



## Australian Government

### Cancer Australia

## Supporting Cancer Clinical Trials in Australia

### Underperformance Policy

#### Introduction

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 Germ Cell 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; and
- Trans-Tasman Radiation Oncology Group.

Under the *Boost Cancer Research* program, the Australian Government has committed \$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 clinical trials.

The objective of the *Boost Cancer Research* and *Support for Clinical Trials* programs (the 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.**

Cancer Australia will establish new non-industry 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 Groups with the necessary support to apply for competitive research grants for the conduct of specific cancer clinical trials.

### **Performance expectations**

Cancer Australia is responsible for the sound management of the public monies provided for the *Boost Cancer Research* and *Support for Cancer Clinical Trials* programs. Public monies are required to be used in a manner which is efficient, effective, ethical, accountable, transparent, and represents value for money.

The Multi-site Collaborative National Cancer Clinical Trials Groups who receive funding through the *Boost Cancer Research* and *Support for Cancer Clinical Trials* programs are expected to perform to high standards through the setting of performance standards and adherence to governing principles (as described in the *Cancer Australia Principles Document*, a part of the Application Package).

### **Minimum Performance Standards**

This document sets out the minimum standards that Multi-site Collaborative National Cancer Clinical Trials Groups funded under the programs must achieve to receive funding from Cancer Australia. The following performance standards will be reviewed against those outlined in the Groups individual Funding Agreement and Schedule.

1. Clinical Trials
  - Number of randomised clinical trials taking into account incidence (cancer specific)*
  - Number of pilot studies*
  - Number of patients recruited to trials*
  - Number of participating institutions*
2. Geographic Availability of Trials
  - Number of clinical trials by State where similar care is available for target population*
3. Multidisciplinary Coverage
  - Evidence of multidisciplinary members in Group*
4. Financial/Reporting Performance
  - Timely receipt of:*
  - Progress reports*
  - Final reports*
  - Financial statements*
  - Requests for information*
5. Development/ capacity building and succession planning of Group
  - As different Groups are at different stages of development, there is no minimum number of trials, patients or sites which Groups must have, but rather, Groups must be able to demonstrate activity in these areas or progress towards achieving activity in these areas. The performance standards link back to the Cancer Australia Evaluation Framework and Performance Criteria and will be assessed on an ongoing basis.*

## **Review and Audit of Performance**

Upon applying for funding from the *Boost Cancer Research* and *Support for Cancer Clinical Trials* programs, Groups will need to demonstrate compliance with performance standards. With regard to financial and reporting performance, past reporting on funding and activities under this measure will be considered.

In March 2009, Cancer Australia will organise a formal review and audit against the minimum performance standards for all of the existing Multi-site Collaborative National Cancer Clinical Trials Groups funded under the programs. This review/audit may include a site visit and will be undertaken by a member of Cancer Australia's Advisory Council and a member of an International cancer research organisation. This review will serve to identify any issues of underperformance.

## **Underperformance Process**

'Underperformance' means failure to meet the performance standards. A Group that is not meeting the minimum performance standards, in the first instance, will be provided with advice in writing from Cancer Australia. Groups will be provided with recommendations on how to improve their performance by an independent review panel. This review panel will consist of the individuals who undertook the initial review/audit and another Multi-site Collaborative National Cancer Clinical Trials Group Chair. The review panel will provide expert advice and assistance to the Group in order to meet the minimum performance standards.

The Group will be given six months to increase their performance to the minimum performance standards or establish processes and activities which will serve to directly improve their performance standards. Progress will be monitored after six months. If after this six month period the Group has not addressed how it will achieve the minimum performance standards, or has not acted to incorporate the recommendations of the independent review panel, the independent review panel will recommend strategies for action to Cancer Australia.

## **Renewed Funding**

Groups that do not meet the minimum performance standards upon application for continued funding may receive provisional funding if funding is renewed. This may have caveats attached that require the Group to meet specific performance standards in a specific timeframe. Ongoing underperformance or failure to address underperformance may influence future funding provided by Cancer Australia under the *Boost Cancer Research* and *Support for Clinical Trials* programs.