



Cancer Institute NSW

NSW CANCER TRIALS NETWORK

KEY ELEMENTS DOCUMENT

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INDEX

BACKGROUND.....	3
NSW CANCER TRIALS NETWORK.....	3
AIMS OF THE NSW CANCER TRIALS NETWORK.....	3
KEY ELEMENTS OF THE NSW CANCER TRIALS NETWORK	4
1. NSW CANCER TRIALS NETWORK EXECUTIVE COMMITTEE.....	4
Trial Review Committee - Clinical Trial Portfolio.....	4
Site Selection.....	5
2. AREA HEALTH SERVICE NETWORKS.....	5
Management Committee and Clinical Cancer Research Support Program	5
Clinical Research Regulatory Affairs Officers.....	5
Area Health Service Network Trial Portfolio	6
Cancer Trial Nurses and Data Managers	6
Reporting	6
3. KEY PERFORMANCE INDICATORS AND EVALUATION	6
4. CLINICAL TRIALS PARTNERSHIPS	7
NHMRC Clinical Trials Centre (CTC)	7
Kendle Pty Limited.....	8
5. RESEARCH INFRASTRUCTURE GRANTS	8
6. CLINICAL TRIAL MANAGEMENT SOFTWARE.....	8
7. EDUCATION FOR FUNDED POSITIONS.....	9
APPENDIX 1: NSW Cancer Trials Network - Key Elements.....	10
APPENDIX 2: NSW Cancer Trials Network - AHS Network Overview	11
APPENDIX 3: Clinical Trial Activity - Progress Report Template.....	12

BACKGROUND

The NSW Cancer Plan 2007-2010 focuses on programs to strengthen cancer research. This includes the Clinical Trials Program which aims to develop high quality cancer clinical trials in NSW, introduce and study new cancer treatments, increase participation rates in cancer trials and promote a culture of research and innovation in cancer services.

The aim of the NSW Clinical Trials Program is to accelerate the uptake of promising new clinical approaches into practice by providing the evidence of efficacy and improving cancer results through research.

Following a consultative Clinical Trials Workshop conducted in August 2006, it was agreed that the Clinical Trials Program would support the NSW Cancer Trials Network, modelled on the National Cancer Research Network UK.

The NSW Cancer Trials Network has been developed to streamline the conduct of clinical trials across all units within each Area Health Service (AHS), and incorporates all clinical trial positions funded by Cancer Institute NSW research programs. This document provides an overview of the key elements of this Network, and the process for collaboration.

NSW CANCER TRIALS NETWORK

The NSW Cancer Trials Network establishes a formal structure to facilitate clinical trials in cancer throughout NSW and will provide a forum for clinical cancer researchers to exchange ideas and pursue research collaborations. Assistance will be provided to develop trial protocols and accrue patients into a published portfolio of trials.

The key elements of the NSW Cancer Trials Network are detailed on the flowchart which is shown at Appendix 1. All clinical trial units funded through the NSW Cancer Trials Network are required to meet the requirements of the Network model. Clinical Trial Units which are not supported by the Network are not required to participate, however adoption of this model is encouraged for all units undertaking clinical trials in NSW. AHS Networks will be evaluated only on the activities of funded units within their Area.

AIMS OF THE NSW CANCER TRIALS NETWORK

The NSW Cancer Trials Network has the specific aim to make more relevant and robust trials available to cancer patients. This will lead to an increased recruitment of patients into clinical trials.

To achieve this, the program will:

- increase the quality of cancer clinical trials being conducted in NSW;
- increase the number of trials conducted in currently under-represented tumour groups;
- increase the number of patients routinely being offered clinical trial participation in a greater variety of clinical settings;
- increase the timeliness and efficiency of recruitment.

These aims are being achieved through the implementation of various partnerships, grants, collaborations and infrastructure (Shown at Appendix 1). This Cancer Plan 2007-2010 sets the target for the program at 10% of new cancer patients on to clinical trials by 2010. In order to measure the progress of the Network, annual reporting of clinical trial activity will be

performed. This activity will be measured as an increase from baseline data, and annual increases will be reported.

Recruitment levels and efficiencies will be measured by six-monthly reporting of trial activity at each site. Recruitment will be evaluated against Cancer incidence and mortality, by tumour type, which will provide clinical trial recruitment rates compared with the pattern of cancers and their burden of disease.

KEY ELEMENTS OF THE NSW CANCER TRIALS NETWORK

Each of the elements covered by the NSW Cancer Trials Network is discussed in greater detail below. The key elements of the Network are as follows:

1. NSW Cancer Trials Network Executive Committee
 - Trial review committee - Clinical Trial Portfolio
 - Site selection committee
2. Area Health Service Network
 - Management Committee
 - Clinical trial portfolio
 - Cancer Trials Nurses and Data managers
 - Clinical Cancer Research Support Program
 - Reporting
3. Key Performance Indicators (KPIs)
4. Clinical Trials Partnerships
 - NHMRC Clinical Trials Centre (CTC)
 - Kendle Pty Limited
5. Research Infrastructure Grants
6. Clinical Trial Management Software
7. Training

1. NSW CANCER TRIALS NETWORK EXECUTIVE COMMITTEE

The Chairperson of the NSW Cancer Trials Network is Professor Robyn Ward. An Executive Committee is currently being established to guide the implementation of the elements of the NSW Cancer Trials Network (NSW CTN) The NSW CTN Executive Committee will be appointed for a period of 12 months and will be made up of the Chairperson, representatives of The Cancer Council NSW, Directors of Clinical Cancer Research, trial investigators and consumers.

Trial Review Committee - Clinical Trial Portfolio

One of the key new initiatives of the NSW CTN is to develop and endorse a portfolio of cancer clinical trials.

The portfolio will include

- investigator-initiated trials
- NSWOG initiated trials
- trials sponsored by co-operative groups
- trials supported through the Clinical Trials Partnership between the Cancer Institute NSW and NHMRC Clinical Trials Centre,
- Industry sponsored trials

Area Health Service Networks will be autonomous in selecting clinical trials for their Network portfolio. Selection of these trials will be under the auspices the Area Health Service Network management committee, taking into account local pressures and needs and ensuring trials are high quality and feasible within their AHS.

Area Health Service Network portfolios of clinical trials will automatically be included in the NSW CTN portfolio. Clinical trials suitable for multi-centre participation will be appropriately flagged as such.

The NSW CTN Executive will establish a Trial Review Committee for the review of those trials which are put forward for inclusion in the NSW CTN Portfolio by an Area Health Service Network, but which may require additional review at the request of the AHS Network. Terms of Reference and review procedures for this committee will be determined by the NSW CTN Executive Committee.

Area Health Service Networks will be required to participate in trials which are included in the NSW CTN Portfolio. Reporting of clinical trial activity will be against the Clinical Trials listed within the Portfolio.

The establishment of the Clinical Trial Portfolio for the NSW CTN will aid in the development of a NSW cancer trials database. It is anticipated that this database will provide a comprehensive list of the cancer clinical trials conducted in NSW. This database will be made available to Investigators in the first instance in order to gain information on the trials available to patients. It is expected that the database will eventually be made available to patients.

Site Selection

The NSW CTN Executive will establish a Site Selection Committee to review the progress of funded units in line with Key Performance Indicators (refer Section 3) and assess future funding for clinical trial units. It is anticipated that future funding may be assessed at an Area Health Service Network level.

2. AREA HEALTH SERVICE NETWORKS

Funding for clinical trial activity encompasses many roles within each Area Health Service. The NSW Cancer Trials Network is driving collaboration between individual clinical trial units to increase efficiency, increase trial activity and reduce the duplication of workload and effort. As part of this process of collaboration, Area Health Service Networks are being established which will include all key personnel involved in clinical trials within each AHS.

Management Committee and Clinical Cancer Research Support Program

Each Area Health Service Network is headed by the Director of Clinical Cancer Research (supported under the Clinical Cancer Research Support Program). The Director will be Chair of the AHS Network Management Committee consisting of clinical trial investigators, clinical regulatory affairs officers and representatives from the AHS. This committee will develop a strategic plan to improve the quality and quantity of clinical trials across the AHS Network.

Clinical Research Regulatory Affairs Officers

The Clinical Cancer Research Support Program established in January 2007 has provided funding for the appointment of Clinical Research Regulatory Affairs Officers. These positions will have responsibility for the streamlining of the governance processes for each AHS Network to reduce duplication and increase efficiencies in the progress of clinical trials through Ethics and Institutional requirements.

Area Health Service Network Trial Portfolio

Each Area Health Service Network, through its management committee, will streamline clinical trial activity across funded units*, and be responsible for selecting the clinical trials to be undertaken within that Network. The Area Health Service Networks will be autonomous in selecting these clinical trials and will take into account local pressures and needs and ensure trials are high quality and feasible within their AHS.

A Review Criteria Checklist has been developed to assist AHS Networks to determine which trials to undertake. A checklist is included at Appendix 3.

Additional review of trials by the Trials Review Committee will only be required where the inclusion of a specific trial in the NSW CTN Portfolio is requested by the AHS Network.

Cancer Trial Nurses and Data Managers

A major initiative of the Clinical Trials Program under the NSW Cancer Plan 2004-2006 was the establishment of a grant funding scheme for Clinical Trial Nurses and Data Managers. This has been achieved through implementation of the Clinical Trials Nurses and Data Managers Grants and Clinical Trial Units Establishment Grants, which have provided the funding for the placement of 1 FTE nurse or data manager within clinical trial units across NSW.

Currently a total of 49 FTE nurse/data manager positions, supporting 43 individual clinical trial units are being funded. Funding is provided by Cancer Institute NSW and The Cancer Council NSW via the Cancer Trials Nurses and Data Managers Grants. Clinical trial units are provided with funding to employ dedicated clinical trial staff through these grants.

Reporting

All Cancer Trials Nurses and Data Managers will be required to submit progress reports to the Cancer Institute NSW, including a summary of clinical trial activity over the funded period.

Clinical Trial Units receiving funding for the placement of Cancer Trials Nurses and Data Managers under the NSW Cancer Trials Network will be required to provide progress reports on a six-monthly basis, at the unit level. This will mean that clinical trial units receiving funding for multiple positions will only be required to submit a single report detailing the complete clinical trial activity of all staff - those funded under all grant programs as well as staff funded directly by the institution. Reports will be required every six months. A copy of the reporting format is shown at Appendix 2. Summary information on the progress of each unit will be provided to the AHS Network Management Committee following review and assessment.

3. KEY PERFORMANCE INDICATORS AND EVALUATION

The assessment of funded clinical trial units will be conducted in line with the KPIs and targets determined for the NSW Cancer Trials Network. Assessment will be done on a clinical trial unit basis, with each unit requiring only single reporting regardless of the number of positions funded under the Network. Reporting will be delivered at the Area Health Service Network level.

* Funded units - clinical trial units funded by Cancer Institute and/or TCCN

Clinical Trial Progress reports will be reviewed by the Site Selection Committee to assess the impact of funding. This committee will have a membership including representation from the Cancer Institute NSW, The Cancer Council NSW, the Chairperson of the NSW Cancer Trials Network Executive Committee, 2 Clinical Trial Investigators not funded under the grants program (external to NSW) and a consumer. Recommendations made by this committee will be reported back to the NSW Cancer Trials Network Executive Committee.

All Cancer Trial Nurse and Data Manager positions funded under the NSW Cancer Trials Network will be funded on an annual basis. Progress reports will be reviewed 6 monthly, and a summary report of the performance against KPIs and targets will be compiled to show activity at the Area Health Service Network level. Feedback on performance will be provided following review.

Where the performance of a funded clinical trial unit does not meet the required targets, the Principle Investigator of the funded unit, along with the Unit Director will be notified in order to identify recruitment issues, and develop a plan to address these issues. Units not meeting targets will be given a 12 month period to improve clinical trial activity prior to the discontinuation of funding.

The NSW Cancer Trials Network has the specific aims of

- Increasing the quality and quantity of clinical trials conducted in NSW and
- Increasing clinical trials participation to the 10% of new cancer patients by 2010, as set out in the Cancer Plan 2007-2010.

The evaluation of the NSW Cancer Trials Network will be reported by the number of clinical trials conducted, number of patients on trials, types of trials available to cancer patients and their distribution in NSW. This reporting will be against key measurables in line with the NSW Cancer Plan 2007-2010, and mapped by tumour type.

4. CLINICAL TRIALS PARTNERSHIPS

NHMRC Clinical Trials Centre (CTC)

Clinical trial support in NSW has been identified as a key infrastructure requirement for the development of good quality clinical research. The Partnership the NHMRC Clinical Trials Centre (CTC) supports the development of investigator-initiated cancer clinical trials through the provision of operational and statistical support. This Partnership aims to establish and develop new, high quality cancer trials and collaborations in areas which are currently under represented by clinical research. The Partnership will be used to build upon existing expertise, strengths and resources to provide strong links with existing groups and partners.

Clinical trial proposals with the potential to receive support by the Partnership will be initially considered by the Partnership Operational Executive Committee (POEC). This committee comprises of experts from both Partnership participants - the Cancer Institute NSW and the NHMRC Clinical Trials Centre, along with the chair of the NSW Cancer Trials Network.

Clinical Trial proposals for access to the Partnership are encouraged for studies early in their development, requiring support with trial design, protocol development and trial initiation. Proposals for studies in later stages of development may also be considered (eg. trials that are enrolling, nearing completion or ready for analysis). However, the Partnership is focussed on providing support for the development of new trials.

Clinical trial development will be encouraged through investigator collaboration with national co-operative clinical trial groups. Investigator-initiated trials will also be encouraged through collaboration with the tumour specific NSW Oncology Groups (NSWOG). NSWOG members will be provided the opportunity to access the Partnership with the NHMRC CTC to develop clinical trial concepts.

Kendle Pty Limited

The Cancer Institute NSW has established a partnership with Kendle Pty Limited. This partnership aims to develop a high level Quality Assurance Program for the NSW Cancer Trials Network and its affiliated units in NSW. Under this partnership, Kendle will develop generic Standard Operating Procedures (SOPs) which will be trained and implemented across participating cancer trials units across the state, which do not have site specific SOPs.

An audit program will be established to train sites on ICH-GCP requirements, and identify further training needs and process improvements. These audits will be performed against ICH-GCP, site specific SOPs and study specific procedures. The partnership aims to ensure clinical trial activity undertaken in NSW meets the highest international standards. Feedback on issues and training requirements identified by these audits will be provided back to the unit, with a plan for process improvement.

5. RESEARCH INFRASTRUCTURE GRANTS

The Cancer Institute NSW has provided a number of Research Infrastructure Grants directly related to the support of clinical trials. These grants have been provided to national co-operative groups, and are contributing to the development of streamlined processes and programs within these groups.

Clinical trial activity within the groups funded under these grants will be collected to provide a more comprehensive overview of the level of trial activity within NSW. Additional infrastructure grant funding provided for clinical trials will focus on encouraging collaboration within and between groups.

6. CLINICAL TRIAL MANAGEMENT SOFTWARE

The Cancer Institute NSW Research Division is in the process of purchasing and preparing for the implementation of a software solution (InfoEd) to manage the operations of the Clinical Research Ethics Committee and the Population and Health Services Ethics Committee.

With the expanding NSW Cancer Trials Network, the Cancer Institute NSW will also implement a software package for the management of the NSW Cancer Trials Network. This software package will be made available to all clinical trial units funded through the Network for the management of all clinical trial related activity.

Currently Clinical Trials Units are completing retrospective clinical trial activity progress reports on a six monthly basis, collecting data from a number of different sources. The implementation of a software system will allow trial units to record all trial related information in real time which would result in more accurate reporting of patient numbers and trial activity.

A secure, web-based clinical trials management IT platform will be identified, which will provide the following:

- Implementation of a highly advanced system for the collection of clinical trial data
- Access for funded clinical trial units to a system for the management of clinical trial activity, to which they would otherwise not have access
- A single, streamlined clinical trial management system which would replace the different systems currently used within each clinical trial unit

- Real time entry of clinical trial patient data, which would increase the accuracy of the data collected
- An increase in the cross-site consistency of clinical trial data
- Building of a database of the cancer trials which are being conducted in NSW - which will remove the need for a separate Cancer Clinical Trials Register

A working party is being established to clearly define the business requirements for this software. This will ensure clinical trial unit business needs, along with the business needs of the Cancer Institute NSW are clearly defined and can be met by the software selected. The identification of a suitable supplier will be completed mid 2007.

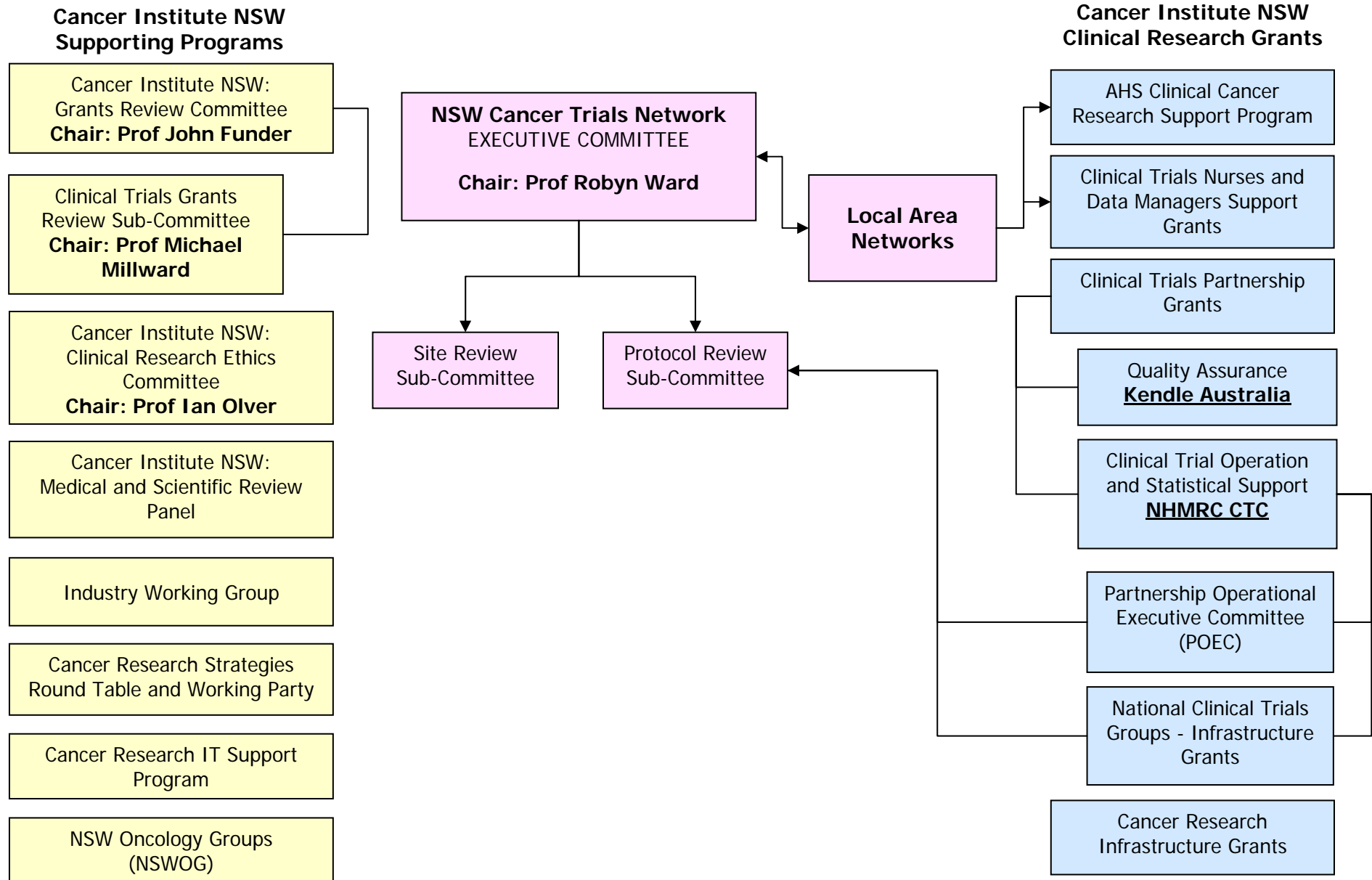
7. EDUCATION FOR FUNDED POSITIONS

The NSW Cancer Trials Network will establish an education program for positions (Cancer Trial Nurses and Data Managers and Clinical Regulatory Affairs Officers) funded by the Network. Education will be conducted on an annual basis, and be available to all funded positions.

The education program will be developed to include all aspects of clinical research from general ICH-CGP requirement through ethics and governance issues, to trial conduct, data quality and analysis.

In addition to clinical research specific issues, general skills such as communication, leadership, patient care and support etc will be covered by the education program. This program will be developed in order to provide professional development for funded positions, and may be used as the basis for the accreditation of clinical trial units. A review of the training and education which has been provided through the Cancer Trials NSW program will be conducted, along with a needs analysis survey of all funded positions.

APPENDIX 1: NSW Cancer Trials Network - Key Elements



APPENDIX 2: NSW Cancer Trials Network - AHS Network Overview

