



Australian Government

Cancer Australia

Supporting Cancer Clinical Trials in Australia Principles Document

Introduction

Cancer Australia is an Australian Government agency established to help reduce the impact of cancer in the community. It provides national leadership to increase coordination of cancer control initiatives and improve outcomes for people affected by cancer.

Cancer Australia collaborates with consumers, health professionals, researchers, cancer organisations, governments and other stakeholders to:

- enhance support, information and participation in decision-making for people affected by cancer;
- improve the quality of cancer care, and support for health professionals; and
- increase coordination and funding of cancer research, and actively support cancer clinical trials.

Background

Through the Support for Cancer Clinical Trials program The Australian Government provides \$5 million per annum to build Australia's capacity to conduct cancer clinical trials. This program is administered through Cancer Australia and currently there are 12 Multi-site, Collaborative National Cancer Clinical Trials Groups supported under this program. They are:

- Australasian Gastro-Intestinal Trials Group;
- Australasian Leukaemia and Lymphoma Group;
- Australasian Lung Cancer Trials Group;
- Australia and New Zealand Melanoma Trials Group;
- Australia New Zealand Gynaecological Oncology Group;
- Australian and New Zealand Children's Haematology and Oncology Group;
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group;
- Australian New Zealand Breast Cancer Trials Group;
- Australian Sarcoma Study Group;
- Cooperative Trials Group for Neuro-oncology;
- Psycho-Oncology Co-operative Research Group;
- Trans-Tasman Radiation Oncology Group; and

Under the *Boost Cancer Research* program, the Australian Government has committed an additional \$5 million per annum through until 2010-2011 for independent clinical trials of drugs and research into cancer treatment. This measure includes options to support the establishment of new Multi-site Collaborative National Cancer Clinical Trials Groups and to provide research grant funding for industry-independent cancer clinical trials*.

Under this program, the Australian Government established the Primary Care Collaborative Cancer Clinical Trials Group.

Objective

The objective of these programs is to build Australia's capacity to conduct cancer clinical trials. It is anticipated that the programs will:

- **increase participation in clinical trials by people affected by cancer and clinical professionals;**
- **increase the number of cancer clinical trials conducted in Australia; and**
- **increase the number of clinical sites actively participating in clinical trials.**

In achieving this program objective Cancer Australia will establish new non-industry based Multi-site Collaborative National Cancer Clinical Trials Groups and support existing Multi-site Collaborative National Cancer Clinical Trials Groups in a way that is efficient, ethical, accountable, transparent and represents value for money.

Cancer Australia will provide funding to Multi-site Collaborative National Cancer Clinical Trials Groups to support the conduct of high-quality, scientifically valid and clinically relevant trials. It is not feasible for Cancer Australia to fully fund large randomised phase-III studies, and trial groups will need to pursue and secure complementary funding sources.

It is therefore intended that these funds will provide the multi-site, collaborative national cancer clinical trials group with the necessary support to apply for competitive research grants for the conduct of specific clinical trials. Funding provided to the multi-site, collaborative national cancer clinical trials groups will be provided to support activities such as trial design and protocol development, salaries of key trials and administrative personnel, education and training for trials personnel, office infrastructure, communications and equipment, relevant IT development and support, and data management frameworks, statistical design and review.

Funding will not be provided for elements associated with trials such as indemnity and insurance costs, legal costs, bank fees, University overheads, clinical service delivery, or infrastructure for clinical services, and time taken to prepare progress/ final reports for Cancer Australia in relation to the grant/ funding agreement. Funding provided through this program must only be expended within Australia. Funding cannot be used to fund overseas sites, international members or industry trials. Australia may be the lead site for international or trans-national trials, especially with New Zealand. Funding from the program may be used to help coordinate such trials providing the money is expended within Australia.

Cancer Australia will also support consumer awareness of, and participation in, cancer clinical trials by providing access to information on current cancer clinical trials for consumers and health professionals.

Guiding principles

The following set of principles forms a guiding framework for the Multi-site Collaborative National Cancer Clinical Trials Groups as they apply for funding from the *Boost Cancer Research* and *Support for Cancer Clinical Trials* programs. It will be a condition of funding that the Multi-site Collaborative National Cancer Clinical Trials Groups demonstrate compliance with these guiding principles. A brief statement of intent accompanies each principle to clarify the purpose of each principle.

- Principle 1 – National, multi-disciplinary membership**
- Principle 2 – Governance structure**
- Principle 3 – Succession planning**
- Principle 4 – Strategic and business planning**
- Principle 5 – Data and quality**
- Principle 6 – Capacity building**
- Principle 7 – Increasing participation in clinical trials**
- Principle 8 – Collaboration and mentoring**
- Principle 9 – Translation into policy and practice**
- Principle 10 – Support services**
- Principle 11 – Evaluation framework**
- Principle 12 – National and international policies and guidelines**
- Principle 13 – Data ownership**
- Principle 14 - Investigator initiated trials**
- Principle 15 – Improvements in health outcomes**

A description of each guiding principle can be found below.

Principle 1 – National, multi-disciplinary membership

Intent: To ensure membership is truly national, encourage involvement of units in all States (and Territories) in cancer clinical trials and to value add to clinical trial research by fostering involvement of different craft groups in the Multi-site Collaborative National Cancer Clinical Trials Group.

The Multi-site Collaborative National Cancer Clinical Trials Groups must be non-industry national cooperative cancer trials groups. Membership of the Multi-site Collaborative National Cancer Clinical Trials Group 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 health care professionals as members of the Multi-site Collaborative National Cancer Clinical Trials Group. 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 experienced members with a strong track record in clinical trials and less experienced 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

Intent: To provide guidance on a governance structure for new groups and existing groups as they are established and develop.

Each Multi-site Collaborative National Cancer Clinical Trials Group will have a defined, documented governance structure. While the exact structure of each group will be determined by the size and membership of that group, it is suggested that all groups have a common basic governance structure. The structure of the group must relate to the functions

of the group and a proposed structure is listed below. Existing/ new structures may include the following elements:

Board/Management Advisory Committee (or equivalent) – to oversee the management and development of the Group

Chair - with finite terms and maximum number of consecutive terms

Chair elect – with finite terms

Secretary

Secretary elect

Treasurer

Treasurer elect

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 Multi-site Collaborative National Cancer Clinical Trials Groups.**

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). Members of this group may include:

Consumer participation on committees is encouraged. While consumer representation on an Operational Committee (or equivalent) is suggested, 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 are defined as patients and potential patients; carers; organisations representing cancer consumer interests; members of the public who are targets of cancer promotion programs; and groups affected in a specific way as a result of cancer policy, treatments or services.

Principle 3 – Succession planning

Intent: To ensure sustainability, encourage leadership and foster growth in the breadth of knowledge across the group in an open, accountable and transparent manner.

A process of succession planning for each office bearer will be documented to ensure transparency. Vacancies will be advertised in a manner that ensures that all members have access to and are aware of vacancies within the group. Office bearers will be appointed through a process of open competition. To encourage leadership it is suggested that the positions occupied by office bearers be of 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, a significant period must elapse.

Principle 4 – Strategic and business planning

Intent: To encourage planning and regular review of strategic focus and business needs of the Multi-site Collaborative National Cancer Clinical Trials Group.

Each Multi-site Collaborative National Cancer Clinical Trials Group will have a strategic plan, business plan and business continuity plan. Both the strategic and business plan will 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 will be made publicly available.

Principle 5 – Data and quality

Intent: To foster the regular review of procedures and data systems to ensure conduct of trials that are of the highest quality.

The Multi-site Collaborative National Cancer Clinical Trials Groups will develop and update, as required, their standard operating procedures. It is encouraged that this be a shared process with other Multi-site Collaborative National Cancer Clinical Trials Groups. Groups will develop, implement, update and review their data collection and data management systems and develop, implement and review agreed minimum audit and quality standards.

Principle 6 – Capacity building

Intent: To increase the ability to undertake and to 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 Multi-site Collaborative National Cancer Clinical Trials Groups must develop a strategy to increase the membership of their groups across all disciplines including a focus on engaging members from regional 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

Approaches should be developed to increase the Group's capacity to undertake trial development studies, national and international clinical trials, engage additional sites/ units (including non-metropolitan 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 especially identifying opportunities to apply for competitive funding.

These strategies should be documented in the Strategic Plan.

Principle 7 – Increasing participation in clinical trials

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

Multi-site Collaborative National Cancer Clinical Trials Groups should develop a strategy to increase participation of people with cancer in clinical trials. In particular, Groups should seek to develop approaches which engage consumers in rural and regional areas, or 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 Cooperative Clinical Trials Groups, other Multi-site Collaborative National Cancer Clinical Trials Groups and Cancer Australia.

Multi-site Collaborative National Cancer Clinical Trials Groups will be encouraged to register trials open to recruitment or follow-up in Australia on the Australian Clinical Trials Registry. The Australian Clinical Trials Registry will link to Cancer Australia's consumer cancer clinical trials portal. The consumer portal is intended to provide consumers with access to information on cancer clinical trials in Australia which are open to recruitment. All phase II and phase III trials open to recruitment in Australia must have information on Cancer Australia's consumer cancer clinical trials portal.

Principle 8 – Collaboration and mentoring

Intent: To encourage collaboration and provide ongoing peer support between all Multi-site Collaborative National Cancer Clinical Trials Groups, and support and guidance for new groups.

Existing Multi-site Collaborative National Cancer Clinical Trials Groups should engage in a process of mentoring new groups. Multi-site Collaborative National Cancer Clinical Trials Groups should also establish methods for regularly communicating with their own group members, and corresponding and liaising with other existing groups. Formal links between Multi-site Collaborative National Cancer Clinical Trials Groups is strongly supported and participation of all Multi-site Collaborative National Cancer Clinical Trials Groups in a defined communication strategy is encouraged. Cancer Australia will work with the Multi-site Collaborative National Cancer Clinical Trials Groups to identify opportunities for developing linkages and process for mentoring new groups and will help facilitate the establishment of effective communication strategies.

Collaboration with, or leadership of, international clinical trials groups to design and undertake clinical trials are strongly encouraged.

Principle 9 - Translation into policy and practice

Intent: To encourage Multi-site Collaborative National Cancer Clinical Trials Groups to include in studies design elements that will facilitate uptake of findings into policy or practice.

Multi-site Collaborative National Cancer Clinical Trials Groups will be encouraged to design trials that will improve health outcomes and can be translated into policy and/or practice. While Groups are expected to publish the outcomes of clinical trials, it is not expected that the Multi-site Collaborative National Cancer Clinical Trials Groups will manage the implementation of translation of results into policy and practice, but rather, groups will design studies in such a way that findings can most easily be translated.

Principle 10 – Support services

Intent: To reduce the duplication in funded activities and achieve best value for money through the provision of centralised support services.

There are economies of scale to be achieved with the centralisation of common support services for groups. In providing a national approach to ensure economic use of public funds and a reduction in the duplication of effort, Cancer Australia will establish:

- A clinical trials development unit incorporating health and pharmaco-economic capacity to provide appropriate support and trial development services including specialist services related to the planning, conduct and analysis of health and pharmaco-economics in all studies. The clinical trials development unit will provide trial development services to all new groups and health and pharmaco-economics services will be available to all new and existing groups.
- A Chair in Cancer Quality of Life (QOL) to assist Multi-site Collaborative National Cancer Clinical Trials Groups to develop QOL protocols and sub-studies, with a particular focus on achieving consistency in the QOL measures and analysis used across trials groups.
- Secretariat support services offering a centralised administration/ secretariat service for new and existing groups to provide support for membership communication including meeting organisation and associated travel.

All new Multi-site Collaborative National Cancer Clinical Trials Groups will be required to use these support services. All existing Multi-site Collaborative National Cancer Clinical Trials Groups will have access to the health economic and pharmaco-economic services and the Chair in Quality of Life. Existing groups will have an opportunity to acquire clinical trial development unit services.

Principle 11 – Evaluation framework

Intent: To provide a common reporting framework by which to measure processes, activities and outcomes funded by the Boost Cancer Research and Support for Cancer Clinical Trials programs.

All funded activities will be underpinned by a strong, transparent evaluation and reporting framework. All Multi-site Collaborative National Cancer Clinical Trials Groups will be required to adhere to *Cancer Australia Evaluation Framework and Performance Criteria*, reporting against identified performance criteria at specified time points.

Multi-site Collaborative National Cancer Clinical Trials Groups are required to comply with the terms and conditions of funding provided by the *Boost Cancer Research and Support for Cancer Clinical Trials* programs. Groups must adhere to research plans and demonstrate financial accountability including identifying specifically how the funds received through the program have been spent.

Principle 12 – National and international policies and guidelines

Intent: To endorse the ethical and accountable conduct of clinical trials by ensuring groups conduct clinical trials in accordance with relevant guidelines and legislation.

Multi-site Collaborative National Cancer Clinical Trials Groups are required to conduct clinical trials in accordance with federal and state legislation, national and international ethical guidelines and relevant legislation including:

- The Declaration of Helsinki (as amended)
- Privacy Act 1988
- National statement of the ethical conduct of human research (2007)
- Joint NHMRC/ AVCC statement and guidelines on research practice (1997)
- Australian Code for the Responsible Conduct of Research
- Note for guidance on good clinical practice (CPMP/ICH/135/95)
- Access to unapproved therapeutic goods in Australia
- Therapeutics Goods Act 1989
- Therapeutics Good Regulations 1990 – medicines regulations
- Therapeutics Good Regulations 2002 – medical devices regulation
- TGA Clinical Trial Exemption Scheme
- TGA Clinical Trial Notification Scheme
- Values and Ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait Islander Health research
- Gene Technology Technical Advisory Committee Guidelines
- Research involving human embryos Act 2002
- Prohibition of cloning Act 2002
- National Occupational Health and Safety Commission Guidelines
- National Code of Practice for the Preparation of Material Safety Data Sets

- Minimum Guidelines for Health registers for Statistical and Research Purposes

Principle 13 – Data ownership

Intent: To guarantee data ownership by Multi-site Collaborative National Cancer Clinical Trials Groups.

To ensure timely reporting of results from clinical trials, clinical trials data should be owned by the research collaborative.

When entering into clinical trials with any partners, including pharmaceutical industry, trial groups should only accept money when:

- Data collection
- Data analysis, and
- Dissemination of findings

lie within the control of the research collaborative .

Principle 14 – Investigator initiated trials

Intent: to encourage the conduct of investigator-initiated clinical trials

Funding from the *Boost Cancer Research* and *Support for Clinical Trials* programs is intended to support the development of investigator-initiated trials. An emphasis on the conduct of non-industry trials by Multi-site Collaborative National Cancer Clinical Trials Groups is a fundamental principle for continued public funding.

Principle 15 – Improvements in health outcomes

Intent: To encourage the conduct of clinical trials that will improve outcomes for people affected by cancer.

It is encouraged that trials undertaken by the Multi-site Collaborative National Cancer Clinical Trials Groups and supported by the *Boost Cancer Research* and *Support for Cancer Clinical Trials* programs will be those whose primary focus is improving potential health outcomes, including registration studies for new agents, new schedules of delivery, dose-finding and multimodality studies. Trials supported through this program will need to be addressing clinically relevant questions. Trials testing therapies which are similar to currently available therapies and which do not ultimately aim to improve health outcomes or demonstrate costs saving will not be supported by funding from the *Boost Cancer Research* or *Support for Cancer Clinical Trials* programs.