May Workshop 2019
Streamlining Clinical Trials and Research: 10 Years in Victoria

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Queensland Government

How QH Operationalised the Teletrials Vision

Understood that:

Needed to be clinically led policy innovation

Needed to be cost neutral for industry

That Industry would require a quality assured standard operating environment so that data could be included in regulatory packages

Implementation into QH required as many push and pull levers as possible

Bringing Clinical Trials Closer to Home

Variation in process

What this looked like in practice

Including Teletrials in Qld Advancing Health Research 2026 Strategy

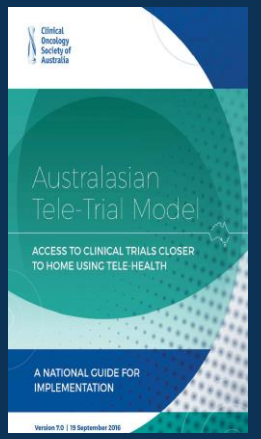
Statewide Teletrial Working Group QCTCU membership

Prof Sabe Sabeson Clinical Champion

Australasian Teletrial Model

RGOs at Primary and Satellite Sites on board

Australasian Teletrial Consortium



AUSTRALIAN ICH GCP (Including Teletrials) STANDARD OPERATING PROCEDURES COMPENDIUM

QH Commonwealth Partnership agreement for establishment of Teletrial model

QLD Health Service Directive

NMA working group

Industry Pilot Eli Lilly and IQVIA Breast Cancer Trial

QH CLINICAL TRIAL RESEARCH AGREEMENT SUBCONTRACT FOR STUDIES CONDUCTED UNDER A TELETRIALS MODEL

The Teletrials Subcontract

The Header Agreement is the CTRA

NATURE OF THIS AGREEMENT This document constitutes a subcontract permitted under the Head Agreement and the Institution remains responsible to the Sponsor under the Head Agreement for its subcontracted obligations and is liable to the Sponsor under the Head Agreement for all acts and omissions of each Subcontractor as if they were the Institution's acts and omissions in accordance the Head Agreement

SUBCONTRACTED ACTIVITIES Each Subcontractor will perform the Activities in accordance with: (a) the Protocol; (b) the terms of the Head Agreement applicable to the Institution which apply to those Activities; (c) the principles of good scientific and clinical research practices; (d) all applicable local, State and Federal laws, legislation, regulations, rules and by-laws; and (e) the Therapeutic Goods Administration approval for the Study, the HREC Approval and all relevant Reviewing HREC directions issued from time to time.

Next Steps

Progress with the NMA

- Jurisdictions to amend or adopt generic AUSTRALIAN ICH GCP (Including Teletrials) STANDARD OPERATING PROCEDURES
- Standard sub-contract made agnostic to jurisdictional legislation, agreed with Medicines Australia and published on the MA and MTAA website
- Communication, education and more Teletrials

QUESTIONS?