Australian Clinical Trials Alliance

Clinical trial network governance structure

Guidance for CTNs

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PURPOSE OF DOCUMENT

This document will assist clinical trial networks (CTNs) to develop their formal governance structure.

ROLE OF ACTA IN DEVELOPING CLINICAL TRIAL NETWORK GOVERNANCE STRUCTURE

The Australian Clinical Trials Alliance (ACTA) is providing advice to assist CTNs to make decisions on the most appropriate governance structure. The generic advice provided by ACTA should be considered and applied by each CTN taking into account the specific individual circumstances and needs of the network. The following principles are integral to successful CTN operations.

- Decisions should reflect good governance practices, including transparency, identification and management of conflicts of interest, and rules that are applied consistently.
- A recognition of the diversity of roles in potential membership and their contributions to a successful CTN.
- The CTN governance structure should be both representative of and responsible to its members.

ACKNOWLEDGEMENTS

We acknowledge the contributions of ACTA CTN members and members of ACTA's Efficient and Effective CTNs Reference Group in the preparation, development and review of this document.

USE OF THIS DOCUMENT

ACTA requests that the following acknowledgement is included in any CTN operational processes that are developed and documented using knowledge gained from this document. This will assist ACTA in identifying the usefulness and impact of this document in creating efficient and effective processes for CTNs.

"[name of CTN] acknowledges the contribution of ACTA to the development of operational processes within our network (reference: clinical trial network governance structure)."

DISCLAIMER

The information in this document is for general guidance only. ACTA does not make any representations or warranties (expressed or implied) as to the accuracy, currency or authenticity of the information provided.

DOCUMENT HISTORY

Version	Date	Changes made to document	Author
1.0	26 November 2018	First version	MS, KG, KL, KB

TABLE OF ABBREVIATIONS

ACTA	Australian Clinical Trials Alliance
CTN	Clinical Trial Network
DSMC/SDMC/DSMB	Data and Safety Monitoring Committee/Board
GCP	Good Clinical Practice

ORGANISATIONAL STRUCTURES FOR CLINICAL TRIAL NETWORKS

There are a number of different types of organisational structures under which networks have been established or may consider establishing. These include:

- A subcommittee or sub-entity of a parent organisation (e.g. a professional society or college)
- An independent registered company or association (legal entity)
- An independent registered charity (legal entity)
- A stand-alone informal entity
- An informal entity within an institution

There are a variety of advantages and disadvantages to each of these structures. For example, being part of a parent organisation may provide access to infrastructure support but may also limit your membership; becoming a legal entity provides more autonomy but the CTN will require a formal constitution and there will be costs to gain legal status; being a stand-alone informal entity may be easiest to set-up but without a legal status it may be difficult to receive funds or establish a memorandum of understanding with an institute that could receive funds on your behalf; positioning a CTN within an institute may overcome these issues but may also incur significant overhead costs.

Each CTN needs to consider individual needs both at the time of formation and as the CTN matures. ACTA recommends new CTNs or those CTNs planning to change their organisational structure should consider seeking further advice (legal and/or accounting/auditor) regarding the variety of options and to establish a best fit for the individual CTN. ACTA can provide an introduction to suitable agencies for this purpose. Please contact ACTA for more assistance.

ORGANISATIONAL MODELS FOR CLINICAL TRIAL NETWORKS

Previous work conducted by ACTA has described two main models for undertaking multicentre clinical trials research that have been developed by Australasian and Australian CTNs (ACTA 2015):

- **Facilitating Network**. In the Facilitating CTN model, the network facilitates the collaborative development and funding of trials, but generally has little or no role in the direct day-to-day management and coordination of trials.
- **Coordinating Network**. In the Coordinating CTN model, the network also takes on the role of coordinating clinical trials and providing direct project management for aspects of trial conduct such as adherence to regulations, site liaison and management, recruitment, data management and statistical analysis. Coordinating CTNs may or may not be study Sponsor as per the Good Clinical Practice (GCP) definition, and thus may also need to take on the roles required by a Sponsor.

For groups that use the Facilitating Network model, the work associated with conducting trials, such as project and data management, is devolved to a relatively small number of specialist trial coordinating centres aligned with the network.

The type of organisational structure and model chosen will influence the governance framework to be adopted.

GOVERNANCE FRAMEWORKS

An overall description of the network's governance framework including individual committees, their purpose, responsibilities, and reporting lines where several committees exist, should be documented. Consider a schematic if there are several committees (see APPENDIX 1)

Each committee should have its own Terms of Reference.

Governing committees should consider a range of internal and external stakeholder relationships, including relationships with members of the CTN that are not part of committees. Governing committees should also consider the need for independence from the management and day-to-day operations of the CTN. It is recommended that all committees include consumer representation.

The following committees and applicable areas of responsibility may be considered when establishing CTN governance structure.

Board of Directors, Executive Committee or Steering Committee

- This committee is a selection of appropriately experienced people who jointly determine strategy and oversee the governance of the CTN. Their powers, duties and responsibilities should adhere to the CTN constitution (if a separate legal entity) and take into account any applicable laws. This committee should not be responsible for the day-to-day decision-making, or execution of operational decisions; the execution of the strategy developed by this committee and the daily decisions of an organisation should be undertaken by the entity's executive officer/network manager. Membership of this committee should cover required areas of expertise e.g legal, financial, knowledge of disease area and consumer representation, to adequately address the future strategy needs of the CTN. (See APPENDIX 2 for assessment of committee skills matrix)

Finance, Audit and Risk committee

- This committee plays a key role in assisting the Board of Directors or Executive/Steering Committee to fulfil its governance and oversight responsibilities in financial reporting, internal controls, risk management and fulfilling any requirement for internal and external audit determined by legal status of the CTN.

Scientific Advisory Committee

- This committee plays a key role in determining the program of research to be conducted under the auspice of the CTN (regardless of whether a facilitating or coordinating network) and which is aligned to the strategy developed by the Board of Directors or Executive/Steering Committee. This committee reports to the Board of Directors or Executive/Steering Committee with membership made up of individuals with a mix of skills, including consumers if consumer review of the program of research is not encompassed elsewhere. This committee may oversee: research priorities for the network; trial concept development; trial endorsement processes; trial protocol approval; aspects of trial conduct such as development, approval and review of the standard operating procedures of network endorsed trials; and trial conduct monitoring. In larger networks this committee may choose to form sub committees (e.g disease-specific, operational committee, safety committee) to delegate some of these activities.

Consumer Advisory Group

- CTNs are encouraged to include consumer representation across their governance framework and/or have a dedicated consumer group who are appropriately trained and resourced to provide representation when needed.

Safety Committee or Data and Safety Monitoring Committee

- Taking into account whether the network has a facilitating or coordinating CTN model, the CTN should consider its responsibilities and role in safety oversight for trials endorsed by the CTN[1] and establish appropriate procedures.

- Where the CTN is required to maintain a role in oversight of trial safety, this may require establishment of an independent Data and Safety Monitoring Committee (DSMC) that is responsible for an individual trial or all trials within the CTN. The investigator(s), protocol development committee or trial steering committee may also play a role in oversight of trial safety.

- In general, the individual/committee delegated the responsibility of oversight of trial safety should consider any new information arising from the literature (including safety documents), other trial results, the current trial data or clinical practice that may influence the continued equipoise, safety, or likelihood of obtaining results that will contribute to the relevant evidence base from the trial. Decisions made by this committee may include approval of the final protocol before the trial commences, approval of protocol amendments, further review of arising data or cessation of trial recruitment or closure of the trial. Pre-emptive 'stopping rules' may be considered to facilitate review.

- It should also be considered whether Data and Safety Committees are also involved in monitoring the timely return and quality of trial data, site selection and/or site performance and the procedures that will be undertaken to assess this. An alternative approach may be to implement a Charter or Standard Operating Procedure for each trial conducted by the CTN to describe these duties, roles and responsibilities.

COMMITTEE TERMS OF REFERENCE

Terms of Reference should be established for each committee within the CTN as separate documents.

In general, Terms of Reference should provide the following:

- Membership of the committee, how they are selected and term of committee membership. This should include process on how to replace committee members if they retire or step down prematurely, and the procedure to stand down committee members
    - Consider whether membership to committees is open to all categories of membership
    - Consider diversity in committee representatives e.g regional versus metropolitan, Australian states and New Zealand, discipline and gender.

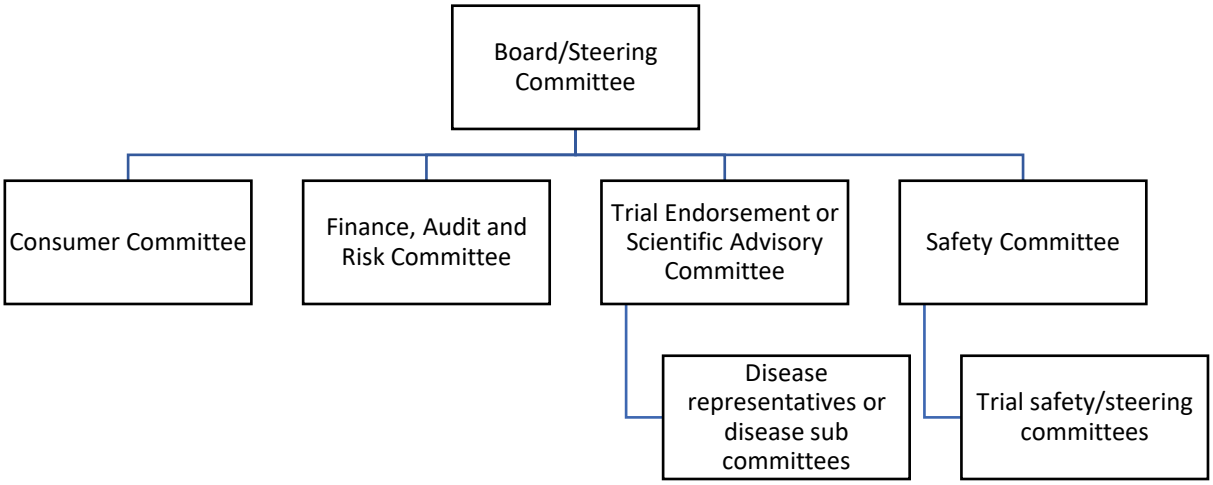
[1] Consider the TGA Act and other local laws in countries of operation, and guidance documents including but not limited to the Declaration of Helsinki, Guideline for Good Clinical Practice, The National Statement on Ethical Conduct in Human Research, 'Safety and Monitoring in Trials involving Therapeutic Goods' November 2016 and subsequent supplementary guidance documents.

    - Consider whether the option to co-opt members is required and if co-opted members will have voting rights.
    - Consider staggering of terms for committee members to maintain corporate knowledge when a committee is first established.
    - Consider whether retirement by rotation is appropriate for the committee
- The names of the office-bearing positions and how they are selected, and appropriate term if this differs to term on the committee. E.g Chair, Deputy Chair, Treasurer
- Meeting frequency and format (face to face or tele/videoconference) and process for meetings by exception
- Definition of a quorum and voting procedure for decisions within the committees
- Confidentiality of meeting agenda content, minutes and decisions and whether confidentiality agreements are required
- How conflicts of interest will be identified, monitored and dealt with
    - Potential conflicts of interest should be declared at the start of each meeting, assessed by the chair and the conflict and decision documented in the minutes of the meeting
    - If a conflict arises, the conflicted individual should absent themselves from voting on the conflicted agenda item(s), and possibly also the discussion of the agenda item(s)
    - Consider whether new members to the committee need to sign a declaration of interests to allow assessment of any conflicts
    - Consider whether an annual request for declaration of interests also needs to implemented
    - Consider whether any conflicts of interest would render an individual ineligible to sit on a committee
- Documentation of committee secretariat support, what this will entail and timeframes for deliverables (e.g minutes, agenda circulation, communications arising from meeting)
- Signatory policy and approval of communications arising from the meetings
- Adoption and review of Terms of Reference
    - Consider the review requirements before adoption of the Terms of Reference, the review process and timelines for review.
- An agreement that members should use their best endeavours to promote and protect the standing and reputation of the CTN, notwithstanding that tensions and disagreements will arise, and members should commit to participation in resolution processes as defined in the governance framework.

REFERENCES

Australian Clinical Trials Alliance (ACTA), (2015) *Report on the Activities & Achievements of Clinical Trial Networks in Australia 2004-2014* Available at: http://www.clinicaltrialsalliance.org.au/about-acta/major-initiatives/ Accessed 10 October 2018

APPENDIX 1 SCHEMATIC OF GOVERNANCE FRAMEWORK



APPENDIX 2 COMMITTEE SKILLS MATRIX

Board Skills Matrix - Self-Assessment		Importance	Insert Director Name	Insert Director Name	Insert Director Name	Insert Director Name
Committee should comprise a balance of these skills						
Financial & Audit	Qualifications and/or experience in accounting and finance to analyse statements, assess financial viability, contribute to financial planning, oversee budgets, and oversee funding arrangements.	**High**				
Strategy	Ability to identify and critically assess strategic opportunities and threats to the organisation. Experience in the development of strategies within the context of our business objectives.	**High**				
Risk & Compliance	Able to identify key risks to the organisation related to each key area of operations. Ability to monitor risk and compliance and knowledge of relevant legal and regulatory requirements.	**Medium**				
Policy Development	Ability to identify key issues for the organisation and develop appropriate policy parameters within which the organisation should operate.	**Medium**				
Technology	Knowledge of IT Governance including privacy, data management and security.	**Medium**				
Executive Management	Experience in evaluating performance of senior management and overseeing strategic human capital planning. Experience in industrial relations and organisational change management programmes.	**Medium**				
Leadership	Able to make decisions and take necessary actions in the best interest of the organisation, and represent the organisation favourably. Ability to critically analyse issues and contribute at Board level to solutions.	**High**				
Organisation Specific Skills						
Therapeutic Area	Experience in specific therapeutic area.	**High**				
Clinical trials	Experience with clinical trials and their administration.	**High**				

Business development	Experience in the development of strategic partnership and relationships with key stakeholders	**Medium**				
Government advocacy	Experience in Government and/or Peak Body advocacy.	**Medium**				
Information Management	Experience in the development and implementation of information management strategies.	**Medium**				
Communication	Experience in the development and implementation of appropriate communication strategies.	**Medium**				
Crisis Management	Ability to constructively manage any crisis, provide leadership around solutions and contribute to the communications strategy with stakeholders.	**Medium**				

Self-Assessment Rating Definitions
3 = Formal qualification and extensive experience, including previous role responsibility for this function
2 = Extensive experience without formal qualification
1 = Some experience
0 = No experience