Teletrial implementation: Interplay between governments and clinics

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Clinical Oncology Society of Australia

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Australian clinical trial landscape

While significant investment has been made on improving clinical trial capabilities in metropolitan settings by governments, regional and rural communities continue to experience limited access to clinical trials closer to home

Australasian Teletrial Model

Use of telehealth to connect regional and rural sites to major centres and provide trial medications closer to home

Australasian Tele-trial Model

Primary Site

Specialists

Clinical Trial Coordinators

Specialist Pharmacy, Nursing and Allied Health Clinicians

Administration Support Officers

Tele-health

Patients are consented, recruited and managed at satellite sites in partnership between clinicians from satellite and primary sites.

Satellite Site

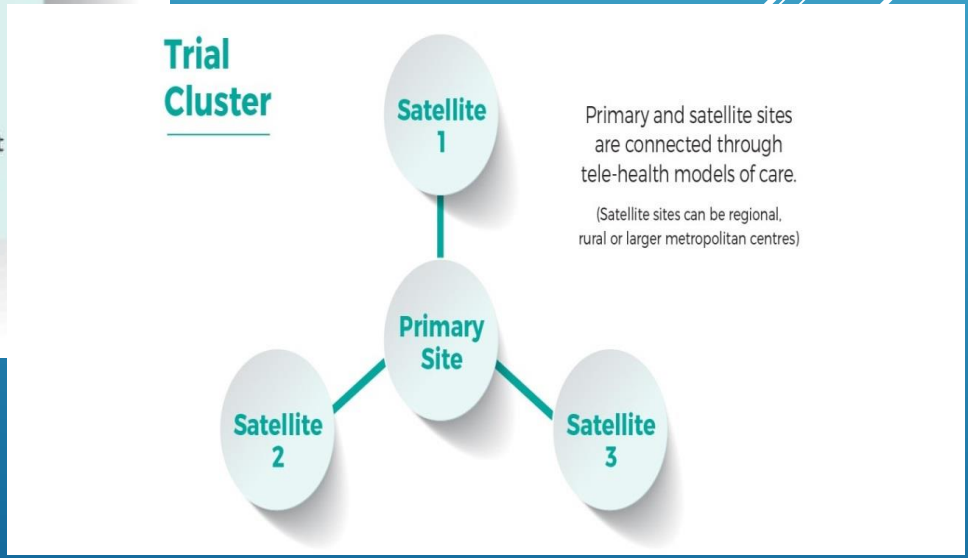
Patients and Families

Medical Officers

Nursing, Pharmacy and Allied Health Clinicians

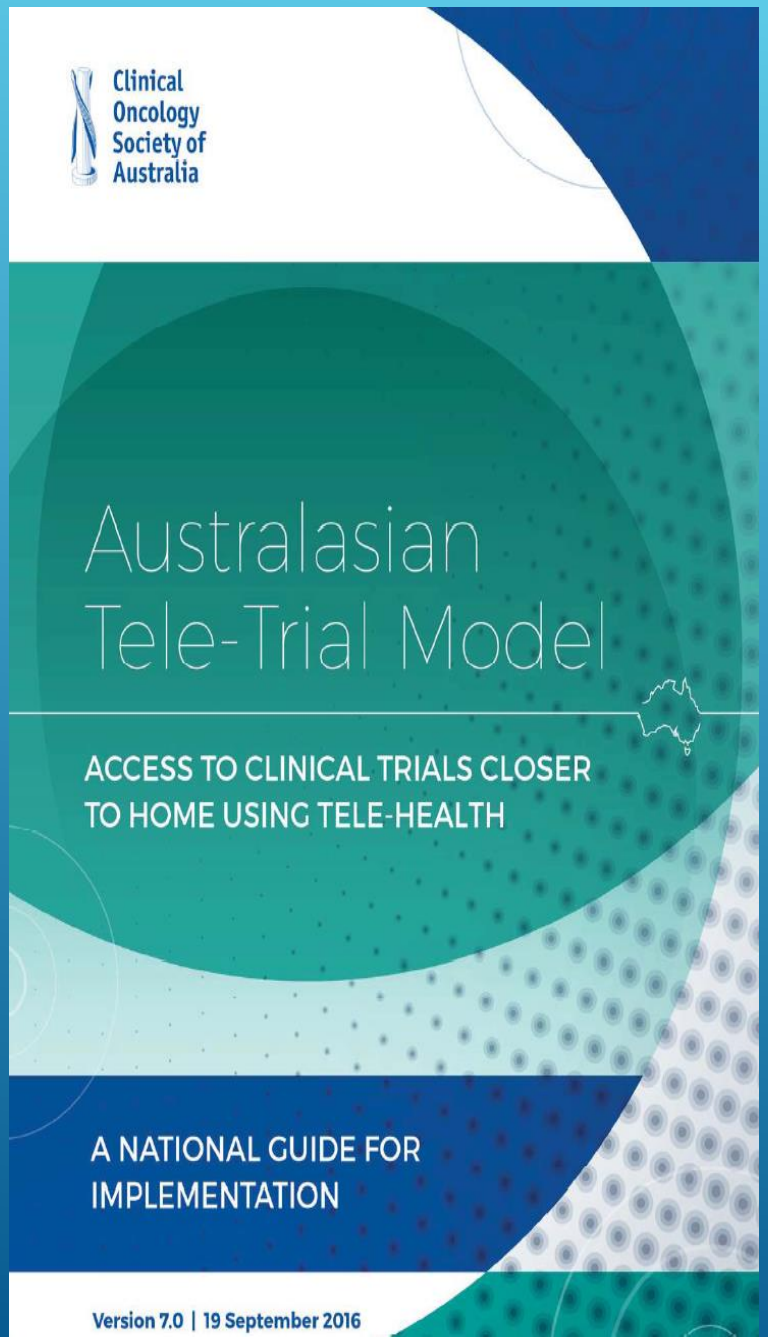
With/without Trial Coordinators

(Larger centres may have specialist doctors, nurses, pharmacies and allied health clinicians)



Sabesan & Zalcberg, EJCC, 2016

Teletrial governance and standards



Ethical and safe conduct of clinical trials using this model requires that the following aspects are considered and addressed by implementation plans

Primary site is the coordinating site and remunerated accordingly

(1) Selection of satellite sites and suitable trials including accreditation of sites, supervision plans and site visits

(2) Work force

(3) Good clinical practice

(4) Roles and responsibilities

(5) Training for individual staff, site initiation meetings and trial updates

(6) Technology and support

(7) Participant screening and recruitment Obtaining participant consent

(8) Medication handling

(9) Managing and reporting serious adverse events

(10) Patient reported outcomes

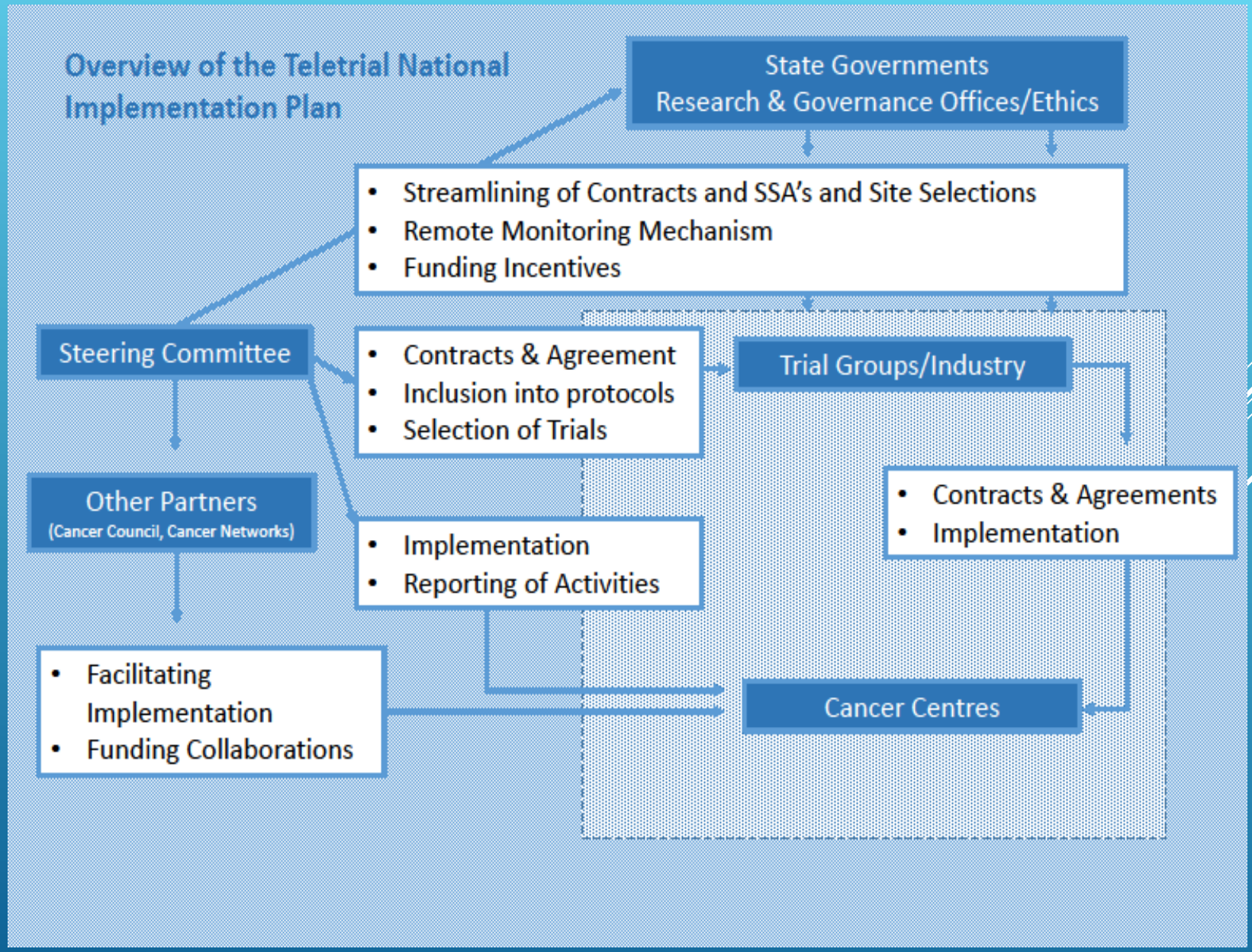
(11) Documentation and reporting

(12) **Financial considerations**

(13) Regulatory considerations, Indemnity, Insurance and clinical trial agreements

Implementation of the Teletrial Model at state and national levels

- COSA Teletrial Consortium and steering committee
- QH State-wide Working group
- VCCC Steering committee
- NSW steering Committee
- WA steering Committee



Implementation of Teletrials in Queensland

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Trial update:

IliLilly Adjuvant breast cancer trial

- 2 clusters- Northern (Townsville, Cairns, Mackay & Mt Isa) and Gold Coast/Hervey Bay cluster
- 4 additional sites with trial capabilities
- 8 satellite staff with GCP training and trial capabilities
- 11 additional patients were enrolled who otherwise would have missed out
- Regular cluster meetings; consolidating the collaboration
- No protocol deviations or breaches identified by monitors

Novartis- Combination melanoma trial

- Cairns as the primary site with Townsville and Mackay as satellites
- Awaiting governance approval

Roche- Adjuvant lung cancer trial

- PAH as primary with Townsville, Toowoomba, SCUH, GCUC and Cairns as satellites

* trials involving intravenous therapy are being negotiated with trial groups and pharma.

Australian Genomic Alliance-MOST trial (genomics driven therapy)

Plan is to have one primary site in Queensland with QUT/PAH and rest of the state on a cluster model

BMS Metastatic SCC of the Oesophagus: Chemotherapy vs Chemotherapy with Immunotherapy

Plans are underway to add Cairns as a satellite to Townsville

Main early hurdle is developing mechanism for IP handling (not as difficult as developing the algorithm for finding the black hole)

Victoria

- VCCC with Bendigo, A-W, Warrnambool activated a thrombo-prophylaxis trial
- Monash partners have begun discussions

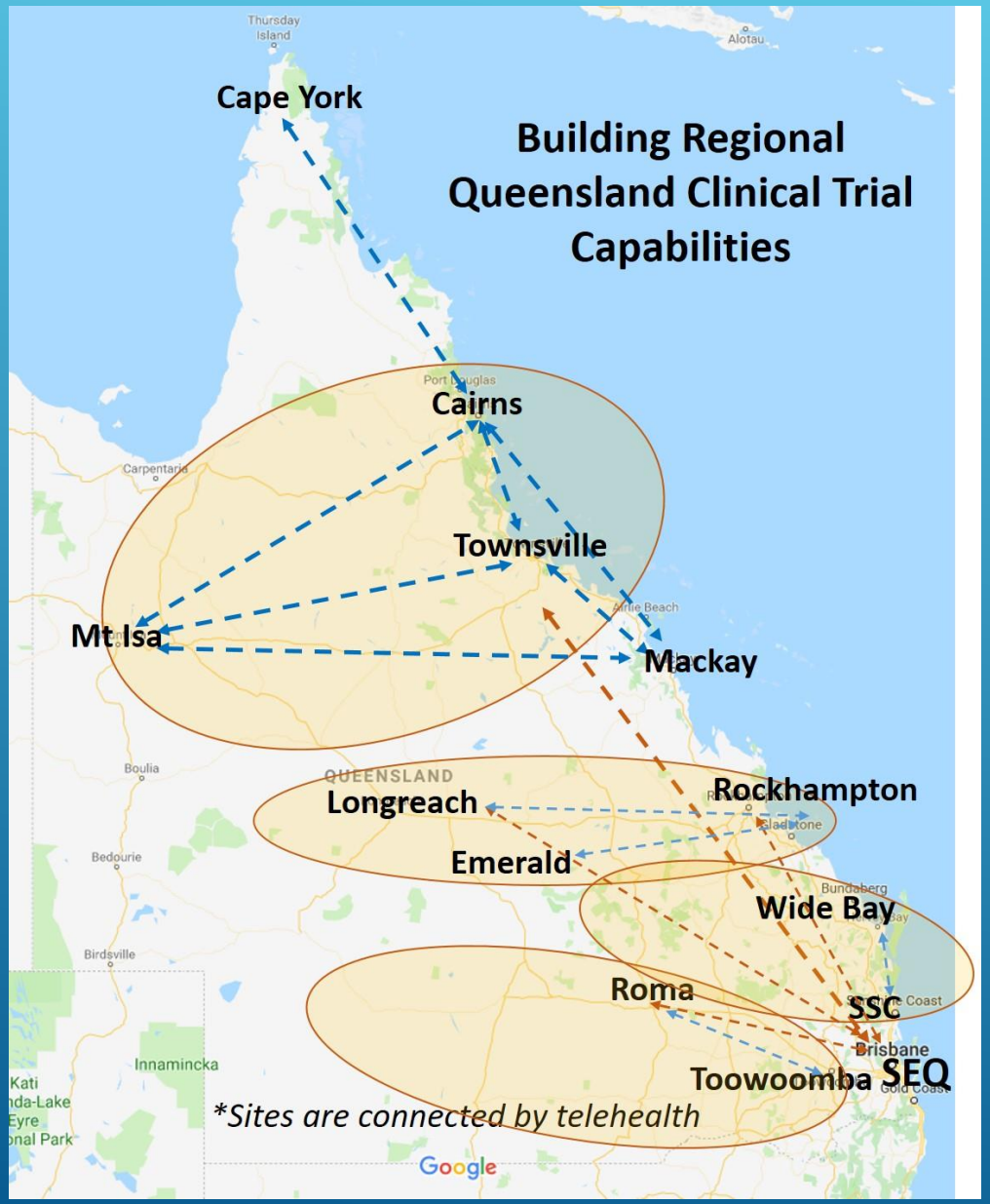
NSW

- Orange-Dubbo: AGITG ASCOLT study begun recruiting
- St Vincents/Wagga/Riverina—Two studies have been activated through a Vendor style arrangement

SA

- Flinders-Mt Gambier: one study activated

Creation of interconnected clinical trial networks and remote medical therapy systems across the state and country using telehealth



- More satellites acquired trial capabilities
- More rural/regional staff underwent GCP training
- Enhanced collaboration between sites at clinical, management and RGO levels
- Ability to have multiple primary sites depending on the nature of trials
- More patients gained access locally

Cluster model be a better way of upskilling small sites than trying to establish them as stand alone trial sites in line with network proposals

Experience of primary and satellite site staff- Early results of a qualitative study in Qld

1. Early studies involved extra workload for primary sites and sponsors to develop the processes: SOPs, Supervision plans, sub-contracts, IP handling, SSA approvals, advocating for isolators at satellites
   This workload should become smaller due to established processes by QH and Qld & VCCC clusters

2. Additional workload for primary sites:
   organising cluster meetings and SIVs via V/C
   submitting and tracking ethics and governance forms and developing multisite PICC
   coordination, documentation handling and oversight

3. Rewarding to work with multiple sites in collaboration

4. Rewarding to see patients having access to trials closer to home

5. Pleasing to see RGOs working together due to Government directive

We wouldn't be where we are without COSA and government drive. So, Government endorsement and drive are essential for broader uptake and sustainability (Trial manager).

Early hurdles:

1. Developing processes for IV IP handling
2. Minimise satellite activation costs through agreements with CEOs and through directives since the aim of the model is to help the satellites to access trials locally for their patients
3. Trial groups remain nervous
4. Government drive is not consistent in terms of achieving their strategic vision of enhancing rural clinical trials- PTSS is not the answer
5. Perception that new rural health models should not cost money

Most new models require additional FTEs and funds for implementation; exactly the same as building tunnels, airport links and highways. If Governments want to abolish out of pocket expenses for patients, then they have to fund these models to minimise expenses for rural and regional patients related travel, relocation and consequences of relocation including disruption to routine life and jobs.

Conclusion:

1. Regional and rural trial capabilities can be enhanced through teletrial model
2. Teletrial model enables rural and regional patients' access to trials closer to home
3. Sites can be part of multiple clusters depend on the nature and availability of trials; thus creating an interconnected clinical trial system
4. Government endorsement at all levels, resourcing, and uniform regulatory reforms are essential for ease of implementation within intra and interstate jurisdictions
5. Broader uptake may be driven through government/NHMRC/MRFF incentives for incorporating teletrials in protocols or KPIs


Greetings from Townsville