Clinical Oncology Society of Australia

Pilot Implementation of the Australasian Tele-Trial Model

ACCESS TO CLINICAL TRIALS CLOSER TO HOME USING TELE-HEALTH

PROJECT COMPLETION REPORT

1 August 2017 to **30 September 2020**

This venture has received funding through the MTPConnect Project Fund Program – a dollar-for-dollar matched program investing in big, bold ideas to improve the productivity, competitiveness and innovative capacity of Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect is supported by the Australian Government Industry Growth Centres Initiative – learn more at mtpconnect.org.au

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Executive Summary

The COSA project to pilot the implementation of the Australasian Tele-Trial Model commenced on 1 August 2017 and concluded on 30 September 2020. The aim was to facilitate the adoption of the Model nationally through engagement with government, regulatory bodies, hospitals, and insurers to drive regulatory reform and through assisting cooperative trial groups, pharmaceutical industry sponsors, and researchers, adopt the Tele-Trial Model as part of standard practice.

This report summarises the activities and achievements of the project including:

- Project description
- Project deliverables, achievements, and learnings
- Major project outcomes
- Future considerations

Key deliverables and achievements are:

1. Establishment of tele-trial clusters within 5 project funded primary sites
2. Key stakeholder engagement including State and Territory Departments of Health, and trial sponsors from industry and investigator groups
3. Tele-trial Model implemented and tele-trials opened within all project clusters
4. Tele-trial Supervision Plan template developed and implemented to ensure subject safety and data integrity protected within tele-trial clusters, and tele-trial resources and information developed to support implementation
5. Regulatory and governance issues identified and implemented including tele-trial SOPs and tele-trial subcontracts
6. Seven tele-trials were opened in project funded clusters and two completed recruitment during the pilot
7. Four tele-trials were also opened outside project funded clusters nationally and three were closed to recruitment during the pilot
8. 135 patients were recruited to tele-trials in project funded clusters

Future Considerations are:

1. To support the widespread adoption of the Tele-Trial Model within Australia investment in tele-trial infrastructure is required
2. Expedited research governance processes must be adopted nationally to provide certainty for sites and sponsors, to allow interstate collaborations and to provide the essential flexibility needed to conduct tele-trials efficiently and effectively
3. A national standard for tele-trial cluster fees is needed to realise the many benefits of tele-trials to patients and sites without making them financially unviable for sponsors
4. A formal process to enable the rapid initiation of satellite sites using pre-accreditation processes or Just-in-Time Site Activation Models which also consider contracting and indemnity issues both within and across state boundaries will ensure an agile responsive tele-trial system
5. The Tele-Trial Model is primarily for patients, therefore assessing whether the Model is addressing the needs of patients with a large-scale review is a vital next step in the evolution of the Tele-Trial Model
6. Further engagement and education is needed at local health level, with hospital Chief Executives and with sites that remain unfamiliar with the Tele-Trial Model
7. The Tele-Trial Model can be applied to clinical trials for any disease and any type of clinical research including psycho-social research, and medical device research. Work to facilitate adoption beyond oncology is now required
8. Adoption of the Tele-Trial Model as a tool for ensuring and enhancing equity of access and expedited recruitment to clinical trials ultimately requires the uptake of the model through policy and strategy within all levels of the health system from the department of health at Commonwealth and state levels, local health services, and hospital and clinician levels

The pilot implementation of the Australasian Tele-Trial Model demonstrated that tele-trials can be safely and ethically implemented. The COVID-19 pandemic also highlighted the significant advantages and utility of the Tele-Trial Model in Australia and internationally. The pilot demonstrated that an interconnected clinical trial system can be created through the Australasian Tele-Trial Model, resulting in more regional and rural sites acquiring clinical trial capabilities, and more regional and rural patients accessing clinical trials closer to home without disrupting continuity of care. This evidence was used to support a Medical Research Futures Fund (MRFF) grant application under the Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program. In October 2020, the Federal Government announced grants totalling $125 million “to give patients access to clinical trials where they live” by bridging the metro-regional trials gap and addressing inequity in access to clinical trials for rural, regional and remote patients. $75.2 million was awarded to the Australian Tele-Trial Program championed by COSA project co-chair Professor Sabe Sabesan and led by Queensland Health; with two other successful grants in NSW and Victoria also including tele-trial components. This guarantees the continued development and integration of tele-trials into standard clinical trial practice in Australia thereby providing equity of access to clinical trials for hundreds of patients.

1. Background

The Australasian Tele-Trial Model released in September 2016 was developed by the Clinical Oncology Society of Australia (COSA) Regional and Rural Group in consultation with clinical trial sponsors, clinicians, health administrators and regulatory bodies.[1] The Model uses tele-health to enable clinicians from larger centres (primary sites) to enrol, consent and treat patients on clinical trials at regional and rural centres (satellite sites). The primary and satellite sites together are referred to as a tele-trial cluster (Figures 1. and 2.) The tele-trial model benefits are not limited to regional areas, with the same model having the potential to connect larger centres even within the same city, thereby improving the rate of recruitment to highly specialised clinical trials such as those for rare cancers. The model carefully considers the requirements for the proper conduct of clinical trials in such a geographically spread setting, ensuring the protection of the rights and safety of trial participants while also ensuring the quality of data collected to determine the safety and efficacy of cancer treatments.

Figure 1: Australasian Tele-Trial Model

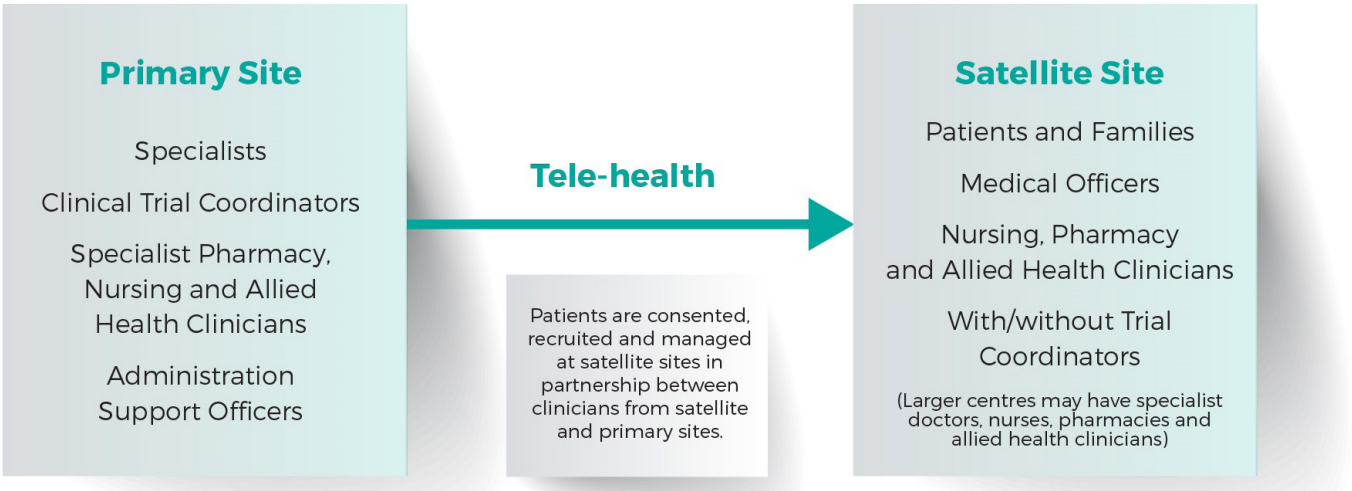
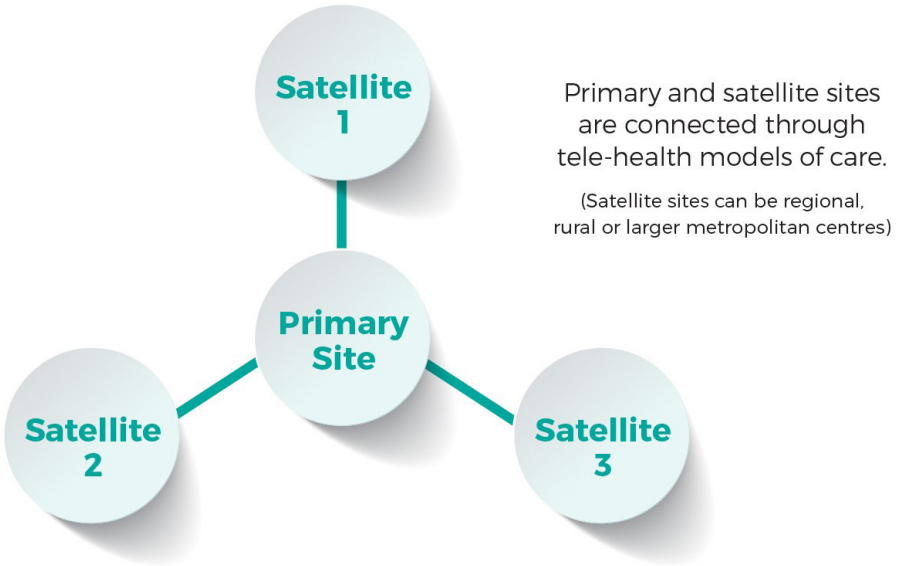


Figure 2: Trial Cluster



Access to clinical trials for people diagnosed with cancer is a core component of providing optimal cancer care through specialist cancer centres, hospitals, and other treatment facilities. The Australasian Tele-Trial Model was developed to overcome the barriers faced by regional and rural patients wishing to participate in clinical trials, including the limited availability of trials and trial sites closer to home which lead to the increased cost and inconvenience of travel to major centres where the trials are taking place. [2-3]

Establishing clinical trials at large regional cancer treatment centres is feasible, however, the logistics of maintaining a skilled workforce and undertaking the ethical and regulatory requirements associated with clinical trials is difficult at smaller regional and rural sites with limited resources and low patient numbers.

The Australasian Tele-Trial Model builds on the work done in providing standard clinical care through telehealth and tele-oncology. Tele-oncology models of care have enabled many cancer centres to facilitate the administration of complex chemotherapy in rural and regional areas. [4-6] The model outlines a practical and effective tele-health strategy to increase access to clinical trials closer to home, while ensuring the ethical and safe conduct of clinical trials.

2. Piloting the Implementation of the Australasian Tele-Trial Model

2.1 Project description/ overview

COSA was successful in securing funds from an MTPConnect project grant in 2016. MTPConnect is a not-for-profit company established by the Commonwealth as an Industry Growth Centre in the medical technology, biotechnology and pharmaceutical (MTP) sector. The granting scheme in which COSA was successful was established for projects to improve the productivity, competitiveness and innovation capacity of the MTP sector. COSA convened a funding consortium with funds matched by MTPConnect and COSA to pilot the implementation of the Model over two years. The project officially commenced on 1 August 2017, with the aim of facilitating the adoption of the Model nationally through engagement with government, regulatory bodies, hospitals, and insurers, to drive regulatory reform and through assisting cooperative trial groups, the pharmaceutical industry, and researchers to adopt the Tele-Trial Model as part of standard practice.

Five sites in NSW, Queensland and Victoria received project funding to support employee costs (0.2 FTE) to assist with implementation of the Model as the primary sites for a tele-trial cluster.

In 2019 the project was extended for a further year to enable time to fully embed the Model at sites and allow time for regulatory reform to be concluded.

2.2 Funding Consortium Partners

MTPConnect funding was matched by COSA and 12 funding consortium partners from industry, research institutes and consumer groups. Industry partners included: Medicines Australia (MA), AbbVie, Icon Group, Janssen, Novartis and Pfizer. Research institute partners included: Australian Institute of Tropical Health and Medicine (AITHM), Garvan Institute of Medical Research, St John of God, and the Walter and Eliza Hall Institute of Medical Research (WEHI). Consumer advocate partners included: Cancer Voices Australia and Rare Cancers Australia.

In 2019, the funding consortium agreed to extend the project for a third and final year, and at that time additional funding was sought from the project's industry consortium partners and three new funding consortium partners AstraZeneca, BMS and MSD.

2.3 Project Governance

The project was supported by a part-time COSA project manager. Strategic oversight was provided by the two Co-Chairs Professors Sabe Sabesan (Townsville) and Professor John Zalcberg (Monash) and a Steering Committee (SC), with a representative from each funding consortium partner (Appendix 1). In the project extension phase SC, members were joined by a representative from MSD. AstraZeneca and BMS declined to nominate a representative as the project was well underway. The SC convened 2 or 3 times per year via teleconference and

once a year face to face, to guide the strategic direction of the project and establish the ongoing priorities.

A small Executive Committee (EC) with the two Co-Chairs and one nominated representative from each of the industry, research institutes and consumer group consortium partners provided operational oversight for the project (Appendix 1). The EC met monthly for the first two years and in the extension phase of the project, the EC meetings alternated with a smaller operational group meeting of the two Co-Chairs and the project manager.

In addition to the SC and EC, five advisory groups were convened to guide and inform the project and to facilitate engagement with stakeholders (Appendix 2):

- MA Industry Advisory Group – representatives from Medicines Australia, Eli Lilly, Roche and Pfizer
- Cancer Cooperative Trials Group Advisory Group – representatives from Australasian Gastro-Intestinal Trials Group (AGITG), Australasian Leukaemia & Lymphoma Group (ALLG), Australasian Lung Cancer Clinical Trials Group (ALTG), Australia New Zealand Gynaecological Oncology Group (ANZGOG), Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP), Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), Melanoma and Skin Cancer Trials (MASC Trials), Psycho-Oncology Co-operative Research Group (PoCoG), and Trans Tasman Radiation Oncology Group (TROG)
- Investigational Medicinal Product (IMP) Advisory Group – representatives from industry consortium partners and MA Industry Advisory Group
- Department of Health Advisory Group - representatives from NSW, Queensland, Victoria, South Australia, Western Australia, Northern Territory, Tasmania plus Federal Department of Health
- Consumer Advocacy Group – representatives from Medicines Australia, Rare Cancers Australia and Cancer Voices NSW

Quarterly reports were submitted to MTPConnect reporting on progress against the agreed project milestones and expenditure. Primary sites funded by the project were required to submit quarterly progress reports and regular project updates were submitted to the COSA Board and Council.

2.4 Budget

The project budget was $345,000 for the first two years. Three quarters of this funding was allocated to administration and staff costs (project manager salary and 0.2 FTE funding for 5 primary sites) and the remaining quarter was allocated to stakeholder communications and meetings.

An additional $80,000 was budgeted for the extension phase of the project for the project manager salary and ongoing project committee and stakeholder meetings.

3. Project deliverables and achievements

Project deliverables were based on the milestones provided to MTPConnect as part of the funding agreement. A summary of achievements against the deliverables is provided in Table 1. A detailed description of project deliverables, achievements and **learnings** is provided at Appendix 3.

Table 1.

Deliverable	Achievement against deliverable	
Selection of 5 primary sites to implement the Tele-Trial Model Trial clusters for 5 primary sites confirmed and agreements in place	Primary Site	Satellite Site(s)
	St Vincent's, Sydney, NSW	· Riverina · Dubbo
	Westmead, Sydney, NSW	· Orange
	Victorian Comprehensive Cancer Centre (VCCC), Victoria	· Border Medical Oncology · Bendigo Health · Ballarat Health · Goulburn Valley Health
	Monash Partners, Victoria · Alfred Health · Monash	· Royal Hobart · Bendigo
	Royal Brisbane & Women's Hospital (RBWH), Queensland	· North Lakes · Hervey Bay · Rockhampton · Bundaberg · Townsville
Project meetings convened in NSW, Victoria, and Queensland	· Multiple project meetings held at site, local health authority and state level · Steering Committees in Victoria, Queensland and NSW with key stakeholders including Department of Health representatives are in place	

Deliverable	Achievement against deliverable
Negotiation with trial sponsors from both industry and investigator groups re suitable trials	• Sponsors were engaged through the SC, MA Industry Advisory Group, the Cancer Cooperative Trials Group (CCTG) Advisory Group, COSA member engagement and presentations at major conferences including ARCS, ACTA and ASCO breakthrough • The first CCTG sponsored tele-trial was opened by the Australasian Gastro-Intestinal Trials Group (AGITG) in 2017 • A project presentation to the MA/MTAA Research and Development Taskforce in October 2017 resulted in the implementation of the first industry sponsored tele-trial in Australia by Eli Lilly which opened in 2018
1-2 suitable trials identified within industry and/or trial groups for each cluster	• Suitable trials were identified within both industry and CCTGs for each cluster • An investigator-initiated trial was identified for the VCCC cluster
Regulatory and governance issues within clusters identified and strategy to address these issues confirmed	• Standard Operating Procedures (SOPs) for tele-trials, streamlined Research Governance at the satellite sites and sub-contracting of satellite sites were identified as the most important regulatory and contractual issues to be addressed • Australian ICH-GCP SOPs (including tele-trials) and a template Trial Supervision Plan template were developed in collaboration with Queensland Health (QH) and published in June 2018. The SOPs were widely reviewed by industry and cooperative group sponsors and updated following feedback from the Eli Lilly tele-trial pilot • The Australian ICH-GCP SOPS (including tele-trials) were developed to be adopted as national documents and were submitted to National Mutual Acceptance (NMA) in January 2019 and were approved in April 2020
Workforce roles and responsibilities identified for each cluster	• A Trial Supervision Plan template was developed in collaboration with Queensland Health and was released with the Australia ICH-GCP (including tele-trials) SOPs in 2018 • Example Trial Supervision Plan templates for satellite sites with and without clinical trials units and sites without a medical oncologist are available on the COSA website Tele-Trials Resources page.[7]

Deliverable	Achievement against deliverable
Confirmation of 5 governance staff at primary sites	· Project funding was accepted by 5 primary sites, and used to support staff costs to implement the Model
Development of remote monitoring systems by trial sponsors	· Sponsors have instituted remote monitoring in the areas of source document verification and IMP logistics and accountability
Final selection of trials for inclusion	· 9 tele-trials have opened within project clusters · 2 tele-trials are now closed to recruitment
Model implemented within all 5 clusters	· The Tele-Trial Model has been implemented within all 5 project clusters · In addition to project funded clusters there are a total of 13 tele-trial clusters in Queensland, Victoria, NSW, South Australia, and the ACT
Workforce training complete	· Workforce training is complete and ongoing as the tele-trial model is introduced at new sites. · A number of resources developed in collaboration with QH, RGO's and Townsville Hospital for sponsors and sites are available on the COSA website. [7] These include: · Supervision Plan templates · Steps to establish a Tele-Trial cluster · Post approval steps for tele-trial amendments and documents · Question and Answer documents for sponsors and sites and FAQ · Checklist of documents for RGO submission at Primary and Satellite Sites · Sample PICF for tele-trial clusters · VCCC have also developed an extensive suite of tele-trial resources and an e-learning module about implementing tele-trials which are available on the VCCC website

Deliverable	Achievement against deliverable
Streamlining of contract and governance processes	• A tele-trials subcontract for use between the primary and satellite sites was developed by Queensland Health for the Eli Lilly sponsored tele-trial and the subcontract was released in September 2018 • VCCC engaged a lawyer to develop a contract to support investigator initiated tele-trials and this was accepted by satellite sites for their first tele-trial which opened in November 2018 • Victoria published a tele-trials subcontract based on the Queensland Health subcontract in April 2020 • The Southern and Eastern Border States (SEBS) Review Panel comprising of Health Departments from NSW, Queensland, Victoria, South Australia, and Tasmania have proposed a tele-trials subcontract based on the Victorian tele-trials subcontract. This is currently under review by MA and once approved will be published on the MA website • Queensland will adopt streamlined research governance for the tele-trial model in which the primary site completes the full Site-Specific Assessment (SSA) application and satellites sites complete a sub-form with local details • The groundwork for a national SSA form (incorporating tele-trials) has been done by NMA. This is currently under discussion by the Clinical Trials Project Reference Group
Clinical trials using Model approved and open in each cluster	• Clinical trials using the Model are open in all project funded clusters
15 patients participating in tele-trials (total across all clusters)	• There are currently 135 patients recruited to tele-trials in project funded clusters • 124 patients have been recruited to regional and rural satellite sites and 11 patients at metropolitan satellite sites

4. Risks and Mitigation

A number of risks and mitigation strategies were identified throughout the project as outlined in Table 2.

Table 2.

Potential risk	Mitigation
Operational risks:	
• Primary site workloads delaying implementation of the Model	• Close ongoing engagement with primary sites and primary site quarterly reporting requirements • Active involvement in local steering committees, education, and mentorship of clinical trials staff • Tele-Trial champions at primary sites to drive implementation of Model
• Delayed approval of key tele-trial documents by government regulatory bodies	• Active engagement, advocacy, and education of regulatory authorities through DOH Advisory Group • Participation in steering committees with local Research Governance Offices (RGOs) and close collaboration with state government departments of health • Advocacy through MA
Performance risks:	
• Failure of sites to implement the model	• Selection of large well-established clinical trial units with tele-trials champion to drive implementation
• Failure to identify suitable trials	• Collaboration with sponsors through SC, MA Industry and CCTG advisory groups • Education of sponsors through conference presentations and journal articles
Financial risk:	
• Escalation of project costs	• Detailed project budget defined to include all expected costs including cost to achieve each milestone • Quarterly reconciliation of expenses

Potential risk	Mitigation
Reputational risks:	
• Failure of Tele-Trial Model to deliver clinical trials safely and ethically	• Tele-Trials SOPs developed prior to commencement of first industry sponsored tele-trial • Trial Supervision Plan template developed to ensure responsibilities for trial activities clearly articulated for each trial and taking into account differences in satellite site capability within a cluster • Oversight of each trial within clusters through regular trial-cluster meetings • Close collaboration and engagement with sponsors and clinicians
• Resistance to change by government, regulatory authorities, sponsors, and sites	• Early and extensive engagement with all stakeholders • Careful selection of sites to pilot the Model • Ongoing engagement and advocacy • Incorporation of the Model into policy and strategy. An example of this is the incorporation of the Australasian Tele-Trial Model into the VCCC strategic plan

4.1 Global pandemic

The last 7 months of the project were impacted by the COVID-19 pandemic. Clinical trial recruitment at sites was placed on hold and the opening of new tele-trials postponed. Clinical trial resources at sites were channeled into COVID-19 related research and activities. One project primary site was about to open their first tele-trial and this was put on hold by the sponsor for several months directly impacting one of the project's key milestones to have all primary sites open a tele-trial.

As well as these negative impacts, the COVID-19 pandemic also highlighted the significant advantages and utility of the Tele-Trial Model in Australia and internationally. Researchers and sponsors were advised to educate themselves about novel approaches to the conduct of clinical trials including tele-trials [8] and tele-trials were presented and discussed at numerous forums. The response to the pandemic resulted in greater collaboration across clinical trial organisations, increased responsiveness and flexibility of HRECs and RGOs, and fostered an environment of collaboration and cooperation between key stakeholders all of which facilitated the progress of tele-trials within Australia. An example of this is the initiation of an interstate tele-trial between the Alfred Hospital in Melbourne and Royal Hobart Hospital in Tasmania in just 6 weeks to allow a young mother to continue to receive treatment on a commercially sponsored Phase I trial during COVID-19 border closures.

5. Major Project Outcomes

5.1 The Successful Implementation of Tele-Trials

The pilot implementation of the Australasian Tele-Trial Model demonstrated that tele-trials can be safely and ethically implemented and that an interconnected clinical trial system can be created through the Australasian Tele-Trial Model, resulting in more regional and rural sites acquiring clinical trial capabilities, and more patients accessing clinical trials closer to home without disrupting continuity of care. The pilot also demonstrated that trial recruitment can be expedited and that a networked approach for rare cancer trials facilitated access to more patients.

There are currently 24 sites conducting tele-trials in NSW, Queensland, Victoria, and South Australia. The AGITG sponsored ASCOLT trial opened between Orange and Dubbo in November 2017 and the Eli Lilly sponsored MonarchE trial opened between Townsville, Cairns, Mackay, and Mt Isa in October 2018. Since then the number of sites participating in tele-trials has increased dramatically and this is set to continue as sponsors and sites become increasingly familiar with the Australasian Tele-Trial Model.

At project commencement there were no tele-trials open within Australia.

- At the conclusion of the pilot there were 11 tele-trials open to recruitment nationally
- Five tele-trials undertaken during the project are now closed to recruitment
- A further nine tele-trials were pending approval at close of the pilot
- 24 sites have participated in tele-trials, 16 of which have been regional or rural. Four of these sites had never opened a clinical trial prior to their participation as a satellite site
- 12 health professionals acquired Good Clinical Practice training for the first time

150 patients have been enrolled in tele-trials, 135 of these patients live in regional and rural areas.

Evidence from the successful pilot of the Australasian Tele-Trial Model was used to support a Medical Research Futures Fund (MRFF) grant application under the Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program. In October 2020, the Federal Government announced grants totalling $125 million over the subsequent five years “to give patients access to clinical trials where they live” by bridging the metro-regional trials gap and addressing inequity in access to clinical trials for rural, regional and remote patients. [9] Included in this grant is $75.2 million to the Department of Health, Queensland for the Australian Tele-trial Program, which will oversee the establishment of Regional Clinical Trial Coordinating Centres (RCCCs) in Queensland, Western Australia, Victoria, Tasmania, South Australia and the Northern Territory. RCCCs will focus on removing the barriers to establishing tele-trials at satellite sites including infrastructure, equipment and training barriers as well as

facilitate the coordination and operational activities of tele-trial clusters. Other grants also funded in the same round were $18.6 million to the Border Medical Oncology Research Unit for the 'ReViTALISE Project', and $30.6 million to the NSW Ministry of Health for the 'Improving access to innovative healthcare in rural, regional and remote NSW and ACT Project'. These projects also have tele-trial components.

Tele-trials will now have the necessary funding, infrastructure and government support to become mainstream in Australia and provide access to clinical trials for hundreds of patients throughout Australia.

5.2 Regulatory and Governance Reform

The regulatory and governance reforms achieved in the last three years are significant. Clinical trials are highly regulated and governments and regulatory authorities are risk adverse. Approval processes for the NMA scheme and SEBS took significantly longer than expected. In the absence of an approved contracting process negotiation of an agreement to conduct tele-trials between two Local Health Districts took two years. Despite these challenges, tele-trials are now supported by both national SOPs and state specific tele-trial SOPs in NSW, Queensland, and Victoria. Queensland and Victoria have approved tele-trial subcontracts and a national tele-trial subcontract through MA is imminent.

In March 2021, the National Teletrials Compendium was released to support a national approach to tele-trials. [10] The Compendium consists of two publications, one covers National Teletrial Principles in Australia based on the Australasian Tele-trial Model and the other covers standard operating procedures for clinical trials and teletrials. They have been developed for the National Mutual Acceptance (NMA) Scheme in Australia and to support a consistent approach to national implementation more broadly. They have been endorsed by all states and territories, together with the Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC), through the Clinical Trials Project Reference Group (CTPRG).

5.3 Stakeholder Engagement

The project engaged widely with stakeholders through the SC and Advisory Groups and through engagement with clinicians, sites, and regulatory authorities. The Tele-Trials Model was presented at major cancer and clinical trial conferences between 2018 and 2019 (Appendix 2). A supplement to the Asia-Pacific Journal of Clinical Oncology – the Australasian Tele-Trial Model: Lessons from Practice was published in October 2019 on the Wiley Blackwell Online Library. [10]

The project also stimulated the Canadian Cancer Clinical Trials Network's initiative to create the Canadian Remote Access Framework for Clinical Trials which was released in May 2020. [11]

5.3.1 COSA Clinical Trials and Research Professionals Group (CTRPG) 2020 Clinical Professional Day

A tele-trials workshop for clinical research professionals was held prior to the COSA ASM in 2020. The workshop outlined implementation of the Australasian Tele-Trial Model from a site perspective with presentations from clinical trial managers and research coordinators, pharmacy, pathology, research governance, and sponsors.

Many sites have successfully implemented the Tele-Trial Model by adapting existing clinical trial processes or when necessary creating new processes to support implementation. Some of the issues faced by sites are:

- Differences in local fees across sites for pharmacy, medical imaging and pathology
- Different finance processes across different health services requiring additional administration support
- Difficulties meeting needs of multiple stakeholders and implementing effective communication strategies
- Inconsistent application of the Tele-Trial Model across sites
- IMP logistics – Temperature controlled supply chain, IMP expiry/stability, couriers/deliveries, site workflows e.g. randomisation and IMP allocation
- Adequate resourcing for increased workloads at primary sites

Strategies identified to address these issues were:

- Standardisation of fees e.g. Queensland has established state wide pharmacy fees
- Clear communication pathways
- PI committed to investigator oversight and regular tele-trial meetings
- Adequate protected clinical trial staffing and administration support
- Capability matrix to assess which clinical trial protocols are suitable for the Model that aligns with the service capability of the satellite/s
- Development of workflow processes for pharmacy, imaging, IMP management and pathology

5.4 Sponsor Surveys

Two surveys to capture the sponsor experience in tele-trials were circulated to industry and Cooperative Group sponsors through the SC, MA Industry Advisory Group, the CCTG Advisory Group and through the membership of MA in July – August 2020. The first survey captured sponsors who have implemented tele-trials and the second survey sought feedback from sponsors who have not implemented tele-trials but have considered implementing tele-trials. The aim of both surveys was to identify the barriers and enablers for tele-trials within Australia and to inform the ongoing implementation of the Tele-Trial Model in Australia.

5.4.1 Sponsors who have implemented tele-trials

5.4.1 (a) Results

The survey was completed by 8 sponsors, 5 sponsors from industry and 3 from Cancer Cooperative Trial Groups. Each sponsor has opened 1 or 2 tele-trials and most of these tele-trials have opened in Queensland and NSW.

Primary sites were both metropolitan and regional and the majority of satellite sites were regional. On-site oncology resources were not available at all satellites sites. 2 satellite sites did not have a dedicated oncology unit, 4 satellite sites did not have a dedicated oncology clinical trials unit and 1 satellite site did not have an oncologist on staff

Table 3.
Number, Location and On-Site Oncology Resources of primary and satellite sites

	Metropolitan	Regional	Rural
Primary Sites	6	5	0
Satellite Sites	1	17	1
· No oncology unit		(2)	
· No oncology clinical trials unit		(4)	
· No oncologist on staff			(1)

Staff received GCP training for the first time in 2 tele-trials.

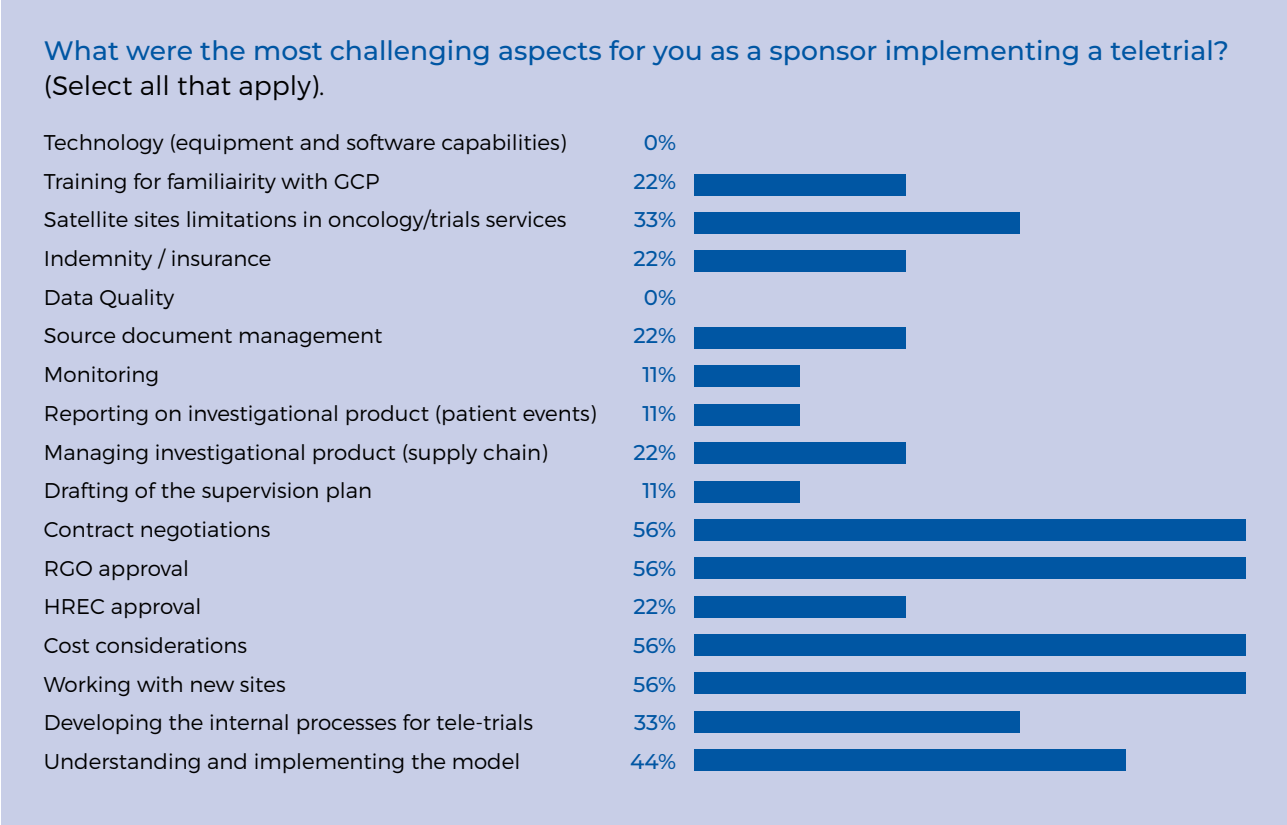
87% of sponsors added a satellite site to a clinical trial which was already open.

While HREC submission approval times were not longer for tele-trials, 50% of sponsors indicated that the RGO approval was slower for tele-trials than standard clinical trials. Sponsors reported that RGO approval was delayed at both the primary and satellite site with one sponsor commenting, 'The delay was at both.
The delay at the primary site was that they needed a thorough review as this was an initial full review. As teletrials was added on to an existing study, the delay from the satellite RGO was their requirement to review all historical HREC submissions, approvals, documentation and the primary site RGO approvals (they required review of the full package from the primary site RGO as well). This is an ongoing challenge as all governance submissions continue to be processed through the primary site and also the satellite site which isn't in the spirit of the teletrials model.'

Sponsors were able to implement remote monitoring for satellite sites for source document verification, Investigational Medicinal Product (IMP) logistics and accountability, and review of electronic medical records (EMR). Remote monitoring was especially facilitated by a shared EMR between primary and satellite sites, and if an IMP distribution Model was in place where the primary site distributed IMP to satellite sites.

56% of sponsors indicated the most challenging aspects of implementing a tele-trial were working with new sites, cost considerations, timelines for RGO approval and contract negotiations. Other challenging aspects identified included understanding the tele-trials model and its practical implication, developing the internal sponsor processes necessary to implement tele-trials and limitations in the satellite sites specialty 'oncology service', knowledge and/or oncology trials practices. Data quality and technology were not considered to be challenges (Figure 3).

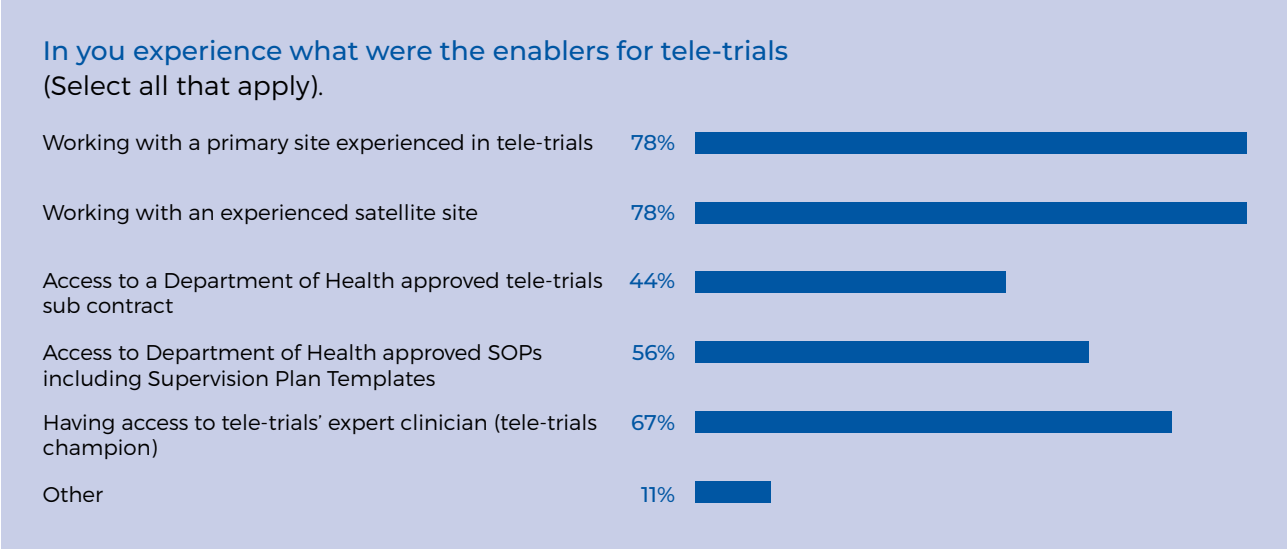
Figure 3. The most challenging aspects for sponsors implementing a tele-trial



All sponsors indicated these challenges would not prevent them from initiating another tele-trial.

78% of sponsors indicated the enablers for tele-trials were working with an experienced primary site and working with an experienced satellite site. Having access to a tele-trial expert clinician was also an important enabler for 67% of sponsors. All sponsors considered increasing remote monitoring as part of a whole monitoring package to be an advantage (Figure 4).

Figure 4. Enablers for tele-trials



Sponsors consider the following factors are important to facilitate tele-trials:

- Consistent standardised tele-trial implementation processes across Australia including research governance and contractual processes
- Single RGO review for a cluster
- Implementation of a standard agreed fee schedule for tele-trial clusters
- Adequate clinical trial workforce and infrastructure at sites
- Shared Electronic Medical Record
- A tele-trials champion within the tele-trial cluster
- Education of sites about tele-trials
- Established drug supply chain and logistics for distribution of IMP from primary site to satellite sites
- Funding support for tele-trials

89% of sponsors indicated that the most rewarding aspect of implementing a tele-trial was providing access to clinical trials for patients in regional and rural Australia. Over half of sponsors indicated providing access to trials for rare cancers/rare tumour sub-types and increased patient recruitment were rewarding aspects. 45% of sponsors indicated working with new sites was rewarding.

All sponsors surveyed, plan to initiate more tele-trials in the future.

5.4.1 (b) Conclusions

The large number of regional satellite sites reflects sponsors' desire to extend the reach of clinical trials to regional areas and tap into greater patient pools. By utilising the supervision of experienced trial sites (as Primary Sites) through the Tele-Trial Model, this allowed regional hospitals/health centres without a medical oncology department or a medical oncologist on staff and also regional hospitals/ health centres without an oncology trials unit to access clinical trials (as Satellite Sites).

Most sponsors surveyed added satellite sites to an already open clinical trial. This is expected to change in the future as sponsors consider all protocols as early as concept development stage for tele-trials and as tele-trial clusters become an established option for new trials. However, the option of adding satellite sites to increase recruitment to slowly recruiting trials will remain an attractive option provided this can be achieved expeditiously.

Challenges with arduous and duplicative approval processes and budget negotiation pose a challenge for clinical trials in general but are exacerbated in the Tele-Trial Model and need to be addressed at the system level. Survey results highlight very clearly the need for expedited RGO approval for tele-trials (especially for adding satellite sites to existing trials), an established approved contracting/indemnity process, and a standard schedule of fees for tele-trials that fits within budget limitations for sponsors.

Concerns have been raised about potential issues with indemnity/insurance, source document management and remote monitoring in the Australian environment to support the implementation of the Australasian Tele-Trial Model, however it is interesting to note that these challenges were able to be overcome by many sponsors.

5.4.2 Sponsors who have not opened a tele-trial

5.4.2 (a) Results

13 sponsors completed the survey, 8 industry sponsors and 5 Cancer Cooperative Trial Group sponsors. The majority of sponsors who completed the survey conduct Phase 2-3 interventional drug device trials and have conducted 20 or more clinical trials at multiple sites including global multicenter studies.

Most sponsors would consider implementing a tele-trial for

- a study designed to support global health authority submission (global phase 2-3 registration studies)
- a study that does not have complex requirements (e.g. PK sampling, in hospital monitoring etc.)
- a study where the logistical requirements of the study can be met within the geography of the tele-trial cluster
- an observational, non-interventional or epidemiological study

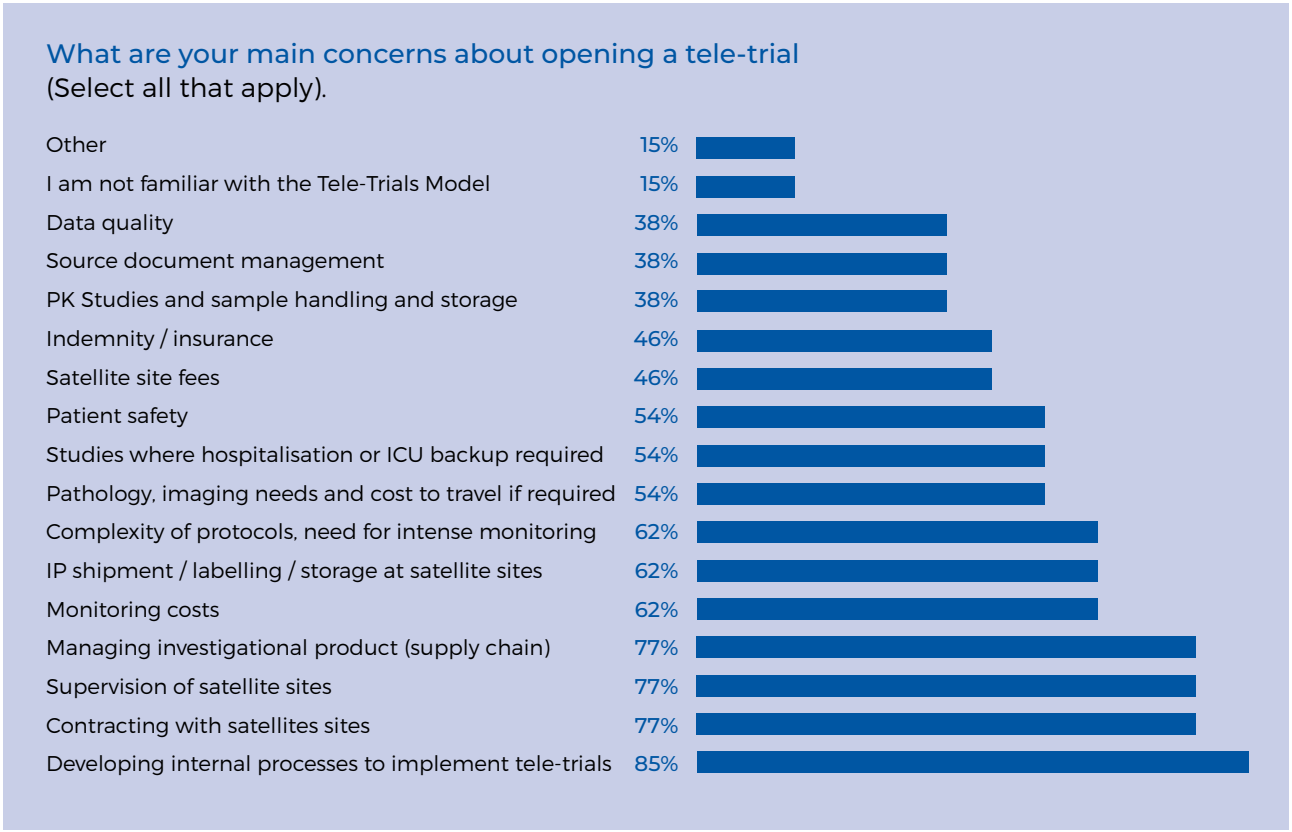
Two thirds of sponsors would also consider implementing a post marketing, real world evidence (RWE), Quality of Life or Patient Reported Outcome study.

11 out of 13 sponsors have identified at least 1 clinical trial protocol suitable for tele-trials with 2 sponsors identifying more than 5 suitable protocols. 1 sponsor who has not found a suitable protocol commented that identification of clinical trial protocols suitable for tele-trials should be initiated by sites.

85% of sponsors specified concern about developing the internal sponsor processes

necessary to implement tele-trials with 77% of sponsors also concerned about contracting with satellites, supervision of satellite sites, and managing investigational product (supply chain). 62% of sponsors are concerned about monitoring costs, IMP shipment and management at satellites sites, and protocols that need intense monitoring, observations, and testing (Figure 5).

Figure 5. Main concerns about opening a tele-trial



Lack of familiarity with the Tele-Trial Model was not identified as a concern by most sponsors and one sponsor commented that lack of leadership within groups leading tele-trials was a concern.

Sponsors reported these concerns can be addressed by:

- National and state guidelines that can be referenced by global divisions to promote tele-trials as a viable option in Australia
- Standardised approach to monitoring and trial procedures at satellite sites
- EMR accessible by Clinical Research Associates for remote monitoring
- Standardised fee schedule for satellite sites
- Clearly established, rapid and non-duplicative Research Governance approval processes
- MA approved tele-trials contract, established contracting processes harmonized across states
- Guidelines for ethics and research governance in tele-trials
- Dedicated trial infrastructure at satellite sites
- Tele-trials considered at concept development stage not once clinical trial is launched

5.4.2 (b) Conclusions

Many of the concerns expressed by sponsors who have not implemented tele-trials echo the factors identified as being important to address by sponsors who have implemented tele-trials. There is no doubt that if these concerns are addressed more sponsors from both industry and cooperative trial groups will initiate tele-trials. The results suggest there is a need for a forum where tele-trial experienced sponsors can share their experience and knowledge with tele-trial naïve sponsors. The CCTGs have indicated that they will work together in the future to develop and refine tele-trial processes for all CCTG sponsors. This leaves industry sponsors to explore the possibility of a forum to enable this exchange perhaps through ARCS or MA.

6. Future Considerations

6.1 Establishment of Tele-Trial Infrastructure

The pilot implementation of the Australasian Tele-trial Model has demonstrated how to scale systems and infrastructure to ensure a rapid, co-ordinated and sponsor trusted clinical trial option that will vastly increase rural, regional and remote patient access to clinical trials. To support the widespread adoption of the Tele-Trial Model within Australia investment in tele-trial infrastructure is required. This must include vendors and services to support Investigational Medicinal Product dispensing and transport and blood sample transport. The recently announced MRFF grants under the Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program will ensure the establishment of the necessary infrastructure and work is already underway to progress this as rapidly as possible.

6.2 Expedited Research Governance

Expedited research governance review covering the satellite site is essential for the full potential of tele-trials to be realised. In the Australasian Tele-Trial Model, the full research governance review is conducted by the primary site on behalf of the cluster. The satellite site then conducts an expedited review that addresses local services/issues only. Without this cluster approval process, research governance review at

both the primary and satellite sites doubles or triples (depending on the number of satellites) the workload, time, and cost to initiate a tele-trial. For global clinical trials, recruitment is competitive and slow start-up at satellite sites can mean additional expense without additional recruitment occurring to offset it. This is unacceptable for sponsors and patients who are waiting to enrol in clinical trials.

A research governance fee should be paid once for the primary site review and not for the satellite sites – alternatively a cluster research governance fee should be applied. An expedited review at the satellite site following a full review at the primary site is less work for the satellite site RGO and this justifies a cluster fee approach.

Expedited research governance processes must be adopted nationally to provide certainty for sites and sponsors, to allow interstate collaborations and to provide the essential flexibility needed to conduct tele-trials efficiently and effectively.

6.3 Fee Structures for Tele-Trial Clusters

The cost of conducting clinical trials in Australia has been raised as an issue by academic and industry sponsors globally. This highlights the importance of assessing the fees associated with conducting tele-trials now so that a uniform approach can be established going forward. Sponsors have raised concern about unsustainable incremental costs for adding a satellite site in tele-trials with satellite sites charging fees that are difficult to support for the roles required. The benefits of increased recruitment from tele-trials cannot justify unrealistic expectations of the fees sponsors are able to pay.

Sponsors and sites need certainty about what is realistic and acceptable within this new Model. Sponsors have requested that negotiation of fees is done entirely by the primary site and a cluster fee presented to the sponsor. A national standard agreed schedule of fees for the tele-trial cluster model would assist primary sites to fulfill this responsibility and to address the potential issue of overcharging. An essential component of the discussion about a national standard for tele-trial cluster fees is how to realise the many benefits of tele-trials to patients and sites without making them financially unviable for sponsors.

6.4 Pre-Accreditation of Sites and Just-in-Time Site Activation Models

Pre-Accreditation of potential satellite sites and just-in-time site activation models allow a satellite site to be initiated once an eligible patient is identified. Development of a pre-accreditation process as discussed in the Australasian Tele-Trial Model [1] where the focus is on the capability of the site and the investigator at the satellite site, or institution of the just-in-time site activation model as a mechanism for patient centred trial activation will increase the speed with which a satellite site can be initiated if an eligible patient is identified. This is particularly relevant for rare cancers. Currently this has not been widely implemented and a formal process to enable the rapid initiation of satellite sites which also considers contracting and indemnity issues both within and across state boundaries will ensure an agile responsive tele-trial system.

6.5 The Patient Experience in Tele-Trials

The focus of the project has been to support the implementation of tele-trials, to establish their safety and viability and to drive the necessary reforms to enable adoption of the Model. Many tele-trials around Australia are open or pending and patient recruitment is well established. To date there has been no large-scale review of the patient experience in tele-trials. The Tele-Trial Model is primarily for patients, therefore assessing whether the Model is addressing the needs of patients is a vital next step in the evolution of the Tele-Trial Model.

6.6 Education

The project has engaged widely with sponsors, state and federal government departments and many sites. There is a need however, for further engagement and education at local health level, with hospital Chief Executives and with sites that remain unfamiliar with the Model. The aim is for all large institutions and clinical trial units to be familiar with the Model so they in turn can take on the role of educating and mentoring smaller institutions and trial units.

6.7 Adoption beyond Oncology

The Tele-Trial Model can be applied to clinical trials for any disease and any type of clinical research including psycho-social research, and medical device research so the next step is for the Model to be applied more broadly. The Australian Clinical Trials Alliance (ACTA) have agreed to facilitate adoption of the Model by trial groups outside of cancer. The SOPs, Supervision Plan, and subcontract developed by COSA and QH are not cancer specific and can be adopted for tele-trials within any disease discipline. The establishment of Regional Clinical Trial Coordinating Centres with funding from the Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program will also support adoption of the Model beyond oncology.

6.8 Incorporation of the Teletrial Model into Policy and Strategy

Adoption of the Tele-Trial Model as a tool for ensuring and enhancing equity of access and expedited recruitment to clinical trials ultimately requires the uptake of the Model through policy and strategy within all levels of the health system from the department of health at Commonwealth and state levels, local health services, and hospital and clinician levels. The uptake of the Model could also be facilitated by funding bodies through incentives and through requiring proportional regional and rural representation in trial participation.

Appendix 1 - Committee Members

Steering Committee Members

Member	Representation	Position	Active
Professor Sabe Sabesan	Co-Chair Australian Institute of Tropical Health and Medicine (AITHM)	Clinical Dean, THHS/JCU Medical Training Director of Medical Oncology, Townsville Cancer Centre	Project duration
Professor John Zalcberg OAM	Co-Chair	Tony Charlton Chair of Oncology, Alfred Health Head, Cancer Research Program, Public Health and Preventive Medicine, Monash University	Project duration
Ms. Marie Malica	COSA	Chief Executive	Project duration
Dr Mahmood Alam	Pfizer	Cluster Medical Lead Oncology, Developed Markets Asia	Apr 2019-present
Mr. Andrew Bowskill	Medicines Australia	Manager, Industry Policy and Research	May 2018-Mar 2019
Ms. Maureen Davis (shared position with Toni Hopkins and Shin Jiyoung)	MSD	Therapeutic Area Head - Oncology Solid Tumours ANZ Global Clinical Trial Operations	Oct 2019 to project end
Dr Vicki Gardiner	Medicines Australia	Director, Policy and Research	Apr 2019 – Jul 2019
Ms. Chantal Gebbie	COSA	Project Manager	Project duration
Ms. Samantha Guthrie	Janssen	Clinical Research Manager, GCO	Project duration
Ms. Toni Hopkins (Shared position with Maureen Davis and Shin Jiyoung)	MSD	Clinical Research Manager	Oct 2019 to project end
Mr. Mitch Kirkman	Novartis	Cluster Head - Asia/Australia/ New Zealand Country Clinical and Pharmacovigilance Quality	Project duration

Member	Representation	Position	Active
Ms. Elisabeth Kochman	Cancer Voices NSW	Chair, Cancer Voices NSW Member of the Executive, Cancer Voices Australia	Project duration
Ms. Larissa Karpish	Medicines Australia	Manager, Industry & Regulatory Policy	Project start to Apr 2018
Mr. Peter Komocki	Medicines Australia	Manager, Industry and Regulatory Policy	Jul 2019 to project end
Ms. Emma Pinkerton	AbbVie	Clinical Operations Manager ANZ Development Operations, R&D	Project start to Dec 2020
Dr Sangeetha Ramanujam	Pfizer	Associate Medical Director	Project start to Nov 2018
Professor Clare Scott	Walter and Eliza Hall Institute of Medical Research (WEHI)	Laboratory Head, Walter and Eliza Hall Institute of Medical Research Medical Oncologist, Peter MacCallum Cancer Centre and Royal Melbourne Hospital	Project duration
Ms. Jiyoung Shin (shared position with Toni Hopkins and Maureen Davis)	MSD	Clinical Research Manager	Oct 2019 to project end
Ms. Elizabeth Stares	MTPConnect	Director - Corporate Reporting and Risk Management	Project duration
Mr. Adam Stoneley	Icon	Research Operations Manager Icon Research Head Office	Project duration
Professor David Thomas	The Garvan Institute of Medical Research	Head, Cancer Theme Garvan Institute of Medical Research Director, The Kinghorn Cancer Centre	Project duration
Mr. Richard Vines	Rare Cancers Australia	Chief Executive	Project duration
Ms. Joanne Youd	St John of God	Project Manager - Clinical Trial Development	Project start to Nov 2019
No representative	BMS		
No representative	AstraZeneca		

Executive Committee Members

Member	Representation	Position	Active
Professor Sabe Sabesan	Co-Chair	Clinical Dean, THHS/JCU Medical Training Director of Medical Oncology, Townsville Cancer Centre	Project duration
Professor John Zalcberg OAM	Co-Chair	Tony Charlton Chair of Oncology, Alfred Health Head, Cancer Research Program, Public Health and Preventive Medicine, Monash University	Project duration
Ms. Marie Malica	COSA	Chief Executive	Project duration
Mr. Andrew Bowskill	Medicines Australia	Manager, Industry Policy and Research	May 2018-Mar 2019
Dr Vicki Gardiner	Medicines Australia	Director, Policy and Research	Apr 2019 – Jul 2019
Ms. Chantal Gebbie	COSA	Project Manager	Project duration
Ms. Larissa Karpish	Medicines Australia	Manager, Industry & Regulatory Policy	Project start to Apr 2018
Mr. Peter Komocki	Medicines Australia	Manager, Industry and Regulatory Policy	Jul 2019 to project end
Professor Clare Scott	Walter and Eliza Hall Institute of Medical Research (WEHI)	Laboratory Head, Walter and Eliza Hall Institute of Medical Research Medical Oncologist, Peter MacCallum Cancer Centre and Royal Melbourne Hospital	Project duration
Mr. Richard Vines	Rare Cancers Australia	Chief Executive	Project duration

Departments of Health Advisory Group

Member	Representation	Position
Professor John Beltrame	South Australia	Director of Research Central Adelaide LHD
Dr Lewis Campbell	Northern Territory	NMA jurisdictional representative Chair – Menzies and Dept of Health human research ethics committee
Mr. James Cockayne	NSW	Principal Policy Officer, Research Ethics and Governance Unit, Office for Health and Medical Research
Ms. Catherine Farrington	Victoria	Project Officer I Systems Coordination, Coordinating Office for Clinical Trial Research
Ms. Julia Farrington	NSW	Policy Officer | Research Ethics and Governance Unit, Office for Health and Medical Research
Ms. Chantal Gebbie	COSA	Project Manager
Dr Jodi Johnson-Glading	Tasmania	Deputy Principal Medical Advisor, Tasmanian Department of Health and Human Services
Ms. Melissa Hagan	Queensland	Manager, Health Innovation, Investment and Research Office (HIIRO), Office of the Director-General, Department of Health
Dr Suzanne Hasthorpe	Victoria	Manager Coordinating Office for Clinical Trial Research
Ms. Sue Inglis	Tasmania	Department of Health and Human Services
Ms. Anita John	WA	A/Director of Research
Dr Wei-Sen Lam	WA	Medical Oncology Clinical Lead | WA Country Health Service
Dr Veronica McCabe	NSW	Director, Strategic Research Investment, Cancer Institute NSW
Ms. Marie Malica	COSA	Chief Executive Officer
Ms. Terrie O'Brien	Federal	Director, Clinical Trials Section, Health and Medical Research Office, Department of Health
Dr Annette Pantle	Tasmania	Executive Director for Patient Safety, Tasmanian Health Service
Professor Sabe Sabesan	COSA	Co-Chair Tele-Trials Project
Professor John Zalcberg OAM	COSA	Co-Chair Tele-Trials Project

Cancer Cooperative Trials Group Advisory Group

Member	Representation	Position	Active
Associate Professor Victoria Atkinson	ANZMTG	ANZMTG Executive committee member	Project start – Jun 2019
Ms. Linda Brown	PaCCSC	PaCCSC/CST National Manager	Project duration
Mr. Russell Conley	AGITG	Chief Executive Officer	Project duration
Ms. Sara Corcoran	ALTG	Research Manager Lung Cancer - ALTG/TACT	Project start – Oct 2018
Professor Ian Davis	ANZUP	Chair, ANZUP Cancer Trials Group	Project duration
Ms. Chantal Gebbie	COSA	Project Manager	Project duration
Ms. Susan Goode	TROG	Chief Executive Officer	July 2018 – project end
Associate Professor Victoria Mar	MASC Trials	Executive Member MASC Trials	July 2019 – project end
Professor Jane Phillips	PaCCSC	Professor Palliative Nursing, Director IMPACCT	Project duration
Professor Tim Price	AGITG	Chair of the GI Cancer Institute	Project duration
Professor Sabe Sabesan	Co-Chair Tele-Trials Project	Project Co-Chair	Mar 2019 – project end
Ms. Megan Sanders	ALTG	ALTG TACT Executive Officer	Feb 2020 – project end
Ms. Joanne Shaw	POCOG	Executive Director	Project duration
Ms. Delaine Smith	ALLG	Chief Executive Officer	Project duration
Ms. Joan Torony	TROG	Chief Executive Officer	Project start – April 2018
Professor John Zalcberg OAM	Chair	Co-Chair Tele-Trials Project	Project duration

Medicines Australia Industry Advisory Group

Member	Representation	Position	Active
Ms. Helen Aunedi	Roche	Country Head, Country Clinical Operations	Project start-Apr 2019
Mr. Andrew Bowskill	Medicines Australia	Manager, Industry Policy and Research	May 2018-Mar 2019
Ms. Trish Church	Pfizer	Site Excellence Partner Global Site & Study Operations	Feb 2019 – project end
Dr Vicki Gardiner	Medicines Australia	Director, Policy and Research	Apr 2019 – Jul 2019
Ms. Chantal Gebbie	COSA	Project Manager	Project duration
Mr. Tyron Johnson	Eli Lilly	Senior Clinical Development Liaison, Oncology and Diabetes	Project duration
Ms. Larissa Karpish	Medicines Australia	Manager, Industry & Regulatory Policy	Project start to Apr 2018
Mr. Peter Komocki	Medicines Australia	Manager, Industry and Regulatory Policy	Jul 2019 to project end
Ms. Majella O'Leary	Pfizer	Start Up Project Manager, Global Site & Study Operations	Jun 2018 -Jan 2019
Ms. Michelle Tuer	Roche	Therapeutic Area Leader - Oncology Country Clinical Operations Australia	May 2019-project end

Investigational Medicinal Product Advisory Group

Member	Representation	Position
Ms. Trish Church	Pfizer	Site Excellence Partner Global Site & Study Operations
Dr Vicki Gardiner	Medicines Australia	Director, Policy and Research
Ms. Chantal Gebbie	COSA	Project Manager
Ms. Samantha Guthrie	Janssen	Clinical Research Manager, GCO
Mr. Tyron Johnson	Eli Lilly	Senior Clinical Development Liaison, Oncology and Diabetes
Mr. Mitch Kirkman	Novartis	Cluster Head - Asia/Australia/New Zealand Country Clinical and Pharmacovigilance Quality
Mr. Peter Komocki	Medicines Australia	Manager, Industry and Regulatory Policy
Ms. Emma Pinkerton	AbbVie	Clinical Operations Manager ANZ Development Operations, R&D
Professor Sabe Sabesan	Chair	Co-Chair Tele-Trials Project
Ms. Michelle Tuer	Roche	Therapeutic Area Leader – Oncology Country Clinical Operations Australia
Ms. Lorie Wishart	Roche	Country Study Specialist

Consumer Advocacy Group

Member	Representation	Position
Mr. Richard Vines	Rare Cancers Australia	Chief Executive
Ms Elisabeth Kochman	Cancer Voices NSW	Chair, Cancer Voices NSW Member of the Executive, Cancer Voices Australia
Mr. Peter Komocki	Medicines Australia	Manager, Industry and Regulatory Policy
Professor Sabe Sabesan	Chair	Co-Chair Tele-Trials Project
Ms. Chantal Gebbie	COSA	Project Manager

Appendix 2 - Stakeholder Engagement

Conference Presentations

2020

Clinical Oncology Society of Australia Annual Scientific Meeting Pre-Conference Workshop
10th November 2020
Oral Presentation: *Driving Teletrials Forward*
Presenter Sabe Sabesan
Oral Presentation: *The Teletrials Model*
Presenter: Chantal Gebbie

Clinical Oncology Society of Australia Annual Scientific Meeting
Virtual – 11th- 13th November 2020
Plenary Presentation: *Translating ideas into action: Lessons from the COSA Tele-Trial Project*
Presenter: Sabe Sabesan
Oral Presentation: *Technology in tele-health - to further improve patient outcomes*
Presenter: Sabe Sabesan

NZ Society for Oncology
Virtual – 16th October 2020
Plenary Presentation: *Teletrial model for enhancing clinical trial access and recruitment*
Presenter: Sabe Sabesan

2019

ASCO Breakthrough: A Global Summit for Oncology Innovators
Bangkok, Thailand – 11-13 November 2019
Oral Presentation: *Enhancing rural and regional access to clinical trial using the Australasian Teletrial Model (ATM): Experience from MonarchE adjuvant breast cancer trial in Queensland, Australia.*
Presenter: Sabe Sabesan

Clinical Oncology Society of Australia Annual Scientific Meeting
Adelaide Convention Centre, Adelaide, South Australia – 12-14 November 2019
Oral Presentation: T*he Australasian Tele-Trial Model – access to clinical trials closer to home using tele-health*
Presenter Sabe Sabesan
Oral Presentation: *Implementation of teleoncology models of care within health systems*
Presenter: Sabe Sabesan

Australian Clinical Trials Alliance International Conference 2019
Sydney ICC Darling Harbour, Sydney NSW – 4 October 2019
Oral presentation - *The Australasian Teletrial model – access to clinical trials closer to home using telehealth*
Presenter: Sabe Sabesan

ARCS Annual Conference 2019
Sydney ICC Darling Harbour, Sydney NSW – 8th August 2019
Oral Presentation: *Implementing Teletrials across Australia*
Presenters: Sabe Sabesan, Craig Underhill, Narelle McPhee, Tanya Montaldo
Oral Presentation: *Teletrials a national approach*
Presenters: Roberta Lusa, James Cockayne, Suzanne Hasthorpe, Bernadette Morris-Smith
Oral Presentation: *Enabling clinical trial capacity, capability and collaboration: Spotlight on Queensland*
Presenter: Melissa Hagan

The eHealth Expo
Brisbane Convention and Exhibition Centre, Brisbane, Queensland - 6 June 2019
Oral Presentation: *Creating an interconnected clinical trial system in Queensland to enhance rural and regional access to clinical trials using teletrials*
Presenter: Sabe Sabesan

Victorian Office for Clinical Trials Research Annual May Workshop
Melbourne Victoria – 2nd May 2019
Oral Presentation: *Incorporating Tele-Trials into standard practice.*
Presenter: Sabe Sabesan

2018

ARCS Annual Conference
Royal Randwick Racecourse, Sydney NSW – 22-23 August 2018
Oral presentation: *Teletrials - Where else but Queensland...reaching rural and remote recruits*
Presenters: Chantal Gebbie, Tyron Johnson, Roberta Lusa, Berni Morris-Smith
Oral presentation - *Applying telemedicine, e-consent and e-signature to clinical trials*
Presenters: Roberta Lusa, Chantal Gebbie, Berni Morris-Smith, Vu Nguyen

Australasian Telehealth Conference
Novotel Sydney Centre, Sydney NSW - 12 April 2018
Plenary Presentation: *Building virtual care scalability into regional health services for conducting clinical trials*
Presenter: Sabe Sabesan

Australasian Ethics Network Conference
Rydges Southbank Townsville, Queensland – 28 September 2018
Oral Presentation: *Implementation of the Australasian Tele-Trial Model increasing engagement between researchers, health administrators and regulatory bodies to transform clinical trials*
Presenter: Melanie Poxton

Victorian Office for Clinical Trials Research Annual May Workshop
Royal Australasian College of Surgeons, Melbourne Victoria – 2nd May 2018
Oral Presentation: *Clinical Trial Access for Regional, Rural and Rare Cancer Patients using Telehealth -The Australasian Tele-trial Model*
Presenters: Chantal Gebbie and David Speakman

Cancer Institute NSW - Innovations in Cancer Treatment and Care Conference
The Sofitel Sydney Wentworth, Sydney – 13 September 2018
Poster Presentation: *The Australasian Tele-Trial Model – Access to clinical trials closer to home using tele-health*
Presenter: Chantal Gebbie

Journal Articles

Asia-Pacific Journal of Clinical Oncology
Volume 15, Issue S8, November 2019
'Implementation of the Australasian Teletrial Model: Lessons from practice'
Sabe Sabesan, John Zalcberg, Craig Underhill, Rob Zielinski, Kate Burbury, Zia Ansari, Natalie Rainey, Ian Collins, Richard Osbourne, Jasotha Sanmugarajah, Anthony Joshua, Florian Honeyball, Melanie Poxton, Chantal Gebbie, Sue Jenkins Marsh, Roberta Lusa, Tyron Johnson, Amanda Garbutt, Maree Bransdon, Sue Richmond, Rachel Waye, Hannah Cross, Robert Kent, Jacob Darch, Amy Brown, Natalie Rainey, Zia Ansari, Sue Richmond

Medical Journal of Australia
19 August 2020
'Telehealth can be used to deliver clinical trials, improve access to novel therapies and develop clinical networks'
Ian M Collins, Kate Burberry, Craig R Underhill

Letter to the Editor - The New England Journal of Medicine
n engl j med 378;4 nejm.org January 25, 2018
Sabe Sabesan, Ph.D. Townsville Cancer Centre Townsville, QLD, Australia sabe.sabesan@ health.qld.gov.au John Zalcberg, Ph.D. Monash University Melbourne, VIC, Australia

Cognitio - ARCS Australia publication - Spring 2017 Issue Number 29
'The COSA Australasian Tele-Trial Model – Access to clinical trials closer to home using telehealth'
Professor Sabe Sabesan, Professor John Zalcberg, Professor Ian Olver, Associate Professor Eva Segelov, Professor Tim Price, Dr Craig Underhill, Professor Stephen Ackland, Professor Ian Davis, Dr Rob Zielinksi, Ms Rhonda DeSouza, Professor David Goldstein

Interviews

ABC News
'Queensland doctors hope to give remote cancer patients access to clinical trials using telehealth extension'-10 October 2016

ABC RN Breakfast
'Australia's first telehealth cancer drug trial' – 3 December 2018

ABC Health Report
with Norman Swan –
Treating remote cancer patients with telehealth'- 10 December 2018

MTPConnect Podcast 47:
47. Spotlight: 'How Tele Trials Are Giving Rural Cancer Patients Access to New Treatments with COSA' - 12 March 2020

Appendix 3 - Project Deliverables, Achievements and Learnings

<table>
<tr><th>Deliverable</th><th colspan="2">Achievement against deliverable</th><th>Learnings</th></tr>
<tr><td>Selection of 5 primary sites to implement the Tele-Trial Model</td><td colspan="2">5 primary sites selected:
St Vincent's Sydney, New South Wales
Westmead Sydney, New South Wales
Victorian Comprehensive Cancer Centre (VCCC), Victoria
Monash Partners, Victoria
Royal Brisbane and Women's Hospital (RBWH), Queensland</td><td>Project support of primary sites within different jurisdictions enabled broad engagement with state governments responsible for clinical trial regulation. Government support and engagement with the Model varied from state to state.

Primary sites selected had adequately resourced, well established clinical trial units with experienced clinical trial staff. A tele-trial 'champion' to advocate for and drive adoption of the Model within institutions was critical to the successful adoption of the Model.</td></tr>
<tr><td rowspan="6">Trial clusters for 5 primary sites confirmed and agreements in place</td><td>Primary Site</td><td>Satellite Site</td><td rowspan="6">Initially project primary sites connected to satellite sites to form a tele-trial cluster before identifying a suitable trial. This was to enable engagement with clinicians, Chief Executives (CEs) and Research Governance Offices (RGOs) at satellites sites, to introduce the Model and facilitate engagement and support. Once primary sites became familiar with the Model clusters were formed as trials were identified or additional satellites added to existing tele-trials to boost recruitment and familiarize more sites with the Model.

Primary sites demonstrated the implementation of the Tele-Trial Model between, metropolitan primary sites and regional and rural satellite sites, a metropolitan primary site and a metropolitan satellite site, and a metropolitan site in one state and a metropolitan satellite site in another state (cross-jurisdictional).</td></tr>
<tr><td>St Vincent's</td><td>Riverina Dubbo</td></tr>
<tr><td>Westmead</td><td>Orange</td></tr>
<tr><td>VCCC</td><td>Border Medical, Bendigo Health, Ballarat Health, Goulburn Valley Health</td></tr>
<tr><td>Monash Partners
Alfred Health
Monash</td><td>Royal Hobart

Bendigo</td></tr>
<tr><td>RBWH</td><td>North Lakes
Hervey Bay
Rockhampton
Bundaberg
Townsville</td></tr>
</table>

Deliverable	Achievement against deliverable	Learnings
Trial clusters for 5 primary sites confirmed and agreements in place *Continued*		The 5 project primary sites operated as primary sites only during the project. However large well-established trial sites can also be satellite sites. This is especially relevant for rare cancer trials and has been successfully demonstrated in Queensland with Townsville Hospital functioning as a primary site in one cluster and a satellite site in another. When a sponsor is restricted to opening a limited number of sites the tele-trial model enables more sites to access the trial. A primary site working with multiple satellite sites is considered to be one site when the primary site is responsible for all clinical trial activities conducted within the cluster. This is a significant benefit of the Model that has not been successfully piloted to date. This may require large experienced metropolitan sites agreeing to participate as satellites and this can be problematic if sites, RGO's and clinicians are not familiar with the Model. Further education and engagement to familiarise sites and RGO's with this as an acceptable option to access clinical trials for their patients would address this.

Deliverable	Achievement against deliverable	Learnings
Project meetings convened in NSW, Victoria, and Queensland	· Multiple project meetings held at site, local health authority and state level · Steering Committees in Victoria, Queensland and NSW with key stakeholders including Department of Health representatives are in place	A key aim of the project was to consolidate the efforts of all centers establishing tele-trial procedures or conducting tele-trials across Australia not just in NSW, Victoria, and Queensland. The project was in a unique position to advise, mentor and provide information to any institution, group or health service wishing to implement tele-trials regardless of their location. Widespread collaboration at all levels ensured vital information sharing to reduce unnecessary duplication and ensure consistent processes. Meetings were also convened with international groups interested in implementing tele-trials including trial groups in NZ and Canada, the Union for International Cancer Control (UICC) and the City Cancer Challenge.
Negotiation with trial sponsors from both industry and investigator groups re suitable trials	· Sponsors were engaged through the SC, MA Industry Advisory Group, the Cancer Cooperative Trials Group (CCTG) Advisory Group, COSA member engagement and presentations at major conferences including ARCS, ACTA and ASCO breakthrough · The first CCTG sponsored tele-trial was opened by the Australasian Gastro-Intestinal Trials Group (AGITG) in 2017 · A project presentation to the MA Research and Development Taskforce in October 2017 resulted in the implementation of the first industry sponsored tele-trial in Australia by Eli Lilly which opened in 2018	The SC and Advisory Groups provided an important forum for information sharing. Proposed trials were discussed, and issues explored in a collaborative effort to facilitate implementation of tele-trials. Industry and CCTG sponsors expressed strong support for the Model. After the groundbreaking work to implement the Eli Lilly sponsored tele-trial in Queensland the Model was quickly embraced by other industry sponsors. The Eli Lilly tele-trial established that the Tele-Trial Model could be safely and ethically implemented at regional and rural sites while increasing access and reducing travel time for patients. Successful implementation of this tele-trial greatly enhanced acceptance of tele-trials as a viable Model by sponsors and health authorities.

Deliverable	Achievement against deliverable	Learnings
1-2 suitable trials identified within industry and/or trial groups for each cluster	• Suitable trials were identified within both industry and CCTGs for each cluster • An investigator-initiated trial was identified for the VCCC cluster	Phase III clinical trials with oral Investigational Medicinal Product (IMP) were initially identified as the most suitable trials for implementation by tele trial naïve sites. Transport of IMP to the satellite site and administration of the IMP were important considerations. Phase I or II trials were ruled out as being too resource intensive and complicated to administer for the Model. However the successful implementation of a Phase 1 trial with intravenous IMP in The Alfred and Royal Hobart Hospital cluster highlighted that site selection is an equally important consideration when selecting suitable trials.

Deliverable	Achievement against deliverable	Learnings
Regulatory issues within clusters identified and strategy to address these issues confirmed	• Standard Operating Procedures (SOPs) for tele-trials, streamlined Research Governance at the satellite sites and sub-contracting of satellite sites were identified as the most important regulatory and contractual issues to be addressed • Australian ICH-GCP SOPs (including tele-trials) and a template Supervision Plan template were developed in collaboration with Queensland Health (QH) and published in June 2018. The SOPs were widely reviewed by industry and cooperative group sponsors and updated following feedback from the Eli Lilly tele-trial pilot • The Australian ICH-GCP SOPS (including tele-trials) were developed to be adopted as national documents and were submitted to NMA in January 2019 and were approved in April 2020	Engaging governments to ensure the necessary regulatory and contractual changes needed to implement an innovative model to deliver clinical trials was challenging. State and Territory Department of Health representatives and a federal government representative were engaged early on through the Department of Health Advisory Group. All states and territories expressed interest in the Tele-Trial Model but were cautious about committing to the necessary reform. Collaboration with the Queensland Health initiative to enable state-wide implementation of the tele-trial model was important. By addressing the regulatory and contractual issues to implement the Model the Queensland Health Innovation, Investment and Research Office demonstrated the successful implementation of the Model by a State government thereby paving the way for tele-trials in other states and territories. Harmonisation of tele-trial processes between states and territories is particularly important for interjurisdictional tele-trials. VCCC developed and published tele-trial SOPs for adoption by Victorian institutions in October 2018 and NSW released a Clinical Trials Toolkit in April 2020 including tele-trial specific SOPs, supervision plan and other templates. These SOPs are consistent with the Australian ICH-GCP SOPs (including tele-trials) however have been developed to reflect local practices and operationalise tele-trials according to the implementation of tele-trials within those states.

Deliverable	Achievement against deliverable	Learnings
Workforce roles and responsibilities identified for each cluster	• A Supervision Plan template was developed in collaboration with Queensland Health and was released with the Australia ICH-GCP (including tele-trials) SOPs in 2018 • Example Supervision Plan templates for satellite sites with and without clinical trials units and sites without a medical oncologist are available on the COSA website Tele-Trials Resources page.[7]	The Supervision Plan was developed at the same time as the SOPs and has been identified by sponsors as one of the most critical documents for tele-trials. The Supervision Plan details the level of oversight of the satellite site by the primary site by identifying the roles and responsibilities of each site within a cluster and clearly articulating the agreed level of supervision of a satellite site by the primary site. The level of supervision may change over time as satellite sites become increasingly skilled with clinical trial processes, therefore the Supervision Plan can be amended over the course of a clinical trial to reflect the increasing expertise at the satellite site. Experienced trial sites considering joining a tele-trial cluster as a satellite site expressed concern that the 'supervision' of a satellite by a primary site suggests the satellite site is subordinate to the primary site. This is a misunderstanding of the intention of the supervision plan which documents agreed responsibilities between the primary and satellite sites for different trial activities and does not imply that supervision is necessary or required for all trial activities.

Deliverable	Achievement against deliverable	Learnings
Confirmation of 5 governance staff at primary sites	• Project funding was accepted by 5 primary sites and used to support staff costs to implement the Model	Clinical trial units are busy and training and retention of clinical trials staff is an ongoing issue. The uptake of project funding by primary sites was slow due to difficulty securing clinical trials staff to do the work and concern over accepting the funding without dedicated resources to implement the model. Some hospitals take staff out of the clinical trials team if there is a staff shortage in patient wards and this creates further strain on existing resources. Amending existing clinical trial processes for the tele-trial Model, adding new processes for contracting, drafting the supervision plan, and liaising with the sponsor and satellite(s), created a substantial additional workload for primary sites particularly for the first tele-trial. The funding of primary sites was critical to ensure that this additional workload was supported. In addition to the COSA project funding VCCC received state government funding to implement the VCCC Teletrials Program as part of their clinical trials expansion program. This additional funding enabled the VCCC in collaboration with the Victorian Office of Health and Medical Research to create a robust framework for the conduct of tele-trials in Victoria. Similarly, state government funding in Queensland has enabled the successful roll out of the Model state-wide.

Deliverable	Achievement against deliverable	Learnings
Development of remote monitoring systems by trial sponsors	• Sponsors have instituted remote monitoring in the areas of source document verification and IMP logistics and accountability	Remote monitoring of satellite sites is important in the tele-trial model to prevent the increased costs associated with monitoring at multiple sites and travel to and from regional and rural satellite sites. However, oversight is important where auditing is concerned and due diligence at satellite sites must also be completed. There is a tension between the frequency and diligence of monitoring and the cost and resourcing. A shared EMR greatly facilitates source documentation for remote monitoring however some sites in rural areas still have paper based medical records. IMP management also impacts remote monitoring. If the IMP is shipped directly to satellites by the sponsor (instead of the primary site distributing IMP to the satellite sites) then monitoring for drug accountability must be conducted at the satellite sites. The preferred IMP distribution model for sponsors is shipping IMP to the primary site only and the primary site distributes IMP to satellite sites. An IMP Advisory Group was convened to address this issue and a guidance document outlining the requirements for each model was developed along with an SOP for IMP distribution by the primary site. [7]

Deliverable	Achievement against deliverable	Learnings
Final selection of trials for inclusion	• 9 tele-trials have opened within project clusters • 2 tele-trials are now closed to recruitment	Trials were accepted throughout the duration of the project with most primary sites implementing more than one tele-trial.
Model implemented within all 5 clusters	• The Tele-Trial Model has been implemented within all 5 project clusters • In addition to project funded clusters there are a total of 13 tele-trial clusters in Queensland, Victoria, NSW, South Australia, and the ACT	The speed of implementation of the Tele-Trial Model within project funded sites was influenced by workload in the trials unit, access to an approved tele-trials subcontract or alternative cluster contracting model, and acceptance of the Model by institutions including CE's, lawyers and RGOs. At one primary site the work to establish the Model was done after hours by clinical trials staff. Staff turnover was another issue with much of the work falling to Clinical Trial Unit Managers. Educating CE's, RGOs, legal staff, clinicians, pharmacy, and trial units about the Model and eliciting their agreement and support early on was important and a tele-trial champion at the primary site was essential to drive implementation.

Deliverable	Achievement against deliverable	Learnings
Workforce training complete	• Workforce training is complete and ongoing as the tele-trial model is introduced at new sites • A number of resources developed in collaboration with QH, RGO's and Townsville Hospital for sponsors and sites are available on the COSA website. [7] These include: › Supervision Plan templates › Steps to establish a Tele-Trial cluster › Post approval steps for teletrial amendments and documents › Question and Answer documents for sponsors and sites and FAQ › Checklist of documents for RGO submission at Primary and Satellite Sites. › Sample PICF for teletrial clusters • VCCC have also developed an extensive suite of tele-trial resources and an e-learning module about implementing tele-trials which are available on the VCCC website	One of the major advantages of the Tele-Trial Model is the opportunity for sites without clinical trials experience to be trained and mentored by the primary site. The Tele-Trial Model strengthens the working relationships and capabilities amongst all sites. In the Eli Lilly tele-trial alone eight satellite staff underwent GCP training and acquired trial capabilities. Workforce training and education will be ongoing as the tele-trial Model is rolled out across Australia. There are now many sponsors, sites and clinicians who are familiar with the Model and will be a valuable resource in the future.

Deliverable	Achievement against deliverable	Learnings
Streamlining of contract and governance processes	• A tele-trials subcontract for use between the primary and satellites sites was developed by Queensland Health for the Eli Lilly sponsored tele-trial and the subcontract was released in September 2018 • VCCC engaged a lawyer to develop a contract to support investigator initiated tele-trials and this was accepted by satellite sites for their first tele-trial which opened in November 2018 • Victoria published a tele-trials subcontract based on the Queensland Health subcontract in April 2020 • The Southern and Eastern Border States Review Panel comprising of Health Departments from NSW, Queensland, Victoria, South Australia, and Tasmania have proposed a tele-trials subcontract based on the Victorian tele-trials subcontract. This is currently under review by MA and once approved will be published on the MA website	Streamlining contract and governance processes to enable the Tele-Trial Model took significantly longer than expected and was complicated by a lack of consensus between states about the best contracting model for tele-trials. The approval of a national tele-trial subcontract initially submitted to the South Eastern Border States review committee (SEBS) in September 2018 and then re-submitted to National Mutual Acceptance (NMA) in January 2019, has taken over two years and is still in progress. One reason for this delay is the time taken by NSW to consider other tele-trial contracting options. In the initial absence of DOH or MA approved tele-trials contracting processes in NSW and Victoria widespread adoption of the Model was slower. The release of the QH tele-trials subcontract in 2018 enabled Queensland sites to gain valuable early experience implementing tele-trials. Experienced tele-trial sites plus approved contracting and regulatory processes has made Queensland the preferred option for sponsors wishing to pilot the Tele-Trial Model. In NSW, the two project funded primary sites adopted different contracting processes. St Vincent's Hospital (SVH) successfully adopted a contracted vendor arrangement for tele-trials. Vendor agreements already used for pathology and imaging services were extended to healthcare facilities. The staff in these healthcare facilities collect data for a clinical trial for a contracted fee. Liability remains with SVH and all clinical trial decisions are made by the Principal Investigator (PI) at SVH. Research Governance approval is not required because the research activity takes place at SVH.

Deliverable	Achievement against deliverable	Learnings
Streamlining of contract and governance processes *Continued*	• Queensland will adopt streamlined research governance for the tele-trial model in which the primary site completes the full Site-Specific Assessment application and satellites sites complete a sub-form with local details • The groundwork for a national SSA form (incorporating tele-trials) has been done by National Mutual Acceptance. This is currently under discussion by the Clinical Trials Project Reference Group	In the Westmead and Orange cluster in NSW an inter district agreement (IDA) between Western Sydney Local Health District (WSLHD) and Western NSW LHD to enable tele-trials between Westmead and Orange took more than two years to execute. This was despite a firm commitment from both Westmead and Orange clinical trials staff to establish Teletrials between the 2 sites and consensus & commitment from both LHD's Research Education Departments to establish tele-trials. The barriers were gaining consensus with WSLHD Medical & Dental Advisory committees and obtaining approval from both LHD Chief Executives with numerous sub approvals from many different levels required along the way.

Deliverable	Achievement against deliverable	Learnings
Clinical trials using Model approved and open in each cluster.	· Clinical trials using the Model are open in all project funded clusters	The biggest delay in tele-trial approvals for project clusters were due to contracting issues, and research governance approval. One cluster also had difficulty identifying a suitable trial. The IDA for tele-trials between Westmead and Orange took two years to be finalised and now requires further amendment. The progress of tele-trials in this cluster has been severely affected by the IDA contracting process conducted between two local health districts in the absence of a state-wide DOH approved tele-trials subcontracting process. The initiation of a tele-trial cluster between the Alfred Hospital and the Royal Hobart Hospital was accomplished in just 4 weeks allowing a clinical trial participant, on a Phase 1 trial to continue receiving study treatment in Hobart instead of travelling to the Alfred in Melbourne, thus avoiding the border and travel restrictions imposed by COVID-19. This highlights what can achieved by a motivated team in an environment of cooperation between stakeholders.
15 patients participating in tele-trials (total across all clusters)	There are currently 135 patients recruited to tele-trials in project funded clusters. 124 patients have been recruited to regional and rural satellite sites and 11 patients at metropolitan satellite sites.	Increasing patient access to clinical trials increases recruitment. This is the case for regional and rural sites as well as metropolitan sites. This also applies to rare cancer trials. An example of this is a BMS rare cancer trial opened at Townsville Hospital. Recruitment was challenging so Cairns Hospital was added as a satellite site to boost recruitment. A patient was recruited at Cairns within a month of opening just prior to global recruitment closure effectively doubling patient recruitment and prompting a letter of congratulations from the global BMS team.

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