SEBS Panel - Facilitating Clinical Trial Agreements

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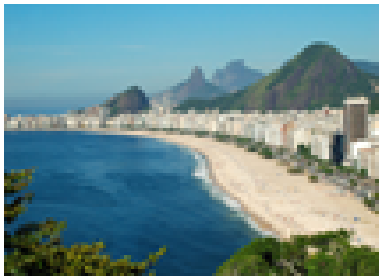
NSW GOVERNMENT | Health

Overview

- Case for an efficient model
- Objectives / Provenance
- Southern & Eastern Border States (SEBS) Panel
- Basic CTRA Structure
- Issues for International Sponsors
- What working with SEBS can do for you!

Key Focus areas for Global Competitiveness – How Does Australia Perform?



✗ **Speed**
- ethics and governance approval times

✗ **Cost**
- total cost per pt visit (incl. internal / external costs)

✗ **Patient Recruitment**
- productivity and efficiency

✓ **Quality**
- medical and scientific excellence
- research standards

MEDICINES Australia

Objectives

- Maximise efficiency in trial approvals
- Avoid Site Specific Assessment delays
- Streamlined review and approval
- Lower cost by avoidance of legal review
- BUT – one size doesn't & can't fit all trials

Provenance

- First CTRAs developed in 2007 (updated twice)
  - New updated set of CTRAs in March 2017
- Negotiated outcome between Medicines Australia and Eastern Border States
  - Medicines Australia representing the interests of commercial entities
  - States representing the interests of Public Health Organisations

Clinical Trial Research Agreement

Medicines Australia – Standard Form

This document has been password-protected to ensure the integrity of the document. Text can be inserted into the areas of the document where details are requested as well as all of the Schedules

Details of the parties

Institution:

Name:

Address:

ABN:

Contact for Notices:

Fax for Notices:

Phone Number:

Name Of Sponsor:

Clinical Trial Research Agreements (CTRAs)

- Standard (Commercial) CTRA
- Contract Research Organisation acting as Local Sponsor CTRA
- Collaborative / Cooperative Group CTRA
- Phase IV CTRAs (Standard and CRO)
- Clinical Investigation Research Agreements (CIRAs)
  - with Medical Technology Association of Australia (MTAA) for device trials
- NEW – Investigator-initiated (Company support)
  - Mid-way through discussions with MA

AMWG

Clinical Trials

Clinical Trials Action Group

Clinical Trials Research Agreements

Indemnity & Compensation Guidelines

Oncology Industry Taskforce

Publications

On this page

1. Guidance for seeking amendments to the Clinical Trial Research Agreements
   1.1. Initial Contact Point for Submissions:
2. Closing Dates for Submissions and Meeting Dates for 2017:
3. Standard Clause: Extending Third Party Beneficiary rights to International Organisations

Clinical Trials Research Agreements

The NSW, Qld, Vic and SA Health Departments (the SEBS States), together with Medicines Australia, have developed four Clinical Trial Research Agreements (CTRAs) in order to provide template agreements that are fair and reasonable for both sponsors and institutions and provide certainty of application in the commercial trial environment. Some of the individual clauses have been the subject of long negotiation through this process.

The current versions of the Clinical Trials Research Agreement are available below:

- Clinical Trial Research Agreement – Medicines Australia Standard Form 159k
- Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor 144k
- Clinical Trial Research Agreement – Collaborative or Cooperative Research Group (CRG) Studies 154k
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines) 143k

The four Clinical Trial Research Agreements are available as unlocked Word 97-2003 documents. In using the standard CTRAs note in particular that: "Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 7 (or Schedule 4) by way of Special Conditions".

Guidance for seeking amendments to the Clinical Trial Research Agreements

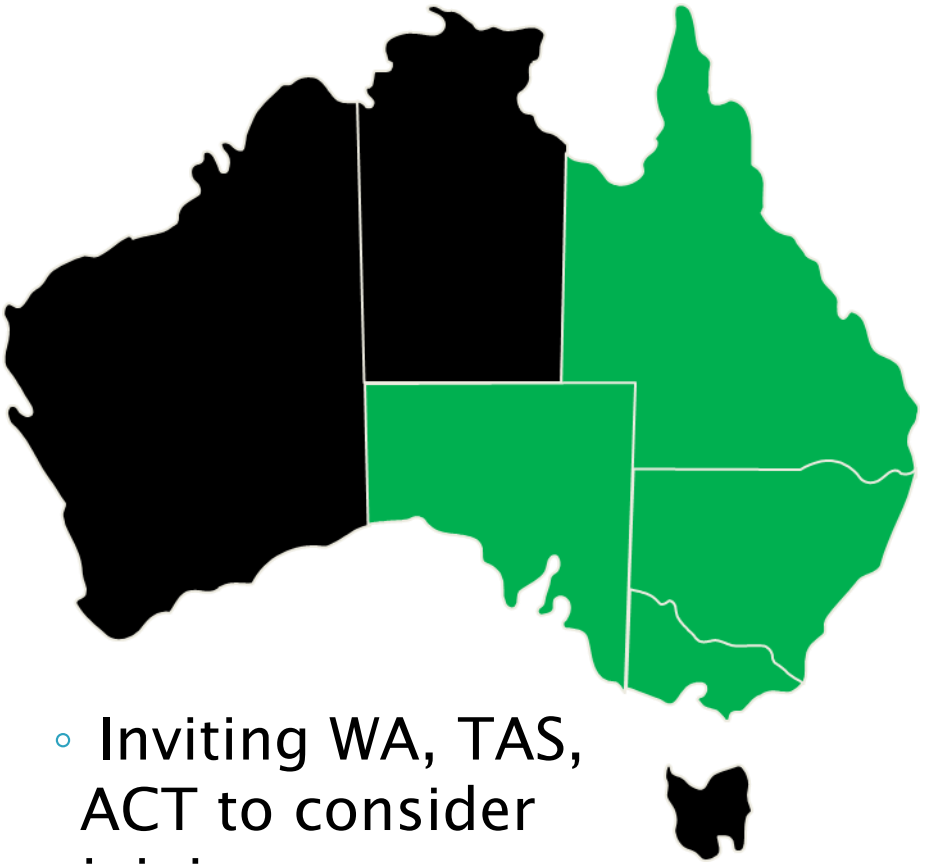
The template CTRAs can be executed without the need for any amendments via Schedule 7 (or Schedule 4 in the case of the CRG and Phase IV templates). This is preferable for SEBS jurisdictions, as there will be no requirement to involve the SEBS Committee, and SEBS Institutions can accept the unmodified CTRAs without requiring further legal review and therefore imposing further delays.

Structure of CTRAs

- Sets up Sponsor – Site (Institution) relationship
- Standard Commercial CTRA
  - Assumes Australian entity as Sponsor
- CRO CTRA
  - Global sponsor with no Australian subsidiary
  - Therefore, cannot sponsor trial in Australia
  - Needs to engage CRO to act as local sponsor
- Amendments to standard template through Schedule 7

Southern and Eastern Border States (SEBS)

- NSW, VIC, QLD, SA
  - Monthly meeting
  - Considers clause amendments to Schedule 7 of CTRAs
  - Advises on and can agree to most clause amendments
  - Broad acceptance of agreed clauses by all public hospital sites



- Inviting WA, TAS, ACT to consider joining

Basic provisions

- Parties (Sponsor/site) agree to conduct the study according to:
  - TGA requirements; GCP; Declaration of Helsinki; National Statement
- Acknowledges the role of the Principal Investigator (PI)
  - Though not a party to the contract
  - Institution responsible for the PI's actions
- Sponsor required to:
  - Provide the product and payment;
  - Associated equipment and software
  - Adverse event notification to site

Key Sponsor Obligations

- Indemnify Site
  - Medicines Australia Standard Indemnity
- Compensation Guidelines for Injured Participants
- Maintain appropriate clinical trials insurance

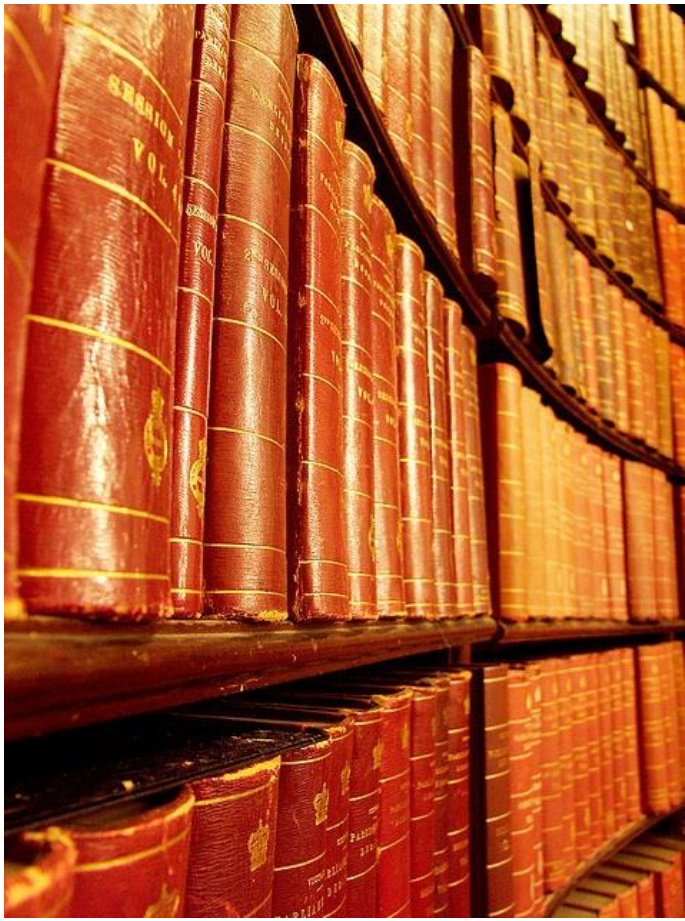
Clauses in Sponsor's favour

- Confidentiality
  - Embedded
- Publications
  - Generous timeframes
- Intellectual Property
  - All arising to Sponsor

- Termination for Convenience

Clauses in Institution's favour

- Indemnity
- Payments
- Applicable Law
  - Jurisdiction of site



SEBS positions

- SEBS try to accommodate company-specific clauses, however, not clauses that:
  - are clearly contrary to, or modify, core provisions;
  - delete / substantially modify essential clauses: eg/ Publication, Confidentiality, Intellectual Property, Governing Law and Termination;
  - merely restate ("wordsmith") existing provisions;
  - seek to override the applicability of the CTRAs;
  - are contrary to government insurance arrangements.

Issues for International Sponsors

- Use Contract Research Organisation CTRA
  - CRO acts as Local Sponsor
- International Sponsor tries to become party
  - Problem with TGA – requires Australian entity as 'Sponsor'
  - GST issue
  - SEBS have grown wary of this arrangement
  - Developed third party beneficiary clause
    - Greater comfort for O/S sponsor

Issues for International Sponsors

- Particularly US-based
  - *Equal Opportunity for Veterans*
  - *Utilization of Small Business Concerns*
  - *Prohibition on Contractor Involvement with Terrorist Activities*
  - *Affirmative Action for Workers with Disabilities*
  - *Clean Water Act*

Issues for International Sponsors

- Codes of conduct
  - SEBS offers:

Australian Code for the Responsible Conduct of Research

Why work with SEBS?

- No cost to apply for amendments
- Supports Pharma industry conducting trials in Australia
- High demand / high compliance from sites
- Ultimately, greater speed to start-up for multicentre trials