting up the cluster, supporting both the commercial sponsor and CRO through what is required to conduct a clinical trial as a teletrial as well as the three sites in the cluster. The site is now enrolling participants and the community will benefit from assessment and identification of the Sexually Transmitted Infection (STI) which can be insidious, not causing any symptoms but can have health impacts well into the future for those that have the STI.

Furthermore, there are 28 more teletrials in the pipeline as listed below, the graphs provide an overview of the trial sponsor type and the medical specialty:



PS – Primary Site; RGO – Research Governance Officer; CRC – Clinical Research Coordinator; HREC – Human Research Ethics Committee; SS – Satellite Site

Trial	Trial Sponsor	Status
Australian Lung Screening Trial Preventative Oncology	Collaborative	HREC approved
Alexion Children's Rare Disease Paediatric	Commercial Sponsored	HREC approved
CBD4TS (Tourette's – Children's) Paediatric	Investigator led	RGO
Children's Palliative Care Trial Paediatric	Investigator led	HREC
DRUMBEAT Paediatric	Investigator led	HREC
EZEF (LPa) Cardiology	Commercial Sponsored	Approved and open
Beigene_BGB43395-101 Oncology	Commercial Sponsored	Potential
Anaesthetic Trials (ANZCA Trials)	Investigator led	Open
Fittest UQ (Allied Health)	Investigator-led	In HREC
MEDCAN 3 Palliative Care	Investigator-led	RGO approved
Most- Circuit Oncology	Collaborative	Open
MoST-TAP Oncology	Collaborative	HREC
P3BEP Oncology	Collaborative	Open
pre-ANVU Oncology	Investigator-led	HREC
QLD Family Cohort (QFC)	Investigator-led	HREC
REIMAGINE 2 Endocrinology	Commercial Sponsored	PS – Open SSs - RGO
REMODEL DT2DGP Endocrinology	Investigator-led	HREC
Impede Renal	Collaborative	Open
Phosphate Renal	Collaborative	Open
SWIFT Renal	Collaborative	Open
Renal Lifecycle Renal	Collaborative	RGO
Captivate Renal	Collaborative	-
Beat-Calci Renal	Collaborative	-
REZOLV3R Oncology	Collaborative	-
SANOFI VAV00007 Public Health	Commercial Sponsored	Open
STOPNET Oncology	Collaborative	HREC
Strong Families Study_ First Nations-Mater First Nations	Investigator-led	
XPORT-EC-042-ANZGOG Oncology	Collaborative	RGO

In addition, the QRCCC is resourced to provide additional funding to incentivise these sites and support the growth of the program and access to clinical trials outside of metropolitan areas. All teletrials primary sites can receive the Teletrial Support Payment, and in August 2024, ATP received permission to include MM2 postcodes for satellite payments per patient.

South Australia:

SA is working through the process to establish a mental health trial in the prison population.

Through a collaboration with University of South Australia Department of Rural Health, a new teletrial has been designed to support the mental health needs of people in custody in rural South Australia. This study is addressing pressing, yet underserved, mental health needs of people in custody, especially those in rural areas.

Accessing mental health services in rural communities in Australia and including South Australia is challenging. The University of South Australia is investigating the effectiveness of evidence-based mental health treatments within the correctional system. Prison nurses are being trained in online Cognitive Behavioural Activation Training and then delivering it to persons in custody.

Working across four prison sites – Port Lincoln, Port Augusta, Mobilong (near Murray Bridge) and Cadell – nurses are completing UniSA's online Professional Certificate in Behavioural Activation for Depression with researchers assessing their ability to better support people in custody experiencing symptoms of depression.

Australian Teletrial Program – South Australia is supporting this study by providing hands on resources through the regional Nurse Consultants – Clinical Research Coordinators and the Cluster Start Up Specialists. The ATP-SA Clinical Trials Liaison Officer is also a co-investigator on this study. The Teletrial Support Program payments have been a key factor in driving this feasibility study so the data can be used to inform future work in this area.

Prison nurses are receiving specialist psychosocial training as part of this new University of South Australia research project to support the mental health needs of people in custody in rural South Australia. The ATP-SA Nurse Consultant – Clinical Research Coordinator in the Riverland is involved in screening and consenting participants at Mobilong and Cadell prisons.

Tasmania:

While Tasmania is yet to establish its first Teletrial, the Tasmanian RCCC have negotiated several potential studies that address an unmet need, including:

Gynaecology: one trial involving a potential change in the diagnosis and treatment of rare vulva cancers, which was identified as an area lacking in research and resource.

Service areas where there is a very active research unit at one health service but much less at another health service:

Women's and Childrens services research at Launceston General Hospital (LGH) to be developed learning from substantial work at the Royal Hobart Hospital (RHH).

Clinical Trials within cardiology at the LGH learning from the unit at the RHH that has a strong research culture and willingness to collaborate. This may be facilitated through the Statewide Cardiac Network.

Victoria:

RCCC-VIC: *There are 23 trials in place and with 11 in established and 12 in start-up phase encompassing various specialties.*

Trial Name	Sponsor (CRG, Commercial)	Therapeutic Area	Activity Status (Ongoing, established) -Include any discussions/information sharing
SEALAND	Collaborative Group	Haematology	Established/Active Recruitment
FRAIL M	Collaborative Group	Haematology	Established/Active Recruitment
DASL HI-CaP	Collaborative Group	Prostate Cancer	Established/ In Follow Up
IRIL	Collaborative Group	Myeloma	Established/Active Recruitment
LIBRETTO-432	Commercial Sponsor	Lung Cancer	Established/Active Recruitment
RESOLUTE	Collaborative Group	Colorectal Cancer	Established/Active Recruitment
TARGET-TP	IIT	Oncology	Established/Active Recruitment
DURATION	IIT	Lung Cancer	Established/Not Recruiting
UNICAB	Collaborative Group	Oncology	Established/Recruiting
COAST-1	Commercial Sponsor	Dermatology	Established/Recruiting
SUNRAY-01	Commercial Sponsor	Lung Cancer	Established/Recruiting
TRIGS	Collaborative Group	Anaesthesia/Surgical	Startup
FITTIST	University	Geriatric	Startup
Back on Track	University	Mental Health	Startup
FLASH GM	University	Diabetes	Startup
EXTEND-IADNase	Collaborative	Stroke	Startup
STOPNET	Collaborative	Neuroendocrine Tumours	Startup
icuRESOLVE	University	Recovery for ICU survivors	Startup
ACCLAIM	Commercial	Cardiovascular	Startup
BONEZONE	Collaborative Group	Osteoporosis/Critical Illness	Startup
CADET	Collaborative Group	Depression and bipolar disorders	Startup
PRIME	University	Epilepsy	Startup

REZOLV3R	University	Oncology/Malignant Ascites	Startup

IIT = Investigator Initiated Trial

Victorian Hubs:

Bendigo

At Bendigo Health we have recognised stroke research as a specific health need for our community. With this in mind we are currently working through converting 3 stroke trials and becoming a site once conversion is complete.

GV Health

Currently, five teletrials are being conducted at GV Health and two new teletrials are pending approval. As an example, 46% of total cohort of the TARGET-TP trial consisted of regional/rural patients. Patients at GV Health were able to access and experience the benefits of this trial which targets thromboprophylaxis in ambulatory patients receiving anticancer therapies for lung or gastrointestinal cancers. Furthermore, patients with locally advanced or metastatic non-clear cell renal cell carcinoma post immunotherapy or who are unsuitable for immunotherapy were able to access cabozantinib as part of a phase 2 UNICAB trial, under the Teletrial model. Rare oncology/haematological conditions are targeted at GV Health, this often results in a high number of screen failures for teletrials where patients are not recruited, however site resources are used.

Latrobe Regional Hospital

Teletrials have enabled our local patients access to new and innovative treatment options. We have recently opened a teletrial as a satellite site with a metro primary site which enables access to treatment for atopic dermatitis. Dermatology is not a service offered locally requiring individuals to travel large distances to seek specialty treatment. With the opening of this trial Gippsland residents can now receive treatment closer to home. In addition, the trial enables clinicians and research nurses to receive specialised training from a metropolitan centre thus providing an opportunity to expand their current skillset. Ultimately the model will improve our capacity in a speciality area where we previously were unable to provide care.

Northeast Health Wangaratta

Individual meetings with potential PIs to understand patient cohorts and specific areas of interest/need

Continuous updates to our Site Profile to reflect capacity and capability to potential sponsors

Our current teletrial is targeting a rare subset of a larger health condition. It is enabling treatment to occur locally for some components thus decrease travel to metropolitan sites. (Experiencing delays to recruitment related to a major protocol amendment)

Continuous review of Clinical Trial Databases to facilitate match of site unmet need with current clinical trial opportunities with respect to Teletrials.

South West Healthcare

Education and Training log has shown a substantial amount of education for our clinical trials team, as well as SWH clinicians who will become PIs on upcoming/new teletrials and trials.

New staff members recruited and trained within the Clinical Trials team, increasing our capacity and expertise.

Enabled SWH to build and set up clinical trials in disciplines outside of Oncology and Haematology, providing better access and potential outcomes to our community. Utilising the teletrial model we are undertaking feasibilities to participate in trials in diabetes, stroke, emergency care and anaesthetics.

Set up is almost complete for teletrials that will enable regional residents access and care closer to home (BoneZone and FITTEST). Increasing the ability to participate in a clinical trial that they would otherwise need to travel a substantial distance to participate in.

Western Australia:

WA has identified the inability to deliver clinical trials in rural, regional and remote areas as their primary area of unmet need.

A state-wide, change management approach has been taken to ensure WA Health sites adopt Teletrials safely and with confidence, especially within the context of critical workforce shortages and budgetary constraints.

The development of a regional, patient-centred trial eligibility and prioritisation review process was a significant focus of 2023/2024. Epidemiological data and areas of unmet need across the state are considered in the trial review process. A prioritisation framework is under development in consultation with the Clinical Advisory Group and Consumer Reference Group to systematically ensure areas of unmet need are prioritised in a way that is meaningful to regional communities. A formal regional clinical review pathway is also an evolving process within this governance model. At time of submission, 56 trials have been reviewed for eligibility and priority. Of the Teletrials that have initiated, we have had very successful launch in the regions with recruitment to trials occurring within the first week of activation for both studies.

A central service has been set up to flexibly support regional staff with experienced clinical trialists. The WARCCC staff can provide either virtual or ground support, depending on the capability of regional staff and the complexity of the trial. While local employment is supported where feasible, this model ensures that the program's central aim of improving patient equity of access to clinical trials across all regions is not compromised by the deployment of limited staff at certain sites.

Measure Two: More Australians access clinical trials.

This measure considers the extent to which outcomes of MRFF-funded research:

create better opportunities for Australians to access clinical trials by funding activities that support research to progress to the clinical trial stage, and directly supporting additional clinical trial activity.

builds Australia's clinical trial capability and leadership at the national and international level.

The jurisdictions have responded to capacity building under these four headings: **knowledge building, leadership, valuing community, community building.** Some of the jurisdictions have chosen not to respond as they have addressed these in other sections.

Northern Territory:

As part of our ongoing commitment to advancing clinical research and promoting excellence in healthcare, we have been actively engaged in a range of capacity building activities at our sites. These initiatives aim to enhance skills, foster leadership, value community involvement, and strengthen networks, ultimately contributing to the success of our clinical trials endeavours. Below, we outline examples of our efforts across these key areas:

Knowledge Building:

We've been actively engaged in enhancing skills through various initiatives, such as collaborating with the NT Health Education Department to integrate the A-CTEC training platform into the NT Health education and training portal. Additionally, we're planning to conduct another face-to-face Good Clinical Practice training/certification session in the coming months, further empowering our clinicians with the skills and proper certification to participate in clinical trials.

Leadership:

The ATP-NT has successfully establishment of the RCCC as a central coordination point for research and clinical trials activity in the Northern Territory. Moreover, we've initiated and are chairing the research coordinators support group, facilitating connections among research coordinators in the NT for mutual support and knowledge sharing, thus nurturing leadership at various levels.

Valuing Community:

The ATP-NT actively participates in all ATP working groups and committee meetings, fostering collaboration and unity with the ATP team at a national level. Furthermore, we've prioritized establishing relationships with First Nations communities and organizations, ensuring that cultural safety is embedded in the ATP-NT platform, thereby valuing, and respecting the diverse communities we serve.

Network Building:

We recognize the importance of partnerships and alliances in advancing our objectives. Our participation in events such as the Australian Clinical Trials Alliance (ACTA) conference in Melbourne and hosting our inaugural clinical trials showcase event in December 2023 has enabled us to forge new partnerships and strengthen existing ones. These efforts have resulted in collaborations with eight new sponsors and abstract submissions to conferences like the A-CTEC 2024 conference and the National Nursing Forum. We're thrilled that our abstract for the A-CTEC conference has been selected, affording us the opportunity to present a poster at the upcoming event.

Queensland:

The Queensland Regional Clinical Trial Co-ordinating Centre (QRCCC) has led by using their knowledge and expertise in teletrials to support sites through the whole processes and flow of how a clinical trial works and then how that can be expanded using the teletrial model. Articulating the benefits of using the teletrial model to allow RRR patients to have access and presenting to all levels of the health service personnel so that understanding is gained by the relevant parties. Underpinning the progress of Queensland has been a mobile workforce, a commitment to building relationships across the hospital and health services and educating and training staff through information through building a Community of Practice for Teletrial Coordinators and Clinical Research managers in Queensland, regularly presenting the Research Directors and Health Services Chief Executives Forum. Finance, business, clinicians, executives, research teams and supporting departments required for trials to take place have all been involved and now we have a good platform and pipeline of teletrials in Qld.

South Australia: **Not answered.**

Tasmania: **N/A**

There are no current clinical trials under the ATP in Tasmania.

While Tasmania is disappointed it has not yet generated a clinical trial under the ATP project, there are currently two trials very close to commencement under the program.

Victoria:

Knowledge building:

Training Opportunities. Clinical trial coordinators and assistants from departments at each organisation continue to attend a variety of training sessions and workshops to increase knowledge and capacity of clinical trial and teletrial projects. Workshops include reviewing local trial SOPs, local safety reporting procedures and collection and collation of trial data.

CTRSS-ATP Medical Officer developing roadshows for clinical staff at regional hubs.

RCCC-VIC teletrial training sessions for research team members, sponsors and CROs. Sessions are conducted via Microsoft Teams and are instructor-led.

Three teletrial training modules are available:

Introduction to Teletrials

Setting up a Teletrial- Evaluation and Feasibility

Setting up a Teletrial- Ethics and Governance

Three ethics and governance Ethics Review Manager training modules are available:

Introduction to ERM

SSA Application

Post-approval/Post authorisation

Education. Clinical trial staff actively engage in education including GCP and completing VCCC SKILLED and A-CTEC courses.

Work completed by several sites for ACTA conference including:

LRH completing two poster presentations at ACTA

Study Start-Up Specialist in collaboration with 7 hubs created the ATP-VIC teletrial brochure for distribution at ACTA promoting teletrials across rural and regional Victoria.

Study Start-Up Specialist (SSSs) work collaboratively with new CTRSS-ATP staff providing initial orientation and training and this is ongoing. SSSs more involved with new teletrial proposals and meeting with potential companies/ researchers.

ERM Training

GVH- ATP staff attending ERM training sessions to translate knowledge to trial staff on submission of clinical trials and teletrials for ethics review.

SSSs provided education and support regarding the TSP and IMP management for a potential teletrial to the CTRSS-ATP and Clinical Trial Pharmacist at Grampians Health and Bendigo Health's Cancer Research Manager.

Leadership:

Sharing Information. Seven Regional hubs (CTRSS-ATP members) and SSSs collaborate and meet to share clinical trial and teletrial information, discuss potential new teletrials and gather new learnings.

SSSs continue to build relationships, facilitate meetings with sponsors and collaborative groups and promote hubs capabilities.

Meeting of Operations Advisory Group (RCCC-VIC) monthly agenda supports shared learnings and information.

Valuing community:

Promotional. Wider reach into social media via organisation Facebook pages to promote clinical trials unit, clinical trials activity and highlighting the potential access to clinical trials in regional areas.

SWH- Participant story highlighting their involvement in a clinical trial and attending the trial closer to home published on SWH Facebook page. (Status Report)

NHW- Publication of interview with CTRSS-ATP and participating in trials closer to home in local newspaper.

LRH-Presentation at the Gippsland Regional Showcase of trial and teletrial activity at LRH.

RCCC-VIC. Consumer Engagement Group- Infographic (see attached)

Network building:

Events. Several regional hubs have hosted events at their organisations showcasing and promoting trials and teletrials.

Barwon hosted their annual research symposium highlighting the dedicated research community and the work carried out to improve the health outcomes of the community. CTRSS-ATP coordinator submitted posters for the symposium and also made a presentation.

Bendigo Health Research Week contributed article in teletrial newsletter.

ACTA conference was attended by RCCC-VIC and regional hub representatives including from Southwest Healthcare, Latrobe Regional Hospital and Bendigo Health.

Industry Engagement Group (RCCC-VIC) meeting to engage commercial sponsors to adopt the teletrial model and learn about their perceived barriers to taking up teletrials.

RCCC-VIC meeting with Investigator Initiated and Collaborative Groups to promote understanding of the teletrial model and provide information and resources (see Measure 1)

ATP-VIC- In Feb 2024, ATP-VIC hosted the National Clinical Trials Governance Framework- Learnings from 2023. The aim of the event was to present the learnings shared from the Short Notice Assessments conducted from 2023 with a metropolitan and regional public health service perspective. This engagement activity included Victorian HREC Managers and Research Governance Officers (RGOs), clinical staff, quality and administration.

The breakdown of individuals that registered, attended in person, and virtually is presented in the table below.

Number Registered	Number Attended- In Person	Number Attended- Virtually
97	93	4

The outcomes of the event included increased understanding and sharing the learnings from 2023 short notice assessments against the two new standards for clinical trials. Shared learning and discussion, all presentations were shared with attendees.

Please complete the tables on the following pages to record:

the number of new or improved clinical trial **sites** (TABLE 1),

the number of new clinical trial **participants** (TABLE 2), and

the number of new **clinical trials** (TABLE 3);

directly linked to your project activities.

TABLE 1: Number of new or improved[1] clinical trial sites by state or territory and MMM Code

(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

Note: enter 'N/A' in the respective State or Territory field if it does not apply to your project.

State/ Territory		**Target** for achievement by Project Completion	**Actual number of new or improved sites (cumulative total, project to date)**							
			MM1	**MM2**	**MM3**	**MM4**	**MM5**	**MM6**	**MM7**	**Total**
NT	New Sites	32	0	5	0	0	0	0	4	9
	Improved Sites	11	0	0	0	0	0	1	0	1
QLD	New Sites	851	6	16	1	1	0	0	0	24
	Improved Sites	283	10	13	0	0	0	0	0	23
SA	New Sites	332	0	0	1	1	1	1	0	4
	Improved Sites	111	3	0	1	0	0	0	0	4
TAS	New Sites	32	0	0	0	0	0	0	0	0
	Improved Sites	11	0	0	0	0	0	0	0	0
VIC	New Sites	972	0	0	8	0	0	0	0	8
	Improved Sites	324	6	1	0	0	0	0	0	7
WA	New Sites	211	0	0	2	0	0	0	0	2
	Improved Sites	70	0	0	2	0	0	0	0	2
Total	**New Sites**	**2430**	**6**	**21**	**12**	**2**	**1**	**1**	**4**	**47**
	Improved Sites	**810**	**19**	**14**	**3**	**0**	**0**	**1**	**0**	**37**

[1]clinical trial sites with improved capacity (i.e. increased trials) and/or capability (i.e. new types of trials)

TABLE 2: Number of clinical trial participants by state or territory and MMM Code

(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

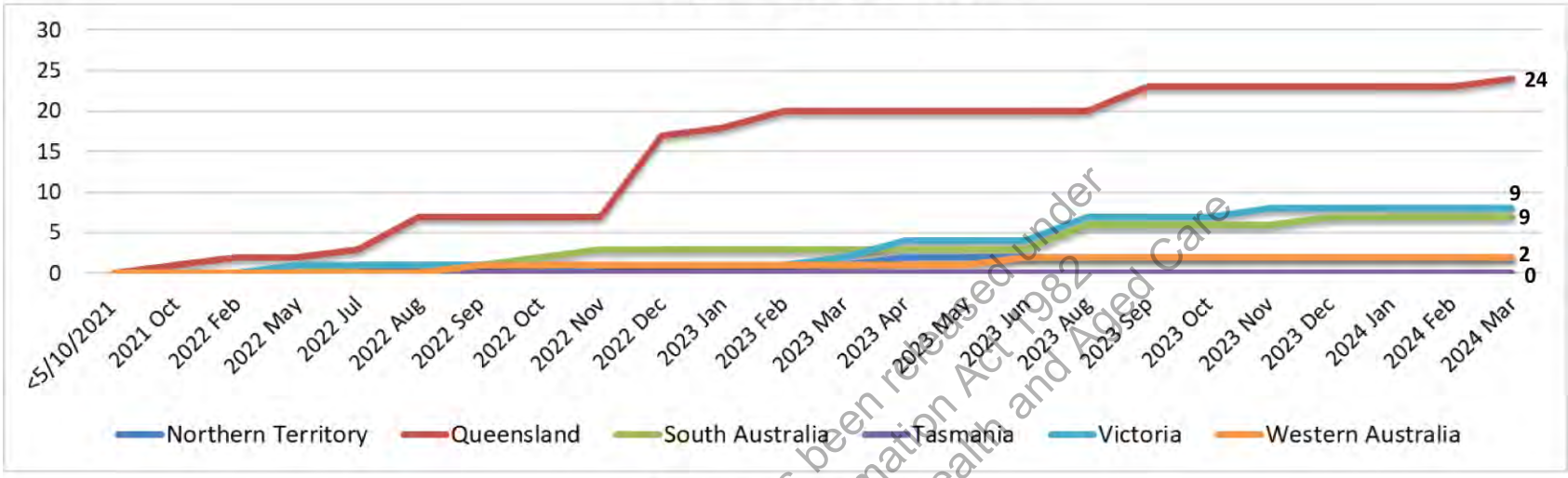
State/ Territory	**Target** for achievement by Project Completion	**Actual number of new clinical trial participants (cumulative total, project to date)**							
		MM1	**MM2**	**MM3**	**MM4**	**MM5**	**MM6**	**MM7**	**Total**
ACT	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NSW	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NT	68	S47F							
QLD	1750								
SA	682								
TAS	68								
VIC	2000								
WA	432								
Total	**5000**	S47F							**127**

TABLE 3: Number of new clinical trials by state or territory and MMM Code

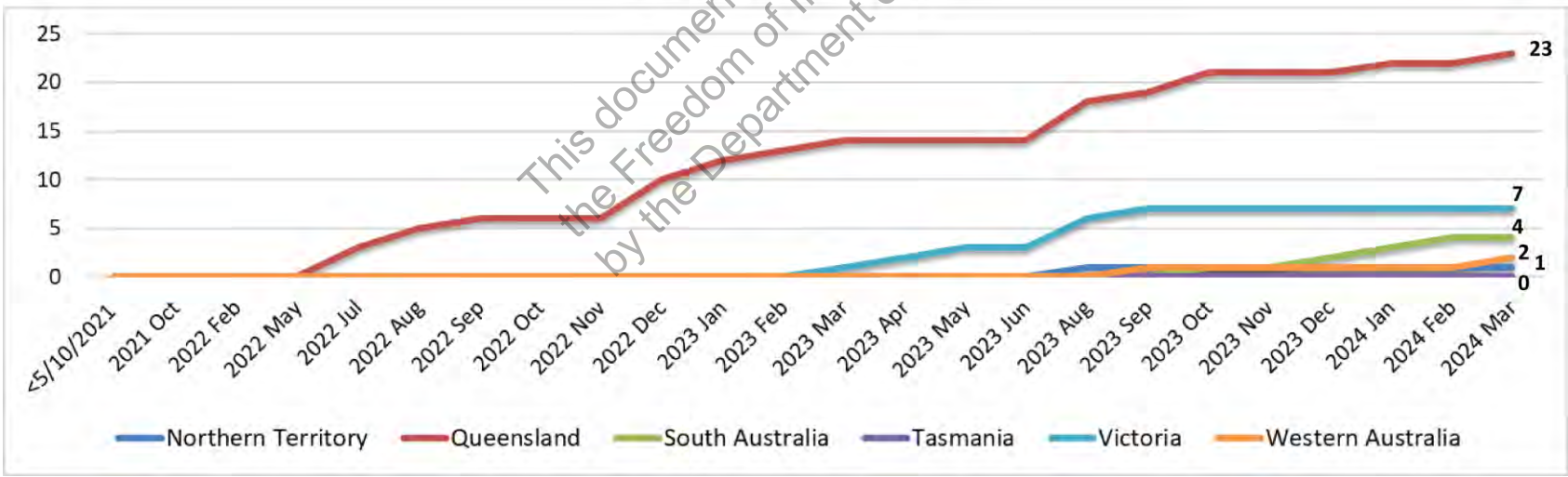
(For MMM Code guidance: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator)

State/ Territory	**Target** for achievement by project completion	**Actual number of new clinical trials (cumulative total, project to date)**							
		MM1	**MM2**	**MM3**	**MM4**	**MM5**	**MM6**	**MM7**	**Total**
ACT	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NSW	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NT	3	S47F							
QLD	71								
SA	28								
TAS	3								
VIC	81								
WA	17								
Total	**203**	S47F							**43**

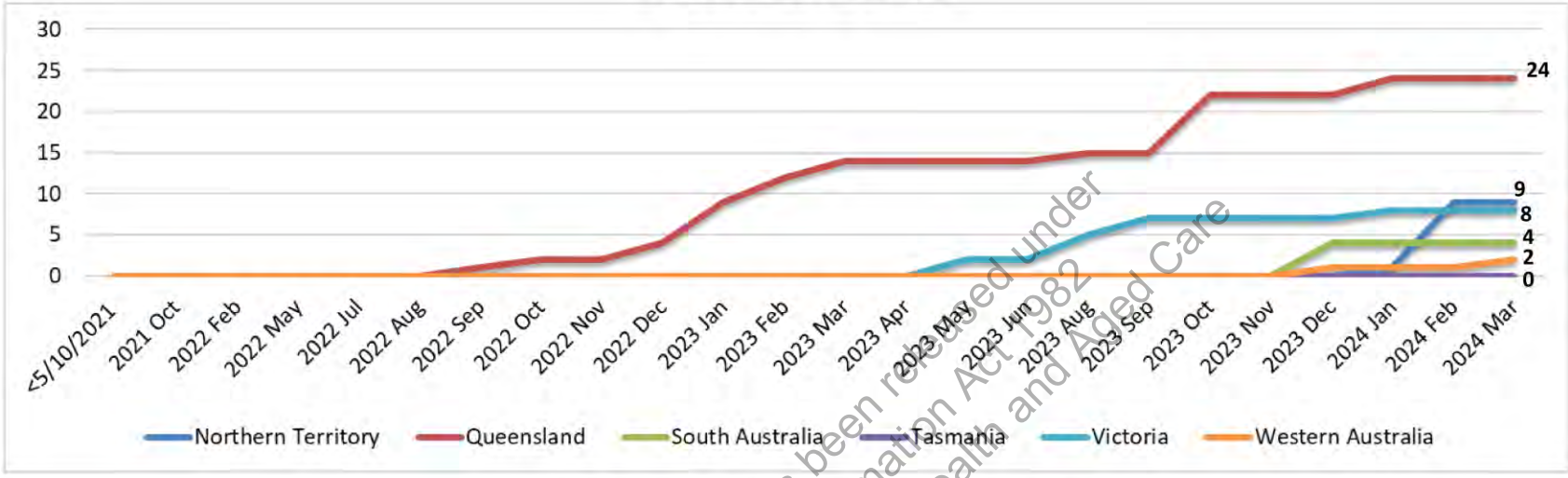
Trial Registrations



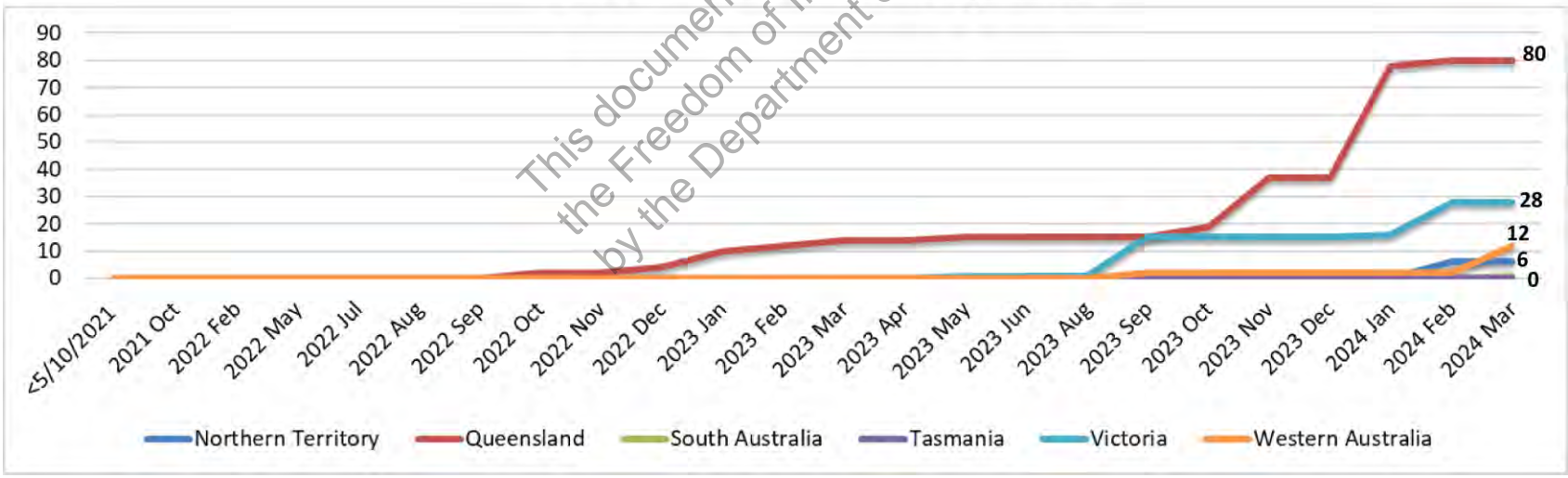
Primary Sites



Satellite Sites



Satellite Site Participants



For new clinical trials generated by your project activities, please provide the number of clinical trials by:

Demographics of population (e.g. ATSI, CALD)

Age group of target population (i.e. youth/paediatric; adult; older people)

Disease type (e.g. oncology)

Sponsor type (i.e. investigator initiated, commercial, etc.)

You may either provide the information below, or attach it to this report. If you attach a document, please provide the name of the document below.

Data as provided through REDCap data base

Disease Type	Trials#
Renal	3
Cardiovascular Disease	1
Cancer and Other Malignant Neoplasms	27
Intensive Care	2
Palliative Care	1
Public and Population Health	1
Endocrine Disorders and Metabolic Conditions	2
Mental Health	2
Obesity	1
Diabetes Mellitus	1
Physiotherapy	1
Infectious and Parasitical Diseases	1

Sponsor Type	Trials#
Investigator Initiated Group	6
Commercially Sponsored	11
Collaborative Group	19
University	5
Institution	2

Obtaining written consent for age group and demographics information has been particularly challenging for the national office due to privacy laws and this information being classified as personal information have delayed this process.

After intensive discussion and consultations, work is currently underway to collect information regarding demographics and age group of participants through verbal consent. This will help in collection of information relating to demographics and age group of trial participants.

Describe the progress towards target recruitment numbers and the retention rate for clinical trials.

Northern Territory:

In our efforts to meet and maintain target recruitment numbers and enhance retention rates for clinical trials, we've implemented several initiatives during the reporting Oct-March period. Notably, we've bolstered our team by hiring four new staff members, including a program manager, a senior project officer/start-up specialist, and two research coordinator nurses. This expanded team is pivotal in facilitating increased Teletrials activity in the Northern Territory and ensuring we are able to support clinicians involved in conducting clinical trials.

We are also actively seeking to fill the position of medical director with ATP-NT, underscoring our commitment to ensuring strong leadership and oversight within our organization. Recognizing the importance of cultural safety and including First Nations voices in everything we do, we're planning to allocate some funding to the Aboriginal Liaison Offices in Darwin and Alice Springs. This funding aims to enhance our cultural coordination efforts, ensuring that cultural safety is embedded in our practices.

Moreover, each workshop hosted by ATP-NT now includes a section introducing the A-CTEC platform, accompanied by a link or QR code for easy access. This integration not only enhances the learning experience for participants but also promotes broader engagement with clinical trial specific training and resources.

These initiatives reflect our proactive approach to optimizing recruitment and retention efforts while prioritizing cultural competence and technological innovation in our operations.

For clinical trial target numbers, please see below:

Authorised Recruiting TELETRIALS - 4

- ASCEND – Gem/Nab + Placebo/CEND-1 for metastatic pancreatic Cancer – this trial is in the process of being closed/completed in the NT
- Telekinesis - The Telenutrition and Kidney Health Study using a digital health app
- Agile Echo - Use of Artificial intelligence-Guided echocardiography to assist cardiovascular patient management
- Socrates HCC - A randomised controlled trial of Standard Of Care versus RadioAblaTion in Early Stage HepatoCellular Carcinoma

Authorised Recruiting Trials - to be converted to Teletrials (in the future)- 2

- EMBER- oral endocrine treatment for Breast Cancer- Phase 3
- Tapistry- Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

In Submission - 10

- Carbuncle- A RANDOMISED CONTROLLED TRIAL INTO THE SURGICAL TREATMENT OF CARBUNCLES
- WIDER – NT is the lead site- with CTU; potentially can be converted to Teletrials
- ALST - Australian Lung *Screen* Trial Low Dose CT Screening to Detect Lung Cancer

- Librexia- Phase 3 Placebo-controlled Study of Milvexian after an Acute Ischemic Stroke or High-Risk Transient Ischemic Attack
- Mega-Rox- Single blinded clinical trial comparing conservative oxygen therapy to liberal oxygen therapy in mechanically ventilated adults in the intensive care unit
- GOLSEEK-1 (BMS trial) – Phase 3, oral (Golcadomide) Plus R-CHOP Chemotherapy Versus Placebo Plus R-chop Chemotherapy In Subjects With Previously Untreated Aggressive B-Cell Lymphoma
- Pre-ANVU- groin UTZ for Vulvar Cancer
- SELECT SLE – Phase 3 – for Upadacitinib in Subjects with Moderately to Severely Active SLE
- Primary 2 – Phase 3 additive diagnostic value of PSMA PET in men with negative/equivocal MRI in the diagnosis of significant prostate cancer
- 68Ga-TLX007-101 Phase 1 trial – for Prostate Cancer Patient with Ga PSMA-11

In Review/Discussion - 11

- Arise Fluids - Australasian Resuscitation In Sepsis Evaluation: FLUid or vasopressors In emergency Department Sepsis
- Most-LLy - Molecular Screening and Therapeutics in Leukaemia and Lymphoma
- LPa – oral drug for MI- cardiology Trial
- The National HCV Point – Hepa Screening
- ABC-HCC - AGITG Hepatocellular Carcinoma Trial:
- TAPER – ANGOG trial
- Socrates- Melanoma
- Artemis- s/c Cardiology Trial
- Sanofi Kidney - Renal Trial
- Myelofibrosis – Haematology Trial

Primary Sites:

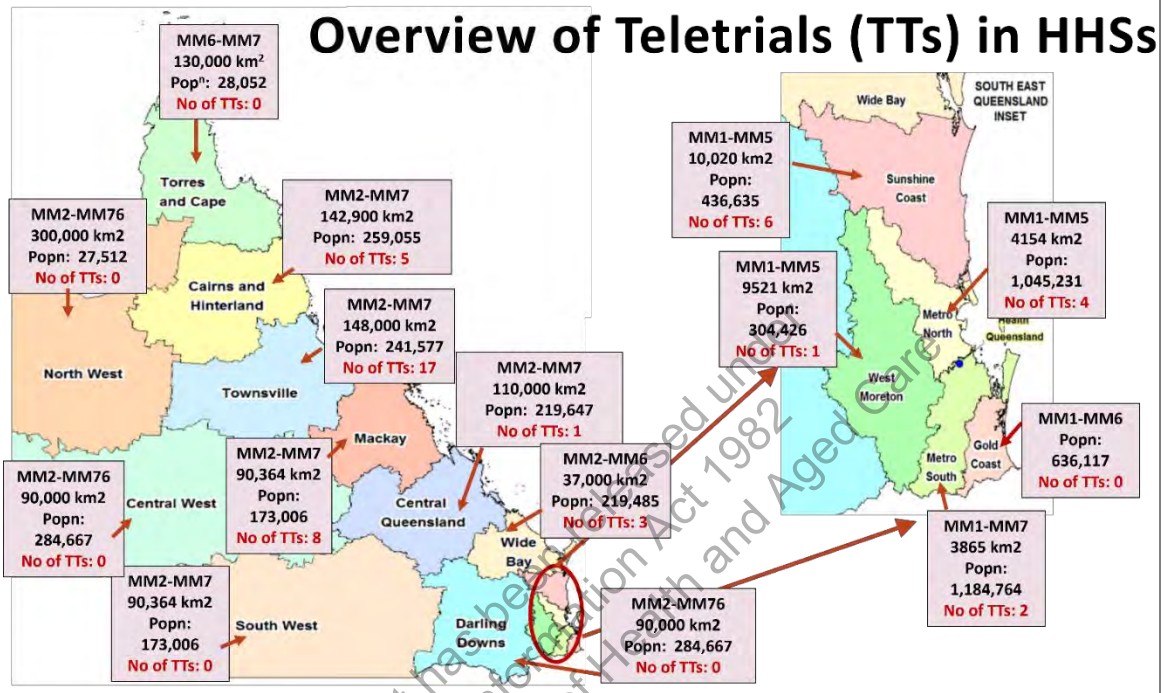
- Royal Darwin Hospital
- Alice Springs Hopsital

Satellite Sites:

- Royal Darwin Hospital (cross-jurisdictional Teletrials with SA and QLD)
- Palmerston Regional Hospital
- Ti Tree Community Health Clinic
- Hermannsburg Community Health Clinic
- Tennant Creek Hospital

Queensland:

QRCCC is a state-wide service based in Townsville. While most of this team are in Townsville, they are a mobile and highly skilled CT clinician workforce that works across RRR Queensland supporting TT coordinators employed in nearly all the HHSs'. The QRCCC has two years of experience providing front-line support to implement teletrials. 104 patients have been recruited, with 23 teletrials in progress, across 22 primary sites and 24 satellite sites across various clinical specialities and diseases across various hospital and health services (HHS)



63 people trained.

Sponsor on-site trial training.

Onsite training for CRCs

Onsite support for new TT

Walk in my Shoes for CRCs at Sunshine Coast – s47F - CT Manager providing an opportunity for new CT staff to experience a unique program of education

South Australia:

ATP- SA Training and Development Initiatives:

ATP-SA Resource Library – a dedicated clinical trials training resource that currently includes over 120 entries

ATP-SA acronym glossary – a valuable clinical trials resource that currently details 340 acronyms with definitions and explanations

Training Courses – ATP-SA funded

Behavioural Activation Training – Online training for nurses involved in prison study

Praxis GCP Training – 7 October 2022

IATA Dangerous Goods – regional Nurse Consultant – Clinical Research Coordinators

Innovation Experience Workshop – 3 April 2024 for ATP-SA team members. A custom designed workshop designed to develop skills in delivering value propositions for each different stakeholder.

• Conference attendance o ARCS Annual Conference 2022 and 2023

o ACTA International Clinical Trials Symposium 2023

o 23rd Successes and Failures in Telehealth Conference 2023

o Rural Pharmacy Conference 2023

o 2023 Australia and New Zealand Site Solutions Summit

o South Australian Rural Health Research and Education Conference 2023

o Australian College Medicine National Conference 2023

Tasmania:

Tasmania has not yet recruited toward target recruitment numbers, however anticipates this to commence with two new clinical trials close to commencement. Despite this, significant background work has been undertaken with researchers to increase awareness and knowledge of the ATP. To foster further development of trials and recruitment of patients the Tasmanian team are developing resources to help illustrate the differences between intra/inter-state requirements, as well as providing a breakdown of the Supervision plan and the payment matrix in lieu of a sub-contract. The Teletrials Coordinators have also presented in numerous fora, including presenting to the Tasmanian Collaboration for Health Improvement (TCHI) and at the Southern Research Council.

Western Australia:

On the ground support has been provided for both Teletrials First Patient First Visit. This was prioritised by WARCCC to ensure that the visits were successful to support our regional colleagues and patients. It was also important to ensure learnings from our regional colleagues and their experience could inform WARCCCs recruitment strategy.

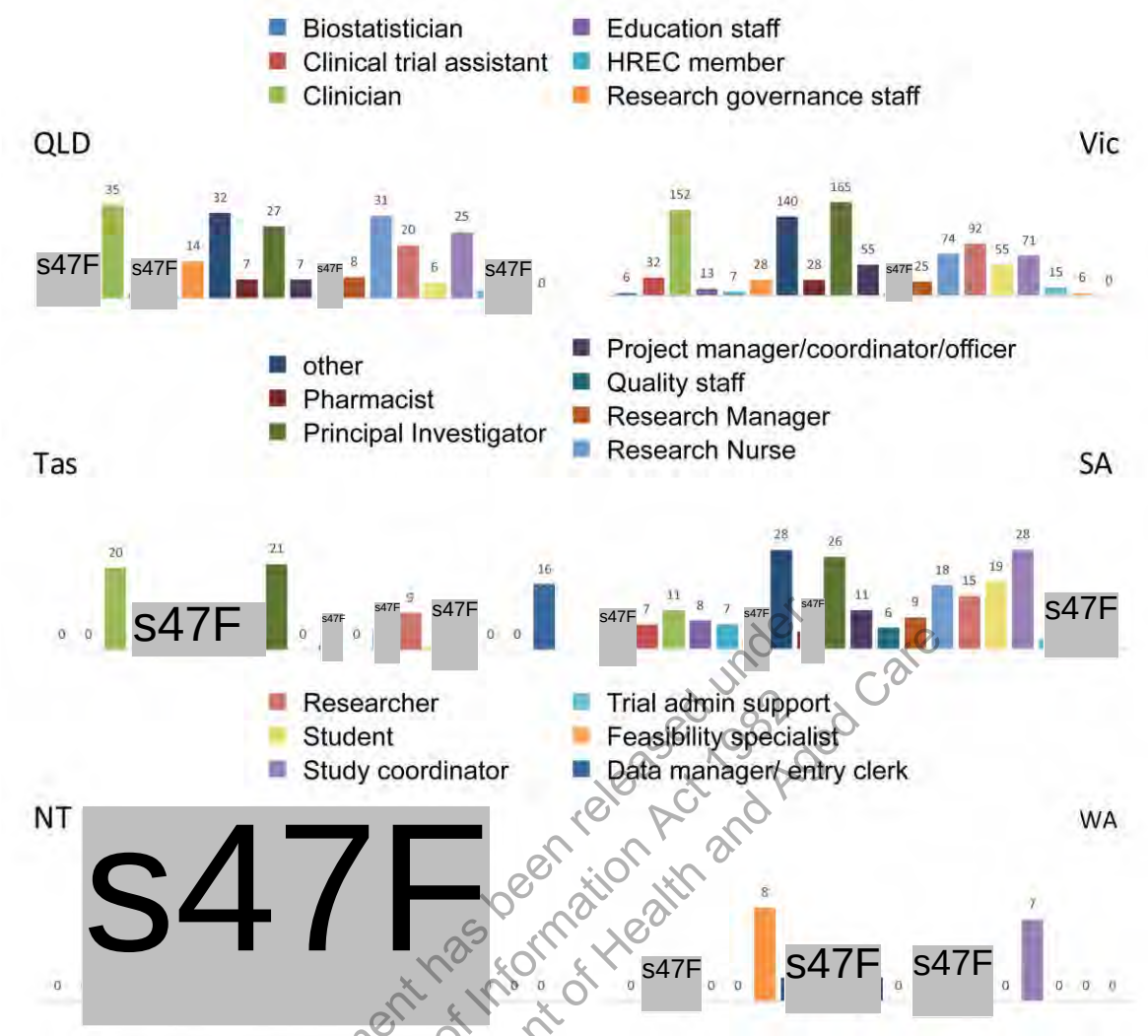
The second Teletrial demonstrated the success of this approach. This experience was enthusiastically received by the regional satellite dialysis unit and their dedication was pivotal to the success of the Teletrial. The principal investigator highlighted the critical role of the dietetics and dialysis nursing staff at the satellite site. Through the collaboration and support provided by the Primary Site and WARCCC, the site set a national precedent by being the first regional group in Australia to meet their recruitment goal for the study.

When considering underserved populations such as the Aboriginal patient community in WA, we have begun to introduce Teletrials to the various Aboriginal Research groups connected with WA Country Health Service. We have had early opportunities to discuss the Teletrial model and learn how the research forums might want to engage with the program. We have also engaged early with the Western Australian Aboriginal Health Ethics Committee to understand how to best support the committee when clinical trial opportunities become available. It is critical to build relationship with these communities early to ensure we meet their needs to provide care through clinical trials and widen the recruitment opportunities available to Aboriginal patients. This engagement and support from Aboriginal health colleagues and Aboriginal Controlled

Community Organisations is expected to take more time. Individual ethically approved Teletrials involving Aboriginal patients may be activated in 2024, however more time is required to raise awareness of the program and develop community–informed system changes to increase equity of access for community members in remote settings.

To undertake clinical trials involving medications administered as infusions, WACHS relies on a private TGA licenced facility to manufacture and courier these medicines to regional sites. There is currently a contract under review to initiate this service however, with WACHS General Counsel temporarily unavailable, this contract has been re-routed to the State Solicitors Office to review, which will create delays. In addition, the facility has submitted a request to the Therapeutic Goods Administration to include clinical trial manufacturing within their licence and estimate the permit will be issued late 2024.

	Target	Actual to date Progress against target
How many staff have been trained on clinical trial related methodology?	5000	**TOTAL -** Victoria – 544 Queensland - 885 Tasmania –437 South Australia –853 Western Australia – 432 Northern Territory -161



The above figure depicts a representative example of the depth of professionals being trained through the program across the six jurisdictions.

Measure Three: New health technologies are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- *identifies or validates new health technologies, including precision medicine*
- *measures the awareness of new health technologies among clinicians and patients*
- *embeds new health technologies into clinical practice*

Where applicable, are new and emerging health technologies[2] being embraced by clinicians and patients involved in the clinical trials funded through this project? If so, how?

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

Northern Territory:

Case Study:

Implementation of the Telekinesis trial in Alice Springs, Northern Territory under the Australian Teletrial Program.

In 2023, the Telekinesis trial was initiated as a Teletrial in the Northern Territory (NT) after the ATP-NT was approached by a Alice Springs (AS) based s47F regarding her interest to lead the study as its Principal Investigator (PI). This case study explores the implementation of this health technology-based trial which uses a digital health application for the management of serum phosphate levels in dialysis patients.

About the trial:

The Telekinesis Study is a 6-month randomised control trial comparing standard care versus digital health technology to optimise serum phosphate control in dialysis patients. The aim of this study is to assess the effectiveness of using a digital app for education and prompting via pictorial messages, visual food swaps and food information to improve management of serum phosphate levels in patients on maintenance dialysis. Participants enrolled in the intervention group for the trial would receive bi-weekly dietary education via the app (1).

Establishing the Teletrial Cluster:

s47F was introduced to the ATP after the ATP-NT hosted a face-to-face Good Clinical Practice (GCP) training in Alice Springs in early 2023. s47F expressed her interest in being involved with the CT but was unsure about the submission process and seeking Ethics and Research Governance Office (RGO) approval to set up the trial in the NT. After reviewing the trial protocol and participating in meetings with the trial sponsor, it was decided that the Telekinesis Study would work well as a Teletrial under the ATP-NT and a Northern Territory trial cluster was established with Alice Springs Hospital acting as the Primary Site, and Royal Darwin Hospital and Tennant Creek Hospital acting as Satellite Sites. The distance between the sites is as follows: Alice Springs to Darwin - 1,500kms; Alice Springs to Tennant Creek – 500kms.

Observed benefits:

Digital health technology is at the forefront of health care optimisation and innovations such as the digital app used in the Telekinesis study which offers an innovative way for patients living in RRR areas access to specifically developed education and interventions (1). There is limited access to specialists for those living in RRR regions and enrolment to this Teletrial enabled participants to connect with a specialist renal dietician for the duration of the study.

s47F, who acted as the PI for the Telekinesis study, said during a presentation at the launch of the ATP-NT in December 2023 that it would be difficult or unachievable for dieticians to be involved in clinical trials without the assistance of the ATP due to workforce shortages and inexperience in conducting CTs. The ATP-NT was able to provide support in the establishment of this trial by way of research coordination and assistance in drafting and submission of ethics and governance documents. Furthermore, setting up the Telekinesis study as a Teletrial with the support of the ATP-NT team not only aided MM6 classified Alice Springs to act as a Primary Site, MM7 classified Tennant Creek was able to be included as a Satellite Site, offering patients living in this very remote area access to this trial (2).

Enablers and challenges:

Though this was the first time Alice Springs would be a Primary Site for a Teletrial, and the first time the dietician involved would acting as a PI, the dedication of s47F and the commitment of Associate Investigators at the Satellite Sites ultimately ensured this Teletrial was successful. The dieticians involved in this trial all had some experience in using digital health technology in the care of their clients which eased concerns around how the digital app would work.

The ATP-NT had experience in establishing Teletrials under the ATP model which streamlined start-up processes, however, understaffing during this time meant the ATP-NT team was taking on duties outside their regular scope and therefore managing a larger workload.

Lack of reliable mobile phone reception in remote areas of the Northern Territory that were included in this CT had to be taken into consideration when enrolling participants to this trial, as did ensuring each participant owned a smart phone that was in their possession all, or at least most, of the time.

Recommendations/Future directions:

Digital health technology offers and innovative way for patients living in RRR areas to be involved in health research while allowing those clients to remain close to home and their support networks, lessening the burden of travel for the patient and reducing the financial cost for the patient and/or the health system. For such technologies to be accessible for all Australians, ensuring adequate internet access and phone reception needs to occur in conjunction with or prior to the roll-out of such digital health technologies and devices. Unfortunately for Australian living in extremely remote areas of the country, especially in remote First Nations communities, such services are limited or non-existent, while some individuals are unable to utilise these technologies as they don't have access to a smart phone or other smart devices.

References:

1. Beer J. The Telekinesis Study: Telekinesis Protocol. 2022 Sep.

2. Australian Government Department of Health and Aged Care. Modified Monash Model [Internet]. Australian Government Department of Health and Aged Care. 2019. Available from: https://www.health.gov.au/topics/rural-health-workforce/classifications/mmm

Queensland:

There are trials in progress in Qld as teletrials that are using new devices and others using AI to support better ways of monitoring patients and the impacts of their condition on them.

Victoria:

Clinical trials and Teletrials currently being conducted at GVH are investigating the application of organised knowledge and skills in the form of devices, medicines, methods, and systems, in order to elucidate health problems and improve patient's and community quality of life.

GV Health mostly focusses on phase 2-4 studies, however opportunities for First in Human (FIH) cancer trials, early phase trials, and studies utilising new health technology are still shared with our relevant researchers. As part of promoting clinical/teletrials at GV health between October 2023 to March 2024, 18 different CROs, Collaborative groups, public hospitals, universities and pharmaceutical companies were contacted via email, phone and online enquiry/forms.

Telecommunications are pivotal to the success of our teletrial models given the geographical conformation of regions. Modalities include the use of remote video imaging to enable real time

skin scoring at a metro centre some 200 kms away and virtual meetings via teams and zoom to link clinicians.

There are several sites that do not currently have any teletrials that involve new and emerging health technologies.

Western Australia:

The second WA Teletrial is investigating an innovative software application that will assess the impact of technology on haemodialysis patients managing their blood phosphate levels through diet adjustments, compared to standard of care counselling. WARCCC provided on the ground support at this regional site to support the primary and satellite site with Site Initiation, Site Activation and First Patient First Visit (FPFV).

The strategic selection of this trial as the second Teletrial within WACHS aligns with the broader priorities of the service to mobilise regional staff with the skills required to provide digitally enhanced care to patients. The positive experience of this Teletrial for staff supports future service provision to patients. It provided an opportunity for staff to become upskilled supporting patients with personal digital care interventions. This team now has proficiency and confidence to support patients in future digital care interventions, which will allow for rapid activation of best practice digital care as this sector evolves. More specifically, this is one of the larger regional dialysis sites in WACHS and if the intervention is successful and the app is released for general use, the team will be able to adopt this rapidly across the dialysis patient population to ensure that all patients benefit from the new treatment modality. This is a positive example of how involvement in the resource intensive learning opportunities that clinical trials provide can prepare a workforce to adopt interventions into standard clinical care rapidly in the future.

[2]A health technology is defined by the World Health Organisation as “the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.”

Measure Four: New health interventions are embedded in health practice

This measure considers the extent to which outcomes of MRFF-funded research:

- *identifies or validates new health interventions*
- *measures the awareness of new health interventions among clinicians and patients*
- *embeds new health interventions into clinical practice*

Where applicable, how are the health interventions[3] changing health practice amongst medical practitioners involved in the clinical trials?

Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

Northern Territory:

The Australian Teletrial Program (ATP) as a health intervention has had a significant impact on healthcare in the Northern Territory (NT), particularly in rural, regional, and remote areas. Before the ATP, NT Health faced challenges in conducting and accessing clinical trials due to limited visibility, geographic barriers, and workforce capacity issues. However, the implementation of the ATP-NT initiative marked a turning point, focusing on expanding clinical trials beyond the Top End Region/Royal Darwin Hospital to other NT regions.

ATP-NT's strategic objectives included enhancing clinical trials capacity and capabilities while promoting a cultural shift to emphasize the importance of clinical trials more broadly and specifically Teletrials as an innovative new approach. Between the October 2023 to March 2024 period, significant milestones were achieved with the ongoing progress of our three active Teletrials, and the launch of the cross-jurisdictional hepatocellular carcinoma Socrates Teletrial with South Australia. As well as the current trials active in the NT, there six additional trials in various stages of the start-up process from specialty areas including cardiology, gynaecological surgical oncology, rheumatology, and medical oncology. Initial discussions have also taken place with sponsors for trials in anaesthetics and speech pathology. While oncology-based trials are well established in the NT, the ATP has been able to support other departments wanting to be involved in clinical trials by linking potential sponsors with interested clinicians, and offering workforce and logistical support to clinicians new to research.

One example of a Teletrial that illustrates the networking of clinical trial sites allowing access to a new health intervention is the Agile-ECHO cardiology trial. This exciting study utilises Artificial Intelligence (AI) technology in echocardiography (echo) in inpatient and outpatient settings (1). The goal of the trial is to establish if AI-guided echo technology is feasible and of value in improving access to echos, which may reduce the time to diagnosis, a significant issue in the diagnosis of heart failure and heart valve disease (1). MM6 classified Alice Springs Hospital acted as the Primary Site for this Teletrial, and the ATP model enabled MM7 classified Tennant Creek Hospital, Hermannsburg Community Health Centre, and Ti Tree Community Health Centre to be included in the trial as Satellite Sites. The inclusion of these remote sites gave clients living in these areas the ability to take part in this trial while allowing participants to remain in their local communities.

The success of ATP-NT is evident in the increased accessibility and participation in clinical trials, such as the Agile-ECHO trial, where previously underrepresented communities now have access to cutting-edge research and therapies. Despite challenges such as workforce support and

logistics, ATP-NT provided crucial assistance to trial teams, ensuring compliance, offering remote support, and facilitating education and training.

Overall, the ATP-NT's introduction of Teletrials has transformed clinical trial accessibility in the NT, empowering local healthcare professionals, bridging gaps in healthcare disparities, and integrating trials into routine healthcare operations. Continued efforts will further accelerate access to clinical trials across the NT, ensuring equitable healthcare delivery and evidence-based practice for all communities.

Reference:

Baker Heart & Diabetes Institute. Use of Artificial Intelligence-Guided

Echocardiography to Assist Cardiovascular Patient Management (AGILE-Echo). 2023 Apr.

Queensland:

There is a clinical trial being set up as a teletrial in QLD for a child with a rare disease. The intervention in terms of a medicine will be given on the trial to determine if it has health benefits for this rare disease and provide a better health outcome for children with the condition. The child will have access where they live in a regional hospital but will remain also under the care of the specialist children's hospital. This will reduce travel and the burden of travel on the whole family.

South Australia:

Prior to the Australian Teletrial Program, very little research activity was occurring outside metropolitan Adelaide and clinical trials were not recognised as an important priority for the six regional Local Health Networks. There were no established research units in any of the regional LHNs and no dedicated research workforce existed.

Since the inception of ATP-SA in May 2022, the total resourcing of clinical trial nursing workforce positions in the regional LHNs has increased from 0.4 FTE to 2.4FTE through the creation of a number of Nurse Consultant – Clinical Research Coordinator positions. In three out of the four LHNs where the nurses are based, no similar positions have previously existed, and no clinical trials have been conducted.

As a result of ATP-SA and the increase in focus for research and clinical trials in the regional LHNs, RMCLHN has established a Research Unit and a Research Governance Committee, the first for a regional LHN in SA. The main hospital in RMCLHN is the Riverland General Hospital located in Berri and is MM5. RMCLHN has established the Riverland Academy of Clinical Excellence (RACE) to boost clinical training and employment across the region. This combined with the newly established RACE Research Unit is attracting and retaining clinical workforce.

The ATP-SA Cluster Start Up Specialists are working closely with the regional Research Governance Officer and the six regional Local Health Networks to establish research governance approval processes for clinical trials and teletrials that previously did not exist.

The first commercially sponsored teletrial commenced in South Australia in February 2024 with a cluster between Southern Adelaide Diabetes and Endocrine Service at Flinders Medical Centre, SALHN and Mount Gambier Hospital, LCLHN.

ATP-SA has facilitated new clinical trials, entirely based rurally, to be contemplated, designed as a teletrial, and successfully commenced. Thus, ATP-SA has not just expanded access to

existing trials but have supported rurally based researchers to develop clinical trials specifically relevant to their own context.

Additionally, two cross jurisdictional teletrials between metropolitan Adelaide sites and Royal Darwin Hospital have been set approved in the discipline of oncology.

Tasmania: Still in development

Victoria:

State-wide in Victoria the activity in the sector and appetite to explore teletrials has increased markedly in the past 6 months (October 2023 to end of March 2024). Implementing a new clinical trial delivery model requires years lead time**.** Victoria's experience over the past 2 years has built the capability, trained workforce and networks in the clinical trials environment. We are working with a very time-poor medical research sector that slows implementation due to clinicians' availability, with lack of funding and resources in regional and rural health delivery services.

Victorian Regional Clinical trial Coordination Centre (RCCC) located in the Coordinating Office for Clinical Trials and Research (COCTR), Safer Care Victoria has two ATP supported staff and four staff contributing their time in-kind to the program. There is a robust governance structure with monthly Operations Advisory Group meetings (regional ATP-VIC funded staff), quarterly Industry Engagement Group, and quarterly Consumer Engagement Group.

Part of capability building has been engagement with the overall sector and events were targeted to pain-points for Teletrials.

The Industry Engagement Group supported an event that resulted in developing targeted teletrial training modules (Introduction to Teletrials, Ethics & Site Governance, Evaluation & Feasibility.). These training modules have been implemented since November 2023 and are ongoing (see training numbers Measure two)

Another recent event (6 February 2024) addressed the Clinical Trial Governance Framework and two new standards for clinical trials in accredited health services. The lead Commonwealth agency, Department of Health & Aged Care attended and provided expert advice and update on policy and progress of short notice assessments at public health services. Metro, outer-metro and regional health services presented their assessment experience and shared learnings and participated in the forum working towards harmonisation.

ATP-VIC governance structure

The Operations Advisory Group have an invited sponsor each month to stimulate uptake of teletrials and to directly present to the regional clinical trial coordinators that follow up on the opportunities. This aids translation to new teletrials.

Industry Engagement Group provide a 'temperature check' on uptake of the Australian Teletrial Program and advise on needs of commercial sponsors for teletrials to guide the Forum on requirements specifically focussing on teletrials. Another outcome from this Forum was a three module teletrial training program. More recently, they advised of their teletrial interest and need for case studies to inform global headquarters. These and analysis of cost-benefit for commercial sponsors will drive their investment in teletrials. Some are working actively to implement teletrials but others are still to convince global headquarters.

Consumer Engagement Group has membership from consumer-specific therapy areas and others have been trial participants. The work has been applied and a consumer infographic (see

attached) for teletrials has been developed to give participants more detailed information on time and other commitments when in a teletrial. This is aimed at adding information that is not on the Participant Information and Consent forms so participants will be aware of their commitment and not drop out of the trial. That will support retention and retaining participant recruitment number. Future projects will be aimed at promoting participation in teletrials.

Overall, teletrial interest in Victoria is very high and RCCC-VIC actively meets with potential teletrial investigators and sponsors to provide clarity and discussion face-to-face and involves relationship building. Following these meetings, the regional study start-up specialists take over with the regional trial coordinators to establish the teletrials. Currently, trials are being converted to teletrials in many cases, especially for long-term studies.

Western Australia:

The first WA Teletrial as an enhanced service model was a positive experience for the clinicians. It focused on patients with diabetes, which is a high burden of disease for this region. The success of this pilot Teletrial in WA allowed WARCCC to demonstrate the success of the benefits of the enhanced service model at multiple key forums in the regions. The chief investigators had not considered Teletrials as an option. WARCCC was able to promote the clinical trial experience directly gained by the investigators through the Teletrial model. As a result, the clinician was accepted as the Principal Investigator (PI) for a subsequent study that is specifically designed for diabetic Aboriginal and Torres Strait Islanders patients, which is a population particularly aligned with the investigators interests and WACHS' broader priorities for patient care. The PI will also be supporting another smaller satellite site within the same region. WARCCC considers this a successful implementation of this new clinical trial service model to regional areas, as it has allowed for a valuable treatment pathway to become available for a priority WACHS population, enabled the Associate Investigator to progress to a PI, and also enabled a smaller, more regional satellite site to participate in clinical trials.

[3] A health intervention is defined by the World Health Organisation as an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions.

Measure Five: Research community has greater capacity and capability to undertake translational research

This measure considers the extent to which outcomes of MRFF-funded research:

- *increases researcher capacity*
- *improves the awareness of translational research within the research community*
- *supports capability development to undertake translational research*

	Full Time	Part Time	Casual
Target number of positions to be created	**TOTAL -** Northern Territory –5 Queensland - South Australia –9	**TOTAL -** Northern Territory – 4 Queensland - 17 South Australia –1	

	Tasmania -5 Victoria -9 Western Australia –4	Tasmania –4 Victoria – n/a Western Australia -	
Actual number of new positions created	**TOTAL –** Northern Territory –5 Queensland – South Australia -7 Tasmania –5 Victoria –6 Western Australia -3	**TOTAL -** Northern Territory –1 Queensland –16 South Australia –5 Tasmania –1 Victoria –5 Western Australia -2	

Please provide details on the number and nature of the positions created.

This may include, but is not limited to, study coordinators, research nurses, pharmacists, clinicians, and researchers

Northern Territory:

Recruited to date: Highlighted areas are for recruitment in Oct 2023 – March 2024 reporting period. These positions are entirely funded by the ATP-NT and are not permanent positions, with contracts for these positions extending only for the length of the funding period (to end in 2026).

- Program Manager 1.0 FTE since Oct 2023
- Senior Project Officer 1.0 FTE since Jan 2024
- Study coordinator Top End Region (1) 1.0 FTE since Jan 2023
- Study coordinator Top End Region (2) 1.0 FTE since April 2024
- Study coordinator Central Australia Region 0.8 FTE since Feb 2024
- Senior Pharmacist 1.0 FTE since May 2023 (s47F , position filled April 2024)

Recruitment in progress:

- Medical Director Top End Region 0.2 FTE

Recruitment in planning:

- Aboriginal Health Practitioner Top End Region 1.0 FTE
- Aboriginal Health Practitioner Central Australia Region 0.5 FTE

Queensland

The positions in Qld are still temporary at this stage and six Health and Hospital Services have had funding extended beyond the initial two years to ensure they can continue with the work they have started. The QRCCC has been working with the 16 HHSs in QLD to embed the NCTGF and this has used time of the CRCs that required training and support from the team to understand what would be required. Business modelling is being shared to lay the platform for sustainability and growth over time.

Australian Teletrial Program National Office team

Senior Program Manager x 1 (full time)

Project Officer x 1 (full time)

Principal Program Officer x 3 (1 full time; 2 part time 0.5 and 0.8 FTE)

South Australia:

ATP-SA roles as of 31 March 2024:

Medical Director 0.2FTE

Project Manager 1FTE

Clinical Trial Liaison Officer 1FTE – located in s47F SA

Administrative Officer 1FTE

Cluster Start-up Specialist SA 1FTE

Cluster Start-up Specialist SA/NT 1FTE

Training and Development Officer 1FTE

Nurse Consultant – Clinical Research Coordinator – South East 0.8FTE – permanent

Nurse Consultant – Clinical Research Coordinator – Riverland 0.8FTE – permanent

Nurse Consultant – Clinical Research Coordinator – s47F 0.4FTE – permanent

Nurse Consultant – Clinical Research Coordinator – Whyalla – vacant

Clinical Research Coordinator 1FTE – 12 month contract

Clinical Trials Pharmacy Support – 1FTE to be split across primary and satellite sites. Ongoing discussions regarding the best approach for distribution of the role (pharmacist or pharmacy technician), FTE and location (ideally employed through a regional LHN).

Tasmania:

The Department of Health Research Ethics and Governance Unit is a relatively new unit and the system. At commencement of the ATP, the system would have been assessed as meeting 'initial' stages under the National Clinical Trials Governance Framework.

As is the experience of many RCCCs, governance barriers have been extensive.

Researcher capability has been increased by:

delivery of education via face to face workshops, online modules via ACTEC, collaboration on research training and education via the Tasmanian Collaborative of Health Improvement, and development of process guides such as for the use of REGIS in Tasmania. Education has included education on research ethics and governance for researchers, but also education on clinical trials finance to business managers, for example.

Provision of REGIS for research governance and LRR ethics applications 437

Researcher capacity will be further improved by: the TC's guidance of teletrials through the REGU.

There are currently two Teletrial coordinators working 1.0FTE total, s47F .

Other team members supported through the ATP include:

Clinical Trials Liaison Officer 0.8FTE

Research Governance Officer 2.0 FTE

Research Coordinator 1.0 FTE

ICT Officer 1.0 FTE

No new positions created for Teletrials within the health services. However, Tasmania is currently reviewing the structure of the ATP and considering health service based TCs to work across clinical disciplines within a service or region. For example, a TC at the RHH and a TC at the LGH.

Victoria:

RCCC – VIC

A trial coordinator 1 FTE mid-career (Fixed term) and 1 FTE (fixed term) experience in clinical trials research and trial management.

Bendigo

At Bendigo Health we have employed a Clinical Trial Assistant 0.5. He contributes to our Teletrial work by assisting in feasibilities and adjusting documents required for trials converting into Teletrials.

GV Health

1 x FTE ATP clinical trials coordinator (split between 2 part time fractions)

Latrobe Regional Hospital

The ATP program has enabled our site to employ a dedicated clinical trials coordinator(s) who have worked primarily in the development of our non-cancer space and the promotion of the tele trial model. To date we have several trials open in this space including teletrials, primarily as a satellite site.

Northeast Health Wangaratta

Currently funding:

1 Part-time Study Coordinator (0.8 FTE) & part FTE (0.5 FTE) of a second study coordinator

1 Full-time Teletrial Start-Up Coordinator (covering Northeast Health Wangaratta, Goulburn Valley Health & La Trobe Regional Hospital)

1 Part-time Clinical Lead position (0.2 FTE) to cover all Victorian Hubs

From these positions NHW has been able to activate 1 Teletrial, work towards converting 2 further teletrials, plan for a conversion of a further 2 teletrials.

South West Healthcare

Utilising the allocated project funding SWH created and recruited to the position of 1 FTE CTRSS ATP Clinical Trials Project Coordinator.

This role has undertaken extensive expert training, education of and awareness raising to clinical and healthcare staff (including the recruitment of new P.I.s), collaborators and sponsors; undertaken key networking and conference attendance. Our Project Coordinator is also the key on site facilitator for site feasibility and start up for the 4 teletrials currently being worked on at their various stages whilst investigating further trial opportunities we could take on. The Project

Coordinator is also our key liaison with RCCC-VIC and the ATP project staff, undertaking reporting and regular meetings for the project.

Western Australia:

In the latter part of 2023, we enhanced our clinical trial team by welcoming six skilled members. This team, comprising a Clinical Research Nurse, three Clinical Trial Coordinators, one Clinical Trial Pharmacist, and a business support officer brings a diverse and comprehensive background in clinical trials, pharmaceutical practices, and regulatory processes. Their collective expertise extends into critical areas such as clinical care and Safety & Quality. This strategic augmentation of our team is pivotal in supporting the implementation of the National Clinical Trials Governance Framework, ensuring our commitment to excellence in clinical research is maintained and advanced.

For any research roles created by your project, please detail the career stage(s) of the researcher(s) (early, mid or established).

Northern Territory:

- Program Manager - early/mid-career in research
- Senior Project Officer – early career in research
- Study coordinator Top End Region (1) – experienced career in research
- Study coordinator Top End Region (2) – experienced career in research
- Study coordinator Central Australia Region – early career in research
- Senior Pharmacist 1.0 FTE since May 2023 (maternity leave as of April 2024, position filled April 2024) – early/mid-career in research

Queensland:

Early researchers in most cases, across the 16 HHSs in Qld and some PHD CRCs or working towards but most have had limited clinical trials experience prior to ATP.

South Australia:

The Nurse Consultant – Clinical Research Coordinator roles employed through the Riverland Mallee Coorong Local Health Network are joint appointments with ATP-SA, Flinders University and University of South Australia. The South East, Riverland and s47F roles are filled, and incumbents also hold university academic status. These roles are early stage researcher roles.

Victoria:

Bendigo

This role is an early career position and is the first CTA Bendigo Health has employed.

Latrobe Regional Hospital

During the course of this initiative, we have had several people employed in the coordinator role. They have had varied backgrounds and experience ranging from medical researcher, someone with limited previous trials experience and research nurses. The common denominator has been that they were all relatively new to the tele trial and clinical trial space but at varying stages in their career development.

Northeast Health Wangaratta

For the teletrial we have activated, it was a first clinical trial at NHW for a mid-career clinician who has gone on to be PI for a number of standard clinical trials also.

South West Healthcare

One funded role-CTRSS ATP Clinical Trials Project Coordinator – early.

3 SWH clinicians have been recruited to the roles of P.I.s for potential upcoming trials, having not worked in clinical trials before, on top of their regular contracted duties. These P.I.s have undertaken the required training (including GCP and teletrial specific) guided by the Project Coordinator and SWH CTU team – all 3 are established in their careers.

Western Australia:

The new clinical trial staff are all at the established stage of their research careers. Their varied experience in public and private research roles are complementary to provide a well-rounded workforce.

Clinical Research Nurse has s47F She has worked in leadership roles within WA Health developing a broad professional network. Her extensive Safety & Quality experience is being used to support implementation of the National Clinical Trials Governance Framework.

Clinical Trial Coordinator 1 has extensive clinical trial experience at a large metropolitan HSP. Her research governance knowledge is supporting the development of guidelines and being applied to streamline regulatory processes for trial start-up.

Clinical Trial Coordinator 2 has extensive clinical trial experience overseas, interstate and most recently at a local not-for-profit research organisation. Her background as a registered nurse and conducting trials from start-up to close-out is vital to the Teletrial implementation process.

Clinical Trial Coordinator 3 has extensive academic and commercial expertise in primary research and clinical trials from overseas and interstate. He has translational research experience s47F bringing a critical analysis of processes and strategic decision-making to the team.

Clinical Trial Pharmacist has over s47F. She supports the team with guideline development support and desktop analysis of current systems practices, as well as digital software development support.

Business support officer has regional administration experience and is networked with northern WA. She provides significant media and graphic support, as well as efficient business administration.

Integrating such varied expertise has profoundly enhanced our team's ability to handle the intricacies of clinical research with a blend of precision and professionalism. It's a testament to the strength that lies in diversity—the varied backgrounds of our team members contribute significantly to our strategic approach, allowing us to address challenges with innovative solutions and a broadened viewpoint.

Provide a catalogue of new infrastructure developed by the project to date and use of infrastructure by researchers in a collaborative manner.

Northern Territory:

• Ongoing update on NT Health clinical trials register NT Health clinical trials register | NT Health

• A-CTEC – live and accessible to the NT at no cost to the end user since 1st March 2023 with a plan to extend clinical trial's education beyond the one year agreement with A-CTEC.

• NT Health education team to embed research/clinical trials education into main learning system with assistance from the ATP-NT

• Development of induction packages for new research staff

ATP-NT Pharmacy infrastructure developed:

Clinical Trials Pharmacy Standard Operating Procedures:

Development and approval of NT Health clinical trials pharmacy services standard operating procedures (published)

Addition of a clinical trial medication to the NT Health electronic Medication administration system (eMMa) (draft – submitted to Pharmacy Operations Group meeting for endorsement)

Maintenance of equipment (draft – submitted to Pharmacy Operations Group meeting for endorsement)

Destruction of investigational medicinal products (draft)

Clinical trial dispensing (draft)

Stock control of investigational medicinal products (draft)

Other forms/label:

Overall drug accountability log

Clinical trials pharmacy prescription

Quarantined IMP label

Purchasing of the following equipment:

For Alan Walker Cancer Care Centre:

s47G(1)(a)

For Royal Darwin Hospital Pharmacy:

s47G(1)(a)

s47G(1)(a)

South Australia:

The ATP-SA Medical Director has been employed at 0.2FTE and also holds the position of Executive Director of Clinical Innovation based in Riverland Mallee Coorong Local Health Network (RMCLHN) which is an MM5 region. Through this opportunity, RMCLHN has used the salary cost savings to further increase the capacity and capability of research. The funds have been redirected into the establishment of the Riverland Academy of Clinical Excellence Research Unit. The Research Unit currently employs 2.4FTE across a number of Research Coordinator positions that are all permanent positions and through recent research grant success has recently employed a 1.0FTE Research Project Manager.

The four Nurse Consultant – Clinical Research Coordinator positions all have a physical presence within their respective LHN's in the form of desk space. Each nurse has a nursing equipment kit and has established strong connections through engagement activities in each of their LHNs. Importantly, the Nurse Consultant – Clinical Research Coordinator located in Mount Gambier has desk space within the LCLHN Executive Office area. SA Health launched a new clinical trials portal on 20 March 2023 with a fresh new look and updated information: http://www.sahealth.sa.gov.au/saclinicaltrials

Queensland:

Funding approved for equipment to the following HHSs – Townsville, Central QLD, West Moreton, Sunshine Coast, Gold Coast, external entity Heart of Australia

Items include Temperature logger, -80C Freezer, Centrifuge, ECG Machine, Medical Refrigerators. office equipment and other laboratory equipment.

Qld is planning to work with HHSs to establish clinical trial units with a standardised business model of commercial sponsor/Collaborative/investigator led CTs which would provide a basis for reinvesting in the establishing key skills, employing permanent workforce, reinvesting into a dedicated CT cost centre.

Qld has also found that additional resources in the form of a mobile workforce have recently proven to be more effective and has succeeded in attracting new commercial sponsors. This revenue stream now needs to be preserved to support investigator led teletrials and HHS research priority areas.

From Qld's perspective seamless adoption of teletrials relies on a "cluster approval system" where there is mutual acceptance of the primary site research governance to speed the process and concurrent review of Site Specific Assessments by Research Governance Officers for all satellite site documentation (including consent, budget, and contracts). Qld has recently requested this system-wide transformation to be authorised from the Health services Chief executives committee within Qld.

Tasmania:

The program has facilitated the provision of REGIS, the online Clinical Trial Management System that has greatly improved management and oversight of research. The program has also

enabled the provision of Good Clinical Practice (GCP) education and training for Tasmanian researchers.

Western Australia:

A pilot Power BI Dashboard was recently developed through a collaborative summer internship program administered through the WACHS-Curtin University Alliance. WARCCC is capturing the site wide capabilities of the country health service to promote regional sites for clinical trial activity and assess site feasibility. Detailed information is included on available equipment, medical specialisation, and support services at each regional site. This has been used to support primary sites when discussing potential opportunities to work with regional sites.

A licence to a conjoint analysis decision making tool has been procured by WARCCC. This has enabled us to host forums with the WA Teletrial Clinical Advisory Group to map a strategic Teletrial prioritisation framework to guide our trial selection. Our next forum will be hosted with the Consumer Reference Group to further inform the framework.

Co-location of the WARCCC pharmacy personnel within the pharmacy department within another metropolitan health service, located near strategic freight links. This is the first time in WA Health that a pharmacy service from a Health Service Provider (HSP) has co-located at another HSP. This also involved creating a new procedure within the WA Department of Health for management of co-locating Poisons Permits for medicines handling.

Development of statewide research governance procedures, codesigned by the statewide WA Teletrial Research Governance Office working group. This procedure is currently in draft form and in the final stages of piloting the co-review process across HSPs.

An amended commercial clinical trial research agreement and sub-contract was produced for Teletrials. Sub-contracts for studies sponsored by collaborative research groups or institutions are still outstanding and are not available nationally on the Medicines Australia website. There is potential for delays to trial start-up if the addition of a Satellite Site requires local/state-based legal review or drafting of agreements.

A digital investigator site file with electronic consent has been procured, to allow for appropriate oversight of satellite sites by the principal investigator, as well as high quality data documentation in alignment with national and international requirements. This concept has been socialised with multiple primary sites who are very interested in the tool, and as a result have begun to consider digital uplift of their own clinical trial infrastructure. Lessons learnt from this first digital infrastructure procurement is the lengthy delays and high level of complex governance required for digital software into the state health departments. This has allowed the WA Teletrial team to provide feedback on system improvements relating the software purchases, however it is expected that when research digital infrastructure is required across multiple health services and relies on interoperability with clinical databases these delays will impact on the Teletrial Program ability to deliver improvements within the timeframe of the grant.

The Supervision Plan editorial group, co-led by WARCCC with National Office, underwent a national harmonisation practice to update the supervision plan, a key document for teletrials. This supervision plan has been endorsed by all jurisdictions and is currently being published on Medicines Australia.

Development of a proof-of-concept video as a micro-learning tool to support new staff with completion of the supervision plan. This was collaboratively developed between WARCCC and the editorial group and will be further developed into a formal online learning.

WARCCC supported the year one annual fee for the Australian Clinical Trial Education Centre, which can be accessed by any WA researcher or support staff for training.

Please provide the total number of conference presentations, publications, citations, mentions in social media, workshops, etc. generated to date in relation to the project.

Northern Territory:

5 December 2023- Inaugural NT Clinical Trials Showcase Event

18 December 2023- NT Chief Minister Media Release- Territorians to join clinical trials closer to home.

Quotes attributed to Chief Minister Natasha Fyles:

“Having access to these clinical trials is important for Territorians.

“Access to teletrials locally in the NT will help to improve health outcomes for Territorians. Other benefits will include a reduction in the need to travel long distances and costs related to clinical trial participation for patients and their families.

“Participation in the ATP will boost the NT’s clinical research sector, with flow-on effects to include improvements in facilities, equipment, services and systems in both urban and remote locations, and greater opportunities for the research workforce.”

7 November 2023 – workshop with the Allan Walker Cancer Care Unit Nursing staff

18 December- Media re: Media release

16 February 2024 - Presentation to CCAG - Clinical and Consumer Advisory Group

5 March 2024 – Presentation to NT Health Executive

6 March 2024 – Presentation/workshop with Royal Darwin and Palmerston Regional Hospital Clinicians

6 March 2024 – Presentation to Flinders University

6 March 2024 - Presentation to Menzies School of Health Research

6 March - NT Australian Teletrials Advisory Committee Meeting

7 March 2024 – Alice Springs presentation to the Executive

7 March 2024 – Alice Springs presentation to the Alice Springs Hospital Clinicians

7 March 2024 – Alice Springs presentation to the Alice Springs Primary Health Care

8 March 2024 – Alice Springs presentation to the Alice Springs Pathology Manager

8 March 2024 – Alice Springs presentation to Pharmacy Manager

8 March 2024 – Alice Springs presentation to Central Australian Aboriginal Congress

8 March 2024 – Alice Springs presentation to Manager of Alice Springs Clinical Education

Queensland:

AGITG ASM Nov 2023- Teletrials- s47F

Teletrials QLD experience- National clinical and consumer group of ATP NO- s47F

Mental Health Trials ASM, Perth Nov 2023- s47F

Palliative care 21st Annual Research conference – s47F Presentation

AGITG – s47F key speaker – NZ Christchurch and co facilitated a workshop on Teletrials

QRCCC training TEAMS lunchbox sessions

Several mentions in social media

Publications in the last six months:

1. Patient and carer experiences of lung cancer referral pathway in a regional health service: a qualitative study. Otty Z, Brown A, Larkins S, Evans R, Sabesan S. Intern Med J. 2023 Nov;53(11):2016-2027. doi: 10.1111/imj.16022. Epub 2023 Mar 6. PMID: 36710377
2. Implementation of the Australasian Teletrial Model: Translating ideas into action using implementation science frameworks. Sabesan S, Malica M, Gebbie C, Scott C, Thomas D, Zalcberg J. J Telemed Telecare. 2023 Sep;29(8):641-647. doi: 10.1177/1357633X211017805. Epub 2021 Jul 7. PMID: 34233548
3. Decentralized Clinical Trials as a New Paradigm of Trial Delivery to Improve Equity of Access. Underhill C, Freeman J, Dixon J, Buzza M, Long D, Burbury K, Sabesan S, McBurnie J, Woollett A. JAMA Oncol. 2024 Apr 1;10(4):526-530. doi: 10.1001/jamaoncol.2023.6565. PMID: 38358756
4. Clinicians' Experiences and Perspectives about a New Lung Cancer Referral Pathway in a Regional Health Service. Otty Z, Larkins S, Evans R, Brown A, Sabesan S. Int J Integr Care. 2024 Apr 4;24(2):3. doi: 10.5334/ijic.7627. eCollection 2024 Apr-Jun.MID: 38618045
5. Health equity in clinical trials for regional, rural and First nations communities: Need for networked clinical trial system, through a values and purpose-aligned system culture. Sabesan S, Poxton M. Aust J Rural Health. 2024 Apr 17. doi: 10.1111/ajr.13122. PMID: 38629873
6. Patient and carer experiences of lung cancer referral pathway in a regional health service: a qualitative study. Otty Z, Brown A, Larkins S, Evans R, Sabesan S. Intern Med J. 2023 Nov;53(11):2016-2027. doi: 10.1111/imj.16022. Epub 2023 Mar 6. PMID: 36710377
7. Implementation of the Australasian Teletrial Model: Translating ideas into action using implementation science frameworks. Sabesan S, Malica M, Gebbie C, Scott C, Thomas D, Zalcberg J. J Telemed Telecare. 2023 Sep;29(8):641-647. doi: 10.1177/1357633X211017805. Epub 2021 Jul 7. PMID: 34233548
8. Decentralized Clinical Trials as a New Paradigm of Trial Delivery to Improve Equity of Access. Underhill C, Freeman J, Dixon J, Buzza M, Long D, Burbury K, Sabesan S,

McBurnie J, Woollett A. JAMA Oncol. 2024 Apr 1;10(4):526-530. doi: 10.1001/jamaoncol.2023.6565. PMID: 38358756

9. Clinicians' Experiences and Perspectives about a New Lung Cancer Referral Pathway in a Regional Health Service. Otty Z, Larkins S, Evans R, Brown A, Sabesan S. Int J Integr Care. 2024 Apr 4;24(2):3. doi: 10.5334/ijic.7627. eCollection 2024 Apr-Jun.MID: 38618045

10. Health equity in clinical trials for regional, rural and First nations communities: Need for networked clinical trial system, through a values and purpose-aligned system culture. Sabesan S, Poxton M. Aust J Rural Health. 2024 Apr 17. doi: 10.1111/ajr.13122. PMID: 38629873

South Australia:

Rural Prisons: the focus for new mental health research

23rd Successes and Failures in Telehealth Conference 27-29 November 2023 – Adelaide Convention Centre Equity, diversity, inclusion, and accessibility: what the Australian Teletrial Program can offer Country SA residents. Speaker - s47F Best Paper Award Winner

Tasmania:

ATP Booth at the Rural Medicine Australia 2023 conference – 18-21 October 2023

ATP Booth at the Tasmanian Allied Health Symposium – 24th November 2023

Presentation at Regional Visions – Cradle Coast Community of Practice Annual Symposium – 23rd November 2023

Cardiology Network 6mthly meeting – presentation – 20/03/2024

Presentation to Department of Health Clinical Quality, Regulation and Accreditation (CQRA)– 27th September 2023

Presentation to Tasmanian Collaboration for Health Improvement (TCHI) Executive Committee – 8th September 2023

Presentation to Southern Research Council - 13th June 2023

State-wide Pharmacy Executive Meeting – 12th June 2023

UTAS seminar to researchers/students – 6th July 2023

Monthly RG Newsletters

DoH Intranet

Please note these are events for the current reporting period only.

Victoria:

RCCC-VIC

ABC Conversation Hour (ABC Radio-Melbourne) 6 March 2024- '*How do we improve our understanding and access to clinical trials?'*

Forum 6 Feb 2024- *'National Clinical Trials Governance Framework-Learnings from 2023'*

Bendigo

At last year's Bendigo Health research week a poster and presentation were delivered on the Teletrial concept. Our staff profiles which included our work on Teletrials was featured in our organisation wide newsletter. We also attended a workshop as panellists that was designed for research departments in hospitals and research institutions as well as sponsors and CRO's to educate the wider community.

GV Health

A number of Clinical trial coordinator workshops run in conjunction with the Quality Unit for continuous improvement processes e.g. updating clinical trial SOPs, consumer engagement in clinical/tele trials.

GV Health Clinical Trials and Research site profile updated and displayed at the ACTA symposium. The site profile was later shared with the CTRSS-ATP regional hubs as an example of a promotional document.

Page dedicated to the ATP and its objectives in the first issue of the Research News at GV Health.

Latrobe Regional Hospital

s47F, presented at the CTRSS ATP workshop July 23

LRH Research and Clinical Trials Unit Team met with Kaye Hewson and s47F on the ATP Victorian Regional Hubs Visit in February 24

s47F presented a Poster at the 2023 ARCS Annual Scientific Conference November 23

s47F) were invited to participate in a panel discussion at the Alfred TrialHub special showcase event in June 23 to share their experiences of tele trials in practice.

Northeast Health Wangaratta

NHW CEO Newsletter: 3 items

Local Newspaper Article: 2 (Wangaratta Chronicle, Jan 2021 & 11 Dec 2023)

NHW Grand Rounds Presentation: Sep 2023

NHW Graduate Discovery Day: 3 (2022, 2023 & 2024)

NHW JMO Presentation: 2 (2022 & 2023)

Research Week Presentation: "Delivering Clinical Trials & Teletrials in Rural & Regional Victoria" s47F, 08 Sep 2022

NHW Facebook Page: 5

NHW LinkedIn Page: 2

Presentation to CTRSS-ATP – Teletrials Forum 21 Jul 2023. Presented NHW experience of activating Teletrial

South West Healthcare

Social media page for South West Healthcare –

02/12/2023 – social media post mentioned ATP and contact details if the public would like more information

'People Hub' (SWH's internal news site / home page) –

Article shared November 2023 on 'People Hub', mentioned the ATP role, program and details on how to find out more information

Article and case study shared in the Australian Teletrial Program Newsletter (Christmas Edition, 14 Dec 2023), with profile of SWH Clinical Trials team and personalised story of a teletrial that created access for a participant to attend a clinical trial closer to home.

Western Australia:

Conference **presentations (2):**

WA Rural Health Conference booth 16-17/3/2024

23.11.27 Australian Clinical Trial Alliance poster *Pharmacy Connect - Clinical trial initiatives in country WA* and booth attendance

Workshops (4):

23.10 Australian Research Council decentralised and ethical review workshop

23.11.08 - Workshop - Child Health Symposium (PCH)

- 23.12.06 - 1000 Minds workshop - WARCCC Clinical Advisory Group
- 24.02.28 - 1000 Minds workshop - WARCCC Clinical Advisory Group

Teletrial Training (4):

- 24.02.15 - Introduction to Teletrial 2
- 24.02.22 - Teletrial 2 Trial Conduct
- 24.03.14 - HREC Training
- 24.04.03 - Teletrial 2 Trial Training

Presentations (16):

- 23.10.13 - ATP Consumer Clinical Advisory Group
- 23.10.16 - Sponsor Advisory Group National IMP Transport Guideline
- 23.10.19 - Site Inititation Visit Teletrial one Geraldton
- 23.11.07 - WACHS District Health Advisory Council Nov Meeting
- 23.11.27 - Introduction Week New Starters WARCCC
- 23.11.30 - WACHS Board Meeting
- 24.02.12 - Teletrial Meeting Collaborative Research Group Sponsor
- 24.02.22 - Teletrial two Trial PS & SS meeting
- 24.02.24 - ATP Clinical and Consumer Advisory Group
- 24.02.26 - WACHS Teletrial Artificial Intelligence Command Centre Presentation
- 24.02.28 - WA Teletrial Research Ethics Working Group Meeting
- 24.02.28 - NMA committee National IMP Transport Guidelines

- 24.03.20 - Regional Aboriginal Consultants Introduction
- 24.03.25 –TGA and NSQHS National IMP Transport Guidelines
- 24.03.27 - WACHS Clinical Council
- 24.03.27 - WA Teletrial CRG meeting

Reports (2):

WACHS Annual Report 2022-2023 (released 2024) *Executive Summary; Clinical trials closer to home*

Publications (1):

s47F . COSA eNews. Marryalyan COSA Regional & Rural Group September 2023

Media Engagement (7):

24.03.25 - CurtinFM - Teletrial radio promotion

Innovative Teletrial model benefits patients in the Midwest (WACHS News February 2024)

Take a look at all the latest from around country WA (WACHS News February 2024)

Leading the way for improved pharmacy clinical trial services in country WA (WACHS News January 2024)

Congratulations to s47F (WACHS January 2024)

Regional patients to join Perth-based clinical trials closer to home (WACHS News Nov 2023)

WA first service is a step in the right direction for country patients (WACHS News Oct 2023)

Measure Six: Health professionals adopt best practices faster

This measure considers the extent to which outcomes of MRFF-funded research:

- *identifies or establishes best practices*
- *assesses the speed at which best practices are communicated to clinicians and health service administrators*
- *identifies how best practices are understood and adopted*

Where applicable, how well were the best practices4 understood and adopted and how was/will this (be) evaluated? Reporting on this indicator may be presented in the form of a case study. If you have attached a case study to this report, please provide the name of the attachment.

Northern Territory:

The ATP-NT team actively reaches out to other jurisdictions to establish cross-jurisdictional Teletrials, promoting collaboration and shared learning. By engaging in these partnerships, we leverage collective knowledge and resources to optimise trial processes and widen access to clinical trials across regions.

Moreover, we prioritize inclusive collaboration by involving all relevant stakeholders from the outset of trial discussions, allowing for harmonisation at a local level. This includes department

leads, clinicians, pathologists, and pharmacy teams, ensuring that trial feasibility is thoroughly addressed, fostering a cohesive and streamlined approach to trial implementation. One example of this involves working with the Royal Darwin Hospital pathology department to discuss how we can continue clinical trial activities during a time of workforce shortages within the department. As scientists, the pathology team is excited to undertake research but were concerned that would be overburdened with increased clinical trials activity. A solution was to allow ATP research coordinators access to the pathology department to spin and store bloods – a relatively simple task that is within their scope of practice but eased some of the workload of the pathology team.

The ATP-NT actively participates in local and national meetings, working groups and committees to discuss and review our practices and performance metrics to seek feedback in order to refine and improve our practices. Our commitment to harmonization activities and inclusive collaboration reflects our dedication to advancing the Teletrial model and delivering an impactful and sustainable service for patients and communities

Queensland:

The work of QRCCC has advocates for patients includes promoting Teletrials at every opportunity. Teletrials and the methodology which requires sites and people to work together to put patients first and the access that they require to be considered from the outset cannot be underestimated in how this has the potential to reform health care. The networked, connected care required means that the teletrial methodology transcends its intent and can be used for health care delivery so that we truly provide equity of access in the future for all RRR patients in Australia.

QRCCC shares teletrials and opportunities for collaboration across the jurisdictions the Northern Territory example just one of the network of Teletrials this will provide across Australia.

South Australia:

ATP-SA has implemented a research governance process for teletrials when not public health service organisation is involved. This has so far been the case for two teletrial clusters involving universities and private sites such as GPs so do not meet the SA Health research governance requirements to complete a SSA.

The ATP-SA Cluster Start Up Specialists have regular meetings with the regional Research Governance Officer to ensure effective communication around all teletrial documentation and research governance processes.

Close working relationships have been established with ATP-SA team members and relevant stakeholders in the regional LHNs eg clinical governance committee, Head of Departments and Executives to assist with research governance approvals and teletrial documentation.

Plans are underway to launch a SA Clinical Research Coordinator Community of Practice in mid 2024.

In late 2022, ATP-SA was involved in consultations to develop the Draft SA Cancer Plan. As a result of this involvement, there is a significant inclusion of clinical trials and access for underserved populations including rural, regional and remote residents. Tele-trials is also mentioned as an important consideration.

In August 2023, the South Australian Minister for Health and Wellbeing released a Green Paper for consultation on Delivering the SA Health and Medical Research Strategy. Australian Teletrial Program – South Australia submitted a response to this green paper to ensure clinical trials will

continue to be embedded as standard clinical care across all South Australian hospitals, not just the metropolitan sites.

Tasmania:

The Tasmanian Department of Health has implemented mandatory GCP as best practice for research and provided free access to Tasmanians through the A-CTEC.

Victoria:

Communications to inform the sector and to encourage a standard approach to teletrial implementation.

Victoria has a well-recognised website for clinical trials and research. There is a tile with dedicated policy, guidance and template information for teletrials. This is accessed by jurisdictions and globally. A dedicated external access SharePoint site is established to share tools for trials and teletrials developed by Victoria in a previous regional trials program and ATP documents.

A Streamline e-bulletin is emailed to over 3,000 in the clinical trial and research sector monthly with updates of what is happening in our support and services, national news and teletrials feature regularly with new policies, guidance and templates. RCCC-VIC have contributed to the revision of the Supervision Plan developed over the past 6 months by a specialist ATP working group.

The Program Lead for Victoria has advised on the revised ATP governance structure to improve communication and information sharing of the ATP National Office meetings with other ATP committees.

A dedicated staff member to support implementation of the National Clinical Trial Governance Framework in regional Victoria from Commonwealth clinical trial reform funding. Three successful short notice assessments have been completed and working with five regional health services to prepare for assessment. Developing gap analysis, action plans and learning how to present responses to the many assessment Actions for the framework.

RCCC-VIC team members are involved in supporting the progress of the national reform agenda for clinical trials and research and represented on various working groups under the Intergovernmental Policy Reform Group (IG-PRG) One Stop Shop and Ethics accreditation for NMA scheme. Assuring that teletrials are factored into these reform agenda.

Western Australia:

The first Teletrial allowed the purchase of a 3-dimensional wound camera (Silhouette Camera) for the Albany high risk foot clinic. This is best practice equipment for diabetic wound management. The regional team have expressed that this purchase has improved the general care of their regional diabetic foot ulcer patients beyond the Teletrial. Collaboration of the multidisciplinary team between FSH and AHC has been enhanced through the close relationships developed during the trial initiation.

WARCCC is drafting guidelines to support Teletrial practice. New WA governance guidelines were co-designed by the WA Teletrial Research Ethics and Governance Working Group. This group was established to improve working relationships and to support streamlining of Teletrial review processes. This provides the Research Governance offices with a supportive forum to

develop best practice together, which will ultimately be implemented across the WA Health system regardless of where a Teletrial site is located.

Digital solutions are being considered to improve clinical trial infrastructure uplift, which has involved extensive stakeholder engagement. The digital strategy identifies the need for an electronic investigator site file (eISF). This has led to the procurement of an eISF which will be best practice in providing remote oversight of satellite sites and will be implemented across every site in the WACHS 2.5millions sq km health service.

WARCCC is supporting implementation of the National Clinical Trials Governance Framework (NCTGF) within WACHS. The introduction of these Standards provides WACHS with a valuable benchmark to aim towards as clinical trial activity is introduced across the service. A gap analysis currently being undertaken of the NCTGF is promoting collaboration with the Health Service Executive, Patient Safety and Quality, and Research Governance Office.

Evaluation of the WARCCC program is being undertaken by independent researchers at the Queensland University of Technology. The process includes reporting quantitative data from the Australian Teletrial Program RedCap database (hosted by Qld Health), there are some delays to providing patient-level demographics through to the database while arrangements are put in place for a data transfer agreement. The WARCCC team are also seeking clarification about the relevance of all database fields relating to aspects of site and trial data capture.

[4] WHO defines Best Practices as “exemplary public health practices that have achieved results, and which need to be scaled up so as to benefit more people”.

Measure Seven: The community engages with and adopts new technologies and treatments

This measure considers the extent to which outcomes of MRFF-funded research:

- *involves the community in prioritising, designing and conducting research*
- *promotes community awareness of new technologies and treatments, and their benefits*
- *promotes community support for new technologies and treatments*

How were the community members and consumers engaged in prioritising, designing and conducting research through means such as public consultations? Has your governance process changed?

Northern Territory:

One significant initiative has been the creation of the NT's first patient-facing pamphlet on clinical trials and research. This pamphlet serves as a valuable resource to inform and engage consumers about the importance and benefits of clinical trials. Moving forward, we plan to adapt this pamphlet to suit a variety of departments, such as paediatrics and maternity, to cater to diverse patient populations effectively. Furthermore, recognizing the importance of cultural safety in clinical trials, we are collaborating with local communications teams to have the pamphlet printed in multiple First Nations languages, ensuring accessibility and inclusivity.

In addition to printed materials, we are developing video and animation materials to help demystify clinical trials for consumers. These communication materials are being developed in consultation with First Nations organisations, such as the Aboriginal Liaison Office based at

Royal Darwin and Alice Springs Hospitals. This collaborative approach ensures that the content is culturally appropriate and resonates with diverse communities.

The ATP-NT team is also working alongside Aboriginal Health Workers, Aboriginal Cultural Coordinators, and the director of the Aboriginal Engagement and Strategy Unit to ensure proper community engagement with First Nations communities. These pipeline activities demonstrate our commitment to including First Nations perspectives in all aspects of our practices and fostering meaningful community engagement.

Regarding governance, while our core principles remain unchanged, we continuously review and refine our governance structures to ensure alignment with evolving priorities and best practices. At the implementation of the ATP in the Northern Territory, our approach was to offer support to clinical trials regardless of their status as standard trials or Teletrials as a capacity building project. While this method worked well and allowed our team to build effective relationships with clinicians and sponsors, we have now reached a point of reaching capacity as a unit. As such, and as we see momentum grow in the Teletrials space, we have decided that going forward we will be focussing primarily on those trials that are most likely to advance as Teletrials under the ATP model, and disinvesting from trials that don't fit the Teletrials model. While will always offer support and guidance to clinicians undertaking research in the NT, we feel our focus should be building the Teletrials program into a sustainable that is fitting with the vision of the ATP to improve access to clinical trials for patients living in RRR areas.

Queensland:

Qld has s47F consumers who form a group of experienced consumers that engage and provide the team with the patient voice and guides what we are doing and how it has the potential to have impacts on or within the community.

South Australia:

ATP-SA has established the SA Teletrials Advisory Committee with the inaugural meeting held on Thursday 10 November 2022. Meetings are convened twice per year with so far, three meetings being held to date, and the fourth meeting scheduled for Thursday 30 May 2024. This committee has s47F consumer representatives from regional South Australia and a representative from the Aboriginal Health Council of SA.

Engagement activities have occurred with a broad range of stakeholders including investigators, universities, private research organisations, ethics committees, sponsors and consumer advocacy groups, and the SA Health Media and Communications team.

The Department for Rural Health in the University of South Australia has developed a dashboard using Power BI for the Primary Health Networks that provides useful information relating to regional South Australia. ATP-SA continues to have ongoing discussions regarding the best way to contract UniSA to use this data. The dashboard encompasses the collection and analysis of diverse, publicly available datasets pertaining to health status, workforce distribution, population demographics, and socio-economic indicators. These datasets can be aggregated and organized based on Statistical Area Level 3 and Statistical Area Level 2 geographical delineations which can align with the Local Health Network regions in SA.

Plans are underway in 2024 to establish the ATP-SA Consumer Reference Group.

Tasmania:

Tasmania is yet to establish a consumer engagement committee for the research, including for Teletrials.

Victoria:

RCCC-VIC

Consumer Engagement Group- Infographic Poster (see attached) and Measure Four RCCC-VIC activity in governance and sector engagement.

Barwon

A s47F suffered a heart attack and part of the treatment that saved his life in regional Victoria was a drug from a clinical trial at The Royal Melbourne Hospital in1990. He not only received the treatment, but it was a large reward for his family in s47F It is an acknowledgement of the long-term benefit of consumer engagement in research, helping better health of our families, our community and our economy. Equity of access to clinical trials matters for everyone in our community. For all lives have inherent and equal value, whether you are living in regional, rural or metropolitan Australia; whether you are rich or poor, indigenous or Australian, or other ethnicity.

At Barwon Health, our Australian Teletrial Program (ATP) closely mirrors the unmet needs in our community across cancer, acute illness, endocrinology and infectious diseases treatments, with more trials in the pipeline across other specialities.

Our consumers share with us their issues around equity of access to trials, their wish to receive care closer to home and remain linked within their community while undergoing treatment, and their desire for more quality time with the ones they love, rather than time, and money, spent travelling long distances to cities for treatment.

Our ATP-enabled teletrial model responds to the needs of consumers delivering care close to home. What type of learning healthcare service are we if we cannot respond to a simple need with a simple solution? 'Delivering care in the optimal location to benefit our community'. In our work with Wathaurong Aboriginal Cooperative the Aboriginal and Torres Strait Islander community determines the unmet need and we build ATP treatments around this delivered in the community's local health centre. In our cancer care strategy we have partnered with metro hospitals in Victoria (Peter Mac) and interstate (through precision medicine provider Omico) to deliver trial care close to our patients' homes; and our ICU study patients who live near Warrnambool can receive follow up trial care at South West Healthcare, close to home.

Western Australia:

In involving community members and consumers in our program, we developed a comprehensive strategy for consumer engagement. WARCCC received executive approval to form the WA Teletrial Community Reference Group. The creation of this group was informed by the consumer members on the national Teletrial clinical and consumer advisory group, WA experts in consumer involvement, and the WACHS Patient Experience and Community Engagement team, who liaise with 21 District Health Advisory Councils (DHACs) across the entirety of country health and have 167 members. They assisted with the development of the Terms of Reference (ToR) and the Expression of Interest (EOI) for the WA group. Membership was focused in the regions for members with lived experience of being involved in or excluded from clinical trials due to geography. This group has membership from the regional community with lived experience of being involved in or excluded from clinical trials. This is an essential partnership to ensure that WARCCC understands cultural, ethical, and community values during implementation. The TCRG formation aligns with the national Australian Safety and Quality in Health Services Standards. It is also supported by the 2016 Statement on Consumer and

Community Involvement in Health and Medical Research by the National Health and Medical Research Council and Consumers Health Forum.

To assist recruitment WARCCC utilised the WACHS social media platforms, partnered with Curtin University, and collaborated with various health-related consumer engagement institutions. Additionally, word-of-mouth strategies showcased the significance of personal networks in engaging potential group members. From this broad outreach, we selected individuals for our initial meeting, each offering distinct perspectives — including a clinical trial participant, caregivers for patient in clinical trials, a resident from a remote area familiar with healthcare limitations in small communities, and a caregiver experienced in navigating mental health services in regional areas. This diversity ensured first-hand insights across a broad spectrum of community needs.

Our first meeting allowed for WARCCC to introduce staff and meet each of the community members. WARCCC presented the program and discussed future prioritise with the group. The first priority will involve strategic development, followed by trial prioritisation framework development.

Comments

You are welcome to provide any further feedback relating to the monitoring indicators or evaluation outcomes for your project to date.

Northern Territory:

The ATP-NT feels the targets (see table below) set by the Commonwealth are not realistic considering the unique circumstances of the Northern Territory (NT). While we have successfully met our target numbers under the number of trials KPI, the criteria for new and improved sites are not appropriate for our region. The NT faces distinct challenges compared to other jurisdictions, making the current target framework unattainable without significant adjustments.

The current definition of a new site as a new satellite site and an improved site as a primary site, as suggested by guidance from other jurisdictions and our national office, doesn't align with the reality of healthcare infrastructure in the NT. With vast distances and sparse population, establishing primary sites can be exceedingly difficult, and setting a target of 11 improved primary sites in the NT is unachievable given the limited number of viable primary sites in the region.

If the definition of what constitutes a new or improved site included new departments within existing health services participating in clinical trials these targets might be more feasible, but there needs to be clarification and agreement around this. For example, Royal Darwin Hospital (RDH) has been conducting clinical trials for many years, but the implementation of the ATP has facilitated the involvement of new departments like rheumatology and dietetics in clinical trials for the first time.

Additionally, the target number of staff trained seems disproportionately high considering the NT's population represents only 1% of Australia's total population. Transparency regarding how this target was calculated and whether it's realistic for the NT would be appreciated going forward.

In conclusion, the current targets set by the Commonwealth are not fit for purpose in the NT. To address this, there needs to be a clarity around the definitions of new and improved sites, or a reconsideration of the targets themselves, as well as a review of the staff training targets to better reflect the realities of healthcare delivery in the NT. Only with a more nuanced and

contextually relevant approach can the NT realistically meet the targets set by the Commonwealth.

Matrix	Target Numbers	Progress
Number of trials	3	6
Number of new sites	32	8
Number of improved sites	11	2
Number of participants	68	33
Number of staffs trained	833	161

Queensland:

We need policy change to support the regulatory requirements of staring up clinical trials as teletrials. We have a methodology that allows access for RRR patients but still must use existing policy which although has the QRCCC we know what we need, has not been reviewed to the extent that is has been changed to allow streamlined regulatory processes. We need to advocate for policy change to support patients having access as the priority and not allow administrative processes to deny them that right to access.

The risks for the facilities delivering clinical trials when the activity is led by a statewide expert team are mitigated but the risks to the patients being denied access are life changing and costs lives. This must be addressed urgently as it us unethical and cannot continue.

South Australia:

Significant time spent from November 2022 to July 2023 to set up a commercially sponsored clinical trial as a Teletrial that did not eventuate. The HREC amendment and all RGO documentation including contract negotiation, supervision plan, updated CTN, additional site AI CV and GCP, updated Master and satellite site PICF was all prepared, the HREC had been approved. Unfortunately, right as the Primary site and Satellite site RGO submissions were about to be submitted, the sponsor met their target for patients and therefore did not wish to add any more sites. This was despite a lot of time and effort to prepare documentation.

Tasmania:

As a relatively immature system, Tasmania has utilised the ATP to improve capability and capacity for teletrials and also research governance. Reporting numbers do not reflect the amount of work or opportunity for teletrials in Tasmania. It is anticipated that ongoing investment would result in a tipping point for the establishment and cultural shift toward utilising teletrials from which Tasmanian patients would benefit, being a small distributed population on an island State.

Western Australia:

Across regional WA there have 6 large regional health campuses located at country regional centres and 15 district health campuses that act as hubs for sub-regional health district services. The population we service is diverse and expansive and as a result has widely varying health needs. Prior to establishing the WA Regional Clinical trial Coordinating Centre, only one WA Country Health Service site (Bunbury Hospital) had the capacity to offer a clinical trial, the

remainder of regional health sites had to establish clinical trial infrastructure with no prior experience. Without any pre-existing structures, systems, or knowledge to rely on, careful consideration was given to the optimal workforce model required to support Teletrials.

An in-depth knowledge of the four WA metropolitan hospitals currently conducting clinical trials and the experience of two Teletrials informs our prediction that a single Satellite Site per Teletrial is going to be the most likely scenario for the next few years. Each new Satellite Site activation require extensive engagement with Executive, supporting services, local health providers and community groups. While this is resulting is high levels of support and trust, it has meant less patients than expected have participated in WA Teletrials.

Other challenges and lessons learnt that have impacted on the implementation of this infrastructure program include

Sub-contract templates for studies sponsored by collaborative research groups or institutions are still outstanding and are not available nationally on the Medicines Australia website, which has potential to delay trial start-up if the addition of a Satellite Site requires local/state-based legal review or drafting of agreements

Further time is required to raise awareness of the program with Aboriginal health organisations and develop community–informed system changes to increase equity of access for community members in remote settings

There has been lengthy delays and high level of complex governance required for clinical trial-related digital software into the WA Country Health Service

Contract and TGA permit delays have impacted WA's ability to undertake clinical trials involving medications administered by infusions

WA's request for clarification about the relevance of all database fields relating to aspects of site and trial data capture may impact on evaluation data completeness and quality

Jurisdictional capacity and capability building through research activity on trials that did not convert to teletrials

Capacity and capability are built through experience and the jurisdictions have had a huge learning curve in working across the clinical trial environment in RRR places. Knowledge and understanding to utilise this experience have had an extensive impact on building the capacity and capability of the jurisdiction staff. The partner jurisdictions were asked to provide an overview of the research activity being carried out for trials that did not eventuate to teletrials noting that many laborious hours of work have been invested. The information below is to highlight two representative examples of identified key themes for failure of trial conversion and time investment in negotiations with various stakeholders:

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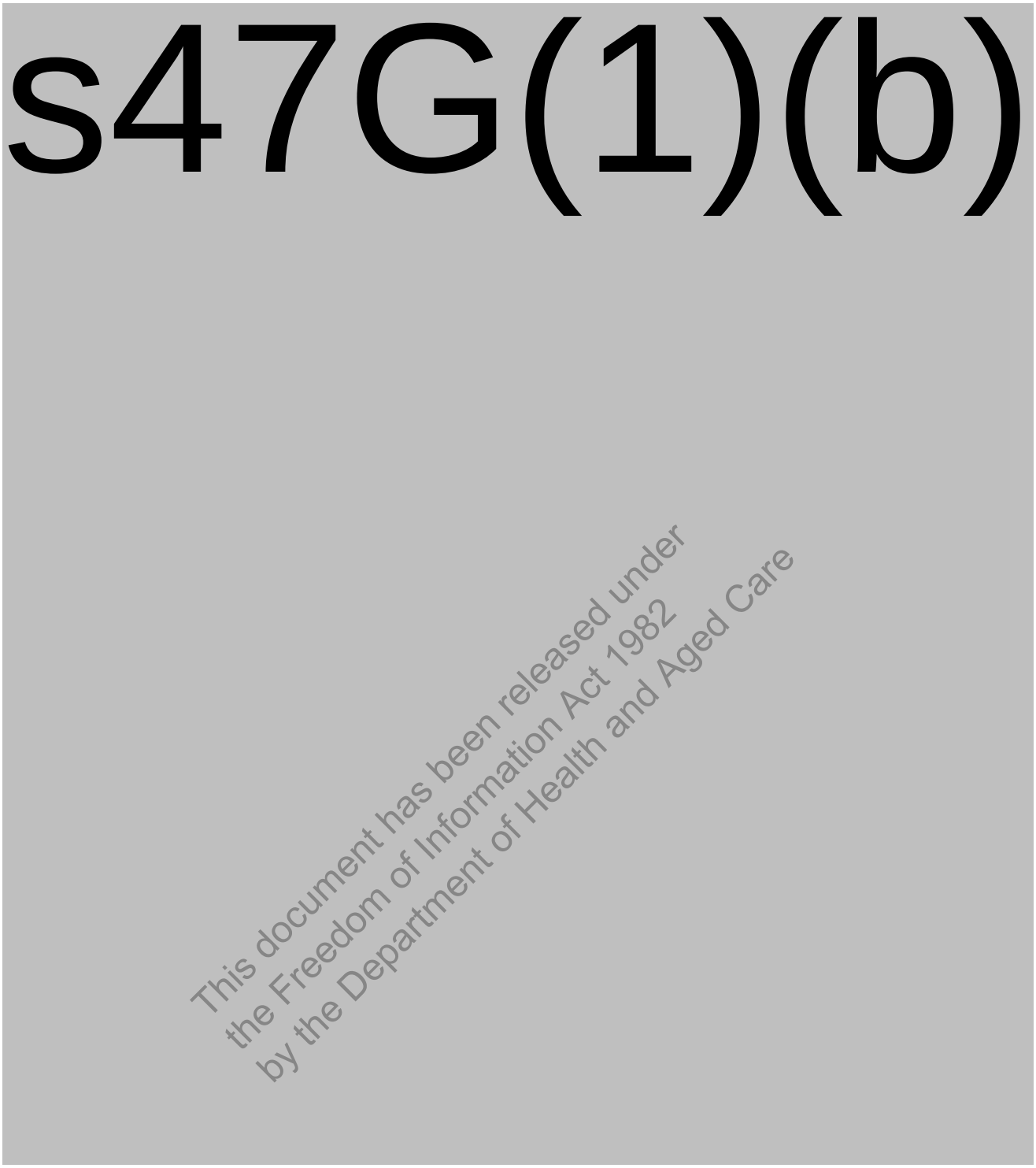
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Promotion of ATP

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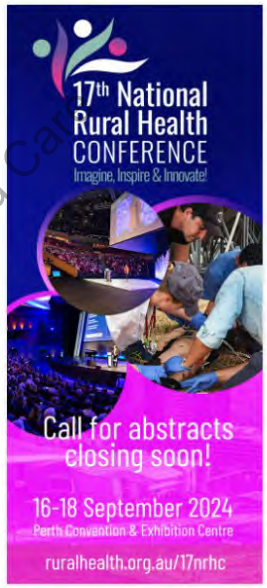
Teletrials provide hope for rural patients

Teletrials first telehealth consult

Australian Teletrial Program, Queensland Government
Issue: 86

An innovative health systems research program is helping improve access to care for patients in regional, rural and remote areas.

One-quarter of Australians living in regional, rural and remote (RRR) areas do so at the expense of their health. According to the Australian Institute of Health and Welfare, RRR populations have poorer health outcomes than those living in major cities, with higher



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expense of their health. According to the Australian Institute of Health and Welfare, RRR populations have poorer health outcomes than those living in major cities, with higher rates of hospitalisations, deaths, and injury combined with less access to and use of primary health care services.

That includes clinical trials and research studies, where people volunteer to try new treatments, devices or tests to help prevent, detect, treat or manage diseases or medical conditions. Clinical trials help determine if new treatments work, and if they are better than what is already available. But even though clinical trials can improve health outcomes, nearly 90% of participants are from metropolitan areas.

For Cairns based anaesthetist Vesselin Petkov, a clinical trial was the best option for a rare form of Hodgkin's lymphoma, but it was only available thousands of kilometres away. He said trying to access that treatment took its toll.

"It's a really tough, tough experience. Not only physically but mentally," he said. "You deal with the side-effects alone, without any family support. When you finish the treatment and get discharged from hospital and don't have anywhere to go. So you go to the airport and hope the side-effects don't kick in."

The Australian Teletrial Program (ATP) meant Dr Petkov could participate in the clinical trial via a teletrial at his local hospital in Cairns.

"It meant no more early morning flights, personal expenses, dealing with side effects alone away from the family," Dr Petkov says. He is now at the end of his maintenance phase and in full remission. He says while it was not all smooth sailing, he generally felt fine and was able to keep working full time.

Teletrials connect rural and regional doctors with metropolitan specialists through digital communication technologies, allowing them to facilitate clinical trials for diseases such as cancer closer to home for the patient.

" The program will help improve more equitable access to care for regional patients, as well as [improve] their health outcomes and quality of life. It can also increase collaboration between clinicians and healthcare workers, and develop workforce capability and capacity," says ATP Director Kaye Hewson.

The program was awarded $75m from the Commonwealth Medical Research Future Fund Infrastructure Grant for critical infrastructure and coordination of ATP, to allow people like Dr Petkov access trials closer to home.

As part of the program, Regional Clinical Trial Coordinating Centres (RCCC) have been established in Northern Territory, Queensland, South Australia, Tasmania, Western Australia and Victoria. New South Wales and Australian Capital Territory are separately implementing measures with a shared vision.

More News

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Clinical Oncology Society of Australia | Marryalyan

Your COSA membership brings you a number of multidisciplinary collaboration opportunities throughout the year, including access to our 26 Groups.

We promote the reports of COSA Groups and Affiliated Organisations monthly via the Marryalyan Report published in COSA eNews and our website.

This month, we hear from the COSA Regional & Rural Group, the Cancer Nurses Society of Australia (CNSA) and the Royal College of Pathologists of Australasia (RCPA).

COSA Regional & Rural Group

All Australians should have access to universal and equitable healthcare based on their individual need. However, nearly one-third of the population face poorer health outcomes because of where they live. Data shows people living in regional, rural and remote (RRR) areas have higher rates of hospitalisation, deaths, injury and poorer access to and use of primary health care services.[1] They also face barriers taking part in clinical trials due to cultural differences and geographic isolation.[2]

In 2016, the Clinical Oncology Society of Australia in collaboration with clinical trial sponsors, health administrators and clinicians to develop the Teletrial Model. Following a successful teletrial pilot study, the Australian Teletrial Program (ATP) is now a federally funded Health Systems Research initiative to reduce this inequity by remotely increasing clinicians and participants' access to clinical trials. This overcomes the need for participants to travel long distances to city areas, and makes clinical trials

overcomes the need for participants to travel long distances to city areas, and makes clinical trials accessible for new novel drugs, technologies and optimal management options for cutting-edge therapies, especially in cancer care.[3]

ATP provides infrastructure grants to build an interconnected network that uses telehealth technology to ensure clinicians and patients participate close to home at the same time as the trial. Currently, 88% of patients taking part in clinical trials are from metropolitan areas.[4]

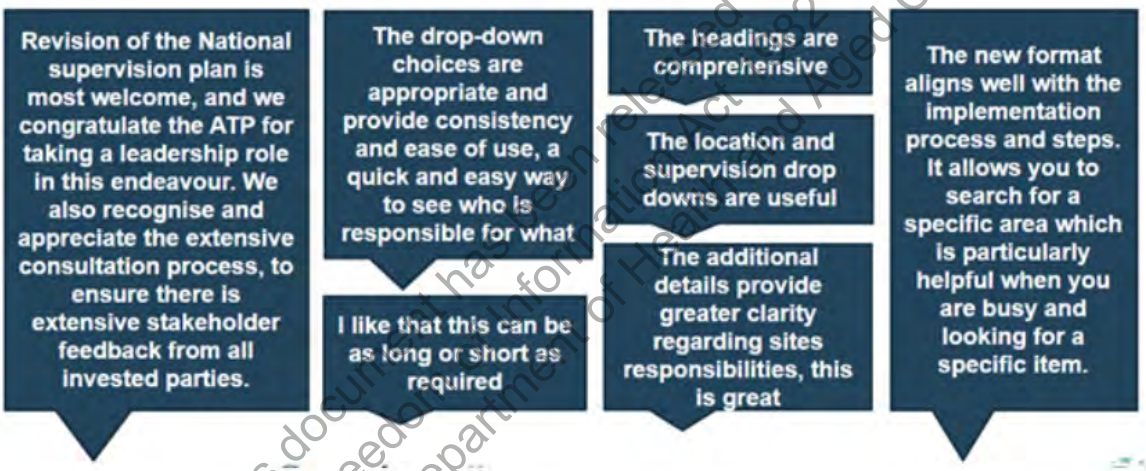
The Teletrial Supervision Plan was a key document in the pilot. As the Teletrial model expanded across jurisdictions, specialties, and interventions, multiple plans started to be used. This resulted in duplication of resources to recreate, different information being collected and inconsistent reporting for Sponsors. National standardisation of documentation was identified as a key priority for national harmonisation and implementation of Teletrials across jurisdictional boundaries.

National Collaboration Process

Collaborating with the Alfred Trial Hub, VCCC Alliance and New South Wales Ministry of Health, the ATP facilitated an extensive review of the Teletrial Supervision Plan to achieve a nationally accepted

Collaborating with the Alfred Trial Hub, VCCC Alliance and New South Wales Ministry of Health, the ATP facilitated an extensive review of the Teletrial Supervision Plan to achieve a nationally accepted document. The revised Supervision Plan has had input from various stakeholders who manage and undertake Clinical Trials and Teletrials. This included Research Governance Offices, Certified Human Research Ethics Committees, and Clinical Trial Sites with and without teletrial experience.

The ATP established an editorial group, engaging representatives from all jurisdictions with specialised expertise in Teletrials. Taking a co-design approach, the group undertook an extensive review of the content and key topics necessary for an effective and user-friendly Supervision Plan. Clinical Directors in each jurisdiction are now sharing throughout their oncology and non-oncology networks before a finalised version is endorsed by the ATP National Steering Committee and released publicly through Medicines Australia.

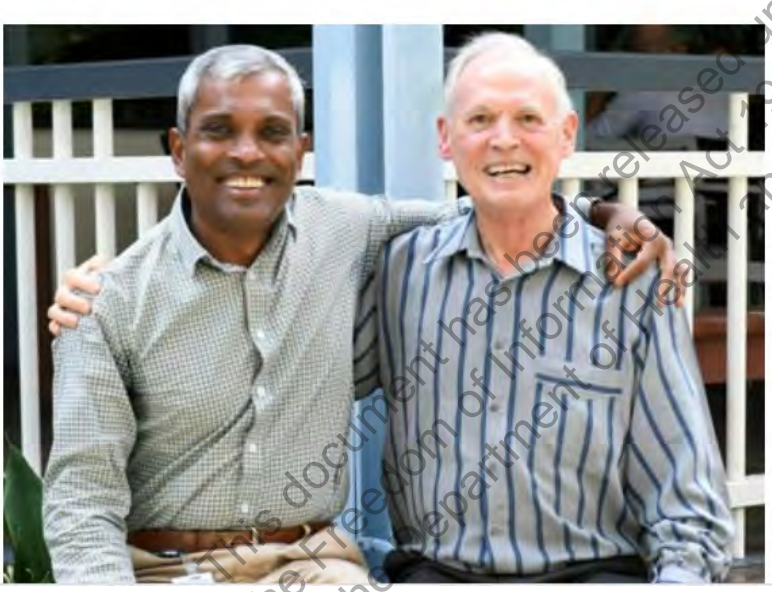


The National Supervision Plan has been harmonised using a rapid governance approach that keeps simplicity in mind. ATP representatives, led by the National Office and Western Australia, collaborated and collectively navigated different stakeholder groups to achieve a harmonised outcome. The success of multiple partners working together across all of Australia signals a clear direction for the future

of multiple partners working together across all of Australia signals a clear direction for the future development of standardisation practices and will become a framework to ensure ongoing collaborative co-design. Efforts now turn to the digital application options of the Supervision Plan to support ease of use, quick completion, and optimal user experience for Clinical Trials sites.

Ultimately, the beneficiary of clear standardised practices that encourage the implementation of Teletrials, are patients like Hugh. The Townsville grandfather was shocked when he was diagnosed with stage 4 lung cancer late last year. Chemotherapy wasn't viable, so Hugh participated in clinical trials for several medications. Traditionally he would have needed to travel to a metropolitan centre to do the trial, but Teletrials enables access for patients like Hugh closer to home. Despite his diagnosis, Hugh considers himself lucky to be given this opportunity. "I am so thankful that I have had the chance to take part in these clinical trials. My weight seems to have stabilised with the medications, and my muscles are not wasting away. In fact, I still walk around the river most days and mow the yard every week".

Should you wish to be involved in Teletrials, please contact Australian Teletrial Program.



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Decentralised trials could be the answer to boosting Australia's R&D profile

There has been a shift in how research into new therapies and medical technologies is conducted globally, and the new format is one that particularly suits Australia, a country nearly as large as the whole of Europe. Decentralised trials are bringing the research to the people, as trial investigators set up shop in more regional and remote areas of Australia.

The COVID-19 pandemic accelerated the uptake of decentralised trials to ensure that research could continue for life-saving therapies and medical technologies, and demonstrated that this model of clinical trial is effective.

MTP Connect, an independent not-for-profit organisation established by the Australian Government, produced an important report in 2021 which covered the clinical trials landscape in Australia.

The report highlighted opportunities to improve patient access and retention in the long term through the increased utilisation of decentralised trials. The report also suggested decentralised trials are a more patient-centric strategy, and improve patient participation and retention by reducing the burden of travel on patients.

Kaye Hewson is the Director of the Australian Teletrials Program, and has spent the last fifteen months years leading the initiative to promote the value of decentralised trials and allocate government funding received in 2021 to boost research across the country.

Speaking with London Agency, Ms Hewson explained the nuances between a decentralised trial and teletrial. Certain online sources use these terms interchangeably, however they do not actually mean the same thing.

"A decentralised trial is, very simply put, a clinical trial that goes into a patient's home from a central point. Teletrials are a sub-component or a type of decentralised trial," said Ms Hewson.

"A teletrial is a primary coordinating site that works with a local site, which is called a satellite site."

The satellite site collaborates with the primary coordinating site through telemedicine and digital health technology, and mobile or local healthcare providers provide the investigational drug or medical technology to the patient.

These types of clinical trials are a golden opportunity for healthcare practitioners in remote and regional areas of Australia to expand their knowledge and experience through administering a novel therapy and working with a primary coordinating site.

One of the challenges that industry and trial sites face when implementing a decentralised trial is the initial set-up cost; which is fixed and irrespective of the number of trial participants recruited.

The Australian Teletrial Program has $75.2 million in federal funding to support infrastructure development to support clinical trial sites closer to home for patients and with their trusted local healthcare providers. Ms Hewson said:

"We've done a lot of work on the infrastructure, setting up these Regional Clinical Trial Coordinating Centres, getting people recruited into these roles, working through what commercial sponsors need and want.

"Supporting our clinician researchers with streamlined processes and start-up specialists is abundant. We are learning from our patient experience and the need to include them in our planning and codesign of clinical trials outside of metro areas. We've developed some resources with for consumers in partnership with Alfred Trial Hub and Cancer Council Victoria. Available on our website."

"Through our funding we fund a primary site with $5,000 every time they bring on a satellite site. And then at the satellite site, we fund per patient, so we can give $700 depending on the location of site."

The Research & Development (R&D) Taskforce is a multi-sector collaboration between Medicines Australia, AusBioTech and the Medical Technology Association of Australia (MTAA). According to the R&D Taskforce, Australia is at the start of its teletrial revolution. *"We're still in the early phases of nutting out the challenges and seeing where we can do better in terms of implementing these solutions."*

The MTP Connect report noted that the clinical trials sector employs 8,000 Australians, and $1.4 billion was spent on clinical trials in Australia in 2019. For the medical technology industry specifically, MTAA reported in 2023 that more than 60% of the companies surveyed had trials starting in the next 12 months, supporting over 400 jobs in the Australian clinical trials sector. Whilst the sector now generates more export revenue than construction, intellectual property charges and government services, Australia's share of global industry-sponsored trials was just 5%.

Industry's answer to boost Australia's profile as a clinical trials destination is to turn as many of their clinical trials into decentralised trials as possible. Members of the Taskforce said: *"We always need more patients. We want to be competitive international and contribute a good number of patients to our trials."*

Members of the Taskforce noted that many healthcare professionals are reaching out to find out how they can be involved in a decentralised trial, which is a step in the right direction.

"The hope is ideally for some patients in the future, they can fully have their trial administered virtually at home. Not every trial, but some trials they could possibly have from their home interacting with their doctor by the phone, with devices to support," noted the Taskforce.

Clinical trials are an important contributor to the Australian economy, and the best way to increase their importance is to scale by expanding outside of the metropolitan areas of Australia.

The government funding to bolster Australia's teletrials landscape is a unique opportunity to determine whether this model will be a long-term solution to bridge the healthcare gap for patients living in rural and remote parts of the country.

Thank you to Kaye Hewson, Director of the Australian Teletrials Program, and the Medicines Australia R&D Taskforce, for their time being interviewed for this article.

Australian Teletrial Program

Access to clinical trials, closer to home

Australian Teletrial Program Webinar for Sponsors – Topic: Update on Teletrial landscape, FAQs

Details

Hello all,

Please join us for an informative and interactive session to hear an update on the Teletrial program, and how the ATP is leveraging enablers and addressing barriers and challenges.

The session will also revisit some of the questions asked in our first Sponsor Webinar and cover specific topics raised by the Sponsor Advisory Group. Your questions are welcomed either at the session or beforehand via australian_teletrial_program@health.qld.gov.au

We look forward to seeing you there.

Many thanks,
Lorelle

This event has passed.

Details

Wed, 06 Dec
09:30 - 10:30 GMT+10
Online

Register

Speakers (1)

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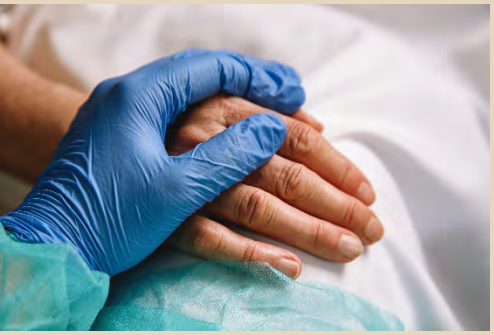
The State of Play in the Clinical Trial Landscape:

Context mapping for the Australian Teletrial Program

A context analysis and baseline report for the Australian Teletrial Program

September 2022



Authors

Project Team for the Evaluation of the Australian Teletrial Program
James Cook University & Queensland University of Technology
September 2022

Provided to the Australian Teletrial Program, Office of Precision Medicine & Research, Queensland Health on 14 September 2022.

Contents

Abbreviations

ACSQHC	Australian Commission on Safety and Quality in Health Care
ACTA	Australian Clinical Trials Alliance
AHRA	Australian Health Research Alliance
AHRTC	Advanced Health Research and Translation Centre
ANZCTR	Australian New Zealand Clinical Trial Registry
ATM	Australasian Teletrial Model
ATP	Australian Teletrial Program
CFIR	Consolidated Framework for Implementation Research
CIRA	Clinical Investigations Research Agreements
CIRH	Centre for Innovation in Regional Health
CT:IQ	Clinical Trials: Thinking Smarter
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
CTPRG	Clinical Trials Project Reference Group
EMR	Electronic Medial Records
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HS	Health Service
HREC	Human Research Ethics Committee
JCU	James Cook University
LHD	Local Health District
LHN	Local Health Network
MMM	Modified Monash Model
MRFF	Medical Research Future Fund
MTP Connect	Australian Government Medical Technologies and Pharmaceuticals Growth Centre
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance Scheme
OPMR	The Office of Precision Medicine and Research, Queensland Health
RCCC	Regional Clinical Trial Coordinating Centres
RGO	Research Governance Office
RRR	Regional, Rural and Remote
QH	Queensland Health
QUT	Queensland University of Technology
SEBS	South Eastern Border States
SSA	Site Specific Assessment
TGA	Therapeutic Goods Administration

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Executive Summary

The Evaluation of the Australian Teletrial Program (ATP) follows the establishment of six Regional Clinical Trial Coordinating Centres (RCCCs) in the health systems of Queensland, Victoria, Tasmania, South Australia, Northern Territory and Western Australia in partnership with respective health departments in a major project funded by the Medical Research Future Fund (MRFF) and administered by the Office of Precision Medicine and Research (OPMR), Queensland Health (QH). From 2021-2026, James Cook University (JCU) and Queensland University of Technology (QUT) will conduct a robust mixed-methods evaluation employing a concurrent triangulation design to quantify benefits, refine implementation strategy and ensure program sustainability beyond the project horizon.

This report details the process and summary findings of the initial evaluation work to establish the baseline context and current state of play of the clinical trials landscape in Australia. This work included review of clinical trials activity in Australia in 2021, a series of consultations with key stakeholders incorporating national and jurisdictional perspectives and a desktop analysis and environmental scan of the current clinical trial context. This baseline summary, which includes consideration of the ATP supporting pillars of policy harmonisation, education and training, recruitment and incentives, and equipment and infrastructure, highlighted that most current clinical trials activity, experience and capacity is anchored in the metropolitan and, to a lesser extent, regional centres. Themes and commonalities around the strengths, opportunities and challenges in the current trial environment are identified.

At this time some of the key strengths identified are the work currently being done to streamline Human Research Ethics Committee (HREC) processes through National Mutual Acceptance (NMA) scheme, the adoption of minimum standard of Good Clinical Practice (GCP) training, uptake and experience of telemedicine nationally to provide clinical services, and the roll out of the National Clinical Trials Governance Framework. It is acknowledged that more work is needed and underway to continue to strengthen the clinical trial sector. The national 'One Stop Shop' initiative, established clinical trial training platforms, and appetite for clinical trials across rural, regional and remote areas of Australia provide opportunity for continued development and leverage. The main challenges facing the clinical trial sector currently is the high degree of variation of research experience, activity and processes across jurisdictions, in addition to the strains already on the public health sector such as workforce and resourcing issues.

Once final analysis of all consultations is complete, the evaluation team will provide a summary of the jurisdictional information to key contacts in each RCCC to support local implementation of the ATP.

Introduction

The Australian Teletrials Program Evaluation Team, led by Professor Sarah Larkins and Professor Steven McPhail, provide this report to the Australian Teletrials Program, Office of Precision Medicine and Research, Queensland Health on 14 September 2022 as the summary documentation of findings related to work for completion of Performance Measure 1, Evaluation of the ATP. The objective of this work is to conduct context mapping and a baseline assessment of the Australian clinical trial landscape and clinical trial activity across Australia. This is the key work of Stage 1 of the Evaluation of the ATP. This report aligns with a summary presentation to the ATP team on 14 September 2022 by Professor Sarah Larkins and s47F , JCU and Professor Steven McPhail and s47F , QUT.

This report provides a baseline summary of the current clinical trials environment and landscape in Australia, including clinical trial activity nationally, with a focus on the supporting pillar areas pertinent to the implementation of the ATP: policy harmonisation, education and training, equipment and infrastructure and recruitment. The remit for the gathering of contextual information was a focus on clinical trials and on hospital and health service located trial activities. For completeness, clinical trial activity data were collected for all Australian jurisdictions. Health service and jurisdictional-specific data were primarily collected for those six jurisdictions that are part of this ATP Evaluation.

Evaluation Approach

Overview

This independent evaluation will take place over five years and is conceptualised in three stages (Figure 1):

1) Stage 1 – Stakeholder engagement and context mapping
2) Stage 2 – Data collection during ATP implementation
3) Stage 3 – Final integrated analysis

The mixed methods evaluation is underpinned by the Consolidated Framework for Implementation Research (CFIR)[1] and will be conducted using concurrent triangulation methodology combining qualitative and quantitative data sources. The CFIR is a framework for implementation research that can guide systematic assessment of multilevel implementation contexts. The framework describes five major domains that interact to shape the effectiveness of implementation[1]. The five domains relate to: (i) intervention characteristics; (ii) the outer setting; (iii) the inner setting; (iv) characteristics of the individuals involved; and, (v) implementation processes. There are various constructs identified in each domain that may be monitored and evaluated prior to, during and following implementation. The data needed for this evaluation is informed by these domains and associated constructs.

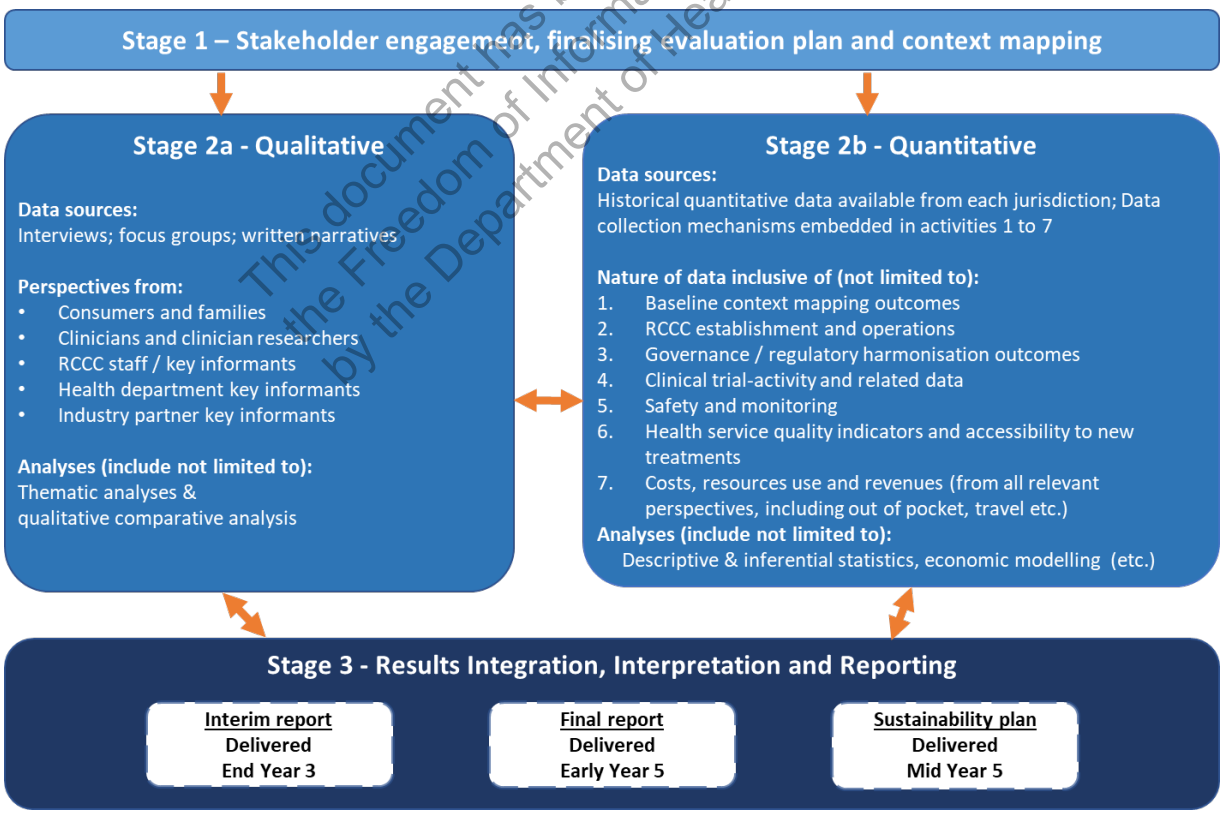


Figure 1. Summary of mixed methods evaluation

Stage 1: Stakeholder Engagement and Context Mapping

Stage 1 has built on prior and ongoing work performed during the Australasian Teletrials Model (ATM) pilot by extending context mapping, policy analyses and engagement with clinicians and other relevant stakeholders from a broad array of clinical areas, contexts and geographical regions. This stage will aid in identifying whether (and how) modifiable components of the ATM should be adapted in each jurisdiction supported by RCCCs and enhanced by the 'supporting pillar' activities. It has also confirmed the requirements for standardising and embedding data collection procedures for the purposes of monitoring and evaluation (Stage 2). This work will be carried out in partnership with RCCC project teams in each state and territory.

Stage 1 work and outcomes will support:

1) Establishing a baseline for the evaluation outcomes (shown in Box 1) to address each of the evaluation objectives;
2) Planning with the project team and partners to help each jurisdiction tailor the RCCC and supporting pillar activity implementation appropriately to local contexts and policy environments; and
3) Ensuring buy-in and engagement of stakeholders in the process.

Box 1. Evaluation objectives

1. Conduct context mapping of the Australian clinical trial landscape and baseline assessment of clinical trial activity across Australia and in each state and territory.
2. Evaluate the impact that the RCCC implementation, operations and supporting clinical trial activities (over five years across six participating Australian states and territories) has on the:
    a. Number of new clinical trial sites and expansion of existing sites, including the type and location of new clinical trials, and their status (commenced or completed)
    b. Number of participants recruited to clinical trials (and safely retained) from regional, rural and remote areas
    c. Quality (including accessibility, acceptability, wider use of telehealth) and safety of clinical trial services provided
    d. Rural and remote clinical and research workforce, and capacity
    e. Perceptions and experiences of key stakeholders and key informants regarding the ATP implementation process within and across the jurisdictions, including the barriers and enablers to successfully implementing the model
    f. Economic impact and sustainability of scaled implementation across Australia from relevant perspectives for informing policy and practice decisions
3. Evaluate the impact and engagement with program elements related to the four supporting pillars (policy, education, equipment, recruitment boosting tools) from the perspectives of stakeholders and by quantifying and describing key outcomes.
4. Generate interim, final and sustainability reports that provide recommendations for implementation modification and sustainability planning based on the findings of the evaluation activities during ATP implementation.

Evaluation Logic Model

This logic model (Figure 2) underpins the overall evaluation of the implementation, impact and sustainability activities of the ATP.

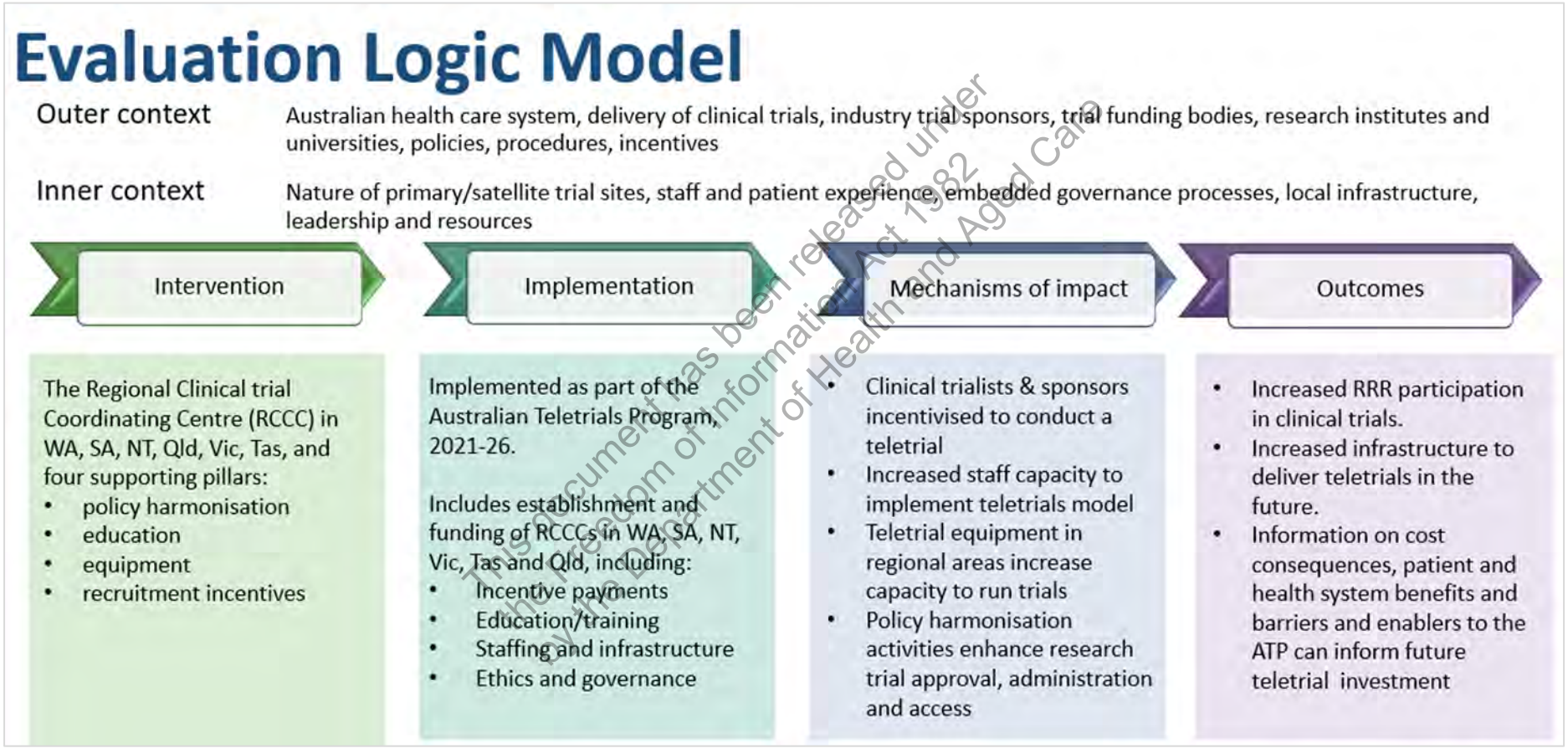


Figure 2. Evaluation logic model

Methods

Overview

We used both qualitative and quantitative methods to complete Stage 1, which involved an environmental scan, stakeholder consultations, policy analysis and process reviews to inform a series of baseline values for the evaluation objectives of each participating jurisdiction. Table 1 outlines the aims and methods of each engagement and mapping activity of Stage 1.

Table 1: Overview – aims and methods context mapping and stakeholder consultations

Context mapping and engagement activity	Aim	Method
Environmental scan	To quantify the extent to which existing clinical trial supporting infrastructure is largely based in major metropolitan centres, with limited supporting infrastructure for clinical trials (sites and participants) in regional, rural and remote (RRR) areas.	Collect and examine information available from secondary and public sources (such as the Australian New Zealand Clinical Trials Registry (ANZCTR) website) on existing clinical trial infrastructure such as resources, supporting systems, facilities, services, technology and so forth.
Policy analyses and process reviews	To identify opportunities for harmonisation and streamlining of existing policies and processes associated with ethics, governance, safety, monitoring and other regulatory requirements.	Identify policies and processes relevant to clinical trials in each jurisdiction. Conduct an analysis to understand their purpose, use and impact to the clinical trial environment. Consult with key stakeholders on their interaction with the relevant policies and processes.
Estimating and quantifying a baseline/pre-implementation of the objectives	To establish a baseline of clinical trial activity in order to determine the degree of impact that implementing the ATP has on the evaluation objectives and clinical trial landscape. In addition, to understand the spread of activity across RRR and metropolitan areas.	Collect data relating to the evaluation objectives from secondary and public sources where possible during the year 2021. For example: Perform a review of clinical trial registries such as ClinicalTrial.gov and ANZCTR to understand the details of all clinical trials active to recruitment in 2021 in each jurisdiction.
Consultation with key stakeholders	To capture narratives of highly experienced stakeholders within the current clinical trial context prior to implementation. The key themes identified will assist in context mapping and informing the next phase of the evaluation.	Consult with experienced stakeholders per jurisdiction on their perceptions, opinions and experiences relating to the current/pre-implementation clinical trial environment.

Clinical Trial Registry Data Analysis

The purpose of the registry analysis was to collate data for approved interventional clinical trials that were active in Australia (all jurisdictions) at some point in the year 2021 as part of a broader environmental scan. The year 2021 was chosen as it was the most recent full year of data available. The registry used was the Australia New Zealand Clinical Trials Registry (ANZCTR)[2], which is the main registry for clinical trials in Australia. Clinical trial data for the 2021 calendar year was extracted in June 2022 from the ANZCTR website and is summarised in Table 2.

Table 2: Data collection - ANZCTR

Activity	Process	Details
Data Extraction	Step 1: Access website Step 2: Advance search	**Date of Extraction:** 13/07/2022 https://www.anzctr.org.au/TrialSearch.aspx **Registry: All (ANZCTR and ClinicalTrial.org)** Description of interventions: *blank* Intervention code: *nil selected* **Study type: Intervention** Allocation to intervention: *blank* Recruitment status: *nil selected* Health condition: *blank* Condition category: *blank* Gender: *blank* Age group: *blank* **Ethics application status: Approved** Healthy volunteers: *blank* **Registration date: *From: 01/01/2021 – To: 31/12/2021*** Trial start day: *blank* **Countries of recruitment: Australia** Location within Australia: *blank* Primary sponsor type: *blank* Funding source type: *blank* Phase: *blank*
Data Cleaning		Data of interest that was entered using free text fields were reviewed for spelling errors or duplications prior to analysis. Despite the attempt to clean data, there were instances where free text data could not be cleaned due to missing information. For example, the name of the approving HREC of a particular study could not be identified because the HREC name was missing.
Collation and analysis	Data underwent descriptive statistical analysis using R software to provide a description on the types of clinical trials, participants, sponsors, funders, clinical trial sites and characteristics of completed studies.	

	Clinical trial site postcodes were categorised according to the Modified Monash Model (MMM) classification. Descriptive statistics were used to determine the count and percentage of sites within each MMM category. These data were visually mapped using the R packages *sf* and *mapview.* *Whole of Australia data* All data were used, and all clinical trial identifiers had "trial" column as Australia. *Jurisdictional data* Data were separated by recruitment jurisdiction "trial" column. The number of trials that were run over multiple jurisdictions was recorded and the trial included in the data set for every state that it lists. For each jurisdiction, separate spreadsheets were developed containing the clinical trials active in each state, along with data linked trials identifiers in all other tabs.
Underpinning assumptions	Phase summaries are only relevant for drug trials and so use of any phase variable would exclude non-drug trials. We used a conservative approach when selecting the MMM classification for each postcode, by taking the *closest* MMM class to a major city when a postcode had multiple MMM categories. Data are summarised as count (percentage) or median (first and third quartile) unless otherwise stated.
Limitations	Not all studies registered on ANZCTR and ClinicalTrials.gov are clinical trials. Due to this, we expect that clinical trial activity in 2021 described using this data is overestimated. The registry data may not be correct or up to date.

Desktop Analysis & Environmental Scan

Process

This scan and mapping activity focussed on available secondary and public sources, and grey literature on existing clinical trial infrastructure, policy and procedures, health service research characteristics, including resources, supporting systems, facilities, staffing and technology. A collated list of all data sources is included in Appendix A. Process details are shown in Table 3 and Table 4.

Table 3: Data collection - Hospital and health service characteristics, clinical trial activity, infrastructure and equipment, education and training, governance and ethics

Activity	Process
Data Extraction	Dates completed: 11/07/2022 - 23/08/2022 1. State-level Department of Health (or equivalent) websites for each jurisdiction were reviewed to confirm the public health services (e.g., Local Health Networks) or hospitals (e.g., where hospitals are governed directly by state-level health department) that fell under each jurisdiction's health department. 2. For the health services or hospitals determined through Step 1, their corresponding website or webpage was searched to address all fields. The list of variables used, inclusion criteria and assumptions made are in Appendix A. 3. Each services' website was searched for the terms 'research', 'ethics' and 'clinical trials'. Where no results were found, it was assumed that the service does not currently have research resourcing or infrastructure. This was reported in our data collection as 'Not Reported'. 4. Webpages that were dedicated to Research and/or Clinical Trials were reviewed to address relevant variables, and webpage addresses were recorded. 5. To address remaining variables associated with health service delivery and capacity, links were followed within the website for the service's latest Annual Report and current Strategic Plan. 6. For all variables, where data was not found through searching within the website, variables were reported in our data collection as 'Not Reported'.
References	Endnote database was compiled as repository of all included service websites and research webpages.

Table 4: Data collection - Policy harmonisation

Activity	Process
Data Extraction	Dates completed: 24/07/22 - 09/08/22 1. Online search of each jurisdiction using 'research ethics', research governance' and 'clinical trials' 2. Searched Therapeutics Goods Australia (TGA), National Health and Medical Research Council (NHMRC), National Mutual Acceptance, Australian Commission for Safety and Quality in Health Care (ACSQHC), Clinical Trial Project Reference Group (CTPRG), MTP Connect. 3. Followed links to national sites, policies, procedures until all required fields for ethics and governance were completed (Ethics, Governance) 4. Followed links from national sites, policies, procedures, peak bodies until no new clinical trial documents were being identified (Policy and process) 5. Included documents that specifically include the term policy, process, procedure. Documents noted as checklist, guides, FAQs, lists, references excluded and saved in separate folder 6. Information cross checked against ACSQHC[3, 4] and the NMA Group[5] documents. 7. End note database as repository of all included materials.
References	Endnote database was compiled as repository of all included materials.

Collation and analysis

Quantitative data and descriptive information collected during the environmental scan, policy analysis and baseline data collection were collated initially into a series of Excel spreadsheets for each jurisdiction and /or activity. The study team systematically reviewed and examined information collected, identifying key and common elements and characteristics and a dashboard was created for each jurisdiction. Information was also reviewed and then extrapolated to each ATP pillar, where relevant.

Consultation Interviews

Ethical and governance approvals

In June 2022 ethics approval was received from the Townsville Hospital & Health Service HREC, approval number s47G(1)(a), to conduct a series of consultation interviews with key stakeholders in the Australian clinical trial and teletrial space. This approval was deemed necessary as the evaluation involves health service organisations and jurisdictions that have a requirement for governance approvals for this type of evaluation activity. It also enables the publication of outcomes from the Stage 1 baseline assessment and mapping activities.

Additional reciprocal HREC approval was granted by Northern Territory Health (NT s47G(1)(a)). Governance approvals were obtained by relevant health services where required to conduct the consultation interviews with health department staff.

Participant group and recruitment

Stakeholders included industry (commercial, university and medical research institutes) representatives, service providers, health service representatives, and RCCC management who were consulted about their perceptions, opinions and experiences relating to the current/pre-implementation clinical trial environment. Stakeholders for consultation interviews were identified by members of the study team as well as snowball sampling (chain referral), or during meetings following discussion of the evaluation during presentations or discussions with stakeholders. Study team members asked potential consultation participants if they were willing to be contacted by a member of the study team. Those who agreed were contacted by the Evaluation Project Manager, JCU by email or phone (depending on preference) and provided with further information and an opportunity to discuss any questions related to participation in the consultation activity.

Process

Stakeholders who agreed to participate were asked a set of open-ended questions relating to their clinical trial and teletrial experience, their opinion on adopting the ATM and their related experience within the 'supporting pillar' activity areas (policy and process harmonisation, education and training, equipment, and recruitment boosting tools and incentives). Questions were tailored to suit the stakeholder and their industry/occupation background.

All consultations were recorded using a digital recorder and all participants consented to having their interview recorded. In addition, the researcher took written notes of the conversation. Prior to each consultation commencing, participating stakeholders were advised that their deidentified responses may be used in publications in the future and that continuing the consultation implied that they consent to this occurring in the future. One participant declined to have their responses directly quoted in publications. Twenty-seven

consultations were conducted between 1 August and 1 September. Details of stakeholder groups and jurisdictions represented are shown in Table 5 (noting that one participant represented both stakeholder groups) and Figure 3.

Table 5: Participant summary at 14/09/22

	Stakeholder Group			
Jurisdiction	Health Service	Service Provider	Industry	RCCC
QLD		1	3	3
WA		1		
SA	1*		1	3*
NT	1	2		2
TAS			1	1
VIC			3	1
National			4	
TOTALS	**2**	4	**12**	**10***

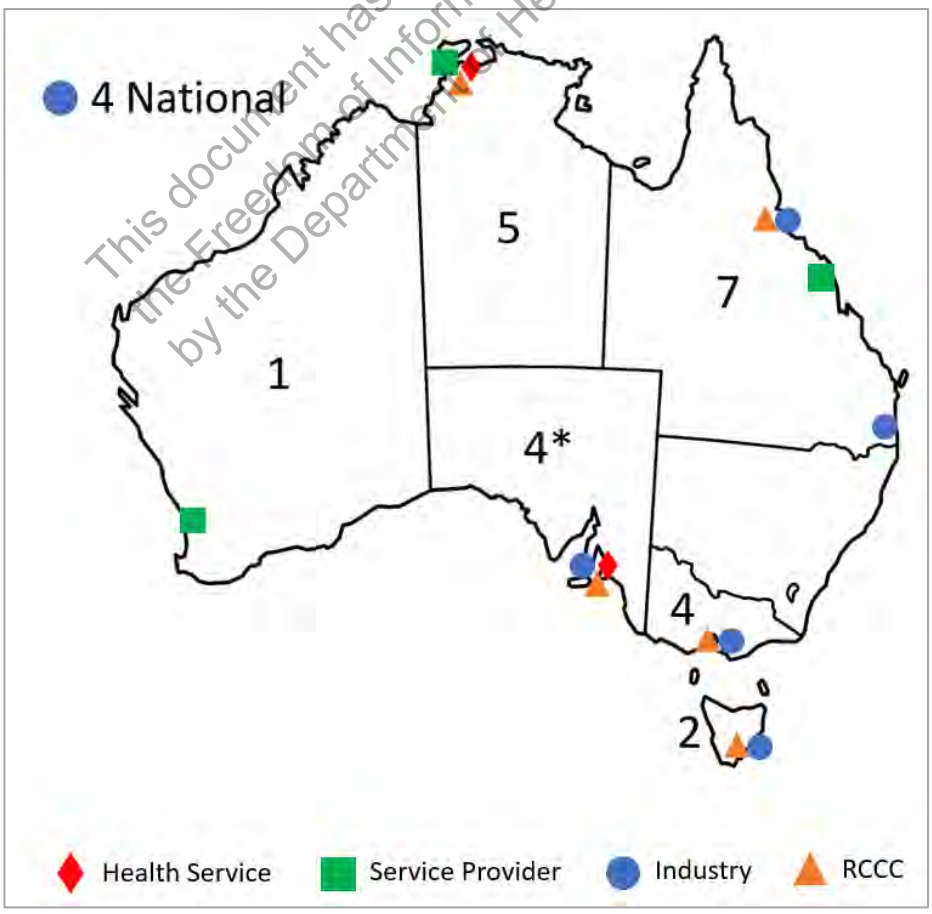


Figure 3. Participant summary at 14/09/2022

Initial data analysis

Audio files were transcribed using software (NVIVO and Otta) and checked for accuracy. During this checking process, the transcripts were anonymised. Transcripts were imported into NVIVO where they were coded by two readers. Analysis of participant responses follows an initial deductive process guided by the CFIR constructs to understand and describe the clinical trial context. followed by line-by-line coding for emerging themes.

Initial outcomes

In the consultations, participants were asked questions about the pillars of policy harmonisation, education and training, and site and participant recruitment. Responses provided were detailed and a range of views were verbalised. The discussions covered many aspects related to the pillars and sometimes points that were discussed in relation to one pillar intersected with points made about others.

Opinions appeared to be both positive and negative, and often a mixture of both, and were often expressed strongly and elaborated on at length. While comprehensive and in-depth analysis will follow, some example quotes that capture some of the sentiments expressed in the interviews are provided under each pillar heading for illustrative purposes.

Additional data collection and analysis

Further consultations will take place once the study team have obtained the additional required governance approvals and so results will continue to be reviewed and analysed. Once additional consultations are completed in October 2022, final analysis will be incorporated into a peer reviewed paper for publication and shared with jurisdictions to assist in their teletrial implementation.

Results Integration

A large volume of data from multiple data sources was collected as part of the desktop analysis, environmental scan and stakeholder consultations. To ensure the accurate and useful integration of the information we completed a process of triangulation of information from each data source and from core reference materials. These data are presented in clinical trial activity and jurisdictional dashboards and pillar summaries. Data relating to resourcing, capacity and infrastructure from each jurisdiction is presented in an aggregate format, except in the case of notable variations or exceptions that warranted further review or discussion. ANZCTR data for trial sites was combined with data collected through the desktop analysis for each of the health services or hospitals. The results were then used to assess the research capacity and readiness for each jurisdiction. A summary by health service or local network using 'capacity' or 'enabling' categories on a continuum of initial, growing or established is included in the jurisdictional reporting, shown in Figure 4.

Figure 4: Research capacity and enabling continuum

Due to the variation in systems and reporting across the six jurisdictions, criteria for reviewing research capacity and readiness were chosen based on data available and reported across all services, and that would support a holistic review of a service's capacity in relation to clinical trial readiness and systems maturity.

Criteria for determining research readiness are:

1. **Research prioritised by the health service** in their strategic plan as reported in 2020-2021 annual report
2. **Research support and resources are in place** at health service
3. **Previous recent experience in clinical trials**, based on 2021 clinical trial registry data

Health services were reviewed against these criteria and were determined to be in the 'Initial', 'Growing' or 'Established' phase of research readiness and maturity.

Where it was found that a health service currently addresses all three criteria, they were determined to be towards the 'Established' phase, whereas those services that did not currently address any of the criteria may still in the 'Initial' phase. Those that addressed some of the criteria fell between the two - for example, a service may have a Director of Research or Research Office, however may not have previously hosted a clinical trial, or has limited infrastructure, workforce or equipment to do so. These services were determined to be in the 'Growing' phase.

Consistent themes and criteria related to capacity and readiness to implement clinical trials emerged. These align with recent publications by MTP Connect[6] and ACSQHC[3] on aspects of the clinical trial landscape in Australia. These are summarised under the headings of baseline context strengths, opportunities and challenges.

Clinical Trial Activity in Australia 2021

The following section provides an overview of clinical trial activity in 2021 from the ANZCTR, as described in 'Methods' (Page 11). Aggregate data on trial types, sponsors and funders, sites, and participants is presented.

Overview

1020*

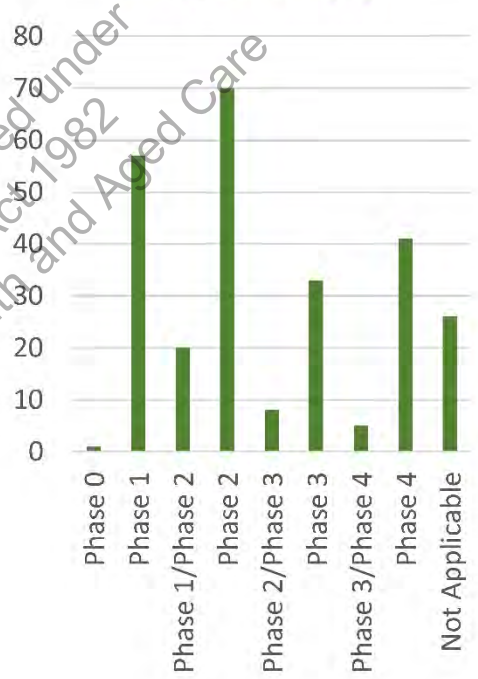
HREC approved trials were registered on ANZCTR and clinicaltrial.gov in 2021

67%	17%	9%	6%
Treatment	Prevention	Education	Diagnosis

Intervention Code (n)

Treatment: Other	336
Treatment: Drugs	261
Behaviour	215
Prevention	163
Treatment: Devices	159
Lifestyle	134
Rehabilitation	84
Diagnosis / Prognosis	60
Early detection / Screening	48
Treatment: Surgery	30
Other interventions	7

Drug Trials (n)



Top 10 Health Conditions

account for 68% of all health conditions represented in 2021

1. Mental Health
2. Cancer
3. Public Health
4. Neurological
5. Musculoskeletal
6. Cardiovascular
7. Respiratory
8. Physical Medicine/Rehabilitation
9. Metabolic and Endocrine
10. Infection

*At 13th July 2022

Overview (continued)

Top 10 Sponsors

Primary Sponsor Name	%
An individual	12
University of Sydney	5
University of Melbourne	4
University of New South Wales	3
University of Queensland	3
Monash University	3
Deakin University	2
University of Newcastle	2
Flinders University	2
University of Adelaide	2

Top 10 Funders

Funding Source Name	%
NHMRC	9
MRFF	3
University of New South Wales	1
Deakin University	1
University of Sydney	1
Flinders University	1
Monash University	1
Griffith University	1
University of Melbourne	1
Australian Government DoH	1

COMPLETED STUDIES

137
studies registered and completed in 2021

184 days
trial duration (median)

101 stopped
primarily due to efficacy and/or safety reasons

Participants

88%
Male & Female

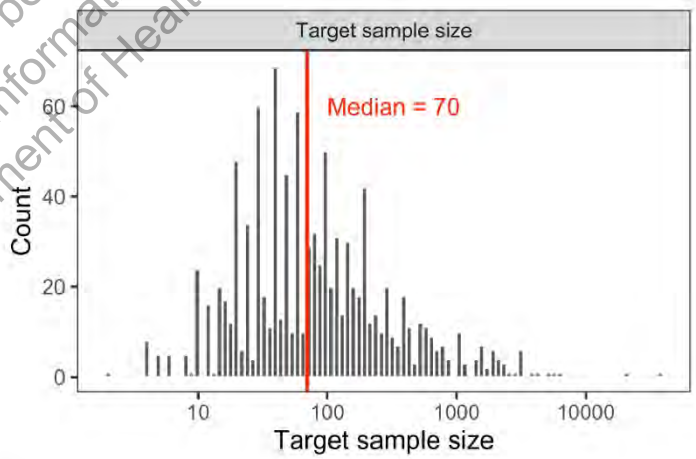
8%
Female Only

4%
Male Only

85%
of studies where minimum age was 18 years or older

15%
of studies where maximum age was than less 18 years

70 participants
Median target sample size



33.6%
Recruited their target sample size

35%
Recruited **more** than their target sample size

31.4%
Recruited **less** than their target sample size

Sites

2,065
Trial sites

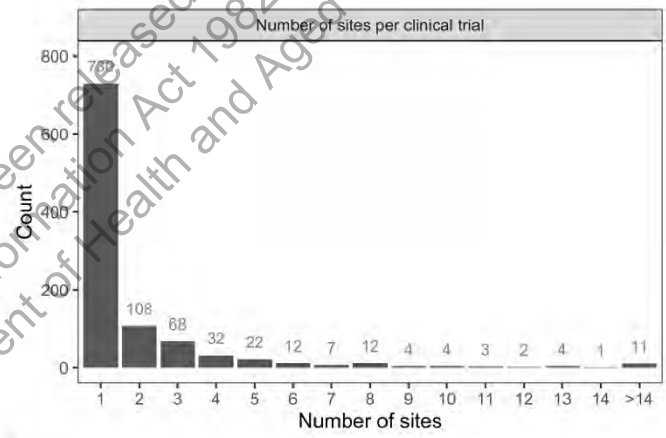
1,873
Hospital trial sites

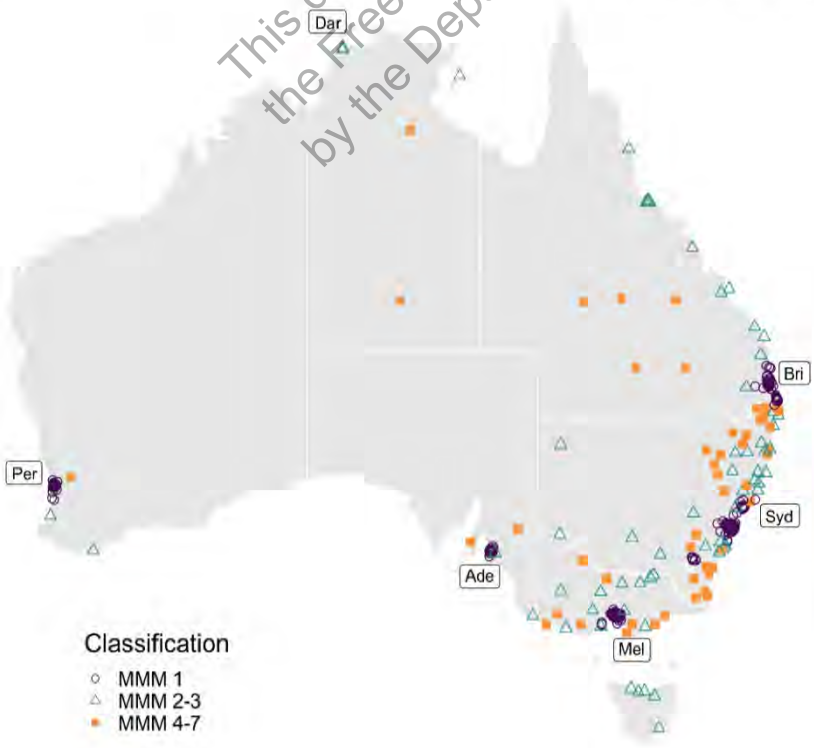
Top 10 Hospital Trial Sites

Hospital Name	n
s47B(a)	

1 site
per clinical trial (median)

24%
Of clinical trials recruit across two or more states





88%
Of clinical trial sites were located in Metropolitan areas (MMM1)

State and Territory Clinical Trial Activity and Capacity

Exploring Research Capacity in RRR areas

This section presents collated information about each jurisdiction from data collected from ANZCTR and the jurisdictions' websites and publicly available documents. It also includes an overview of the level of research readiness for health services in each jurisdiction, using the criteria and approach set out in 'Results Integration' (Page 19).

Queensland

SUMMARY DASHBOARD

~5.3 million
Population

1.853 million km2
Land Area

4.6% Aboriginal and Torres Strait Islander

37% population
live outside of metropolitan areas

Health Department & Hospitals

1 Department of Health

16 Hospital & Health Services

123 Public Hospitals

Major Cities – 20
Inner regional – 27
Outer Regional – 43
Remote – 13
Very remote – 20

Universities

8 Universities

s47B(a)
research income

50% trials
were university sponsored

Clinical Trial Activity

328 trials in 2021

Trial Sites

- Hospitals and Health Service Sites
- Industry, Private and Other

Queensland

RESEARCH RESOURCES AND INFRASTRUCTURE

Research Documentation and Information

14 HHSs mention research as a priority in their Strategic Plans/priorities

↓

Remaining 2 are regional HHSs

12 HHSs provide information on conducting research in the HHS on their website

↓

Remaining 4 are regional HHSs

12 HHSs had at least one clinical trial site registered to ANZCTR in 2021

↓

Remaining 4 are regional HHSs

Research equipment, space and resources

All HHSs report telehealth capabilities

10
NHMRC Registered HRECs*

11
Research Governance Offices

Regional HHSs

None → Small teams or office space → Dedicated research/ trial infrastructure and centres

** HRECs situated under Health Service*

Queensland

RESEARCH CAPACITY AND READINESS

Enablers

- All HHSs report telehealth capabilities
- 14 of the 16 HHSs mention research as a priority in their current Strategic Plan
- All HHSs with an HREC and/or RGO use the ERM system and have a consistent approach to the review and processing of applications
- 12 HHSs had at least one trial site registered to ANZCTR in 2021

Challenges

- Variation in the level of dedicated resources to support research, with those HHSs who report no or limited resources in predominately regional areas
- Workforce capacity and retention, and competition for resourcing
- Large geographical areas for regional health services to service
- Ageing infrastructure across HHSs

Northern Territory

SUMMARY DASHBOARD

~230,000
Population

1.42 million km2
Land Area

26.3% Aboriginal and Torres Strait Islander

100% population
live outside of metropolitan areas

Health Department & Hospitals

1 Department of Health

5 Health Services (Regions)

6 Public Hospitals

Major Cities – 0
Inner regional – 2
Outer Regional – 0
Remote – 2
Very remote – 2

Universities

2 Universities

s47B(a)
research income

67% trials
were university sponsored

Clinical Trial Activity

119 trials in 2021

Trial Sites

- Hospital Sites
- Industry, Private and Other

Northern Territory

RESEARCH RESOURCES AND INFRASTRUCTURE

Research Documentation and Information

NT Health's Strategic Plan mentions research as a priority to the department

Teletrials has a dedicated page on NT Health website

2 Health Services had at least one clinical trial site registered to ANZCTR in 2021

↓

Remaining 3 are Remote/ Very Remote Health Services

Research equipment, space and resources

3 regions clearly report telehealth capabilities

2 are unclear

1
NHMRC Registered HRECs*

1
Research Governance Office
Individual SSAs for each Regional Health Service

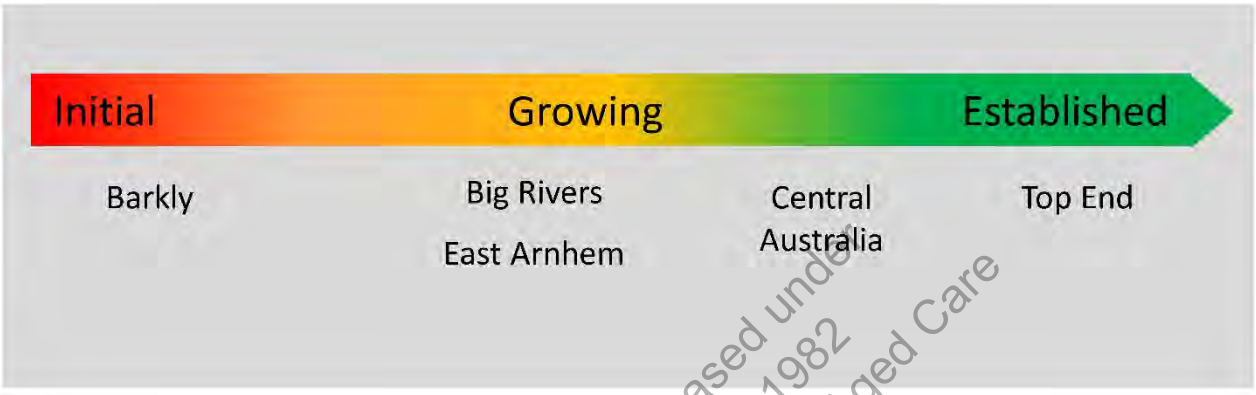
All research governance support is through NT Health

Clinical Innovation and Research Committee supports Top End, Big Rivers and East Arnhem Regions

** HRECs situated under Health Service*

Northern Territory

RESEARCH CAPACITY AND READINESS



Enablers

- NT Health's Strategic Plan mentions research as a priority
- Teletrials has a dedicated page on NT Health's website
- NT Health has strong existing research and education partnerships with Menzies and Flinders Universities

Challenges

- 40% of the NT's population live in remote or very remote areas
- The NT's young Aboriginal population is growing, while its non-Aboriginal population is ageing and often transient
- There are only 6 public hospitals to service the whole state

A recent restructure has reclassified Health Services, from two regions up to five. This restructure includes changes to research support (including clinical trials) which now falls under a single RGO in NT Health, rather than at each site.

This may be seen as both an enabler (e.g. streamlining processes) and a challenge (e.g. capacity and resourcing).

Western Australia

SUMMARY DASHBOARD

~2.6 million
Population

2.5 million km2
Land Area

3.3% Aboriginal and Torres Strait Islander

22% population
live outside of metropolitan areas

Health Department & Hospitals

1 Department of Health

5 Hospital and Health Services

88 Public Hospitals

Major Cities – 19
Inner regional – 11
Outer Regional – 23
Remote – 19
Very remote – 16

Universities

5 Universities

s47B(a)
research income

52% trials
were university sponsored

Clinical Trial Activity

239 trials in 2021

Trial Sites

- Hospitals and Health Service Sites
- Industry, Private and Other

Western Australia

RESEARCH RESOURCES AND INFRASTRUCTURE

Research Documentation and Information

All health services mention research as a priority in their Strategic Plans/priorities

All health services provide information on conducting research in the HHS on their website

4 HSs had at least one clinical trial site registered to ANZCTR in 2021

↓

None registered to WACHS sites

Research equipment, space and resources

WACHS Command Centre 24/7 'virtual' clinical hub provides access through telehealth

8
NHMRC Registered HRECs*

6
Research Governance Offices

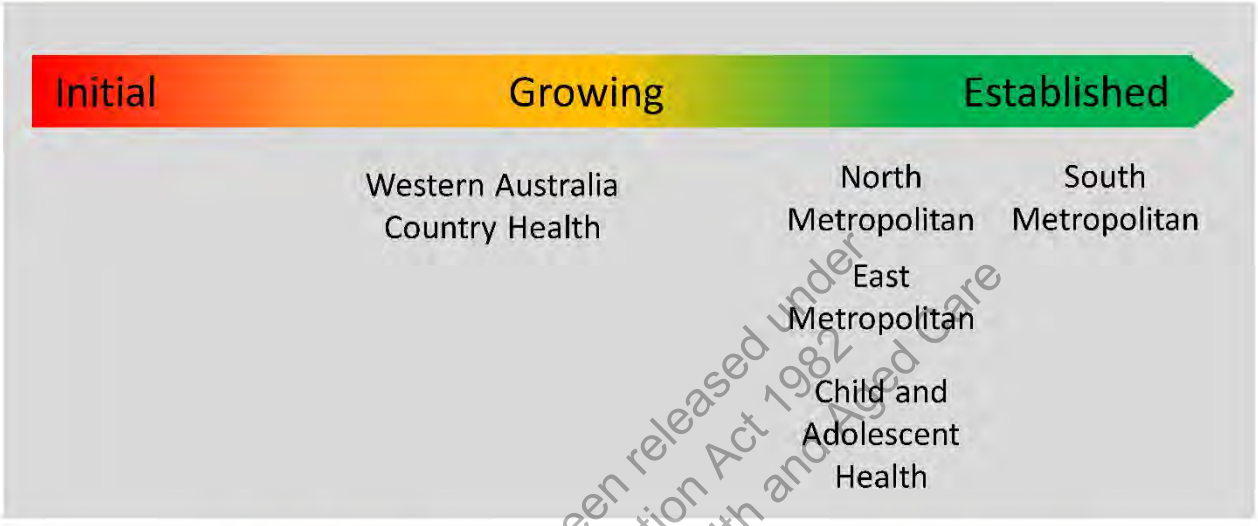
All Health Services have dedicated research support

WACHS Research Governance covers all 7 regions

* *HRECs situated under Health Service*

Western Australia

RESEARCH CAPACITY AND READINESS



Enablers

- WACHS Command Centre brings together new and existing emergency and specialty services in a 24/7 'virtual' clinical hub that provides access through telehealth
- Teletrials was mentioned as a focus area in WACHS' 'Research and Innovation Strategy'
- WACHS Central Office hosts an HREC and RGO
- Strong research experience and capacity in metropolitan WA

Challenges

- WACHS governs 65 hospitals and 48 other public health facilities
- WACHS is the largest area in the world covered by a single health authority
- WACHS HREC and RGO is responsible for the governance of research across the 7 regions across country WA
- WACHS did not have any clinical trial sites registered with the ANZCTR in 2021

South Australia

SUMMARY DASHBOARD

~1.7 million
Population

983,000 km2
Land Area

2.4% Aboriginal and Torres Strait Islander

26.5% population
live outside of metropolitan areas

Health Department & Hospitals

1 Department of Health

10 Local Health Networks (6 Regional)

75 Public Hospitals

Major Cities – 15
Inner regional – 16
Outer Regional – 28
Remote – 12
Very remote – 4

Universities

4 Universities

s47B(a)
research income

50% trials
were university sponsored

Clinical Trial Activity

254 trials in 2021

Trial Sites

- Hospitals and Health Service Sites
- Industry, Private and Other

South Australia

RESEARCH RESOURCES AND INFRASTRUCTURE

Research Documentation and Information

6 LHNs mention research as a priority in their Strategic Plans/priorities

↓

Remaining 4 are regional LHNs

4 LHNs provide information on conducting research in the HHS on their website

↓

No regional LHNs

4 LHNs had at least one clinical trial site registered to ANZCTR in 2021

↓

No regional LHNs

Research equipment, space and resources

7 LHNs report telehealth capabilities

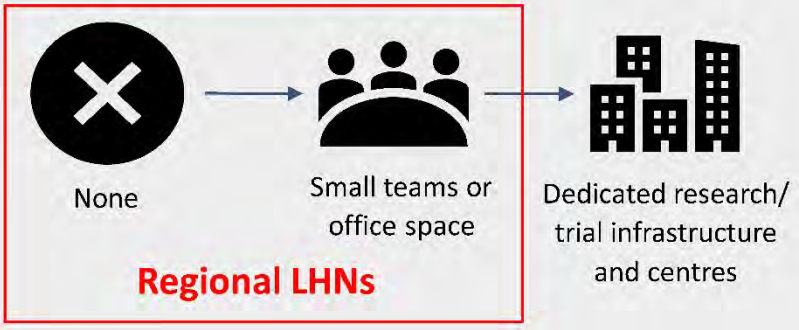
3 unclear

4

NHMRC Registered HRECs*

4

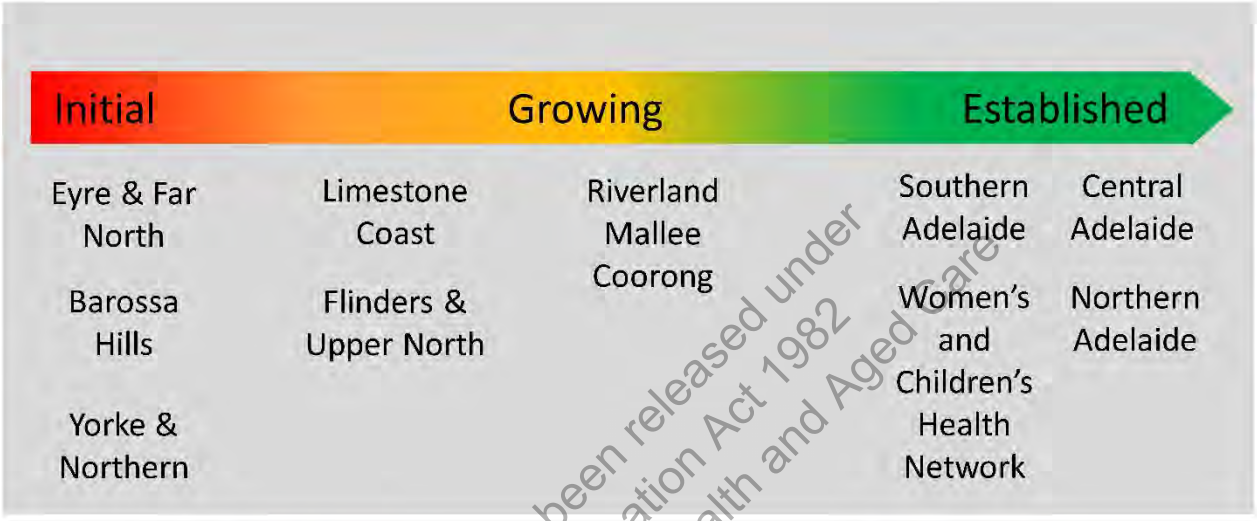
Research Governance Offices



** HRECs situated under Health Service*

South Australia

RESEARCH CAPACITY AND READINESS



Enablers

- RMCLHN has newly established Riverland Academy of Clinical Excellence (RACE). The Network will collaborating with various universities, medical research institutes and organisations.
- Strong existing research centres and partners such as Flinders, University of Adeliade and SAHMRI
- Health Networks are working with SA Health towards all staff involved in clinical research (not only those involved in clinical trials) undertake GCP training

Challenges

- Workforce availability, retention and skill maintenance
- Regional health services cover the vast majority (land area) of SA
- RMCLHN is the first and only regional LHN to have a dedicated Director of Clinical Research
- No regional health services were included as clinical trial sites in 2021

Tasmania

SUMMARY DASHBOARD

~557,000
Population

68,000 km2
Land Area

5.4% Aboriginal and Torres Strait Islander

100% population
live outside of metropolitan areas

Health Department & Hospitals

1 Department of Health

24 Public Hospitals and Health Centers

Major Cities – 0
Inner regional – 7
Outer Regional – 13
Remote – 2
Very remote –2

Clinical Trial Activity

130 trials in 2021

Trial Sites

- Hospitals and Health Service Sites
- Industry, Private and Other

Universities

1 University

s47B(a)
research income

62% trials
were university sponsored

Tasmania

RESEARCH RESOURCES AND INFRASTRUCTURE

Research Documentation and Information

TAS Dept of Health's Strategic Plan **doesn't** mention research as a priority to the department

TAS Dept of Health contains information about conducting research across Tasmania

4 hospitals had at least one clinical trial site registered to ANZCTR in 2021. All 4 hospitals are classed as Inner/Outer Regional

↓

No Remote/Very Remote hospitals as sites

Research equipment, space and resources

Telehealth services provided by *Telehealth Tasmania*

0
NHMRC Registered HRECs*
Only HRECs are at University of Tasmania

1
Research Governance Office

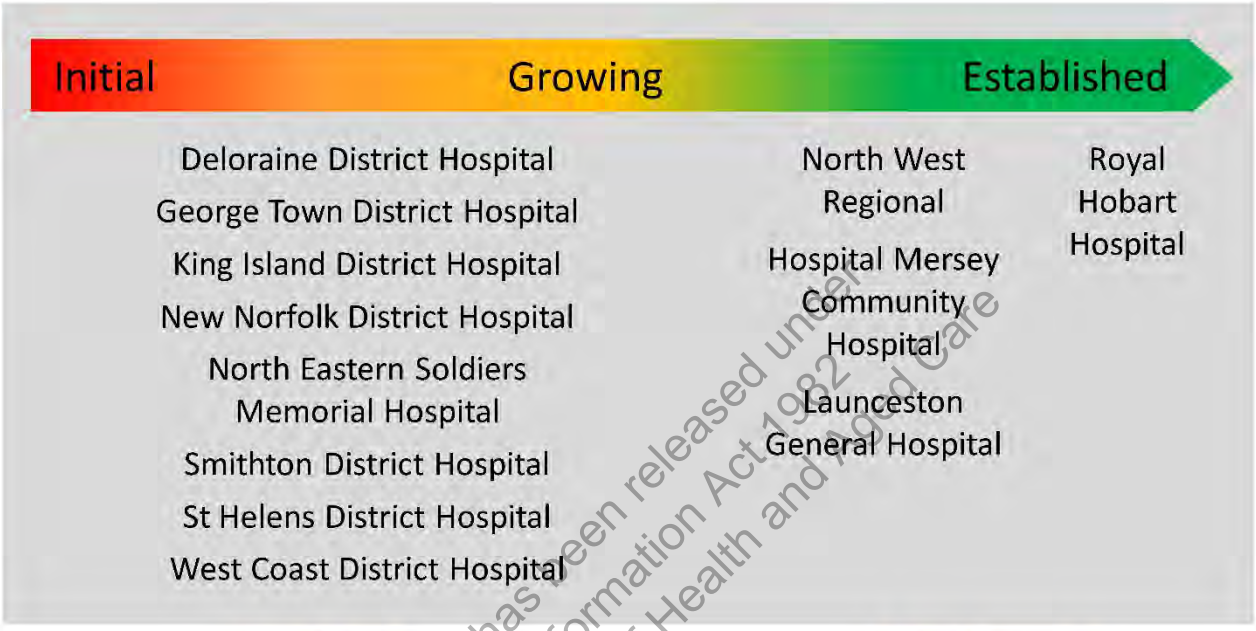
All research governance support is through TAS Dept of Health

Research Governance Unit (RGU) is centralised coordination centre for all research-related enquires

** HRECs situated under Health Service*

Tasmania

RESEARCH CAPACITY AND READINESS



Enablers

- Dept of Health's Research Governance Unit is a centralised coordination centre for all research-related enquires within Tasmania's public health system
- Royal Hobart Hospital hosts a Cancer Clinical Trials Unit

Challenges

- Dispersed population, only 44% living in capital city (compared to 68% nationally)
- No HREC under a health service - only HRECs are at University of Tasmania
- No clinical trial sites at any outer regional/remote/very remote sites in 2021

Tasmania's Department of Health is responsible for all public health services in Tasmania – there are no health service "regions". Research governance is run through a single, state-level RGO, not individual sites.

This may be seen as both an enabler (e.g. streamlining processes) and a challenge (e.g. capacity and resourcing).

Victoria

SUMMARY DASHBOARD

~6.5 million
Population

227,000 km2
Land Area

1% Aboriginal and Torres Strait Islander

23% population
live outside of metropolitan areas

Health Department & Hospitals

1 Department of Health

154 Public Hospitals and Health Services*

Major Cities – 56
Inner regional – 59
Outer Regional – 38
Remote – 2
Very remote – 1

75 *Public Hospitals and Health Services listed on Vic Health website*

Universities

9 Universities

s47B(a)
research income

44% trials
were university sponsored

Health service governance structure in Victoria

Victoria

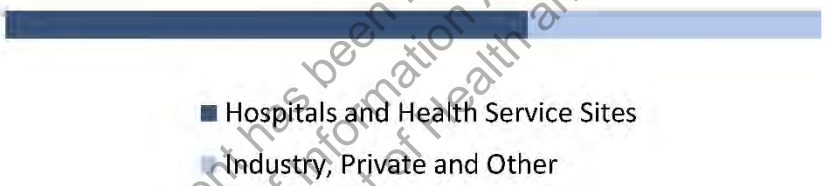
RESEARCH RESOURCES AND INFRASTRUCTURE

Research Documentation and Information

Victoria has a well-established clinical trials network with multiple services and resources in place to conduct and support clinical trials. In recent years, this has increased to form partnerships and establish independent, trial ready sites in regional and remote services in Victoria.

408 trials in 2021

Trial Sites



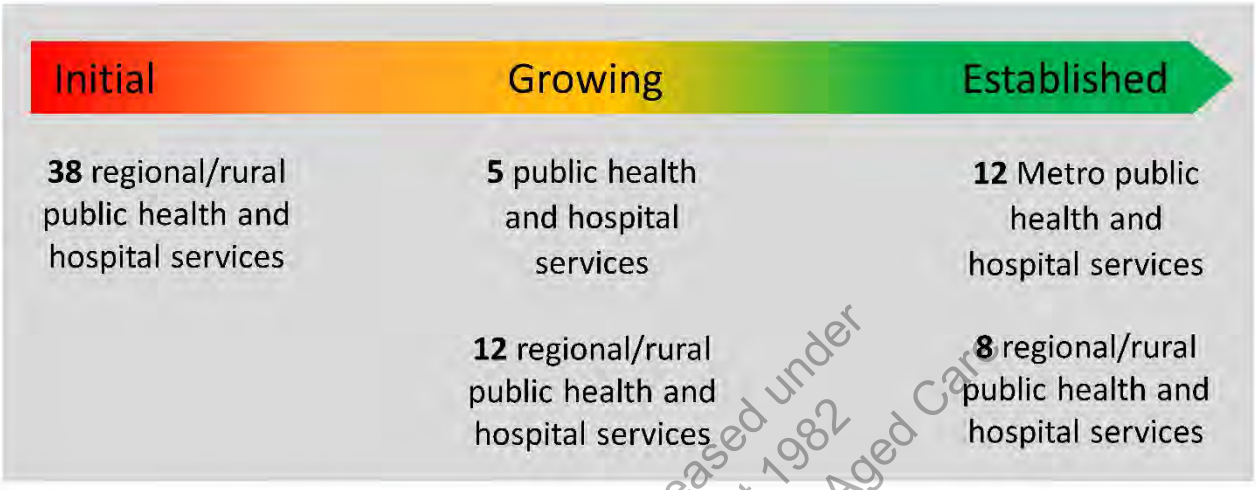
21 hospitals and health services are **Participating Organisations** for streamlined research governance by the Clinical Trials and Research Group Victoria

8 of these are classed as rural health services

76% of 2021 trial sites were on the list of **Participating Organisations**

Victoria

RESEARCH CAPACITY AND READINESS



Enablers

- Well established support systems at various levels of the health system to support trial readiness and implementation
- The Victorian government is supporting the increase in capability for rural and regional Victoria to conduct and participate in clinical trials
- Existing programs have specific elements focused on increasing access to clinical trials in regional/remote areas in Victoria

Challenges

- A large number of regional/remote health services still appear to be in the 'Initial' phases of research and clinical trial readiness
- Research governance in Victoria is site-driven due to the structure of the health system, which may impact research governance processes for multi-site projects, particularly those not on the list of 'Participating Organisations'
- Most of the 'Participating Organisations' are metropolitan services and institutions, with a smaller number of regional services participating

Supporting Pillar: Policy Harmonisation

Policy makers, policies, and frameworks

Streamlining of research policy is essential to increased delivery of and participation in clinical trials in Australia. A review of the current clinical trial policy environment, all via online sources, identified the key national and clinical trial specific policy makers who play a major role in the research - not necessarily clinical trial - landscape and exert influence on the delivery of clinical trials. Key policies and frameworks that are regulatory, guiding or informing for clinical trials activity in Australia are either teletrial specific, clinical trials specific or research specific (Figure 5).

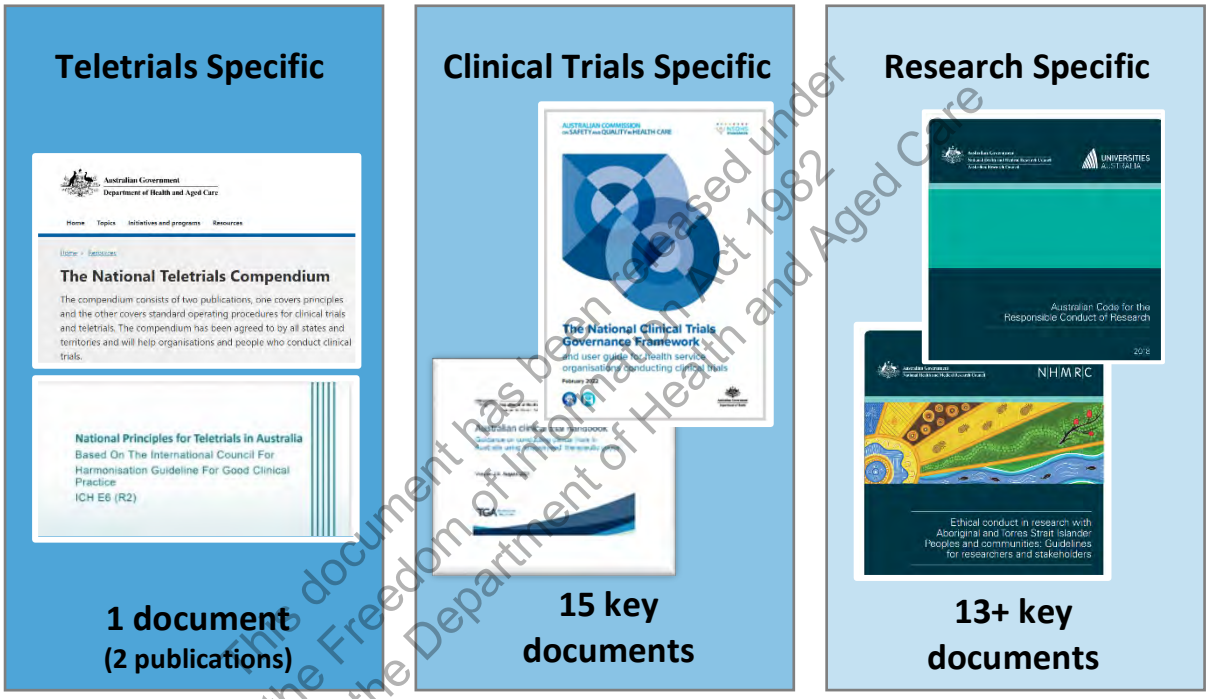


Figure 5. Policy and document focus from Australian policy makers

A summary of the key policy makers and associated documents is shown in Table 6. Detailed list of all relevant policies and documents can be found in Appendix B.

Most jurisdictions refer to the national suite of materials, although at varying levels. At the jurisdictional level, local regulatory documents are generally focussed on the administration and operationalisation of research e.g., Western Australia has a Research Governance policy, and a Research Ethics Policy Directive and a Research Governance Policy Directive; South Australia and Tasmania include clinical trials specific information in their key research portals and sites; and Victoria and Queensland have teletrial information on their portals.

Table 6: Key policy makers

Policy makers	Jurisdiction	Policy focus
NHMRC	National	Research governance; Safety, monitoring and reporting; Indemnity and insurance; HREC and institution certification; Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities; Research code of conduct; Good Clinical Practice; Site Specific Assessments (SSAs) and authorisations for clinical trials
ACSQHC	National	Clinical trials governance framework; 'One stop shop'
Dept of Health and Aged Care	National	National Teletrials Compendium (principles and standard operating procedures for Teletrials)
Medicines Australia	National	Resources and guidelines for Teletrials
Therapeutic Goods Administration	National	Clinical trials guidance
Queensland Health	Queensland	Standard operating procedures for HRECs and Research Governance Offices (RGOs); Teletrial guidance; Research management
NT Health	Northern Territory	Standard operating procedures for RGO
SA Health	South Australia	Ethics and governance directives
Department of Health, Western Australia	Western Australia	Research governance procedures and frameworks
Department of Jobs, Precincts and Regions, Victorian Government	Victoria	Research governance process and practice
NSW Health	New South Wales	Ethics and governance processes
ACT Government Health	Australian Capital Territory	Ethics and governance processes

You know, you got a trial and you've got a good question and you've got funding. You want to get a trial open but it takes 12 months to get it open across the country. And that sort of stuff happens a lot still. The government is working on that. So maybe that will improve things.

- Industry Stakeholder

Peak bodies and initiatives

Peak bodies within the health research and clinical trial landscape impact and influence the progression and development of policy harmonisation across jurisdictions and nationally. Peak bodies may represent key stakeholders or consumers within health research and clinical trials or contribute to the body of evidence to inform future policy development. A summary of current peak bodies and key initiatives across the health research and clinical trial landscape is shown in Table 7.

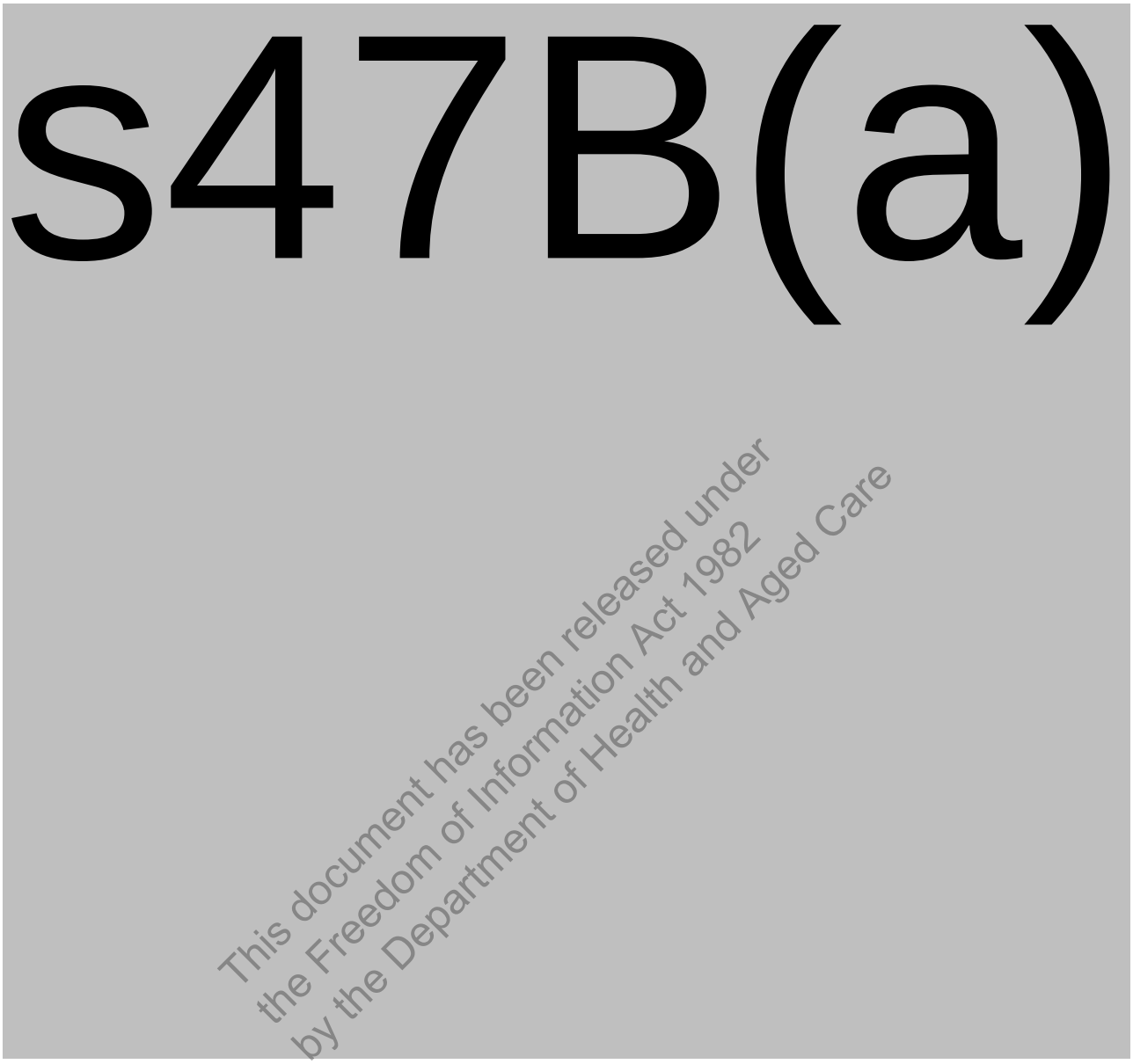
Table 7: Peak bodies and initiatives

s47B(a)

Human Research Ethics Committee (HREC) summary

All jurisdictions are now part of the National Mutual Acceptance (NMA) approach. Variation exists at jurisdiction level in relation to submission platform, requirements for additional

modules and for Aboriginal and Torres Strait Islander research. A summary of health service or departments HRECs and their processes is in Table 8.



Governance summary

Governance approvals for research are the most varied aspect of research regulation and operationalisation. There is no national approach, and while there are jurisdictional policies and procedures, these can be administered and applied very differently across Health Services or Networks, even within a jurisdiction. An overview of jurisdictional processes is in Table 9 and summary of fees charged for ethical and governance approvals, which can also vary within a jurisdiction, is in Table 10.

At the jurisdictional level there is limited mention of nominal or optimal application processing times; those that do vary between 30-60 days, with some Health Services or Networks advising 30-45 days for governance.

> Yeah, I think a regular sticking point is that… governance, just by the sheer workload and approvals, can be significantly delayed.
>
> - Service Provider

> [The clinical trial approval process is] obviously very involved …clinical trials [are] probably the most regulated thing there is. Period.
>
> - Industry Stakeholder

Table 9: Research governance overview

S47B(a)

> So now with the research governance, that is completely transparent, they have the IT system... So, you know, from a health service point of view, it's been a huge improvement.
>
> - RCCC Stakeholder

> *If you've got a private site that only does clinical trials...it's almost treated a bit more like a business. So they have they have set metrics and timelines...You know, so those machines are efficient.*
>
> - Industry Stakeholder

Table 10: Ethical and governance application fees

Fees for the review and processing of ethics and governance applications varies greatly between jurisdictions, and between health services in each jurisdiction. In general,

commercially sponsored research attracted higher fees from both ethics and governance offices, and governance fees attracted high fees than ethics.
Variation also occurred depending on:

- whether the research involved a teletrial.
- whether the research required a CTN or no CTN.
- if the funding was above or below a threshold (e.g., $50,000).
- if the research was low risk.
- whether the research was single or multi-site.

Supporting Pillar: Education & Training

Overview

Access to research and clinical trial education and training for clinicians and research staff varies across jurisdictions. Education, training and support is also provided through a wide variety of sources, from dedicated Research Offices and support services based within health services, to formalised programs delivered by external organisations, to dedicated institutes that deliver clinical trial education and training as a core component of their organisational model or remit.

A selection of key education programs, institutions, and models accessible by clinical and research staff across health services in the six jurisdictions are presented in Table 11. The Victorian model is an exemplar of clinical trials education, with some jurisdictions intending to negotiate access to that system.

> I think some of the core components of how clinical trials work, doing a formalised education certification on those processes would be of merit, for sure. I think that's something that could potentially be supported by the workplace for that individual, like upskilling and whatnot.
>
> – Industry Stakeholder

Table 11: Education and training summary

Jurisdiction	Education programs, centres and initiatives
Qld	Tropical Australian Academic Health Centre MIRI Cornerstone Research Program CQ Health Research Ready Grant Program Metro North STARS Education and Research Alliance Sunshine Coast Health Institute Metro South Research Wide Bay Research Education, Development and Support unit
NT	Menzies School of Health Research Flinders in the NT
WA	Western Australian Health Translation Network Research Education and Training Program Child and Adolescent Health Service Research Education Program WACHS and Curtin University Alliance
SA	PARC Clinical Research (University of Adelaide) Flinders Health Precinct South Australian Health and Medical Research Institute Riverland Academy of Clinical Excellence WCHN Mini Mentor Program

Tas	Department of Health Research Governance Unit Menzies Institute for Medical Research Tasmanian Collaboration for Health Improvement
Vic	Victorian Clinical Trials Education Centre TrialHub Eastern Health Clinical Research Unit Monash Health Research Support Services The Northern Centre for Health Education & Research (University of Melbourne/La Trobe) Peter Mac research education program Western Alliance Clinical Trial Research Support Service

**Not all education and training programs listed*

Good Clinical Practice

Good Clinical Practice (GCP) (ICH E6 GCP) is considered a necessary training requirement when conducting clinical trials, however the extent to which research staff require GCP certification and in what circumstances varies between health services and jurisdictions. Variations include:

- Requirements for governance approval (e.g., proof of certification required as part of the SSA process)
- Which study team members should have GCP certification (e.g., only the Principal Investigator, or all staff involved in clinical trials, or all research staff at the institution)
- Which type of projects require GCP certification (e.g., only clinical trials, or all research projects)
- How and if GCP training is provided (e.g., in-house by the institution, or whether staff are required to source external training)
- Cost and course access, including to GCP refresher courses.

> The minimum level is Good Clinical Practice. That's the minimum level. We've invested heavily in training our workforce and we've done that through the skilled program... They are paid a small stipend and they train on the job, as well as doing the online training. They have a very, very well constructed competencies program. It's extremely well managed.
>
> - RCCC Stakeholder

> *But I think when you look at a site level, study coordinators, research nurses, there isn't basic training for those sorts of people.*
>
> - Industry Stakeholder

Supporting Pillar: Equipment & Infrastructure

Overview

Like education and training facilities, dedicated research and clinical trial infrastructure and equipment varies across jurisdictions, as well as across MMM regions and health services. A range of the current infrastructure or facilities that host or support research and clinical trials and are linked with health services within each jurisdiction is listed in Table 12.

Table 12: Snapshot of clinical trial facilities

Jurisdiction	Clinical trial facilities
QLD	Townsville Institute of Health Research and Innovation Mackay Institute of Research and Innovation Surgical, Treatment and Rehabilitation Service Sunshine Coast Health Institute Translational Research Institute Gold Coast Health and Knowledge Precinct
NT	Royal Darwin Hospital Alan Walker Cancer Care Centre
WA	Telethon Clinical Research Centre Sir Charles Gairdner and Osborne Park Health Care Group Fiona Stanley Hospital
SA	PARC Clinical Research (University of Adelaide) Lyell McEwin Hospital Clinical Trials Unit Northern Adelaide Neurology Clinical Trials Unit South Australian Health and Medical Research Institute
TAS	Clinical Research Facility (Menzies Institute for Medical Research, University of Tasmania)
VIC	TrialHub (Alfred Health, Latrobe Regional Hospital, Bendigo Health, Peninsula Health) Eastern Health Clinical Research Unit Royal Melbourne Hospital Clinical Trials Unit Monash Health Translation Precinct Hudson Institute of Medical Research Peter MacCallum Cancer Centre Ballarat Clinical Trials Unit Melbourne Children's Trials Centre

Telehealth and digital infrastructure

With the increased use of telehealth and virtual care more broadly since the start of the COVID-19 pandemic[7], most health services in all six jurisdictions report offering virtual care-enabled services, including telehealth, as part of their standard clinical operations. Some of

the areas where virtual care capability, capacity, and integration into usual care service delivery were unclear, or where information was not readily available, were focused in regional or remote health services or hospitals. This may not necessarily indicate that these services genuinely lack capacity in virtual care, but rather a function of the extent to which this is presently communicated in accessible outward facing platforms.

> *I think the benefit to us is that, you know, there is a greater use and a greater understanding of what telehealth is and how it can be utilised. And so that's been an effect…. And there's probably been an increased awareness around clinical trial activity as well.*
>
> - RCCC Stakeholder

Similarly, the review of health services indicated that regional and remote areas may frequently have less established and reliable broadband internet connectivity and digital health infrastructure. This is likely to impact the implementation of teletrials. Variation between services using Electronic Medical Records (EMR), which is a key requirement for supporting the full adoption of teletrials, both within jurisdictions and nationally, was evident, particularly in consultation feedback. The actual extent of this was unable to be mapped accurately or systematically across all jurisdictions in the health service review exercise. It will be included as part of the ongoing context monitoring in relation to potential impact on teletrial implementation.

> It hopefully will enable us, but talking to someone yesterday, they said, you know, it's actually really clunky, the EMR. Once you get in the front end of it, it's actually really hard to do anything useful… We are trying to set up a credentialing system for researchers and clinical, you know, clinicians and everyone, to come in the backend of the EMR and setting up a whole lot of data virtualization and visualisation systems.
>
> - Industry Stakeholder

Supporting Pillar: Recruitment boosting tools and incentives

Overview

The overall context of both participant and site recruitment presents some challenges to the delivery of clinical trials, with associated implications, particularly economically, for teletrials.

Sites

Low recruitment is compounded by the general lack of effectiveness in referrals between sites and other healthcare entities. Embedding clinical trials in the routine practices of hospitals may support patient recruitment, which is a key focus of the National Clinical Trials Governance Framework[3].

> I think [team members] see the value in clinical trials to patients…I think they're reasonably well supportive of reasonable clinical trials, you know. I can see other areas where clinicians may be not as engaged in research and clinical trials just because of workload and the support staff required.
>
> - Service Provider Stakeholder

> I think really strong and adequate feasibility assessments always need to really happen at a clinical trial site prior to them being brought on board. Because if that doesn't happen… I mean, it's just a big waste of everyone's time then. And a waste of money.
>
> - Industry Stakeholder

> *And then it's the bigger picture where you've got leadership across the board who are going, "Wow, this is great. Yeah, this is adding value to our health service because our clinicians are really happy that they're doing great things… patients are getting what they needed and this is leading edge technology that's saving their lives."*
>
> - Industry Stakeholder

> Obviously, we're not going to go to a site that's got no experience... So, we've got to really understand and know our sites so that we know where it's safe to put things. And then you start to look at capabilities, capacity…
>
> - Industry Stakeholder

Trial registries, platforms and initiatives

Multiple clinical trial registries exist to support clinical trial activity. This minimally includes ANZCTR and ClinicalTrials.gov as general repositories or portals for all trial activity, at least twelve clinical trial registries and several smaller local, jurisdiction and disease/condition specific registries that support matching eligible participants with available clinical trials, either directly or by supporting a patients' healthcare provider to search for a relevant clinical trial. ACSQHC is leading a National Clinical Trials Front Door initiative reviewing options for a central access recruitment point. Other new and expanding recruitment platforms include ClinTrial Refer and Opin (Table 13).

Table 13: Trial recruitment platforms

Platform	Activities or initiatives
ClinTrial Refer	ClinTrial Refer is a mobile app and website platform that provides searchable access for consumers or health providers to connect with current clinical trials. Its search functions can be used to find for clinical trials that match a patient's health condition and disease specific factors, including those in rural and remote communities.
Opin (created by Opyl)	Opin is a clinical trial recruitment platform created by Opyl that leverages social media, search engine optimisation technology and artificial intelligence to assists consumers to match directly with clinical trials. Patients who are active on social media and the internet, who may be searching for health information and research opportunities related to their condition, are able to identify and express an interest in any registered clinical trial or research study nationally or internationally.
National Clinical Trials Front Door	The Australian Government Department of Health, and in partnership with all jurisdictions via the Clinical Trials Project Reference Group, engaged the ACSQH to conduct consultations with key stakeholders to discuss Options for improving patient recruitment through a National Clinical Trials Front Door, as part of the National One-Stop-Shop initiative.

> Look, I think people in [regional town], they are willing, actually willing to go to [metropolitan city] or somewhere else if they have to, because they don't have any option. Yeah. So most, in my experience, most of the patients that I talk to and if I offer them a clinical trial at home, they'll be, I would say, you know, 95 percent, they're willing to take part in the clinical trial.
>
> - Industry/Service Provider Stakeholder

Current initiatives, especially from ACTA[8] and CT:IQ[9] (Clinical Trials: Thinking Smarter) aim to raise consumer and clinician awareness of opportunities to participate in clinical trials. This builds on some of the increased exposure to and awareness of the role of clinical trials due to the COVID-19 pandemic. Advocacy groups such as CT:IQ also aim to increase recruitment through engaging with consumers and supporting researchers to embed this feedback in their clinical trial recruitment strategies[10, 11].

> You know, it's that consent conversation that an investigator has with a patient that is really critical as well. Particularly when, for example, you've got a study where maybe your control arm is standard care. Why would a patient go into a study, if they can just get the same thing normally anyway?
>
> - Industry Stakeholder

> I have experience pulling out of the trials because we haven't been able to recruit and retain participants because the burden on the participant is just too great. Like, it's not pragmatic, it's not well thought out, in my book, as far as what's actually, in reality, going to be feasible for individuals to participate and achieve in…sometimes these people have a lot of other things medically going on. So it's a really big ask to add on this layer then onto them.
>
> - Industry Stakeholder

Findings

Strengths

Research capacity and readiness

- This work has reinforced that Australia has a strong and mature clinical trials platform, albeit with most expertise and capacity embedded in the metropolitan health services across all jurisdictions.
- Existing teletrial activity in Victoria and Queensland
- High levels of clinical trial activity, particularly in Victoria and Queensland
- Cross-border support for Tasmanian implementation from Victoria, and for Northern Territory implementation from South Australia.
- Victorian Teletrials Taskforce.

Policy harmonisation

- All jurisdictions being part of the NMA scheme
- Clarity, consistency and engagement afforded by this, including process resources available and support afforded through this process for operational aspects of clinical trials.
- ACSQHC initiatives relates to Trial Governance and to a national 'One Stop Shop'.
- Existence of the Australian Government Department of Health and Aged Care Clinical Trials Project Reference Group to lead national systems streamlining and coordination.
- Accessible National Teletrials Compendium, including Standard Operating Procedures for Teletrials.

Education and training

- Increasing requirements for trial staff to complete Good Clinical Practice Training
- The Australian Health Research Alliance, with embedded Health Translation Centres and Centres for Innovations in Regional Health directly supporting clinical trial implementation.
- Victorian Clinical Trials Education initiative

Equipment and infrastructure

- Metropolitan health services tend to be well established in the areas of research and clinical trials, with existing resourcing and infrastructure already in place to support this.
- The publication of the National Clinical Trials Governance Framework 2022 to support the delivery of high-quality clinical trial services and the embedding of these in health services and routine hospital care.
- The expansion of telehealth initiatives and usage during the COVID-19 pandemic has increased familiarity with telehealth, increasing readiness for teletrial implementation.

Recruitment and incentives

- Increased awareness and familiarity with telehealth/telemedicine due to COVID-19 related acceleration of the use of these services and approaches.
- Digital health concepts are gaining traction in clinical trial settings, supporting patient recruitment through online portals.

Opportunities

Research capacity and readiness

- Low base for RRR areas in research and participation levels provides opportunity to build capacity using -- quality system levers and approaches.
- Smoothing out engagement and involvement in teletrials for regional and rural facilities.
- Many regional oncology centres have experience in conducting clinical trials. This experience and expertise can be shared to non-oncology departments who want to conduct clinical trials.

Policy harmonisation

- Build on current initiatives in clinical trials governance, notably the ACSQHC National Clinical Trials Governance Framework and the 'One Stop Shop'.
- Increase consistency from jurisdictional materials and websites of linkage reference to national research policy materials and initiatives.
- Ongoing work of the South Eastern Border States (SEBS) panel to standardise clinical trial agreements.

Education and training

- Use the Teletrial initiative to develop more formal and accredited training qualifications to standardise clinical training and development.
- Review options to leverage the Victorian Clinical Trial Education initiative to support education and training.
- Improved and more consistent access to GCP training.

Equipment and infrastructure

- Leverage the Australian Clinical Trials Alliance capacity to support further and future development including clinical trial networks, coordinating centres and quality registries conducting investigator-initiated clinical trials.

Recruitment and incentives

- Potential to leverage off the recent increases in use of and underlying capacity in telehealth and telemedicine, which makes 'tele' more acceptable and accessible to more of the population.
- Increasing resource and attention to consumer engagement in clinical trials, mainly via ACTA and CT:IQ initiatives. These can be used to support consumer engagement and potentially recruitment for teletrials.
- Engagement with Lowitja Institute to support engagement with ATP and evaluation activities.
- ACSQHC National Clinical Trials Front Door initiative.
- Promotion of clinical trial registry initiatives and availability to consumers/patients.
- Increase teletrial web profile nationally and in jurisdictions.

Challenges

Research capacity and readiness

- Significant variation in clinical trial readiness exists across the 6 jurisdictions with many regional and remote health services still in the 'Initial' or 'Growing' phases of research and clinical trial capacity.
- Within a hospital, clinical trial activity and experience can vary across departments/disciplines leading to siloing of research capacity.

Policy harmonisation

- Inconsistent processes nationally, including fee structure and submission portals.
- Many jurisdictional processes for research governance are time consuming for trial staff, laborious and complex, and create delays in trial timings.
- Inconsistent governance processes and approaches across jurisdictions, including the online systems.
- Inconsistent governance processes and approaches within jurisdictions, including fee structure, multi-site and training requirements.

Education and training

- Clinical workforce capacity in many RRR areas is limited (shortages and turnover), with tension between meeting clinical service delivery needs and research prioritisation.
- Workforce shortages cause with challenges in filling clinical trial positions and maintaining a trained workforce.
- There are increased education requirements in regionally based clinical services on the teletrial process: both the desktop analysis and consultation interviews. demonstrated this gap/need, particularly to ensure trial practices are current.

Equipment and infrastructure

- In RRR areas, logistic issues can occur for transporting, storing and administering a drug or device in Teletrials, particularly for oncology trials.
- Infrastructure required for adequate monitoring and patient care may need to be developed at regional sites, as this may not be pre-existing (e.g., a nearby emergency department at a regional/remote location).

Recruitment and incentives

- Recruiting patients where there is a reliance on technology, with some RRR areas still noting issues with internet access.
- Need to simplify the policies for EMR, digital health, and remote access to EMR and patient data to improve equitable access to clinical trials and patient recruitment.

Conclusion

This report provides a baseline summary of the current clinical trials environment and landscape in Australia, including clinical trial activity nationally, with a focus on areas pertinent to the implementation of the ATP: policy harmonisation, education and training, equipment and infrastructure and recruitment. This summary information is the key output of Stage 1 of the Evaluation of the ATP. It provides a platform for commencement of Stage 2 of the evaluation, with requirements for data collection confirmed and as detailed in the study protocol Version 2, 22.07.22.

References

1. Keith RE, Crosson JC, O'Malley AS, Cromp D, Taylor EF. Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. Implement Sci. 2017;12(1):15.

2. Australian New Zealand Clinical Trials Registry. Australian New Zealand Clinical Trials Registry 2022 [Available from: https://www.anzctr.org.au/Default.aspx.

3. Australian Commission on Safety and Quality in Health Care (ACQSHC). National Clinical Trials Governance Framework & User Guide for Health Services Organisations Conducting Clinical Trials. Sydney; 2022.

4. Australian Commission on Safety and Quality in Health Care (ACQSHC). National Clinical Trials Governance Framework Mapping Exercise. 2018.

5. National Mutual Acceptance Group (NMA Group). National Mutual Acceptance HRECs, RGOs and Organisations. 2022.

6. MTP Connect. Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth. 2021.

7. Australian Government. Enabling digital health services for regional and remote Australia 2022 [Available from: https://www.infrastructureaustralia.gov.au/map/enabling-digital-health-services-regional-and-remote-australia.

8. Australian Clinical Trials Alliance. Consumers 2022 [Available from: https://involvementtoolkit.clinicaltrialsalliance.org.au/consumers.

9. Clinical Trials: Impact and Quality (CT:IQ). Think Smarter About Clinical Trials 2022 [Available from: https://ctiq.com.au/.

10. CT:IQ. CT:IQ's Clinical Trial Site Recruitment Guide 2022 [Available from: https://ct-iq.teachable.com/.

11. CT:IQ. Consumer Involvement & Engagement Toolkit 2022 [Available from: https://involvementtoolkit.clinicaltrialsalliance.org.au/.

Appendix A – Hospital and Health service review: variables, inclusion criteria and assumptions

Variable Name	Variable Value/Description	Data source/s	*Assumptions/rules*
State	Australian State or Territory - based on jurisdictions participating in ATP		
Description of Health Care System in the State			
Health Service	Name of Health Service		
URL - HS	URL of Health Service official home page		
Population serviced	Number of people that live within the Health Service catchment area	As reported on a page on the Health Service website (or reported within a document/s that have been prepared by the Health Service and housed on their website)	*This is not reporting the number of people who have been serviced or occasions of service in the last financial year.*
Land area	Catchment area (in Km2) that is serviced by the Health Service		
# hospitals	Number of hospitals that are governed by the Health Service		
# multipurpose health facilities	Number of health facilities (that are not hospitals) that are governed by the Health Service		*Standalone clinics or health facilities only. Does not include specialty clinics or services housed within the hospital, or research only facilities.*
# nurses	Number of nurses employed by the health service across all facilities in the last financial year	2020/21 Annual report	*Where FTE has been reported, this is taken to be the number of staff. Number is taken from the 2021 end of financial year report.*

# medical staff	Number of medical staff employed by the health service across all facilities in the last financial year	2020/21 Annual report	*"Medical staff" may be reported as: Medical Staff, Medical Officers, Clinicians, or similar. Where these roles have been reported separately, numbers have been combined to report the total. Does not include Medical Support Staff. Where FTE has been reported, this is taken to be the number of staff. Number is taken from the 2021 end of financial year report.*
# allied health	Number of allied health staff employed by the health service across all facilities in the last financial year	2020/21 Annual report	*Does not include Allied Support Staff. Where FTE has been reported, this is taken to be the number of staff. Number is taken from the 2021 end of financial year report.*
Telehealth outpatient occasions	Number of Telehealth outpatient occasions	As reported on a page on the Health Service website (or reported within a document/s that have been prepared by the Health Service and housed on their website)	*Where numbers of telehealth occasions of service is not reported, a note has been made of a reported increase or decrease in telehealth use, and % if reported. Where nothing has been reported, this has been labelled as 'Not stated'.*
Priorities of HHS	Health Service strategic priorities, including those that reference research		*Priorities may be reported as 'Strategic Plan', 'Strategic Priorities', 'Statement of Priorities', 'Service Principles' or similar. Headings or broad descriptions only of priories are listed, except in the case of priorities that describe research activities. Where this is the case, wording provided by the health service that describes specific actions or goals*

			related to research is presented in brackets alongside the priority title, and is highlighted in red.
Challenges	Challenges faced by the health service		*Challenges listed are only those that have been self-reported and described by the health service in documentation such as their Annual Report, Strategic Plan etc*
URL - Research Hub	URL of Health Service's research homepage		
Dedicated research space	Space/s reported by the Health Service that is research-only defined space/s	As reported on the Research page/s on the Health Service website (or reported within a document/s that have been prepared by the Health Service and housed on their website)	*For Metropolitan areas, or Health Services where there is a strong research presence and it would not be feasible to list all available spaces, the value will be 'Yes'. For regional/remote areas, or where research is not a significant priority, individual spaces will be listed if available.*
Research equipment	Pieces of equipment reported by the Health Service that has is available to be used for research, or has been acquired specifically for research.	As reported on the Research page/s on the Health Service website (or reported within a document/s that have been prepared by the Health Service and housed on their website)	*For Metropolitan areas, or Health Services where there is a strong research presence and would not be feasible to list all available equipment, the value will be 'Yes'. For regional/remote areas, or where research is not a significant priority,*

			individual equipment will be listed if available.
DOR/s?	Yes *OR* No *OR* Equivalent (brief description)	As reported on the Research page/s on the Health Service website	*An equivalent example may be an Executive Director who incorporates Research into their portfolio.*
RGO/s?	Yes *OR* No *OR* Equivalent (brief description)		*An equivalent may be where an RGO has been replaced with or incorporate into a unit that performs the same functions as an RGO*
Other research staff (Y/N)	Yes *OR* No		*It is assumed that Research Offices (or equivalent) with an HREC and RGO will have at least a Research Ethics Coordinator and a Research Governance Officer. Where there are research-specific roles that are additional to these (for example a dedicated Research Manager, Library Manager, Research Communications Officer etc) this is recorded here*
Staff roles	Staff roles that are unique or specific to the Health Service		
Associated Research Institutes	Research institutes that are housed within the Health Service, or that have direct ongoing partnerships or links with the Health Service	As reported on the Research page/s on the Health Service website, including via affiliated links that are listed on the website	*This may include universities (with a strong research profile), or research institutes that are housed within universities*

Research Development and Training (pillar) (Infrastructure)	Description of dedicated research development and training opportunities, strategies or priorities reported by the health service	As reported on the Research page/s on the Health Service website (or reported within a document/s, including the Annual Report or Strategic Plan, that have been prepared by the Health Service and housed on their website)	*These may be broad statements or goals related to research development and training of their clinical or research staff as outlined by the Health Service, or the resources that are provided (e.g. research libraries, "drop in" sessions, affiliations with research support platforms or associations) but that are not mandatory as part of conducting research in the Health Service*
Research Web Hub / Online Support	Yes *OR* No	As reported on the Research page/s on the Health Service website	
RGO Process	Standard process *OR* process specific to Health Service as defined by the Health Service	As reported on the Research page/s on the Health Service website (or reported within a document/s that have been prepared by the Health Service and housed on their website)	*It is assumed that the 'Standard' RGO process is 1) Submission to and review by HREC, 2) Approval granted by HREC, 3) Submission to RGO (with evidence of HREC approval), 4) Approval by RGO, 5) Commence at site. It is also assumed that this is submitted through research ethics platform (e.g. ERM, RGS) that is run by a State Health Service - where this is not the case (e.g. the Health Service has created its own submission portal) this is recorded here*
HREC? NMA?	Yes OR No OR Equivalent (brief description)	As reported on the Research page/s on the Health Service website	

Research Development and Training (pillar) (Processes)	Research Development or Training processes that researchers are asked to complete as a mandatory requirement of completing research within the Health Service	As reported on the Research page/s on the Health Service website (or reported within a document/s that have been prepared by the Health Service and housed on their website)	*These are the mandatory or standard processes for researchers or clinicians conducting research within the Health Service (e.g. completion of GCP, online ethics training, meeting with research officers as a standard step in of ethics submissions)*

Appendix B - Data Sources

POLICIES, GUIDELINES AND FRAMEWORKS

NATIONAL

Australian Commission on Safety and Quality in Health Care (ACQSHC). (2022). National Clinical Trials Governance Framework & User Guide for Health Services Organisations Conducting Clinical Trials. ACQSHC. https://www.safetyandquality.gov.au/sites/default/files/2022-05/final_design_-_national_clinical_trials_governance_framework_and_user_guide_-_30_may_2022.pdf

Australian Government, & National Health and Medical Research Council (NHMRC). (2016). Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods. https://www.nhmrc.gov.au/_files_nhmrc/file/publications/guidance_on_the_reporting_of_serious_breaches_of_gcp.pdf

Australian Government, & National Health and Medical Research Council (NHMRC). (2018). Data Safety Monitoring Boards (DSMBs). https://www.australianclinicaltrials.gov.au/sites/default/files/content/For%20researchers/Data%20Safety%20Monitoring%20Boards_1.pdf

Australian Government, & National Health and Medical Research Council (NHMRC). (2018). Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods https://www.australianclinicaltrials.gov.au/sites/default/files/content/For%20researchers/Risk-Based%20Management%20and%20Monitoring%20of%20Clinical%20Trials.pdf

Australian Government, National Health and Medical Research Council (NHMRC), & Therapeutic Goods Administration (TGA). (2016). Safety monitoring and reporting in clinical trials involving therapeutic goods. https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Australian Government Department of Health and Aged Care. (2020). National Teletrials Compendium. https://www.health.gov.au/resources/collections/the-national-teletrials-compendium

Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS). (2020). AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research. https://aiatsis.gov.au/research/ethical-research

Clinical Oncology Society of Australia. (2016). Australasian Tele-Trials Model. Access to clinical trials closer to home using tele-health. A national guide for implementation https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf

Clinical Trials Project Reference Group. (2020). National Principles for Teletrials in Australia. https://www.health.gov.au/sites/default/files/documents/2021/03/national-principles-for-teletrials-in-australia.pdf

Clinical Trials Project Reference Group. (2020). National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia ICH GCP E6 (R2) https://www.health.gov.au/sites/default/files/documents/2021/02/national-standard-operating-procedures-for-clinical-trials-national-standard-operating-procedures-for-clinical-trials-including-teletrials-in-australia.pdf

Clinical Trials: Impact and Quality (CT:IQ), Medicines Australia, Medical Technology Association of Australia, & AusBioTech. (2020). Joint Position Statement: Electronic Signatures and Clinical Trials Research Agreement execution in Australia. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0019/171145/Electronic-Signatures-and-Clinical-Trial-Research-Agreement-execution-in-Australia.pdf

Coordinating Office for Clinical Trial Research. (2021). National Mutual Acceptance (NMA) Ethics and Governance matrix. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0016/171133/NMA-Ethics-and-Governance-Matrix.pdf

Independent Hospital Pricing Authority (IHPA). (2015). Development of a table of standard costs for conducting clinical trials in Australia https://www.ihpa.gov.au/publications/development-table-standard-costs-conducting-clinical-trials-australia

International Council For Harmonisation of Technical Requirements For Pharmaceuticals For Human Use (ICH). (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6 (R1): ICH Guideline for Good Clinical Practice ICH E6(R2). https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

Medicines Australia. (2020). Clinical Trial Research Agreements: Clinical trial research agreement subcontract for studies conducted under a tele-trials model. https://www.medicinesaustralia.com.au/policy/clinical-trials/

National Health and Medical Research Council (NHMRC). (2011). Research Governance Handbook: Guidance for the national approach to single ethical review. NHMRC. https://www.nhmrc.gov.au/sites/default/files/documents/reports/research-governance-handbook.pdf

National Health and Medical Research Council (NHMRC). (2012). Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research

NHMRC. https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research

National Health and Medical Research Council (NHMRC). (2014). Indemnity and insurance arrangements for clinical trials in Australia NHMRC. https://www.nhmrc.gov.au/about-us/resources/indemnity-and-insurance-arrangements-clinical-trials

National Health and Medical Research Council (NHMRC). (2018). The Australian Code for the Responsible Conduct of Research. NHMRC. https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

National Health and Medical Research Council (NHMRC). (2018). Competencies for Australian Academic Clinical Trialists. https://www.nhmrc.gov.au/about-us/publications/competencies-australian-academic-clinical-trialists

National Health and Medical Research Council (NHMRC). (2018). Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders. NHMRC. https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities

National Health and Medical Research Council (NHMRC). (2018). Good Practice Process for Site Assessment and Authorisation of Clinical Trials. NHMRC. https://www.nhmrc.gov.au/about-us/publications/nhmrc-good-practice-process-site-assessment-and-authorisation-clinical-trials

National Health and Medical Research Council (NHMRC). (2018). National Statement on Ethical Conduct in Human Research. NHMRC. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

National Health and Medical Research Council (NHMRC). (2020). National Certification Scheme. NHMRC. https://www.nhmrc.gov.au/sites/default/files/documents/attachments/National%20Statement/list_of_certified_institutions_43.pdf

National Health and Medical Research Council (NHMRC), & Australian Government Department of Health. (2020). COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors. https://www1.health.gov.au/internet/main/publishing.nsf/Content/EE207D978A44E4B8CA257FA90081B212/$File/COVID-19%20Guidance%20on%20clinical%20trials%20for%20institutions,%20HRECs,%20researchers%20and%20sponsors.pdf

National Mutual Acceptance Group (NMA Group). (2019). National Mutual Acceptance Jurisdictional Legislative Requirements. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0013/171130/jurisdictional-legislative-requirements-Nov-2019.pdf

National Mutual Acceptance Group (NMA Group). (2022). National Mutual Acceptance HRECs, RGOs and Organisations. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0018/171306/HRECs,-RGOs-and-Organisations-February-2022.pdf

National Mutual Acceptance Group (NMA Group). (2022). National Mutual Acceptance Monitoring and Reporting Matrix.

National Mutual Acceptance Group (NMA Group). (2022). National Mutual Acceptance Standard Principles of Operation. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0031/171976/Standard-Principles-for-Operation.-March-2022.pdf

National Transport Commission (NTC). (2011). Australian Code for the Transportation of Dangerous Goods by Road and Rail. https://www.ntc.gov.au/codes-and-guidelines/australian-dangerous-goods-code

Therapeutic Goods Administration (TGA). (2000). Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. https://www.tga.gov.au/publication/note-guidance-clinical-safety-data-management-definitions-and-standards-expedited-reporting

Therapeutic Goods Administration (TGA). (2021). Australian Clinical Trial Handbook. https://www.tga.gov.au/resources/resource/guidance/australian-clinical-trial-handbook

QUEENSLAND

Office of Precision Medicine and Research (OPMR), & Queensland Health. (2022). Research Management Policy https://www.health.qld.gov.au/__data/assets/pdf_file/0020/164162/qh-pol-013.pdf

Queensland Health. A Quick Guide to Establishing a Teletrial. https://www.health.qld.gov.au/__data/assets/pdf_file/0017/1123226/Quick-Guide-to-Establishing-a-Teletrial.pdf

Queensland Health. (2013). Standard Operating Procedures for Queensland Health HREC Administrators. https://www.health.qld.gov.au/__data/assets/pdf_file/0034/147598/hrec_sop.pdf

Queensland Health. (2013). Standard Operating Procedures for Queensland Health Research Governance Officers. https://www.health.qld.gov.au/__data/assets/pdf_file/0026/147626/rgo_sop.pdf

Queensland Health. (2020). COVID-19: Queensland Health Operational Guidance for sponsors, trial sites, ethics committees, research governance officer/s and researchers.

https://www.health.qld.gov.au/__data/assets/pdf_file/0024/952251/Queensland-COVID-19-Clinical-Research-Guidance-v-1.1-080420.pdf

Queensland Health. (2021). Guidance Document for Sponsors and Sites to Establish a Teletrial Steps and Documents Necessary within Queensland Health. https://www.health.qld.gov.au/__data/assets/pdf_file/0027/1118358/Guidance-for-Sponsors-and-Sites.pdf

NORTHERN TERRITORY

Northern Territory - Department of Health, & Menzies School of Health Research. (2020). Terms of reference and Standard Operating procedures. https://health.nt.gov.au/data-and-research/nt-health-research/research-governance2

WESTERN AUSTRALIA

Western Australia Government Department of Health. (2021). Research Governance Policy. https://ww2.health.wa.gov.au/About-us/Policy-frameworks/Research/Mandatory-requirements/Research-Governance-Policy

Western Australia Government Department of Health. (2021). Research Governance Procedures. https://ww2.health.wa.gov.au/~/media/Corp/Policy-Frameworks/Research/Research-Governance-Policy/Supporting/Research-Governance-Procedure.pdf

Western Australia Government Department of Health. (2021). Research Policy Framework. https://ww2.health.wa.gov.au/About-us/Policy-frameworks/Research

SOUTH AUSTRALIA

South Australia Health. Research Governance Policy. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/research+ethics

South Australia Health. (2020). Research Ethics Policy Directive.

South Australia Health. (2020). Research Governance Policy Directive.

TASMANIA

Tasmanian Government. Research Governance Documents.

Tasmanian Government. Research Governance Procedures

Tasmanian Government - Department of Health. (2020). Research Governance Policy Framework.

https://doh.health.tas.gov.au/__data/assets/pdf_file/0008/407591/DoH_Statewide_Research_Governance_Policy_Framework_Version_1.0_1_July_2020.pdf

VICTORIA

Department of Jobs Precincts and Regions (DJPR), & State Government of Victoria. (2019). Research Governance and Site Specific Assessment Process and Practice. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0020/171146/Research-Governance-SSA-Process-and-Practice-Jun22.pdf

NEW SOUTH WALES

New South Wales Health. (2010). Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2010_055.pdf

New South Wales Health. (2011). Research Governance in NSW Public Health Organisation. https://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=GL2011_001

AUSTRALIAN CAPITAL TERRITORY

ACT Health. Research Strategic Plan. https://www.health.act.gov.au/research/research-ethics-and-governance/ethics-submission

ETHICS AND GOVERNANCE

NATIONAL

Australian Commission on Safety and Quality in Health Care (ACQSHC). (2018). National Clinical Trials Governance Framework Literature Review. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-literature-review

Australian Commission on Safety and Quality in Health Care (ACQSHC). (2018). National Clinical Trials Governance Framework Mapping Exercise. https://www.safetyandquality.gov.au/sites/default/files/2020-02/national_clinical_trials_governance_framework_-_mapping_exercise_report.pdf

Australian Commission on Safety and Quality in Health Care (ACQSHC). (2022). National Clinical Trials Governance Framework & User Guide for Health Services Organisations Conducting Clinical Trials. ACQSHC. https://www.safetyandquality.gov.au/sites/default/files/2022-05/final_design_-_national_clinical_trials_governance_framework_and_user_guide_-_30_may_2022.pdf

National Health and Medical Research Council (NHMRC). (2020). National Certification Scheme. NHMRC. https://www.nhmrc.gov.au/sites/default/files/documents/attachments/National%20Statement/list_of_certified_institutions_43.pdf

National Mutual Acceptance Group (NMA Group). (2022). National Mutual Acceptance HRECs, RGOs and Organisations. https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0018/171306/HRECs,-RGOs-and-Organisations-February-2022.pdf

QUEENSLAND

Queensland Health. (2019). Queensland Clinical Trials Coordination Unit (QCTCU),. https://www.health.qld.gov.au/hiiro/html/research/queensland-clinical-trials-coordination-unit-qctcu

NORTHERN TERRITORY

Northern Territory Health. Research Governance. https://health.nt.gov.au/data-and-research/nt-health-research/research-governance

WESTERN AUSTRALIA

Western Australia Health. Department of Health. https://ww2.health.wa.gov.au/

SOUTH AUSTRALIA
South Australia Health. Clinical Trials. sahealth.sa.gov.au/clinicaltrials

TASMANIA

Tasmania Health. Research. health.tas.gov.au/research

VICTORIA
State Government of Victoria. Clinical Trials and Research.
https://www.clinicaltrialsandresearch.vic.gov.au/

NEW SOUTH WALES

New South Wales Health. Medical Research. medicalresearch.nsw.gov.au

AUSTRALIAN CAPITAL TERRITORY

Australian Capital Territory Health. Research Ethics and Governance.
https://health.act.gov.au/research/research-ethics-and-governance

HEALTH SERVICES - WEBSITES

QUEENSLAND

Queensland Government. (2022). Cairns and Hinterland Hospital Health Service. https://cairns-hinterland.health.qld.gov.au/

Queensland Government. (2022). Central Queensland Hospital and Health Service. https://www.health.qld.gov.au/cq

Queensland Government. (2022). Central West Health. https://www.health.qld.gov.au/centralwest

Queensland Government. (2022). Children's Health Queensland Hospital and Health Service. https://www.childrens.health.qld.gov.au/

Queensland Government. (2022). Darling Down Health https://www.darlingdowns.health.qld.gov.au/

Queensland Government. (2022). Gold Coast Health. https://www.goldcoast.health.qld.gov.au/

Queensland Government. (2022). Mackay Hospital and Health Service. https://www.mackay.health.qld.gov.au/

Queensland Government. (2022). Metro North Health. https://metronorth.health.qld.gov.au/

Queensland Government. (2022). Metro South Health. https://metrosouth.health.qld.gov.au/

Queensland Government. (2022). North West Hospital and Health Service. https://www.northwest.health.qld.gov.au/

Queensland Government. (2022). Queensland Health. https://www.health.qld.gov.au/

Queensland Government. (2022). South West Hospital and Health Service. https://www.southwest.health.qld.gov.au/

Queensland Government. (2022). Sunshine Coast Hospital and Health Service. https://www.sunshinecoast.health.qld.gov.au/

Queensland Government. (2022). Torres and Cape Hospital and Health Service. https://www.torres-cape.health.qld.gov.au/

Queensland Government. (2022). Townsville Hospital and Health Service. https://www.townsville.health.qld.gov.au/

Queensland Government. (2022). West Moreton Health. https://www.westmoreton.health.qld.gov.au/

Queensland Government. (2022). Wide Bay Hospital and Health Service. https://www.health.qld.gov.au/widebay

NORTHERN TERRITORY

Northern Territory Government. (2022). Northern Territory Health. https://health.nt.gov.au/

WESTERN AUSTRALIA

Western Australia Government. (2022). Child and Adolescent Health Service. https://cahs.health.wa.gov.au/

Western Australia Government. (2022). East Metropolitan Health Service. https://emhs.health.wa.gov.au/

Western Australia Government. (2022). North Metropolitan Health Services. https://www.nmhs.health.wa.gov.au/

Western Australia Government. (2022). South Metropolitan Health Service. https://smhs.health.wa.gov.au/

Western Australia Government. (2022). WA Country Health Service. https://www.wacountry.health.wa.gov.au/

SOUTH AUSTRALIA

South Australia Government. (2022). Barossa Hills Fleurieu Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/barossa+hills+fleurieu+local+health+network

South Australia Government. (2022). Central Adelaide Local Health Network. https://centraladelaide.health.sa.gov.au/

South Australia Government. (2022). Department For Health and Wellbeing. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/department+for+health+and+wellbeing/department+for+health+and+wellbeing

South Australia Government. (2022). Eyre and Far North Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/ab

out+us/our+local+health+networks/eyre+and+far+north+local+health+network/eyre+and+far+north+local+health+network

South Australia Government. (2022). Flinders and Upper North Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/flinders+and+upper+north+local+health+network/flinders+and+upper+north+local+health+network

South Australia Government. (2022). Limestone Coast Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/limestone+coast+local+health+network/limestone+coast+local+health+network

South Australia Government. (2022). Northern Adelaide Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/northern+adelaide+local+health+network

South Australia Government. (2022). Riverland Mallee Coorong Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/riverland+mallee+coorong+local+health+network

South Australia Government. (2022). Southern Adelaide Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/southern+adelaide+local+health+network+salhn

South Australia Government. (2022). Women's and Children's Health Network. https://www.wchn.sa.gov.au/our-network

South Australia Government. (2022). Yorke and Northern Local Health Network. https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+Us/Our+Local+Health+Networks/Yorke+and+Northern+Local+Health+Network/Yorke+and+Northern+Local+Health+Network

TASMANIA

Tasmanian Government. (2022). Deloraine District Hospital. https://www.health.tas.gov.au/hospitals/deloraine-district-hospital

Tasmanian Government. (2022). Department of Health https://www.health.tas.gov.au/

Tasmanian Government. (2022). George Town District Hospital and Community Service. https://www.health.tas.gov.au/hospitals/george-town-district-hospital-and-community-service

Tasmanian Government. (2022). King Island District Hospital and Health Centre. https://www.health.tas.gov.au/hospitals/king-island-district-hospital-and-health-centre

Tasmanian Government. (2022). Launceston General Hospital. https://www.health.tas.gov.au/hospitals/launceston-general-hospital

Tasmanian Government. (2022). Mersey Community Hospital. https://www.health.tas.gov.au/hospitals/mersey-community-hospital

Tasmanian Government. (2022). New Norfolk District Hospital. https://www.health.tas.gov.au/hospitals/new-norfolk-district-hospital

Tasmanian Government. (2022). North Eastern Soldiers Memorial Hospital. https://www.health.tas.gov.au/hospitals/north-eastern-soldiers-memorial-hospital

Tasmanian Government. (2022). North West Regional Hospital. https://www.health.tas.gov.au/hospitals/north-west-regional-hospital

Tasmanian Government. (2022). Royal Hobart Hospital. https://www.health.tas.gov.au/hospitals/royal-hobart-hospital

Tasmanian Government. (2022). Smithton District Hospital. https://www.health.tas.gov.au/service-finder/smithton-district-hospital

Tasmanian Government. (2022). St Helens District Hospital and Community Centre. https://www.health.tas.gov.au/hospitals/st-helens-district-hospital-and-community-centre

Tasmanian Government. (2022). West Coast District Hospital at Queenstown. https://www.health.tas.gov.au/hospitals/west-coast-district-hospital-queenstown

VICTORIA

Albury Wodonga Health. (2022). Albury Wodonga Health. https://www.awh.org.au/

Alexandra District Health. (2022). Alexandra District Health. https://adh.org.au/

Alfred Health. (2022). Alfred Health. https://www.alfredhealth.org.au/

Alpine Health. (2022). Alpine Health. https://www.alpinehealth.org.au/

Austin Health. (2022). Austin Health. https://www.austin.org.au/

Bairnsdale Regional Health Service. (2022). Bairnsdale Regional Health Service. https://brhs.com.au/

Barwon Health. (2022). Barwon Health. https://www.barwonhealth.org.au/

Bass Coast Health. (2022). Bass Coast Health. https://www.basscoasthealth.org.au/about

Beaufort and Skipton Health Service. (2022). Beaufort and Skipton Health Service. https://bshs.org.au/

Beechworth Health Service. (2022). Beechworth Health Service. https://beechworthhealthservice.com.au/

Benalla Health. (2022). Benalla Health. https://www.benallahealth.org.au/

Bendigo Health. (2022). Bendigo Health. https://www.bendigohealth.org.au/

Boort District Health. (2022). Boort District Health. http://bdh.vic.gov.au/

Casterton. (2022). Casterton. https://www.casterton.org.au/

Castlemaine Health. (2022). Castlemaine Health. https://www.castlemainehealth.org.au/

Central Gippsland Health. (2022). Central Gippsland Health. https://www.cghs.com.au/

Central Highlands Rural Health. (2022). Central Highlands Rural Health. https://www.chrh.org.au/

Cohuna District Hospital. (2022). Cohuna District Hospital. https://www.cdh.vic.gov.au/

Colac Area Health. (2022). Colac Area Health. https://www.cah.vic.gov.au/

Corryong Health. (2022). Corryong Health. https://www.corryonghealth.org.au/

Dental Health Services Victoria. (2022). Dental Health Service Victoria. https://www.dhsv.org.au/

East Grampians Health Service. (2022). East Grampians Health Service. https://eghs.net.au/

East Wimmera Health Service. (2022). East Wimmera Health Service. http://ewhs.org.au/

Eastern Health. (2022). Eastern Health. https://www.easternhealth.org.au/

Echuca Regional Health. (2022). Echuca Regional Health. https://erh.org.au/

Gippsland Southern Health Service. (2022). Gippsland Southern Health Service. https://www.gshs.com.au/

Grampians Health. (2022). Grampians Health. https://grampianshealth.com.au/

Grampians Health Ballarat. (2022). Grampians Health Ballarat. https://www.bhs.org.au/

Great Ocean Road Health. (2022). Great Ocean Road Health. https://www.greatoceanroadhealth.com.au/

GV Health. (2022). Goulburn Valley Health. http://www.gvhealth.org.au/

Heathcote Health. (2022). Heathcote Health. https://www.heathcotehealth.org/

Hesse Rural Health. (2022). Hesse Rural Health. https://www.hesseruralhealth.net.au/

Heywood Rural Health. (2022). Heywood Rural Health. https://heywoodruralhealth.vic.gov.au/

Inglewood and Districts Health Service. (2022). Inglewood and Districts Health Service. https://www.idhs.vic.gov.au/

Kerang District Health. (2022). Kerang District Health. https://www.kdh.org.au/

Kilmore District Health. (2022). Kilmore District Health. https://www.kilmoredistricthealth.org.au/

Kooweerup Regional Health Service. (2022). Kooweerup Regional Health Service. https://www.kooweeruphospital.net.au/

Kyabram District Health Service. (2022). Kyabram District Health Service. https://www.kyhealth.org.au/

Latrobe Regional Hospital. (2022). Latrobe Regional Hospital. https://www.lrh.com.au/

Little Company of Mary Health Care. (2022). Calvary Health Care Bethlehem. https://www.calvarycare.org.au/public-hospital-bethlehem/

Maryborough District Health Service. (2022). Maryborough District Health Service. https://mdhs.vic.gov.au/

Mercy Health. (2022). Mercy Health. https://www.mercyhealth.com.au/

Mildura Base Public Hospital. (2022). Mildura Base Public Hospital. https://www.mbph.org.au/

Monash Health. (2022). Monash Health. https://monashhealth.org/

Moyne Health Services. (2022). Moyne Health Services. https://moynehealth.vic.gov.au/

Nathalia Cobram Numurkah. (2022). Nathalia Cobram Numurkah. https://ncnhealth.org.au/

Northeast Health Wangaratta. (2022). Northeast Health Wangaratta. https://www.northeasthealth.org.au/

Northern Health. (2022). Northern Health. https://www.nh.org.au/

Omeo District Health. (2022). Omeo District Health. https://www.odh.net.au/

Orbost Regional Health. (2022). Orbost Regional Health. https://www.orbostregionalhealth.com.au/

Peninsula Health. (2022). Peninsula Health. https://www.peninsulahealth.org.au/

Peter MacCallum Cancer Centre. (2022). Peter MacCallum Cancer Centre. https://www.petermac.org/

Portland District Health. (2022). Portland District Health. https://pdh.net.au/

Robinvale District Health Services. (2022). Robinvale District Health Services. https://www.rdhs.com.au/

Rural Northwest Health. (2022). Rural Northwest Health. https://rnh.net.au/

Seymour Health. (2022). Seymour Health. http://www.seymourhealth.org.au/

South Gippsland Hospital. (2022). South Gippsland Hospital. https://southgippslandhospital.com.au/

South West Healthcare. (2022). South West Healthcare. https://southwesthealthcare.com.au/

St Vincent's Health Australia. (2022). St Vincent's Hospital Melbourne. https://www.svhm.org.au/

Swan Hill District Health. (2022). Swan Hill District Health. https://www.shdh.org.au/

Tallangatta Health. (2022). Tallangatta Health. https://www.tallangattahealthservice.com.au/

Terang & Mortlake Health Service. (2022). Terang & Mortlake Health Service. http://www.tmhs.vic.gov.au/

The Royal Children's Hospital Melbourne. (2022). The Royal Children's Hospital Melbourne. https://www.rch.org.au/home/

The Royal Melbourne Hospital. (2022). The Royal Melbourne Hospital. https://www.thermh.org.au/

The Royal Victorian Eye and Ear Hospital. (2022). Eye and Ear Hospital. https://eyeandear.org.au/

The Royal Women's Hospital. (2022). The Women's. https://www.thewomens.org.au/

Timboon and District Healthcare Service. (2022). Timboon and District Healthcare Service. https://www.timboonhealthcare.com.au/

Tweddle Child and Family Health Service. (2022). Tweddle Child and Family Health Service. https://www.tweddle.org.au/

West Gippsland Healthcare Group. (2022). West Gippsland Healthcare Group. https://wghg.com.au/

West Wimmera Health Service. (2022). West Wimmera Health Service. https://www.wwhs.net.au/

Western District Health Service. (2022). Western District Health Service. https://wdhs.net/v2/

Western Health. (2022). Western Health. https://www.westernhealth.org.au/Pages/default.aspx

Yarram and District Health Service. (2022). Yarram and District Health Service. https://www.ydhs.com.au/

Yarrawonga Health. (2022). Yarrawonga Health. https://www.yh.org.au/

Yea District Memorial Hospital. (2022). Yea District Memorial Hospital. https://yeahospital.org.au/

HEALTH SERVICES - RESEARCH WEBPAGES

QUEENSLAND

Queensland Government. (2022). Cairns and Hinterland Hospital and Health Service - Research. https://cairns-hinterland.health.qld.gov.au/research

Queensland Government. (2022). Children's Health Queensland Hospital and Health Service - Research and Education https://www.childrens.health.qld.gov.au/research/

Queensland Government. (2022). Darling Downs Health - Start A Research Project. https://www.darlingdowns.health.qld.gov.au/health-professionals/start-a-research-project

Queensland Government. (2022). Gold Coast Health - Research https://www.goldcoast.health.qld.gov.au/research

Queensland Government. (2022). Mackay Institute of Research and Innovation. https://miri.health.qld.gov.au/

Queensland Government. (2022). Metro North Health - Research. https://metronorth.health.qld.gov.au/research

Queensland Government. (2022). Metro South Health - Research https://metrosouth.health.qld.gov.au/research

Queensland Government. (2022). Sunshine Coast Hospital and Health Service - Research. https://www.sunshinecoast.health.qld.gov.au/research

Queensland Government. (2022). Torres Cape Hospital and Health Service - Ethics and Research Governance Approval. https://www.health.qld.gov.au/torres-cape/html/research-governance

Queensland Government. (2022). Townsville Hospital and Health Service - Research. https://www.townsville.health.qld.gov.au/research/

Queensland Government. (2022). West Moreton Health - Research. https://www.westmoreton.health.qld.gov.au/research

Queensland Government. (2022). Wide Bay Hospital and Health Service - Research https://www.health.qld.gov.au/widebay/for-health-professionals/research

NORTHERN TERRITORY

Northern Territory Government. (2022). Health Research. https://health.nt.gov.au/data-and-research/nt-health-research/research-ethics

WESTERN AUSTRALIA

Western Australia Government. (2022). Child and Adolescent Health Service - Research https://cahs.health.wa.gov.au/Research

Western Australia Government. (2022). East Metropolitan Health Service - Research. https://emhs.health.wa.gov.au/Research

Western Australia Government. (2022). North Metropolitan Health Services - Research Ethics and Governance. https://www.nmhs.health.wa.gov.au/Research/Ethics

Western Australia Government. (2022). South Metropolitan Health Service - Our Research https://smhs.health.wa.gov.au/Our-research

Western Australia Government. (2022). WA Country Health Service - Research - Ethics and Governance Review. https://www.wacountry.health.wa.gov.au/About-us/Our-structure/Committees-and-networks/WACHS-research---Ethics-and-governance-review

SOUTH AUSTRALIA

South Australia Government. (2022). Central Adelaide Local Health Network - Research. https://centraladelaide.health.sa.gov.au/research/

South Australia Government. (2022). Northern Adelaide Local Health Network - Research Secretariat. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/northern+adelaide+local+health+network/research/nalhn+research+secretariat

South Australia Government. (2022). Southern Adelaide Local Health Network - Research https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/salhn+research

South Australia Government. (2022). Women's and Children's Health Network - Research https://www.wchn.sa.gov.au/research

TASMANIA

Tasmanian Government. (2022). Department of Health - Research. https://www.health.tas.gov.au/about/research

VICTORIA

Albury Wodonga Health. (2022). Albury Wodonga Health - Research. https://www.awh.org.au/health-professionals/research

Alfred Health. (2022). Alfred Health - Research. https://www.alfredhealth.org.au/research/

Austin Health. (2022). Austin Health - Research. https://www.austin.org.au/research/
Barwon Health. (2022). Barwon Health - Research.
https://www.barwonhealth.org.au/research/

Bendigo Health. (2022). Bendigo Health - Research.
https://www.bendigohealth.org.au/research/

Castlemaine Health. (2022). Castlemaine Health - Research
https://www.castlemainehealth.org.au/about-us/research/

Colac Area Health. (2022). Colac Area Health - Research Unit.
https://cah.vic.gov.au/services/colac-area-health-research-unit/

Dental Health Services Victoria. (2022). Dental Health Services Victoria - Research
https://www.dhsv.org.au/research

East Grampians Health Service. (2022). East Grampians Health Service - Research Support.
https://eghs.net.au/news/research-support-at-eghs

Eastern Health. (2022). Eastern Health - Research and Ethics.
https://www.easternhealth.org.au/research-ethics

Grampians Health Ballarat. (2022). Grampians Health Ballarat - Research.
https://www.bhs.org.au/research/

GV Health. (2022). Goulburn Valley Health - Research and Ethics.
http://www.gvhealth.org.au/about-us/research-and-ethics/

Latrobe Regional Hospital. (2022). Latrobe Regional Hospital - Research.
https://www.lrh.com.au/important-info/lrh-information/research

Little Company of Mary Health Care. (2022). Calvary Health Care Bethlehem - Research.
https://www.calvarycare.org.au/public-hospital-bethlehem/services-and-clinics/research/

Mercy Health. (2022). Mercy Health - Research. https://www.mercyhealth.com.au/our-organisation/research/

Monash Health. (2022). Monash Health - Research. https://monashhealth.org/research/

Northeast Health Wangaratta. (2022). Northeast Health Wangaratta - Clinical Research.
https://www.northeasthealth.org.au/clinical-research/

Northern Health. (2022). Northern Health - Research https://www.nh.org.au/research-and-education/research/

Peninsula Health. (2022). Peninsula Health - Research. https://www.peninsulahealth-research.org.au/
Peter MacCallum Cancer Centre. (2022). Peter MacCallum Cancer Centre - Research and Discovery. https://www.petermac.org/research

South West Healthcare. (2022). South West Healthcare - Research https://southwesthealthcare.com.au/health-professionals/research/

St Vincent's Health Australia. (2022). St Vincent's Hospital Melbourne - Research. https://www.svhm.org.au/research

The Royal Children's Hospital Melbourne. (2022). Research at The Royal Children's Hospital Campus. https://www.rch.org.au/research/

The Royal Melbourne Hospital. (2022). The Royal Melbourne Hospital - Research. https://www.thermh.org.au/research

The Royal Victorian Eye and Ear Hospital. (2022). The Royal Victorian Eye and Ear Hospital - Research. https://eyeandear.org.au/research/

The Royal Women's Hospital. (2022). The Women's - Research. https://www.thewomens.org.au/research

Tweddle Child and Family Health Service. (2022). Tweddle Child and Family Health Service - Research. https://www.tweddle.org.au/research/

West Gippsland Healthcare Group. (2022). West Gippsland Healthcare Group - Research. https://wghg.com.au/contact-us/research/

Western District Health Service. (2022). Western District Health Service - Research. https://wdhs.net/v2/education/research/

Western Health. (2022). Western Health - Research. https://www.westernhealth.org.au/EducationandResearch/Research/Pages/default.aspxDistrict Memorial Hospital. https://yeahospital.org.au/

Australian Teletrial Program

RISK REGISTER - Australian Teletrial Program

								Current risk assessment								Projected risk assessment				
Log #	Project Reg # *if app.*	Type of Risk	Description of risk	Risk location	Date identified	Risk owner	Current controls *identify each step as C1, C2, C3 etc.*	Current project consequence	Current likelihood	Current rating	Current Risk score	Response protocol	Treatments *identify steps as T1, T2, T3*	Treatment due date	Treatment status	Projected consequence	Projected likelihood	Projected rating	Projected source	Review comments
		Financial	Expenses ineligible under Grant guidelines being recorded under ATP cost centres.	National	Jul-23	ATP / ORI	C1 Review of ATP transactions only during the Commonwealth Reporting dates.	Minor	Possible	Medium (9)	9	Treat	T1. Monthly review of all financial transactions and GL codes for expenses relating to ATP	30/06/2024	Ongoing	Minor	Unlikely			
		Financial	Underspend of funding allocated inception to date (ITD)	National	Jun-22	ATP / ORI	C1. Financial acquittals C2. Financial reporting / budget development / monitoring.	Moderate	Possible	High (15)	15	Treat	T1. Aquittal reporting keeps accurate record of underspend	30-Sep-23	Ongoing	Major	Likely			
		Legal	Risk of contracts not delivering on contract obligations (contract terms risk where contractual obligations don't align with the contract reality).	National	Perpetual	ATP / ORI	C1. Ramping up activity levels C2. Actual performance and processes setting a precedent for contractual obligations (ie substantiation).	Major	Unlikely	Medium (14)	14	Treat	T1.Monthly status reports T2. Payments on receipt of deliverables achieved.	4-Oct-26	Ongoing	Minor	Possible			
		Operational	Attracting and retaining appropriately skilled RCCC staff	National		Jurisdiitons	C1. Only experienced clinical research coordinators to be engaged	Moderate	Possible	High (15)	15	Treat	T1.Ensure recruitment and retention strategies in place for each jurisdiction T2. Provide appropriate education and support through DoH and RCCC set ups	30-Sep-24	Ongoing	Moderate	Possible			
		Operational	Inclusion of demographic data from jurisdictions	National	Oct-23	ATP / ORI	C1. The National Office is addressing this by working with jurisdictions to understand their concerns and provide advice on consent avenues. C2. The Evaluation Team attended the National Steering Committee meeting November 2023 to raise issues and discuss concerns.	Minor	Possible	Medium (9)	9	Tolerate	T1. Reassurance from Evaluation team of data visability T2. Sharing of best practices among jurisdictions T3. Jurisdictions to seek own legal advice	Sep-24	Ongoing	Extreme	Likely			
		Operational	Issues relating to REDCap data: - Mismatch of information manually provided and data entered in REDCap - Lack of information relating to participants demographics	National	Oct-23	ATP / ORI	C1. Reconciling data in REDCap with data manually provided by partner jurisdictions. C2. No specific controls about demographic information of participants.	Minor	Possible	Medium (9)	9	Treat	T1. Identifying the bugs or issues in REDCap and making relevant changes to the database as necessary T2. Encouraging sites to get consent from participants to collect demographic information	Apr-24	Ongoing	Moderate	Likely			
		Operational	Large labour component not acknowledged in RCCC Clinical Trial work particularly in conversion to Teletrials or not supported through model.	National			C1 Documentation of time spent on TT implementation - conversion of CT to TT and cluster set up of TTs	Moderate	Possible	High (15)	15	Treat	T1. Include in jurisdictional performance indicator report	30-Mar-24	Ongoing	Moderate	Likely			
		Operational	National implementation of NCTGF rollout has resulted in some delays due to timing of this release and roll out of ATP.	National	4Oct-26-	ATP	C1. Through the Executive Committee cross membership of the Interjurisdictional Policy Reform Group this had been raised and a commitment by the Commonwealth to provide additional educational support to regional and rural areas for NCTGF implementation.	Minor	Likely	Medium (10)	10	Tolerate	T1. Reassurance T2. ATP National Office reputation processes for all publicity to be implemented locally	Oct-26	Ongoing	Moderate	Likely			
		Operational	Short term contracts and lack of permanency in clinical trial and teletrial positions inhibits ability to see beyond the number of trials in the pipeline.	National	Oct-24	Jurisdictions	C1 Ongoing Executive Chair and Director ATP National Office visits to jurisdictions to understand and lobby for State/Terrority commitment to positions	Moderate	Possible	High (15)	15	Treat	T1. Increase experience gained in negotiation and stakeholder engagement T2. Build knowledge of processes and familiarity with documentation to create efficiencies T3. Business modelling to demonstrate value of TT program in each jurisdictions	30-Sep-24	Ongoing	Moderate	Likely			
		Operational	Workforce shortage and jurisdictional competition for regional, rural and remote experienced workforce.	National	Mar-24	Jurisdictions	C1. An Education and Workforce Development working jurisdictional group has been convened by ATP NO to provide advice to Executive leadership groups.	Major	Likely	High (20)	20	Treat	T1. Queensland Regional Clinical Trial Coordinating Centre (QRCCC) has started business modelling and provided a Chief Executive Forum with a clear strategy that sees a return on investment for investing in workforce from commercial sponsor opportunities. This has been well received and there is more understanding and support and has moved closer to agreement for future sustainability.	30/09/2024	Ongoing	Moderate	Likely			
		Reputational	Brand reputation risk with negative publicity	National	Mar-24	ATP / ORI	C1 National approach to all communication and publications	Moderate	Possible	High (15)	15	Treat	T1. Review by Communication lead T2. National campaign with recognised expert agency T3. Attend, and Present at National Industry Conferences	30--Jun-24	Ongoing	Minor	Uncertain			
		Social	Lack of consumer engagement	National	Jun-22	ATP / ORI	C1. CHF has finalised the consumer engagement strategy C2. Consumer Engagement strategy has been finalised and discussion to integrate ATSI community engagement strategy is underway.	Moderate	Unlikely	Medium (12)	12	Treat	T1. Acting on feedback from Clinical and consumer health forum and consumer engagement strategy from Consumer Health Forum (CHF) T2. Consumer Engagement Strategy to be implemented including special attention to ATSI community engagement	30-Apr-23	Ongoing	Minor	Unlikely			
		Social	Risk of not representing the diversity of partner jurisdictions' populations	National	Jun-22	ATP / ORI	C1. CHF has finalised the consumer engagement strategy which has been reviewed by C&C Advisory group	Minor	Possible	Medium (9)	9	Treat	T1. Acting on feedback from Clinical and consumer health forum and consumer engagement strategy from Consumer Health Forum (CHF) T2. Employment of Lead communication Officer	30-Mar-24	Ongoing	Minor	Unlikely			
		Strategic	Commercial sponsors not engaging with teletrials	National	Jun-22	ATP / ORI	C1. IQVIA is currently interviewing jurisdictional partners to identify barriers and challenges	Major	Possible	High (18)	18	Treat	T1. Acting on feedback from Sponsor Advisory group and IQVIA T2. National Workshop for sponsors T3. Information webinars T4. Sponsor Guidance documentation	Mar-23	Ongoing	Moderate	Possible			
		Strategic	Integration with NSW and ACT	National	Jun-22	ATP / ORI	C1. 3-monthly meetings are being set-up with NSW and ATP	Minor	Possible	Medium (9)	9	Treat	T1. Regular meetings T2. Sharing of documents, processes and best practices T3. Include NSW in working groups and national events	30-Jun-24	Ongoing	Negligible	Rare			
		Strategic	Lack of engagement with external stakeholder by clinicians	National	Jun-22	ATP / ORI	C1. Queenstand is working on HSCE forum brief and will present to the forum C2. Seek other jurisdictionals plans to engage their clinical and research networks	Moderate	Possible	High (15)	15	Treat	T1. Engage with and present to clinical networks T2. National awareness campaign T3. Clinician stories in videos on website	30-Sep-24	Ongoing	Minor	Possible			
		Strategic	Large investment in this Program not meeting outcomes; KPIs/milestones not being met	National	Jun-22	ATP / ORI	C1.RCCC set up	Major	Possible	High (18)	18	Treat	T1. Extensive engagement with all stakeholders T2. Promoting the program and model through site visits and through attending conferences and seminars	4-Oct-26	Ongoing	Moderate	Unlikely			
		Strategic	RCCCs/Primary site paying Teletrial support Program funds to ineligible primary and satellite sites	National	Jan-23	ATP / RCCCs	C1. Eligible trials reporting through REDCap	Minor	Possible	Medium (9)	9	Treat	T1. For RCCC each memo will include timeline for that trial and will be accompanied by REDCap reporting T2. Ongoing education sessions T3. Data working group T4. JCU/QUT map minimum data set in evalution need against REDCap fields	30-Sep-24	Now	Moderate	Possible			
		Strategic	Risk to harmonisation: * inconsistency of RCCC situated within jurisdiction, * sites operating outside of program model, * misalignment with operating processes and policies between states	National	Jun-22	ATP / ORI	C1. Detailed implementation plan template is prepared for jurisdictional partners	Major	Possible	High (18)	18	Treat	T1. Monthly catch up with jurisdictional partners T2. Detailed implementation plan from jurisdictional partners T3. Restructuring the Executive Committee to have representation from high-enough policy makers/influencers from jurisdictional partners T4. Work program on national TT implementation documentation needs T5. Library of documentation compiled	4-Oct-24	Ongoing	Minor	Possible			
		Strategic	Targets have no linear correlation.	National	30-Mar-24	ATP / RCCCs	C1. Jurisdictons undergoing internal review of success to date and understanding of sites, stakeholders and pieline of current TTs. C2. Discussion paper of environment understanding environmental factors and reflections of program success to date C3. Renegotiate with MRFF at their invitation	Major	Almost certain	Very High (23)	23	Treat	T1. Revision of targets based on actual experience and site knowledge. T2. Negotiation of targets set to be presented to the MRFF executive with a discussion paper for consideration of experience gained to date and lived experience of RCCCs gaining knowledge of their workforce, legal, regularity processes and labour component of setting up TTs.	30-Jun-24	Ongoing	Moderate	Likely			
		Strategic	Securing ongoing funding for ATP beyond 2026	National	8-May-24	ATP and Jurisdictions	C1. Jurisdictional visits by executives and director C2. secruing support from executive leaders.	Major	Possible	High (18)	18	Treat	T1. national meeting with partner jurisdictions, Alfred Trial hub and Revitalise and R3-CTEP executive leaders.	Sep-24	Ongoing	Major	Possible			