



# ANZCA Clinical Trials Network

## Guidelines for Endorsement

### Version 4.1 December 2018

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#### Purpose

This guideline articulates the expectations of the Australian and New Zealand College of Anaesthetists (ANZCA), including the Faculty of Pain Medicine (FPM), in relation to ANZCA Clinical Trials Network (CTN) endorsement of clinical trials in anaesthesia, perioperative and pain medicine. This guideline pertains to applications made by investigators who are Fellows and trainees of ANZCA or FPM.

#### Introduction

The ANZCA CTN aims to be a world leader in delivering high quality trial evidence that translates into safe and effective practice in anaesthesia, perioperative and pain medicine. A clinical trial is 'any research study that prospectively assigns human participants or groups of human participants to one or more health-related interventions to evaluate the effects on health outcomes' (WHO definition).

The purposes of the ANZCA CTN endorsement process are to:

- promote a high standard of clinical trial design, conduct, analysis and reporting
- increase the competitiveness of grant applications of endorsed clinical trials
- strengthen the brand of the ANZCA CTN and its endorsed clinical trials
- encourage participation in endorsed clinical trials by ANZCA CTN-affiliated sites and investigators
- encourage investigators to use the resources of the CTN office for their clinical trials.

Endorsement of a clinical trial by the ANZCA CTN is a powerful badge of quality, adding to the competitiveness of studies in peer-reviewed grant processes, the acceptability of protocols to ethics committees, investigators and study participants, and the attractiveness of completed projects to journal editors and scientific meeting convenors. A rigorous process is vital to maintaining a high standard of research conducted, and evidence quality obtained from, ANZCA CTN endorsed trials, which promotes both the research track record of the CTN, and the prestige of ANZCA CTN endorsement.

## Body of the guideline

### 1. Types of studies that will be considered

Applications for ANZCA CTN endorsement will be considered for:

- Large multi-centre clinical trials in the field of, or related to, anaesthesia, perioperative and pain medicine, that will involve CTN members and/or the CTN office and resources, to promote the study, source sites and investigators, hold investigator and committee meetings or house a trial manager for the project.
- Single centre or multi-centre feasibility and pilot trials, or other preparatory or observational studies in the field, which are intended to lead to a future ANZCA CTN endorsed large multicentre clinical trial.

Final decisions about the eligibility of an application will be made by the CTN Executive Chair.

### 2. The applicants

Applications should come from ANZCA fellows and/or trainees and affiliated investigators who are closely involved with the planning and conduct of the trial. They will likely be named on the protocol of the trial, be members of the trial committees and/or be named investigators on peer reviewed grant applications. It is recognised that trial governance and titles of roles within the trial governance structure vary. If the role of the applicant is unclear, then the chair of the CTN will decide if the applicant has a sufficiently substantive role in the trial governance.

ANZCA/FPM trainees who apply for CTN endorsement must identify a supervisor among the other investigators who is acceptable to the CTN Executive.

Applications from investigators who are not ANZCA/FPM fellows or trainees will be considered at the discretion of the CTN Executive chair. Suitable applications would be those that foster collaboration between the ANZCA CTN and other trial networks locally and internationally.

### 3. The application

Applications for ANZCA CTN endorsement will be made on the approved application form and include a covering letter explaining why their trial should be considered for endorsement. Submitted applications will be checked by the ANZCA CTN Manager and incomplete applications will be returned to the applicants. Study protocols for ANZCA CTN endorsement will be developed in accordance with ICH GCP Guidelines and include:

- The membership of the trial steering committee and administering institution(s)
- The aims of the study and hypotheses to be tested
- A detailed literature review including references
- A detailed research plan

- The proposed budget
- The funding strategy
- Assessment of study size, power, timeline and feasibility
- Demonstration of in-principle support from participating sites
- Consideration of all relevant ethical issues

#### **4. The review process**

The CTN Executive chair or his/her nominee will identify two individuals to undertake a review of the application, including at least one reviewer who is a member of the CTN Executive. The reviewers will provide a written report that may include questions, comments and/or suggestions for improvement. The turnaround time for the initial review is 20 working days from receipt of a complete application. Applicants are allowed two weeks to respond to the reviewers' reports. The reviewers then provide a written recommendation to the CTN Manager regarding endorsement of the study. In the case of a disagreement between the reviewers, the application will be considered by the full CTN Executive.

Trial investigators seeking CTN endorsement prior to applications for grant funding, ethics approvals or other deadlines, are expected to provide adequate notification of intention to submit, with due consideration of the impact of such things as holiday periods on availability of suitable reviewers prior to submission deadlines. Expedited reviews to meet study-related deadlines may be considered but are not guaranteed. Investigators are strongly advised to seek CTN endorsement before the initial grant application rather than during the grant review process or after the trial has commenced.

If a submission for endorsement is rejected the applicant may seek reconsideration or review of the decision, or appeal the decision, under ANZCA regulations.

#### **5. Presentation at an ANZCA CTN Strategic Research Workshop**

Applicants are strongly encouraged to present their proposal at an ANZCA CTN Strategic Research Workshop. Initial presentation at an early stage of development and re-presentation of refined proposals at subsequent meetings are strongly encouraged. Presenters will be asked to identify their intention to seek endorsement when they submit their abstracts for the Workshop. This will allow the CTN Executive Chair or his/her nominee to identify two reviewers who will be present at the Workshop to take notes that will inform the review process. Presentation at an ANZCA CTN Strategic Research Workshop is not an alternative to a written application.

#### **6. Conditions of endorsement**

The trial steering committee is responsible for obtaining resources and conducting the study in accordance with endorsed protocol and in compliance with ANZCA policy and codes of research conduct (e.g. the Australian Code for the Responsible Conduct of Research produced by the NHMRC), including obtaining approval for the study from a recognised ethics committee.

The CTN Executive will consider the strategic objectives of the CTN and optimal deployment of CTN resources when considering applications for trial endorsement. Considerations of such things as appropriateness of research question and methodology, public interest, and competing priorities among investigators and studies, will be made. The CTN Executive will retain to discretion to endorse or not endorse protocols based on these considerations.

Endorsement of a pilot study does not mean automatic endorsement of a subsequent full study.

Endorsement of a full study does not mean endorsement of subsequent sub-studies and post hoc analyses.

A progress report, in the form of a presentation at the ANZCA CTN Strategic Research Workshop, must be offered annually.

CTN Executive reserves the right to withdraw endorsement at any stage should the study not progress adequately, if it is not being conducted in accordance with these conditions, or if irresolvable conflicts of interest arise.

## **7. Trial publication and authorship considerations**

Results of the primary study must be presented at a CTN or ANZCA scientific meeting, and it is preferred that this is the first presentation outside of the study team.

The authorship for all manuscripts arising from CTN-endorsed clinical trials must conform to one of the following patterns:

- 'The X Study Investigators and the ANZCA Clinical Trials Network' or
- 'Listed investigators, the X Study Investigators and the ANZCA Clinical Trials Network' or
- 'Listed individuals, the X Study Investigators, the X Institution and the ANZCA Clinical Trials Network'

Other arrangements may be acceptable but must be prospectively approved by the CTN Chair. In multi-network studies, sites and investigators affiliated with the ANZCA CTN must be clearly identified.

### **Trial funding considerations:**

Investigators must not indicate in a grant application that the study is endorsed by the CTN unless formal endorsement has been provided in writing by the CTN Executive.

NHMRC funding: Applications for CTN endorsement of trials from investigators intending to apply for NHMRC grants in the next upcoming funding round are required to submit their protocols including core data set plans to the CTN Office prior to the last meeting of the CTN Executive for the calendar year, for consideration by the Executive, or formal endorsement may not be considered prior to funding application deadlines. Late applications under extraordinary circumstances or for funding to be sought outside the NHMRC funding cycle e.g. MRFF calls for submission, will be considered at the discretion of the CTN Chair.

Commercial funding: Financial or in-kind support from commercial entities may be acceptable, but only if the trial steering committee retains complete and enduring scientific independence and ownership of data and intellectual property. This must be established in a contract or agreement with the commercial entity.

The CTN Executive may reconsider endorsement if such contracts and agreements are signed which were not part of the original proposal.

CTN Endorsement for large multicentre trials where substantial grants are being sought from funding bodies will require appropriate financial support for the CTN office in their budget. The level of support should reflect the expected level of involvement of the CTN Office in the trial, which includes support and mentorship for principal investigators, trial managers, and site investigators and coordinators, assistance with Ethics and site governance submissions, site initiation, and access to the CTN mailing list and promotion of the trial throughout the College (e-news, bulletin, ad-hoc reports, promotional material, ANZCA ASM and Research Foundation).

## CHANGE CONTROL REGISTER

Version	Author	Reviewed by	Approved by	Changes
1	T Short	Trials Group Executive	Trials Group Executive	Creation
2	T Short K Leslie	Trials Group Executive	Trials Group Executive	Section A Study endorsement criteria
3	K Leslie	CTN Executive	CTN Executive	Major revision
4.1	P Peyton	CTN Executive	CTN Executive	Major revision

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