

# CLINICAL TRIALS PARTNERSHIP (NEW SOUTH WALES)

The Cancer Institute NSW



The NHMRC Clinical Trials Centre



## ACCESS AND OPERATIONAL GUIDELINES FOR PARTNERSHIP ACTIVITIES

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## **INTRODUCTION**

The aim of the Cancer Institute NSW Clinical Trials Program is to increase the number of clinical trials conducted in NSW, the quality of cancer clinical trials and participation in clinical trials by clinical professionals and cancer patients.

Clinical trial support in NSW, such as operational and statistical support, has been identified as a key infrastructure requirement for the development of good quality clinical research. The Cancer Institute NSW has entered into a partnership with the NHMRC Clinical Trials Centre (NHMRC CTC) to provide comprehensive operational and statistical support services for clinical trials in cancer-related research. This partnership is known formally as the Clinical Trials Partnership (referred throughout this document as The Partnership).

This document describes the operational guidelines for access and use of The Partnership support.

## **DEFINITION OF CLINICAL TRIAL SUPPORT**

The clinical trial support will be provided by the Partnership Working Group functioning from within the NHMRC Clinical Trials Centre. This support includes operational services and statistical services.

### ***Operational Services***

Clinical trial operation services supported by the Partnership would include :

- Developing study outlines, protocols, and materials
- Data systems development
- Local monitoring
- Internal quality assurance
- Project management support
- Reporting and publications

### ***Statistical Services***

Clinical trial statistical services will provide the statistical expertise required for clinical trial protocol development and statistical analysis of clinical trial data and outcomes. In addition to the development of clinical trials protocols, the statistical partnership is expected to provide a program aimed at the development of leadership in statistical methods for cancer clinical trials to be achieved.

Activities supported by this partnership would include:

- Developing study outlines, protocols and materials
- Methodological advice
- Selecting the sample
- Randomisation services (in conjunction with the operations service)\*
- Managing the data/analysis (in conjunction with the operations service)\*

\* level of support may be for trial initiation (eg. pilot phase, feasibility study) with additional funding support required for main trial conduct (eg. as part of a NHMRC funded trial, etc)

## **ACCESS OF CLINICAL TRIALS PARTNERSHIP SUPPORT**

The process of accessing Partnership Support for investigator initiated clinical trials and/or development of new collaborative groups undertaken or coordinated in NSW is illustrated in Appendix 2.

### ***Who Can Access the Partnership Support***

Clinical trials supported through the program will include:

1. Clinical trial initiatives developed by the NSWCTN in collaboration with CTC working with individual researcher and/or collaborative groups.
2. Clinical trials initiated by the CTC in partnership with and/or endorsed by NSWCTN.
3. Clinical trials initiated by national and international cancer cooperative groups, coordinated within Australia by the CTC, for trials endorsed by NSWCTN.
4. Clinical trials assessing cancer services in NSW in collaboration with Cancer Institute NSW and NSW Health.

The Partnership will seek to establish and develop new collaborative groups and clinical trials in cancer areas not currently addressed by existing cancer collaborative groups (eg ALTG, genitor-urinary group, trials in palliative care streams). It is anticipated that the NHMRC CTC will use The Partnership to build upon current resources and expertise and will provide strong links with existing cooperative groups and partners.

Where appropriate, clinical trials developed/endorsed by national trials groups will be encouraged to pursue support through the funding of Cancer Institute NSW Infrastructure Grants. This would apply to collaborative groups such as AGITG, ANZBCTG, ANZGOG, etc which have already received infrastructure grant funding (but would not exclude these groups from seeking support in areas not covered by the infrastructure grants, eg. biostatistical support)..

### ***How Do Applicants Apply for Support?***

Access to The Partnership will be by way of referral through the Cancer Institute NSW (via NSWCTN) or the NHMRC CTC. Initial enquiries for support would be handled by the Partnership Working Group, based at the CTC.

The Partnership Working Group is able to assist all applicants to identify whether the proposal falls within the remit of The Partnership. If it is apparent that the research proposal is not suitable, applicants should be referred to another research support system where possible (eg. an established, funded collaborative research group). If the research proposal appears feasible for Partnership support, the Partnership Working Group may provide preliminary assistance in developing the proposal for consideration by the Partnership Operations Committee.

Applicants should note that proposals are particularly encouraged for studies in early development, requiring support for trial design, protocol development and study initiation. While other proposals for studies in later stages may also be considered (eg. trials which are enrolling or nearing completion for enrolment or follow-up), the Partnership support is mainly focussed on developing new trials.

### ***Preliminary Assistance for Application Proposals***

Members of the Partnership Working Group may spend up to eight (8) hours providing preliminary assistance to potential applicants. This includes statistical or operational advice and assistance to write a 'Concept Outline' and application for more support that can be formally considered by The Partnership.

Each initial request for support should be logged by the Partnership Working Committee, together with the preliminary decision (referral to other research support networks or further assistance for Partnership consideration). Time spent by the Partnership Working Group on initial development should be logged.

## CONSIDERATION OF APPLICATIONS

### *Types of Applications*

Applications may request either operational support, statistical support or both. The type(s) of support requested should be clearly identified in the application.

Operational support may include any combination of the following services:

- Trial development, including development of a concept outline, feasibility survey , protocol, CRFs, budget, and grant application, etc
- Operational support in full or in part (for example, randomisation services only) or,
- Operational conduct of the clinical trial including:
  - Pilot phase support
  - Study coordination
  - Data collection and management
  - Ongoing statistical support
  - Monitoring
  - Compliance with national and ICH GCP guidelines

Statistical support may include any one of the following services:

- Statistical review of a completed protocol leading to a report with recommendations
- Statistical development of an early proposal that may lead to a completed protocol with continued collaboration between the Investigator and the statistician.

### ***Partnership Operational Executive Committee***

Clinical trial proposals that could potentially be supported 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.

*Preliminary/Inaugural Membership of the Partnership Operational Executive Committee*

*Chair : Chair or assigned delegate from the NSW Cancer Trials Network*

*CI members : Carmel Edwards (assigned delegate - Jim Bishop)*

*CTC members : Martin Stockler (assigned delegate – John Simes)*

*Partnership staff : Peta Forder (Statistician), Alison Pearce (Operations)*

The Partnership Operational Executive Committee will meet regularly to consider all new proposals and review the progress of on-going work. It would be anticipated that this would occur approximately fortnightly, subject to the provision of new proposals.

In reviewing and approving a request for support through The Partnership, the committee will:

- Ensure the methods are scientifically sound and appropriate.
- Advise on the allocation of resources for approved protocols, in consultation with NHMRC CTC.
- Consider the level of support by the appropriate NSW Oncology Group, new cooperative group/s.
- Consider consistency with the state cancer research priorities.

### ***Approval from the Cancer Institute NSW (Category A Support)***

The POEC will review submissions for either operational and/or statistical support for Category A support (trials initiated by new investigator/new collaborative groups undertaken/coordinated within NSW). Those studies deemed suitable for Partnership support will be recommended to the Cancer Institute NSW for formal endorsement. Within the Cancer Institute NSW, the recommended proposals will be considered by the NSW Cancer Trials Network (NSWCTN). Final approval to access the services provided by The Partnership will be the responsibility of the NSWCTN.

Applicants will be informed, in writing, of the decision by the Cancer Institute NSW, through the NSWCTN. If endorsement is given, a letter confirming support of the trial will be sent to the applicant(s), along with an approval letter to the CTC to commence operational and/or statistical support.

Other applications may be reviewed internally by the CTC to determine whether they are suitable for Category B support (develop current resources and strengthen trial expertise within existing cooperative groups and partners). The decision on these proposals would be made internally within the CTC and is not subject to NSWCTN endorsement.

## **REPORTING AND REVIEW OF PARTNERSHIP SUPPORT ACTIVITIES**

As the funding body for The Partnership grant, the Cancer Institute will receive regular reports about the activities undertaken for the Partnership. A report outlining the resources allocated, timelines and outcomes will be provided to the Cancer Institute NSW as required by The Partnership agreement. The report will be forwarded to the NSWCTN keeping its members informed about how resources are being used for The Partnership and reminding them of its availability to support new trials.

## LIST OF APPENDICES

### Appendix 1 – Glossary of Abbreviations

AGITG	Australian Gastro-Intestinal Trials Group
ALTG	Australian Lung Trials Group
ANZBCTG	Australian and New Zealand Breast Cancer Trials Group
ANZGOG	Australian and New Zealand Gynaecological Oncology Group
CI	Cancer Institute NSW
CTC	Clinical Trials Centre
ICH GCP	International Conference on Harmonisation – Good Clinical Practice (E6)
NHMRC	National Health and Medical Research Council
NSWCTN	New South Wales Cancer Trials Network (division within the Cancer Institute NSW)
POEC	Partnership Operational Executive Committee
PWG	Partnership Working Group

