## CLINICAL TRIAL ACCESS FOR REGIONAL, RURAL AND RARE CANCER PATIENTS USING TELEHEALTH THE AUSTRALASIAN TELE-TRIAL MODEL

**Professor David Speakman** 

**Chief Medical Officer** 

Peter MacCallum Cancer Centre

### **Overview**:

- 1. Importance of clinical trials in Australia and Victoria
- 2. Opportunities for improving Australian clinical trial capabilities
- 3. The Australasian Tele-Trial model (ATM) as a tool for improving regional and rural access to clinical trials
- 4. Implementation of ATM and scalability
- 5. Ensuring sustainability

## Why clinical trials?

- Clinical trials are regarded as best management options or cutting edge therapies for cancer patients as per international guidelines;
  ALL cancer services need to offer clinical trials?
- 2. Help advance the science and practice of health care
- 3. A revenue generating activity
- 4. Job creation
- 5. It is a priority item for Australia and its states and territories

Current status clinical trials in Australia:

- 1. Rate of enrolment in clinical trials is lower than expected according to international recommendations and benchmarks
- 2. For rural, regional and rare cancer patients, rate of enrolment is even lower
- 3. Regulatory and governance processes are duplicative, inefficient, and prohibitive (costing & wasting tax payer funds)
- 4. Main rural and regional barriers are—limited availability of trials closer to home, cost and inconvenience of travel (Sabesan et al, APJCO, 2010)



#### Victoria

- Contains some of the best clinical trial infrastructure in the world
- Clinical trial activity is mainly centered around Metropolitan areas while trials for cancer subtypes and rare cancers are becoming difficult to recruit faster
- Regional and rural patients either miss out or travel long distances
- Despite smaller travel distances, patients often spend significant amounts of time and money travelling for accessing clinical trials within Metropolitan areas.
- Resources and support for clinical trials has been limited for regional centres

## Current government initiatives to enhance clinical trial capabilities

Scoping and analysis of				
recruitment and retention in				
Australian clinical trials				

**Final report** 

June 2016

	Federal	Victoria
	Funding to improve trial capabilities and trial networks	Investment by Victorian state government in VCCC
	Funding to establish Industry growth centres such as MTP Connect	Regional clinical trials network
	Tele-Trials as one of the models	
a better		Clinical Oncology Society of Australia

Hospitals & health services V

Primary & community health V

Public health v

alth 👻 Menta

Mental health 💌

Alcohol & drugs -

Ag

Home > About > Clinical trials and research > Clinical trials

### **Clinical trial research**

Victorian government aiming for faster and more efficient processes to conduct clinical trials at multiple sites

The purpose of a clinical trial is to evaluate new approaches to treat particular conditions or diseases. This involves doing research under controlled conditions to find how people respond and what side effects may occur as a result of a treatment.

Victoria is the premier location for medical research and clinical trials in Australia.

The Victorian Government's Clinical Trial Research initiative aims to ensure Victorians can benefit by:

- Providing a faster, more efficient process to conduct clinical trials at multiple sites
- · Speeding up therapeutic product development aimed at world markets
- Improving delivery of new treatments to patients early in the development of innovative medicines and medical devices.

## National mutual acceptance

National Mutual Acceptance - a national system for mutual acceptance of scientific and ethical review for multicentre clinical trials.

## Streamlining ethical review

Single ethical review of a multi-site clinical trial.

## How to make an HREC application

Information for preparing an ethics application.

Using telehealth to enhance clinical trial access to regional, rural and rare cancer patients

#### **Australasian Tele-trial Model**





### Why telehealth?



#### Supervision, education and training models



Telehealth guidelines

(COSA, RACP, ACCRM)

Queensland remote chemotherapy supervision guide (QReCS)



#### Medical, nursing and allied health consultations

Queensland remote chemotherapy supervision (QReCS) model



CSCF = Clinical Services Capability Framework (Cancer Services)

Treatment models(chemotherapy, thrombolysis, dialysis, robotics

Significant investment by state and federal governments in telehealth





nt of Health



## Implementation of ATM and scalability

## Avoid confusion over "Interventions vs Models of care"

"Telehealth models are not interventions. They are tools for connecting organizations and people. As long as these models are constructed according to accepted governance and standards, they are safe and ready for use"

## THE TELE-TRIAL PROJECT A PILOT IMPLEMENTATION OF THE AUSTRALASIAN TELE-TRIAL MODEL

**Chantal Gebbie** 

### **COSA Tele-Trials Project Manager**

## THE TELE-TRIAL PROJECT

Co-Chairs - Prof Sabe Sabesan (Townsville) & Prof John Zalcberg (Monash)

### COSA Tele-Trial Consortium and Steering Committee members:

**MTPConnect** 

MedTech and Pharma Growth Centre

- Rare Cancers Australia
- Cancer Voices NSW
- Australian Institute of Tropical Health and Medicine (AITHM)
- > The Garvan Institute of Medical Research
- > The Walter and Eliza Hall Institute of Medical Research (WEHI)
- Icon Group
- > St John of God Hospital
- Medicines Australia
- AbbVie Pty Ltd
- Janssen Australia
- > Novartis
- ➢ Pfizer
- > COSA

Participating centres:

Victoria: VCCC (included in their strategic plan and allocated A\$1.5M), Monash Partners, Regional clinical trials network

Qld: State-wide approach through QH Cancer Clinical network (Sponsored by HIRO and clinical excellence division)

NSW: Westmead/Orange, St Vincent's/Wagga/Tamworth, Orange/Dubbo Recently Chris O'Brien Life House and Melanoma Institute of Australia

SA: Flinders/Mt Gambier



## Australasian Tele-Trial Model

ACCESS TO CLINICAL TRIALS CLOSER TO HOME USING TELE-HEALTH

A NATIONAL GUIDE FOR IMPLEMENTATION

Version 7.0 | 19 September 2016

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,	(8) Medication handling
supervision plans and site visits	(9) Managing and reporting serious adverse events
(2) Work force	
. ,	(10) Patient reported outcomes
(3) Good clinical practice	
	(11) Documentation and reporting
(4) Roles and responsibilities	
	(12) Financial considerations
(5) Training for individual staff, site	
initiation meetings and trial updates	(13) Regulatory considerations,
	Indemnity,
(6) Technology and support	Insurance and
	clinical trial agreements
(7) Participant screening and recruitment	Australia
Obtaining participant consent	

#### Overview of the Teletrial National Implementation Plan

٠

#### State Governments Research & Governance Offices/Ethics

Streamlining of Contracts and SSA's and Site Selections

Remote Monitoring Mechanism

**Contracts & Agreement** 

Inclusion into protocols

Funding Incentives

Selection of Trials

#### Steering Committee

Other Partners (Cancer Council, Cancer Networks)

- Implementation
- Reporting of Activities

#### Trial Groups/Industry

- Contracts & Agreements
- Implementation

#### Facilitating Implementation

Funding Collaborations

#### **Cancer Centres**

## **GOVERNANCE & PROCESS REFORMS & STAKEHOLDER ENGAGEMENT**

### **Queensland Health**

- Streamlined SSA Form incorporating tele-trial sub form in development
- Revision of clinical trials Standard Operating Procedures incorporating Tele-Trials
- Sub-Contracts
- Supervision Plan

### **MA Industry Advisory Group**

Proposed development of Medicine Australia sub-contract template Pharma companies allowing Tele-Trial Model in their protocols

### **Cooperative Clinical Trial Groups Advisory Group**

Allowing tele-trial Model in their protocols

### **COSA Tele-Trials Departments of Health Advisory Group**

Most state government research offices have given in principle agreement to adopt uniform processes across Australia

## Progress so far:

- 1. Orange/Dubbo cluster has enrolled three patients already in ASCOLT(AGITG) trial
- 2. MonarchE adjuvant breast cancer phase 3 (Eli Lilly) trial in Northern Queensland and Gold Coast clusters, at final stages of activation
- 3. Queensland, VCCC, Westmead & St Vincent clusters—Formal steering committees in place
- 4. Monash partners have appointed the medical lead (Andrew Hayden) and Steering Committee to be convened in April

## Wish list

- 1. All the state and territory governments' research offices adopt the processes developed by QH( through COSA facilitated national consultation) to have one "clinical trial system" across Australia
- 2. Victorian Department of Health adopts ATM, streamlines governance and contractual processes and facilitates the adoption of uniform processes across the state as suggested in their website
- 3. NSW establishes a statewide Tele-trial working group under the auspices of DOH, though participating cancer centres have their own working groups
- 4. More industry partners and cancer services & clinicians adopt this model for more trials



Tele-trials

## Investment \$1.5m

Use of tele-health technology to provide rural and regional Victorians with the opportunity to have more cancer clinical trial-related treatment closer to home.

Establishing tele-trials will improve clinical trial access and participation for patients living in regional and rural Victoria.

## **Key elements:**

- Appointment of VCCC Regional Oncology Leads
- Building partnerships and networks with regional cancer services
- Implementation and evaluation of pilot teletrials.



VICTORIAN COMPREHENSIVE **CANCER CENTRE** 

## Goals/Desired Outcomes

- Improved access to cancer clinical trials for patients living in regional and rural Victoria.
- Increased participation in cancer clinical trials for patients living in regional and rural Victoria.
- Reduced burden of participation in cancer clinical trials, including time, cost and social disruption, for patients living in regional and rural Victoria.





# What is needed beyond the life of the project?



## Sustainable model of care Across Australia

Federal and state Governments need to:

 Facilitating Implementation
Funding Collaborations Implementation Reporting of Activities

- 1. Incorporate this model into their policy and planning processes
- 2. Resource and monitor as a core business of health service and districts

Contracts & Agreements Implementation

## Conclusion

- The Australasian Tele-Trial Model offers the opportunity to provide rural, regional & rare cancer access to clinical trials closer to home and to increase rate of recruitment
- 2. Widespread implementation requires the involvement of many stakeholders and streamlining of governance processes
- 3. Through the COSA and VCCC project, significant progress has been made so far
- 4. Sustainability of the model beyond the life of the COSA/VCCC project requires state and federal government (Department of Health) ownership