Australian Government
Cancer Australia

Supporting Cancer Clinical Trials in Australia - National Principles

Overview

The *Supporting Cancer Clinical Trials Australia – National Principles*, together with the Australian Cancer Plan, provide the strategic framework for Cancer Australia's Support for Cancer Clinical Trials (SCCT) program. The National Principles set out the Australian Government's expectations for Collaborative Cancer Clinical Trials Groups (CTGs) in developing and delivering high quality investigator-initiated and industry-independent cancer clinical trials that address unmet and emerging needs, improve equitable access and participation, strengthen collaboration and consumer involvement, and accelerate the translation of research into practice.

Compliance with the National Principles is a condition of funding under the SCCT program. The CTGs are required to demonstrate how their activities contribute to the objectives of the Plan and uphold the National Principles throughout the grant funding period. CTGs regularly report against a set of agreed core and CTG-specific measures that reflect their contribution to the National Principles and priorities of the Australian Cancer Plan.

This document outlines the intent of the National Principles and expectations for CTGs funded through the 2024-2027 SCCT program funding round.

Contents - National Principles

Principle 1 – National, multi-disciplinary membership

Intent: *To ensure membership is truly national, encourage involvement of members in all states and territories in cancer clinical trials, and add value to clinical trial research by fostering involvement of different disciplinary groups in CTGs.*

The CTGs must be industry-independent national trials groups. Membership of the CTGs must include multi-disciplinary representation and representation from all states and territories, wherever possible. Group members may be from academic or clinical groups. The range of skills possessed by individuals from different disciplines can add value to clinical trial research and Groups should endeavour to engage a range of relevant heath care professionals as members. Disciplines involved in clinical trial research may include surgery, medical oncology, radiation oncology, nursing, pathology, molecular biology, psychology, health economics, biostatistics, palliative care, allied health and quality of life. Group membership should include a mixture of highly experienced members with a strong track record in clinical trials and early and mid-career members who have the potential to contribute to clinical trials research and become leaders in the research community.

Group members will be expected to attend meetings and contribute to the development of clinical trials activities.

Principle 2 – Governance structure and succession planning

Intent: *To have a defined, documented governance structure and to ensure sustainability, encourage leadership and foster growth and knowledge sharing across each Group in an open, accountable and transparent manner.*

Each CTG will have a defined, documented governance structure that is sustainable and effective. The structure of the Group must reflect the functions of the Group and take into account its size and membership. The governance structure could include:

- **Board/Management Advisory Committee** (or equivalent)
  - Chair – with finite terms and a maximum number of consecutive terms.
  - Secretary
  - Treasurer
  - Ordinary Members (representing different disciplines).
- **Scientific Committee (or equivalent)** – to oversee the scientific research activities of the Group including the development of new trial proposals, provision of internal peer review and prioritisation, incorporation of key translational and research questions into active and proposed trials, monitor ongoing trials and establish research priorities.
- **Independent Data Monitoring Committee** (or equivalent – may be a subcommittee of Scientific Committee) - to oversee and guide data collection and assess safety data; to ensure clinical trials are compliant with relevant regulations and guidelines and to provide recommendations on whether to continue, modify or stop a trial. This group may be shared across CTGs.

- **Operational Committee** (or equivalent or Management Advisory Committee for smaller Groups) – to develop and oversee relevant policies, procedures and activities including business and strategic plans, communications strategies and publication activities. This Committee would be responsible for currency of the Group's Standard Operating Procedures (which may be shared between Groups).
- **Consumer participation** on committees is encouraged and each Group should seek to involve consumers in all aspects of its work. The provision of a consumer on each committee or the establishment and maintenance of a Consumer Advisory Committee will facilitate integration of the consumer perspective and involvement in the design and ongoing conduct of trials.

Consumers include patients and potential patients, carers, organisations representing cancer consumer interests, members of the public who are the target audience of cancer prevention programs, and members of the public who believe that they have been exposed to potentially harmful environments, products or services related to cancer.

A process of succession planning for each office bearer should be documented to ensure transparency. Vacancies should be advertised in a manner that ensures that all members have access to and are aware of vacancies within the Group. Office bearers should be appointed though a process of open competition. To encourage regular refreshment of the leadership it is suggested that the positions occupied by office bearers be for a limited term. A period of three years is suggested with the possibility of an extension for three years. At the end of two terms of office, before a member can reapply for a further term in the same position, it is suggested that a significant period should elapse.

Principle 3 – Strategic and business planning

Intent: *To encourage regular planning and review of the strategic focus and business needs of CTGs.*

Each CTG should have a strategic plan, business plan and business continuity plan. Both the strategic and business plans should have a documented process for regular review and updating. Groups may wish to consider a review and update every 2-3 years. The strategic plan should be made publicly available by the Group.

Principle 4 – Data and quality

Intent: *To foster the regular review of clinical trial standard operating procedures and data systems to support the conduct of high-quality trials.*

The CTGs should develop standard operating procedures (SOPs) and update these as required. It is encouraged that the development and updating of the SOPs be a shared process with other CTGs. Groups should develop, implement, update and review their data collection and data management systems and develop, implement and review agreed minimum audit and quality standards.

To ensure the conduct of trials is of the highest quality and enables meaningful evaluation of patient demographics, CTGs are required to collect, at minimum, the following data items for all new protocols initiated by the CTG and recruiting patients:

- postcode of home address,

- year of birth,
- Aboriginal or Torres Strait Islander status, and
- Culturally Linguistic and Diverse (CALD) status.

For some populations, there are distinct issues relating to cancer, for example increased incidence of specific co-morbidities, difficulties in treatment adherence and delays in diagnosis. This information will allow for improved understanding of the study populations and the coverage of clinical trials. Therefore, it is expected patient reporting forms and corresponding databases should incorporate questions that allow the reporting of such data to Cancer Australia. Only aggregate information on remoteness, Aboriginal and Torres Strait Islander and CALD status will be reported from these data in order to protect patient privacy and maintain anonymity.

Principle 5 – Capacity building

Intent: *To increase capacity to undertake cancer clinical trials and increase the number of cancer clinical trials by engaging a wide range of members and sites, and identifying opportunities to acquire funding support.*

Members

The CTGs must develop strategies to increase membership across all disciplines, including a focus on engaging members from regional and rural centres. Actively seeking new collaborating sites for recruitment to ensure coverage in all States and Territories is strongly encouraged. The involvement of research students, post-doctoral researchers, clinical and research fellows or registrars, is strongly encouraged.

Clinical trials

Each Group should develop approaches to increase the Group's capacity to undertake trial development studies, national and international clinical trials, and engage additional sites/units

(including non-metropolitan sites and sites in the private sector) in ongoing or new trials and improve processes for trial activation.

Funding sources

Strategies should be devised to identify and leverage funding from a range of funding sources, and particularly for opportunities to apply for competitive funding. These strategies should be documented in the Strategic Plan.

Principle 6 – Increasing participation in clinical trials

Intent: *To increase participation of people with cancer in clinical trials.*

CTGs should develop strategies to increase participation of people with cancer in clinical trials. In particular, Groups should seek to develop approaches that engage consumers in rural and regional areas, and consumers in other groups or areas where there is low uptake into clinical trials.

Plans and procedures to monitor and potentially increase trial participation among consumers, in particular those from Aboriginal and Torres Strait Islander and culturally and linguistically diverse

backgrounds, should be developed in conjunction with the consumer representatives in other CTGs and Cancer Australia.

CTGs are required to register and regularly update information on the Australian New Zealand Clinical Trials Registry (ANZCTR) or the Australian Cancer Trials website for all trials open to recruitment in Australia. The Australian Cancer Trials website has been designed to provide Australians with consumer-friendly information about current cancer clinical trials, including treatment, supportive care and quality of life studies, in Australia.

Principle 7 – Collaboration and mentoring

Intent: *To encourage collaboration and ongoing peer support between CTGs, and provide support and guidance for new Groups.*

CTGs should establish methods for regularly communicating with their own Group members, and corresponding and liaising with other Groups. Formal links between CTGs are strongly supported and participation of all CTGs in a defined communication strategy is encouraged. Collaboration with, or leadership of, international clinical trials groups to design and undertake industry-independent clinical trials are strongly encouraged.

Principle 8 – Translation into policy and practice

Intent: *To encourage CTGs to include study design elements that facilitate uptake of findings into policy or practice.*

CTGs are encouraged to design trials that will improve health outcomes and can be translated into policy, practice or further research. While Groups are expected to publish the outcomes of clinical trials, it is not expected that the CTGs will manage the entire process of implementation or translation of results into policy and practice. Rather, Groups should design studies in such a way that findings can most easily be translated and will facilitate the translation of trial outcomes.

Principle 9 – Data ownership

Intent: *To address data ownership, timely reporting of trial results and use of data for further activities.*

To ensure timely reporting from clinical trials, CTGs should address timelines and responsibilities for data collection, data analysis and dissemination of fundings when initiating clinical trials. CTGs will make every effort to ensure that they can use clinical trial data for further research, education or other non-commercial purposes.