



Australian Government

Cancer Australia

Support for Cancer Clinical Trials

DATA COLLECTION FOR SPECIFIC GROUPS

MULTI-SITE COLLABORATIVE NATIONAL CANCER CLINICAL TRIALS GROUPS

Background

The Australian Government, through Cancer Australia, has committed up to \$10 million per annum to support Australia's capacity to conduct industry-independent cancer clinical trials. This support is provided through the *Support for Cancer Clinical Trials* and *Boost Cancer Research* programs. Currently there are 12 multi-site, collaborative national cancer clinical trials groups who receive support through these programs, they include:

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

Additional national groups may be established in the future.

The objective of these programs is to build Australia's capacity to conduct cancer clinical trials by supporting and increasing the number of cancer clinical trials conducted in Australia and increasing participation in clinical trials by cancer patients, clinical professionals and new recruiting sites.

The *Support for Cancer Clinical Trials* program does not support clinical trials per se, but rather provides direct support to the multi-site, collaborative national cancer clinical trials groups to build their capacity to undertake cancer clinical trials - a vital commitment to ensuring the viability of Australian cancer cooperative trials groups.

The *Boost Cancer Research* program supports the establishment of new national Cooperative Cancer Clinical Trials Groups and also will provide grant funding for the conduct of industry-independent cancer clinical trials. Grants will be awarded through Cancer Australia's Priority-driven Collaborative Cancer Research Scheme.

It is a formal requirement that Cancer Australia evaluate and report on these programs. An Evaluation framework and performance criteria have been developed to provide a reporting structure for the national groups assisting them to measure and benchmark their performance across a range of indicators over time.

Regular reporting against these performance indicators will offer a means for Cancer Australia to assess the outcomes and impact of these programs.

One of the measures in the Evaluation framework is the participation of patients from private sector sites, non-metropolitan locations, Aboriginal, Torres Strait Islander and Culturally and Linguistically Diverse backgrounds in cancer clinical trials. While available trial budgets may limit the ability of the groups to conduct all trials at all sites outside of major metropolitan regions, it is important to be able to demonstrate that the funding provided to the national groups under these programs is assisting to increase its reach to these geographic and population groups.

Many of these particular groups have poorer cancer outcomes. For example, although the available evidence suggests that Indigenous Australians from Queensland, Western Australia and South Australia have a slightly lower cancer incidence rate than non-Indigenous Australians in these states, they have a higher rate (1.3 times) of cancer mortality¹. Generally, Indigenous people have a lower survival rate and are more likely to be diagnosed with more advanced cancers than non-Indigenous people, however there are some exceptions².

Clinical trials benefit the community by improving the survival of people affected by cancer, and contribute to a reduction in premature death and disability. They are fundamental to establishing whether new cancer treatments or new ways of using existing therapies, diagnostic tests, preventive or supportive interventions are effective, and they help generate the evidence for best-practice cancer care.

People diagnosed with cancer will benefit from the outcomes of cancer clinical trials through improved therapies in the future and it is important that all population groups have the opportunity to participate in cancer clinical trials.

On 14 November 2007, a meeting was held between Cancer Australia and the Chairs/ Executive Officers of the multi-site, collaborative national cancer clinical trials groups to explore how, and if, these data could be collected for future cancer clinical trials. At this meeting it was agreed that if possible, it is important to collect these data. The difficulties of collecting data relating to participation of privately insured patients was discussed. It was decided that this data on insurance status would not be collected; however, data on the other items could be collected for future trials and a working group would be established to look at this issue in more detail. It was agreed that the Chairs of the national groups and the Executive Officers would be provided with a discussion paper which includes various options for collecting data. The aim is to reach agreement on a minimum data set that can be provided to Cancer Australia as part of the multi-site, collaborative national cancer clinical trials groups reporting requirements.

Aim

To identify and agree on a set of data items that can be collected for all new cancer clinical trials and clinical studies conducted by the multi-site, collaborative national cancer clinical trials groups. These data items will relate to participation of patients in cancer clinical trials by geographic locations, and patients who are from Aboriginal, Torres Strait Islander and Culturally and Linguistically Diverse backgrounds.

This activity does not apply to any international/ global trials in which the national groups participate but may be able to be collected.

Data Definitions

The data definitions are based on those used in the *National Health Data Dictionary Version 12*.

¹ Condon JR, Barnes T, Cunningham J & Armstrong B. Long term trends in cancer mortality for Indigenous Australians in Northern Territory. 2004 Med J Aust 180(10), 504-507.

² Condon JR, Armstrong B, Barnes A, Selva-Nayagam S, Elwood M. Stage at diagnosis and cancer survival of Indigenous and non-Indigenous people in the Northern Territory, 1991-2000. 2005 Med J Aust 182(6), 277-80.

It is recommended that these data could be collected at time of patient entry into a study; the data collected should relate only to the MAIN protocol any given patient is participating in, there is no requirement to report this data for substudies to a main protocol.

Non-metropolitan locations

Data item to be collected: Postcode of usual residence³.

Data type: 4 digit numeric code

Leave Postcode - Australian blank for:

- Any overseas address
- Unknown address
- No fixed address.

Definition: Postcode of usual residence is a four digit numeric code used by Australia Post to define a postal delivery area.

Context: Postcode of usual residence can be used as a means of coding a person's area of usual residence. It can be mapped to Accessibility/Remoteness Index of Australia (ARIA) as ARIA categorises areas according to their distance from "service centres". Service centres are urban centres with a population of 5,000 or more as at the 1996 Census. The ARIA system classifies areas as Highly Accessible, Accessible, Moderately Accessible, Remote and Very Remote as follows:

. *ARIA Remoteness Classifications are:*

- Major cities of Australia – Collectors Districts (CDs) with an average ARIA index value of 0 to 0.2.
- Inner regional Australia– CDs with an average ARIA index value > 0.2 & <2.4.
- Outer regional Australia – CDs with an average ARIA index value >2.4 & <5.92.
- Remote Australia – CDs with an average ARIA index value >5.92 & <10.53.
- Very remote Australia – CDs with an average ARIA index value >10.53.
- Migratory – Areas composed of off–shore, shipping and migratory CDs.

This is consistent to that used in the National Health Data Dictionary by the Australian Institute of Health and Welfare.

This data element can also be used for the calculation of socio–economic status.

Aboriginal and Torres Strait Islander peoples

Data item to be collected: Indigenous status

Datatype: Numeric

1. Aboriginal and/or Torres Strait Islander origin
2. Neither Aboriginal nor Torres Strait Islander origin
9. Not stated/ Unknown

Definition: Indigenous status is a measure of whether a person identifies as being of Aboriginal or Torres Strait Islander origin.

Context: Australia's Aboriginal and Torres Strait Islander peoples occupy a unique place in Australian society and culture. In the current climate of reconciliation, accurate and consistent statistics about Aboriginal and Torres Strait Islander peoples are needed in order to plan, promote and deliver essential services, to monitor changes in wellbeing and to account for government expenditure in this area. The purpose of this data element is to provide information about people who identify as being of Aboriginal or Torres Strait Islander origin and identifying their participation in cancer clinical trials conducted by multi-site, collaborative national cancer clinical trials groups.

This is consistent to that used in the National Health Data Dictionary by the Australian Institute of Health and Welfare.

³ BreastScreen Australia Data Dictionary, Version 1, Updated under the auspices of the National Quality Management Committee, November 2004

Note: There are three components to the Commonwealth definition of indigenous status:

- descent;
- self-identification; and
- community acceptance.

In practice, it is not feasible to collect information on the three sub categories. As such, a person in any one of the three categories would answer '1'.

Culturally and Linguistically Diverse peoples

Data items to be collected: The country in which the person was born and Main language other than English used as the principal means of communication.

Data type: 4 digit numeric code

Standard Australian Classification of Countries 1998 (SACC). Australian Bureau of Statistics Cat. no. 1269.0

Reference through: <http://www.abs.gov.au/Ausstats/abs@.nsf/StatsLibrary>

Select 'ABS classifications'.

Country of birth

Definition: The country in which the person was born (standard international coding systems will be used).

Context: Country of birth is important in the study of access to services by different population sub-groups. Country of birth is the most easily collected and consistently reported of a range of possible data items that may indicate cultural or language diversity.

Main language other than English used as the principal means of communication. (standard international coding systems will be used).

Definition: The language reported by a person as the main language used on a regular basis to communicate.

Context: This data element is important in identifying those people most likely to suffer disadvantage in terms of their ability to access services due to language and/or cultural difficulties. In conjunction with Indigenous status, Proficiency in spoken English and Country of birth, this data element forms the minimum core set of cultural and language indicators recommended by the Australian Bureau of Statistics (ABS).

This is consistent to that used by the Australian Bureau of Statistics (ABS).

Implementation

Cancer Australia and the multi-site, collaborative national cancer clinical trials groups will agree to the data items to be collected and the definitions.

Cancer Australia will provide:

1. A formal list of the data items it wishes to collect including definitions and coding dictionaries.
2. A justification statement that can be used in trial protocols, national ethics applications and patient information sheets to support the collection of this information. These items will be developed in consultation with the multi-site, collaborative national cancer clinical trials groups

Each multi-site, collaborative national cancer clinical trials group and/or Coordinating Centre will then determine how the data will best be collected for all patients at baseline (commencement of participation in the study).

It is recommended that:

- **Groups commence collecting this data for new studies commencing 1 July 2008. However, if groups are able to implement this data collection in currently accruing trials, this approach is encouraged.**
- **Retrospective data collection is not a requirement of Cancer Australia, and, it is at the discretion of individual multi-site, collaborative national cancer clinical trials groups to**

determine whether they wish to or can collect any of the requested data points retrospectively for any of their existing trials. Cancer Australia understands that some data items such as Aboriginal or Torres Strait Islander origin are best collected at the time of recruitment and therefore may not be able to be collected retrospectively.

- **The inclusion of the requested data fields is mandatory for any new trials being commenced by the multi-site, collaborative national cancer clinical trials groups (excluding international trials or those where groups cannot add additional data collection points).**
- Groups incorporate the data points into the study entry or screening Case Report Forms (CRF), either as an integral part or separate page
- Data points be incorporated into the study entry screens for new trials using electronic data capture
- A standard report format be agreed. For example:

Number of trials	Number of Sites	Number of patients recruited	Number of sites in each ARIA category	Number of patients recruited in each ARIA category	Number of indigenous people recruited	Number of people born outside Australia	Number of people speaking language other than English
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- That Groups report this data annually as part of their regular progress reports to Cancer Australia as scheduled in their Funding Agreements.

Next Steps

Upon finalisation of the data collection paper, Cancer Australia will provide a timeline for implementation of the data collection. Cancer Australia acknowledges that many trials pending activation will already have had their CRFs and other data collection tools finalised. However, groups may wish to consider the opportunity of integrating these data items into their data collection tools.