



**Australian
Clinical
Trials
Alliance**

Establishment of New Clinical Trial Networks

Guidance for CTNs

Version 2.0

September 2020

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ACKNOWLEDGEMENTS

This document draws on an original document developed by Dr Jacqui Waterkeyn from Orygen, The National Centre of Excellence in Youth Mental Health, with input from Dr Megan Sanders, Professor Steve Webb and Professor John Zalcborg. The final briefing document was then used as the basis for this guidance.

USE OF THIS DOCUMENT

This document is provided as an editable document to enable editing and addition of appropriate logos by the initiators of Clinical Trials Network (CTN) establishment. The generic advice provided by Australian Clinical Trials Alliance (ACTA) should be considered and applied by each CTN taking into account the specific individual circumstances and needs of the CTN. ACTA requests that documents revised by the CTN are provided to ACTA, to enable ACTA to continue to refine and improve this document for future use.

ACTA requests that the following acknowledgement is included in any documents or processes that are developed and documented using the knowledge gained from this document. This will assist ACTA in identifying the usefulness and impact of this document in CTN establishment.

“[name of CTN] acknowledges the contribution of Australian Clinical Trials Alliance to the development of operational processes within our network (reference: *Establishment of New Clinical Trial Networks*).”

We encourage you to contact ACTA for further advice in establishing a CTN via acta@clinicaltrialsalliance.org.au

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	Authors
1.0	23 May 2019	First version	JW, JZ, MS and SW
2.0	17 August 2020	Minor additions to first version	FN

TABLE OF ABBREVIATIONS

ACTA	Australian Clinical Trials Alliance
CTN	Clinical Trials Network
eDC	Electronic Data Capture
GCP	Good Clinical Practice

BACKGROUND

There is increasing awareness of the value of clinical trials in improving patient outcomes, advancing clinical care through contribution to the evidence base and improving the efficiency of the healthcare system (The Australian Clinical Trials Alliance, in association with Quantum Health Outcomes, 2017).¹ Clinical trials can be conducted at a single site (often a hospital) or they can be opened at several sites simultaneously, (i.e. a multi-site trial). Multi-site trials increase the rate of patient recruitment, the diversity of the patient pool recruited, the generalisability of results and enable several investigators to become familiar with the intervention utilising the guidance outlined in the clinical trial protocol, so in the event of appropriate evidence the intervention can be readily assimilated into routine patient care. Multi-site trials can be conducted through collaborations of investigators, but the capacity of these informal collaborations can be difficult to 'scale-up' beyond the geography or the personal network of lead researchers, limiting the available number of sites. Maximum site participation is especially critical in the conduct of clinical trials in rare diseases, settings of increasing disease diversification, or when clinically meaningful differences require larger sample sizes.

Both internationally²⁻⁴ and in Australasia⁵, Clinical Trials Networks (CTNs) have been effective in a number of disciplines to increase the volume and impact of clinical trials. There is a growing awareness from the Australian Government and research bodies of the valuable contribution CTNs can make to the healthcare system. Since the establishment of the first CTN in Australia in 1973 (The Australian and New Zealand Lymphoma Group, which fused with the Leukaemia Study Group to become the Australasian Leukaemia and Lymphoma Group in 1999), almost 40 CTNs have been established in Australia and New Zealand, spanning many disciplines of medicine. As the peak body representing CTNs in Australia, the Australian Clinical Trials Alliance (ACTA) is uniquely positioned to bring together the collective history and experience to assist in the formation of new CTNs.

CTNs often coalesce around some form of shared identity, related to a specific group of diseases (e.g. gastrointestinal cancer or musculoskeletal diseases) or a non-disease-related clinical discipline (e.g. anaesthesia, primary care). They are typically established via a 'bottom-up' process where a collective agreement and desire exists between key leaders in the field to conduct high-quality, multi-site clinical trials. CTN membership is then expanded, often including multiple disciplines, and typically evolves to encompass both a core group of 'trialists' who design and lead clinical trials and members who participate by recruiting participants to the trials in the CTN portfolio. Individual members of a CTN maintain their autonomy but contribute to their network at their own desired level of intensity. Features of CTNs that contribute to the execution of clinical trials include shared vision and collaboration; potential for recruitment of a diverse patient population to trials; and reusable infrastructure encompassing operating systems, organisations and individuals.

Once the decision has been made to establish a CTN, an initial steering group is often formed from leaders in the field, but this group may have little experience or limited access to information about the steps and challenges associated with forming a CTN. ACTA aims to provide support to groups interested in establishing new CTNs, and to share good practice identified from existing models.

THE ROLE OF ACTA IN CTN ESTABLISHMENT

ACTA (<http://www.clinicaltrialsalliance.org.au/>) is a national body that supports and represents CTNs, Clinical Quality Registries and clinical trial Coordinating Centres. ACTA has several years of experience in liaison with, and providing assistance to, interested investigators who are seeking to establish broader investigator-initiated clinical trials and/or CTNs. ACTA's main role has been to facilitate the establishment of new CTNs and, in a flexible and responsive manner, provide advice for the continued success of the CTN, drawing on ACTA members' collective knowledge and prior experience in a variety of CTNs.

ACTA has received funding from the Australian Government through the Medical Research Future Fund to enhance the effectiveness and efficiency of CTNs in Australia. This work encompasses several Reference Groups, including a program on CTN Sector Expansion that aims to identify areas where a CTN may be of value in improving healthcare, and to facilitate CTN establishment. ACTA will facilitate the formation of CTNs only where the interest is sustained from the relevant discipline. The CTN Sector Expansion Reference Group provides advice about governance, organisation, structure, and processes of a CTN. ACTA leads other Reference Groups that provide guidance on specific aspects of the design and execution of trials.

Although ACTA is unable to provide seed funding for establishment of new CTNs, as a recognised body to connect governments, healthcare policymakers and consumers, ACTA is in a position to advocate with funders regarding the resource requirements for newly formed CTNs. ACTA is also able to use their expertise from profiling approximately 40 CTNs to identify critical success factors and risks in CTN operations and assist with ensuring CTNs succeed and are sustained beyond their establishment years. ACTA can provide mentorship and a pathway to connect with other CTNs, particularly during the early phase of development of a new CTN.

PURPOSE OF THIS GUIDANCE

The purpose of this guidance is to provide a framework for leaders within a discipline to advance through the steps that lead to the establishment of an effective and sustainable CTN.

Components of this process include:

1. An overview of previous observations regarding establishment and success of CTNs
2. Consultation within a discipline to obtain input and 'buy-in', address concerns and achieve consensus about design, structure, governance and management of a CTN
3. Frank and open insight into the advantages and disadvantages of conducting trials within a network structure
4. Evaluation of a potential new CTN in the context of existing clinical trial infrastructure, including infrastructure such as experienced staff and data management platforms that may be available through existing CTNs and registries
5. Engagement of the CTN with the wider sector
6. Discussion of key success factors for a CTN and establishment of strategies to achieve these outcomes.

Typically, these discussions are held between a group of leaders in the field who share an interest in developing a CTN. ACTA's role is to share experiences and facilitate discussion. A sample agenda for these meetings is provided in Appendix 1.

CORE PRINCIPLES OF CTNs

CTNs are examples of successful integration between research and healthcare delivery. CTNs can maximise their capabilities, deliverables and outputs for the benefit of patients. They are positioned to provide a larger capacity for evidence generation, that enhances the external validity of trial outcomes. CTNs provide the opportunity to build a 'brand' with a reputation for: i) trials that are completed on time and within budget; ii) high-impact trials that are recognised as answering questions relevant to clinicians and patients; and iii) an ability to attract and retain research funding nationally and internationally.

The core principles of most CTNs include:

- Collaboration and collegiality including sharing credit for success (e.g. group authorship and mutual ownership of outcomes and achievements)
- Alignment of the best interests of researchers, patients, and the CTN
- Equity
- Creation of a reusable, sustainable, shared infrastructure that improves trial quality and feasibility
- Commitment to improving patient outcomes through generating and implementing evidence derived from trials
- Conduct of high-quality clinical trials that are patient-centred and innovative
- Enhancing efficiency of research through coordination of potentially competing trials and prioritisation of research questions.

ADVANTAGES AND DISADVANTAGES OF A CTN

There are many advantages to the establishment of a CTN, and some real and perceived disadvantages.

ADVANTAGES OF A CTN

These include but are not limited to:

Trial quality, impact and efficiency

- Strengthened quality, efficiency, and impact of trials, establishing minimum standards or endorsement criteria, and drawing on experience, skills, processes and systems within the CTN
- Access to a greater sample size through collaboration of more sites, with more rapid expansion of evidence-base, effective recruitment of trial participants, and the capacity to detect smaller but still relevant differences through larger recruitment numbers
- Internal peer-review of projects for feasibility and validity as well as review of manuscripts prior to submission for publication
- Development and agreement about standardised outcome measures
- Provision of a forum for consumers to share their contribution about research priorities, suitability and acceptability of candidate interventions for trials, outcome measures, and trial protocols and management
- Increased data integrity through consistent GCP implementation, as translated to the investigator-initiated clinical trial sector
- Through consultation with a broadly representative membership, a CTN can foster broader access to and sharing of new research methods, advances in disease biology, trial designs, and strategies for the benefit of the therapeutic area of the CTN
- Ability to facilitate and manage multiple trials at once
- Clinician-led design and prioritisation of trials that can be embedded into healthcare by drawing on existing treatment protocols, response measurements and resources, which ultimately enhances translation of trial results into routine healthcare
- Development of infrastructure that can be reused for subsequent trials including robust site systems, site feasibility assessment and selection, training in research data capture, Case Report Form development and standardisation, electronic Data Capture (eDC) systems, budget negotiation, project management including Clinical Trial Management Systems, sponsor-delegated monitoring and other clinical trial capabilities that are not always readily available at individual institutions
- CTNs can provide operational procedures to maintain regulatory compliance, independent Project Managers and monitors for studies
- Development of standardised study tools
- Maximising research capacity by inclusion of additional complementary studies to enhance research into the disease area.

Reputation and advocacy

- Development over time of a CTN track record. This allows all members of the CTN, particularly early- and mid-career investigators, to take advantage of the combined track record of the network. This builds on itself, allowing growth and impact to grow more rapidly, and experience to date indicates that contributing to the CTN track record does not adversely affect the track record of individual researchers, research groups, or research institutes
- The CTN can become a brand with brand values of high-quality trials completed successfully that provide evidence to improve patient outcomes. This brand development enhances the confidence of funders, industry and other collaborators when evaluating potential success of further grant applications from the CTN
- The CTN can advocate for and support applications for clinical and research fellowships and funding for clinical trials
- Facilitation of international collaboration
- Shared sense of purpose to improve clinical outcomes through generating better evidence
- Mentorship opportunities.

Possible disadvantages of a CTN

- Some loss of autonomy for individual researchers or groups. The development and maintenance of track record (brand) can require processes that determine whether the network endorses or owns a trial, a correlate of which is the requirement that projects and manuscripts meet criteria established and implemented by the network
- Individual research endeavours and research projects might not be endorsed or prioritised
- Reputational risk to all network members from trial failure or other actions by some members
- The resources required for running central network activities need to be found, potentially diverting resources from individual researchers or groups
- A general requirement that the same budget is made available to all sites (even though costs may vary between sites).

EXISTING CLINICAL TRIAL INFRASTRUCTURE AND OVERLAPPING NETWORKS

Evaluation of existing clinical trial infrastructure and stakeholders should be undertaken prior to the formation of a new CTN. Bringing the right people together is critical to a new CTN, and stakeholder mapping is a vital part of this process. Stakeholders are identified by a systematic mapping approach using stakeholder categories. Then an analysis is conducted to determine the potential level of influence and support on a new CTN for each stakeholder identified. For further information see ACTA's *Stakeholder Mapping for Emerging CTNs*.⁶

CTNs have often evolved in disciplines where there have been preceding collaborations in the conduct of clinical trials, but without the formal organisation of a network. Ensuring that the interests of existing researchers and the research group are respected and managed during both the CTN establishment phase and in an ongoing fashion can be critical to the success of the CTN. In this situation, an informal audit of existing groups, their infrastructure and processes, as well as an understanding of their culture and history can be important in determining an acceptable pathway to facilitate these researchers joining and contributing to a new network.

In forming a new CTN it is important to evaluate potential areas of overlap with existing CTNs. As in clinical medicine, there is often an intersection between multiple disease- or discipline-specific practitioners. It is generally not a desirable outcome for a new CTN to form in a disease- or discipline-area that already has a CTN. Even when adopting this principle there is often potential for overlap with an existing CTN. For example, a proposed new CTN in primary care might have an interest in doing trials in musculoskeletal disease, but an existing CTN may exist for musculoskeletal disease, although with an interest that includes primary, secondary, and tertiary care settings. It is ACTA's experience that where some form of shared identity exists and there is not a CTN for a singular 'identity', that there is a need for a new CTN but, as part of forming that CTN, it is important to identify existing CTNs that have an overlapping interest and seek to complement the work of and/ or collaborate with existing CTNs. There is a long history of many highly successful clinical trials that are 'co-owned' by two or more CTNs and this provides one pathway for managing potential overlap in areas of interest. Collaboration on specific clinical trials, between a new and an established CTN, can be highly effective at building the track record of the new CTN.

INTERACTION BETWEEN A CTN AND REGISTRY

There is often substantial synergy between a CTN and a registry in the same disease or discipline area. Some new CTNs have established using an existing registry as the foundation. There are potentially major advantages in associating with a registry, not least of which is utilisation of established infrastructure for potential participant identification and data collection. During establishment of a CTN, and when there is no existing registry, establishment of both a CTN and a registry should be considered, ideally within a single structure, to take advantage of these synergies from foundation.

KEY INGREDIENTS FOR SUCCESS

Factors critical to success are likely to vary between CTNs. ACTA has drawn from the experience of its members to identify the following factors that are likely to be important in the establishment phase of a CTN:

- Consensus among a critical mass of established clinical researchers within the discipline that a CTN should be formed, and with a shared vision
- That a new CTN is neither led nor seen to be led by a single individual or research group but represents a platform for a range of clinical trials to be led by PIs or Co-PIs with a range of specific interests and expertise
- Sufficient resources to employ an Executive Officer⁷ and to sustain an engaged, consultative, and representative committee to guide initial formation (see Group A tool)⁷
- That agreement regarding the structure, governance arrangements⁸, objectives, and management processes should precede discussion or planning of research projects (see Group A tool)⁸
- Written Terms of Reference⁹ that evolve as the CTN grows (see Group A tool)⁹
- A succession-planning strategy to address membership and leadership change over time and maintenance of knowledge
- Identification of research priorities with a flexible and responsive approach to emerging challenges
- That the network is viewed as shared infrastructure that is responsible to and representative of key stakeholders, including active and interested researchers, clinicians, and consumers
- Acknowledgement that tension and disagreements will occur but agreeing processes by which issues can be resolved
- Willingness to be open and transparent about interests and willingness to reach consensus that places the interests of the network above individual researchers, research groups, institutes, or specific research projects
- Adherence to the ‘grand bargain’, which is that researchers enrol participants into each other’s trials, growing the number of sites and participant enrolment.

SECTOR CONSULTATION ON ACTIVITIES CRITICAL TO SUCCESS

The importance of these factors was highlighted in a sector wide consultation on critical factors for success for CTNs that ACTA Group A: Effective and Efficient CTNs conducted. A report on these factors was released in May 2019.¹⁰ (See Table 1 for the factors that were identified in this sector consultation.) Table 1 shows that many of the factors identified in the sector consultation align with the initial factors reported by experts from Group B above. This shows the importance of these factors for CTNs.

Table 1: Activities critical to success of CTNs identified in a sector-wide consultation (Group A tool)

A shared vision and motivation
Strong leaders, governance, and succession planning
Transparent processes
Effective communication
An Executive Officer
Sustainable funding
Diverse representation and consumer input
Prioritisation of research
A strong pipeline of trials
A reputable and recognised CTN brand
An effective group of network sites with skilled site workforce
Embedded trials
Innovation and adaptation.

For further information on the Group A tool see ACTA’s sector wide consultation report on Activities Critical to Success of CTNs.¹⁰

QUESTIONS FOR CONSIDERATION DURING THE ESTABLISHMENT OF A NEW CTN

Interest in establishing a CTN is likely to stimulate discussion on many topics. The following questions are intended as prompts, or a starting point to guide initial discussions, leading into more detailed conversations about the specific issues and objectives of the CTN.

- Can mission and vision be agreed?
- How will the CTN engage with the sector beyond the initial steering group, and interface with professional societies, the College, fundraising organisations, industry, health service providers and any existing clinical trial infrastructure?
- Are there existing registries or CTNs where clinical trial activity may overlap?
- Should the simultaneous establishment of a registry and CTN be considered?
- How will membership be defined? Site and institution membership and/or individual membership?
- What sort of governance structure should be in place? How will the leadership group be appointed? What should be in the Terms of Reference or similar document? What is the process for decision-making?
- How will conflict of interest be identified and managed?
- What will the CTN's relationship with industry look like? Will the CTN support or endorse industry trials as well as investigator-initiated clinical trials?
- Which advocacy or consumer groups should be included and how?
- What type of CTN is needed or desirable? Facilitating or coordinating?
 - > **Facilitating:** Network facilitates collaborative development and funding of clinical trials but has little or no direct role in their management or coordination. The role of management and coordination of clinical trials is allocated to one or more specialist trial coordinating centres. These centres can be based in either medical research institutions or university departments but have governance that is independent of the network (the same individuals can have roles in both the network and the coordinating centre). A facilitating network will not act as study sponsor.
 - > **Coordinating:** Network also takes on role of coordinating clinical trials and provides direct project management for trial conduct (regulatory compliance, site liaison and management, protocol development, recruitment, monitoring, data management, statistical analysis, etc). The institution that hosts the trial coordinating centre will act as the sponsor for investigator-initiated clinical trials or the CTN develops the capability to sponsor individual trials.
- Can criteria and processes for endorsement of projects and manuscripts be agreed?
- Should the CTN operate from within another organisation, such as a clinical society and, if so, as part of that legal entity? If formed within another organisation, this provides immediate access to human resources, banking, and office infrastructure and avoids onerous fiduciary requirements. However, ownership of the network within another organisation often involves trading some autonomy and control to the parent organisation.
- Should a legal corporate entity be established and when?
- What is required in terms of physical office, Executive Officer or Senior Manager/Administrator and human resources? How will this be funded initially? Where will the office be located initially?
- How will the CTN be funded initially and post-seed/establishment phase?
- What communications are required to launch the CTN?

TRIAL ENDORSEMENT

Trial endorsement is a process that often involves peer review of trial protocol and feasibility of a proposed study. It enables a way to gain wider member support. Some benefits of trial endorsement include the use of network processes and branding, including the CTN name and logo. Endorsement of a clinical trial by a well-known CTN may increase the potential to gain funding and publish journal articles due to positive associations with the CTN 'brand'. Trial endorsement can be beneficial but careful consideration and planning is needed as it can also pose risks. Some procedures to ensure high-quality trials to build and maintain the CTN brand may include trial registration, adhering to best practice guidelines of the network and general regulatory standards (i.e. ethical guidelines), regular reporting back to the CTN and following authorship and publication policy guidelines.

It is important that CTNs reserve the right to retract trial endorsement if issues arise with the trial occur such as misconduct or unexplained delays on start up. There should be processes in place to ensure only high-quality trials are conducted and are linked to the CTN brand. For further information see ACTA's *Trial Endorsement and Review*.¹¹

Safety is an important factor to consider for trial endorsement. Journals are wanting to see more focus on safety reporting. For more information on this topic see the NHMRC's *Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods*¹² or ACTA's *Trial Safety Oversight*.¹³

FOLLOW THE ESTABLISHMENT JOURNEY OF A CTN

A recent publication, *Early development of the Australia and New Zealand Musculoskeletal Clinical Trials Network*, describes the steps taken by ANZMUSC when forming its CTN to help others interested in establishing similar networks.¹⁴

FURTHER STEPS

CTNs provide a means of bringing together communities of geographically dispersed and multidisciplinary clinical researchers primarily to design, conduct and publish investigator-initiated clinical trials proposed and supported by the CTN membership. ACTA is positioned to support groups interested in establishing CTNs and encourage these groups to contact ACTA for more information on acta@clinicaltrialsalliance.org.au

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APPENDIX 1: SAMPLE AGENDA FOR ESTABLISHMENT MEETING

CTN ESTABLISHMENT MEETING		
Date and time		
Venue		
AGENDA		
Time	Item	Led By
	1	Welcome and introductions (5 mins)
	2	Why do we need a CTN? (up to 90 mins) <ul style="list-style-type: none"> > ACTA introduction > Why do we need a formalised CTN/value proposition? > Experiences from other CTNs > What is the vision and mission of the CTN?
	3	How will the CTN operate in the sector? (up to 30 mins) <ul style="list-style-type: none"> > Role of College, sub-speciality groups, and societies > Role of industry > Role of fundraising groups, advocacy groups and consumer groups > Engagement of health service providers
	4	What will the CTN look like? (up to 120 mins) <ul style="list-style-type: none"> > Existing clinical trial infrastructure > Should co-establishment of a registry be considered? > Membership structure > Governance structure > Operation within a parent organisation vs establishment of a legal entity > Physical space and staff
The below discussions could occur at a subsequent meeting		
	5	Activities of the CTN (up to 120 mins) <ul style="list-style-type: none"> > Coordinating vs facilitating > Prioritisation and endorsement criteria for trials and publications > Engagement of diverse areas of specialty or disease > Meetings of the membership and special interest areas > International collaborations
	6	Funding and sustainability (up to 60 mins)
	7	Communications required to launch CTN (up to 60 mins)
	8	Next meeting



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ACTA gratefully acknowledges operational funding from the Australian Government's Medical Research Future Fund