



**Australian  
Clinical  
Trials  
Alliance**

# Operational Self- Assessment Tool for CTNs

September 2019

# Operational Self-Assessment Tool

## Background

The delivery of high-quality healthcare relies on the availability of high-quality evidence to inform practice.

In Australia and New Zealand, clinical trial networks (CTN) design, conduct and publish investigator-initiated clinical trials, generating evidence that contributes to a high-quality healthcare system. Utilising qualitative descriptive activities in a sector-wide survey and focus groups, ACTA consulted the CTN sector to identify the structures, operational processes and activities that are critical to effective and efficient network operations, and to identify any unmet needs of CTNs.

The sector consultation identified three main themes that were critical to the success of a CTN, an engaged membership, an established infrastructure and sustainability.

## Purpose of the tool

The purpose of this tool is to self-assess the presence and effectiveness of the success factors that were identified in the [“Activities critical to success and growth of Clinical Trials Networks: Sector consultation”](#) report and provide links to resources supporting these activities.

The results of the assessment tool can be used to plan future network activities and identify areas for improvement.

## How to use the tool

For each item, determine if the factor is present, in development or not present. Some factors may not be applicable to your CTN, due to the function being provided by the organisation your CTN resides within taking on that role or the stage of your network development and/or capacity.

Where the factor is present, identify if it is effective (effective, satisfactory or not effective).

When available a link to additional resources and guidelines have been provided. ACTA is developing new resources and the links will be updated as these become available.

A comment box has been provided to allow CTNs to document where present to a degree or if there is an alternative in place instead e.g. the organisation has a communications plan which the CTN uses.

If you need assistance with any of the factors identified please contact [acta@clinicaltrialsalliance.org.au](mailto:acta@clinicaltrialsalliance.org.au) for additional support.

# 1. An Engaged Membership

Membership engagement was identified to be critical for the success of a Clinical Trial Network. When membership engagement is high, key CTN operations flourish through commitment of members to these activities. The activities associated with membership include:

	Present and up to date	Present but needs review	Under Development	Not present	Not Applicable
<b>Network culture, network champions and key leaders</b>					
Does your network have formal processes in place for growing the CTN leadership and culture?					
Does your CTN have formal mentoring structures and processes?					
<b>Comment</b>					
<b>Uniting the membership with a clear vision and mission</b>					
Does the CTN have a mission statement?					
<b>Comment</b>					
<b>Governance committee membership</b>					
Does the governance committee have a documented term of reference? See <a href="#">Network Committee Terms of Reference</a>					
<b>Comment</b>					
<b>Accountable and transparent processes</b>					
Are there clear document processes in place?					
Can members access these documents?					
<b>Comment</b>					
<b>Scientific meetings, workshops and social events</b>					
Are there opportunities for members to engage with each other through meetings, workshop and social events?					
Is there a database of members, and a record of communications?					
<b>Comment</b>					
<b>Communications</b>					
Does the CTN have a documented communications plan? (i.e. A structured plan with options for regular and consistent communication across CTN members and the public. This should include what information you wish to convey and how will this be achieved (i.e. website, newsletters by email and social media for some CTNs). See: <a href="#">Communications and marketing strategy guidance for CTNs</a>					
<b>Comment</b>					

## 2. An established infrastructure

A Clinical Trial Network needs a structure with effective central network activity that can support and facilitate a pipeline of clinical trials across multiple networks sites. A number of key factors contribute to a well-defined CTN structure and several activities and tools support these factors.

	Present and up to date	Present but needs review	Under Development	Not present	Not Applicable
<b>Executive Officer</b>					
Does the network have an executive officer/network manager? See: <a href="#">CTN Executive Officer/Network Manager Duties</a>					
<b>Comment</b>					
<b>Prioritisation of Research</b>					
Is there any formal process to prioritise research topics or questions? See: <a href="#">Research Prioritization Framework</a>					
<b>Comment</b>					
<b>Peer review, trial endorsement and authorship guidelines</b>					
<b>Are there any guidelines for authorship, peer review and publication processes?</b> See: <a href="#">Authorship and Publication Guidelines</a>					
<b>Comment</b>					
<b>Trial Development Support</b>					
Is support provided to researchers to develop their trials?					
Does the CTN support funding applications or provide opportunities for funding pilot or feasibility studies?					
Is this review multidisciplinary and including consumers?					
<b>Comment</b>					
<b>Activity of the Network Sites</b>					
Does the CTN document metrics on up-coming, active and completed clinical trials? (i.e. A database/spreadsheet record of clinical trial milestones from development through to publication.)					
Is there regular engagement with the recruitment sites to address any issues and ensure recruitment is on track?					

<b>Comment</b>					
<b>Trial Coordination Services</b>					
Does your CTN have documented standard operating procedures (SOPs) templates?					
<b>Comment</b>					

### 3. Sustainability

Several key factors contribute to CTN sustainability including past successes of the network and activities and tools to support maintaining that success.

	Present and up to date	Present but needs review	Under Development	Not present	Not Applicable
<b>Multidisciplinary representation and consumer involvement</b>					
Is the CTN membership multidisciplinary? Is there consumer involvement in the CTN? See: <a href="#">Consumer Toolkit</a>					
<b>Comment</b>					
<b>Succession planning for network champions and key leaders</b>					
Is there a documented plan for succession of network champions and key leaders? See: <a href="#">Network Committee Terms of Reference</a>					
<b>Comment</b>					
<b>Building reputation, brand development and maintenance</b>					
Does your CTN have a website					
Does your CTN have a logo?					
<b>Comment</b>					
<b>Advocacy and raising community awareness</b>					
Does your CTN have a fundraising and marketing plan (i.e. A plan that describes fundraising and marketing goals and targets)? (social media). See: <a href="#">Fundraising strategy: guidance for CTNs</a>					
<b>Comment</b>					
<b>Collaboration</b>					
Does your CTN have documented guidelines or MOU for collaboration with parent organisation or external CTNs? (both local and international)					

(i.e. a document covering key considerations and suggested responsibilities when collaborating with another CTN on a clinical trial.)					
<b>Comment</b>					
<b>Maintaining infrastructure and a research workforce</b>					
Does your CTN have an Executive Officer Manager? See: <a href="#">CTN Executive Officer/Network Manager Duties</a>					
Does your CTN have a Network Trial Chief Investigator?					
Does your CTN have Safety Committee Policies and Procedures (i.e. Suggested procedures, considerations and template documents for oversight of CTN clinical trial safety)?					
<b>Comment</b>					
<b>Sustainable source of funding, resource and infrastructure</b>					
Does your CTN have a strategic plan?					
Does your CTN have a long-term Financing plan? See: <a href="#">Options for funding structures</a>					
<b>Comment</b>					
<b>Responsiveness to change</b>					
Does your CTN have a Risk Management plan? (i.e. A plan that allows Identification of serious risks, development of risk mitigation strategies and procedures for effectively management of risks.)					
<b>Comment</b>					