RESEARCH REPORT 2011

NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

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The NHMRC Clinical Trials Centre (CTC) at the University of Sydney runs large multicentre investigator-initiated clinical trials, takes part in trials of national and international collaborative trial groups and contributes expertise to trials run by others. It also:

- takes a lead in proposing new directions for trial research in Australia, particularly with regard to integrating clinical trials with national policy and clinical practice
- leads, coordinates and participates in national and international research collaborations
- undertakes methodological research in relation to clinical trials and biostatistics
- reviews and synthesises evidence from completed trials, and is at the forefront of developments in methods, such as prospective meta-analysis
- advises on trial design and operation, and randomises patients and analyses data for other groups conducting trials
- offers postgraduate supervision in all of these areas
- offers a postgraduate program in clinical trials research by distance education
- runs short courses in the design and conduct of clinical trials as part of its undertaking to train people for Australian medical research

Core funding is provided by the National Health and Medical Research Council (NHMRC), and specific projects are funded by government, public and private institutions and the pharmaceutical industry.

The CTC is at two sites in Camperdown in inner Sydney — the Medical Foundation Building on Parramatta Road and on Mallett Street.

This report covers the CTC’s achievements for 2011.
CTC executive

CTC operations and research are led by the Executive: John Simes, director; Tony Keech, deputy director; Wendy Hague, clinical trials program director; and Kim Russell-Cooper, general manager.

Professor John Simes is the foundation director of the CTC and represents the CTC on many national and international committees. He has for many years championed the need for evidence-based clinical research.

Professor Anthony Keech is Professor of Medicine, Cardiology and Epidemiology at the University of Sydney. He is chairman of the international FIELD study on heart disease and diabetes and directs the CTC’s research program.

Dr Wendy Hague is primarily responsible for the successful conduct of the CTC’s large-scale, multicentre clinical trials and ensuring that trials systems, procedures and methods are of the highest standard.

Kim Russell-Cooper works with the CTC executive, managers and research staff to improve the business process in the areas of clinical trial research governance, risk assessment, financial planning, management and reporting.

Directors’ report

For more than 20 years now, the Clinical Trials Centre has been working to improve health outcomes, practice and policy through clinical trials research. Broadly, our activities include undertaking trials, trial methodology, evaluating and combining evidence, coordinating and planning translational studies, and clinical trials education and training.

The outstanding success of our research effort has been built on working effectively with national and international collaborative groups, networks and partners.

In 2011, the CTC and its collaborators at the Boden Institute of Obesity, Nutrition, Exercise and Eating Disorders (BIONE) and Macquarie University were awarded a five-year program grant from the NHMRC, to start in 2013. Significantly, this reflects our view of the importance of methodological research and also that our core work goes beyond the CTC and extends our reach to a broader picture of diabetes that includes obesity. These synergistic collaborations will foster growth and development in each area.

Integrating expertise from BIONE and CTC will help us to establish new clinical trials addressing important questions, particularly in obesity, and the metabolic aspects of diabetes and cardiovascular diseases. The joint initiatives will result in shared intellectual understanding of the diseases and the clinical trials process and its outcomes.

Collaboration and integration are key components underpinning our whole research program.

Modern clinical research projects rely increasingly on contributions from people with various skills, knowledge and perspectives, and work at the CTC is consistent with the worldwide trend. In 2011, over 90% of our publications involved cooperation with other organisations, and 30% of the author groups were multinational.

Our research collaborations, which include groupings within the CTC, across Australia and internationally, lead to better coordination of research projects, leverage the different contributions of experts in various fields of research and thus maximise the research effort. The exchange of ideas and the combined intellectual input of people working on a common cause also leads to new research questions and solutions.

Our trials are investigator initiated; that is, they arise from the experience of patients or their doctors perceiving a need for more evidence about particular treatments. Transforming a good idea into a completed trial is a group effort. The CTC takes leading roles to various degrees at various stages, from concept development through trial design, acquiring funding, trial conduct, data analysis, and publication of results.

For example, cancer clinical research in Australia relies on investigators across the country who conceive, initiate and conduct trials in areas of need. We work closely with eight Australian cancer cooperative trial groups. These, in turn, have working relationships with 14 international cancer groups. They currently have nearly 50 trials in recruitment or in follow-up, with many more in development.
2011 was notable for new evidence on neonatal therapies. The INIS trial showed that intravenous immunoglobulin used with antibiotics for neonatal infection did not have benefits. There had been uncertainty about whether this therapy was effective. The new findings will allow hospitals to avoid an expensive treatment. The MAPPiNO international meta-analysis showed that, despite some earlier positive evidence, nitric oxide did not improve lung function in premature infants. Interestingly, both of these studies showed that a new treatment did not work, but this knowledge is just as important to clinical practice as a positive result would be.

In the work we do with others, trials are central, but we now look to the full range of the clinical research pathway, ‘from bench to bedside’. In 2011, we played a part in a significant development for cancer research in NSW—the founding of Sydney Catalyst, which we expect will pave the way for new and exciting developments in oncology. Directed by John Simes, Sydney Catalyst brings together outstanding teams of researchers and clinicians from leading NSW institutions with the ability to undertake the full spectrum of cancer research from basic science to implementing evidence in practice. The secretariat is based at the CTC.

Translating the evidence from clinical trials into better practice is a major focus of the CTC. We evaluate the evidence, combine the evidence in systematic reviews, and translate the evidence into guidelines and protocols, with the aim of improving health in Australia and elsewhere. The ANZ Clinical Trials Registry, based at the CTC, which lists current trials in Australia, New Zealand and elsewhere, is an important link in the process. It is one of the primary international trials registries, whose records can be accessed by anyone. The ANZCTR is helping improve the efficiency and value of clinical trials research undertaken in Australia by enabling researchers and policy makers to identify potential gaps where more research is needed. The trial registry is also alerting patients and their doctors to available trials, easing their access to the best treatment and improving participation in trials.

At the CTC, we aim to share our knowledge. 2011 was the first year of our new postgraduate course in clinical trials research at the University of Sydney. It was developed in response to a need for formal qualifications in this area, and is equipping students to design and lead clinical trials. Australian and overseas aspiring trialists have shown considerable interest in the course, with 23 people enrolling in its inaugural year. The blueprint for the course and its implementation evolved out of the long experience of the CTC in all aspects of trials, particularly methodology, and the Biostatistics Collaboration of Australia in delivering successful postgraduate education by distance means.

Our plans for the future include continuing our efforts to make clinical trials an integral part of routine health care. We will also maintain and build our global collaborative ties with other research networks, universities, government, and industry, to answer important clinical questions in new therapy areas. These plans are on track, thanks to the efforts of our staff, our collaborating investigators and our funders from government, nongovernment organisations and industry.
Not just trials but the full spectrum of research: laboratory, clinical and implementation

Traditionally, laboratory discoveries, such as new drugs, have been developed through human clinical trials, accumulation of evidence, clinical guidelines, and then implementation in clinical practice, a serial operation that has been estimated to take up to 20 years. The CTC, in conducting trials of new treatments, has been at the centre of this process, but increasingly, in its translational research, has been part of efforts to condense the gap between a new treatment and its eventual use to improve patients’ survival and quality of life.

Translational research aims to make medical research findings usable and applicable to patients with minimal delay, by integrating the traditional stages of research in a single program. The CTC’s translational research projects integrate laboratory and clinical research or explore ways of applying evidence-based medicine, recommendations or guidelines to clinical practice. In 2011, the CTC and its collaborators continued to develop and conduct translational programs in the CTC’s main areas of expertise: cardiovascular disease and cancer.

Most CTC trials now include an option for patients to consent to their biological samples (such as tissue and blood) being used in research. Biomarkers detected in these biological samples are studied for their potential utility, for example, as a diagnostic test for a disease. They are also used as markers that predict response to treatment or susceptibility to side-effects, a step on the way to personalising treatments for individual patients. This information may also be used to assess the eligibility of patients for new trials.

Biospecimens are stored in biobanks for the future, because knowledge and technology are developing rapidly, and new research ideas may come about during the course of a trial running over several years.

In oncology, Sydney Catalyst: the Translational Cancer Research Centre of Central Sydney and Regional NSW (p. 6) is a major initiative for New South Wales. The CTC is contributing to its program.

A collaboration comprising researchers from the University of Queensland, the Peter MacCallum Cancer Centre, the Garvan Institute and the CTC were awarded an NHMRC Project Grant to embark on GAP-T, a study of bioimaging and molecular biomarkers to guide treatment of patients receiving preoperative chemotherapy for pancreas cancer.

Two new research institutions joined the EVERSUN trial (p. 12) in blood biomarker studies of renal-cell cancer patients: the Kolling Institute at the University of Sydney and the Australian Prostate Cancer Research Centre based at the Institute of Health and Biomedical Innovation, Queensland University of Technology.
The LIPID Australasian collaboration extended in biomarker studies

The LIPID study was the first major multicentre clinical trial conducted by the CTC. It was one of the largest clinical trials undertaken in Australia, involving over 9000 patients from 87 hospitals in Australia and New Zealand, and a team of biostatisticians, trial coordinators and data managers at the CTC.

The finding from LIPID that the study drug, pravastatin, significantly reduced prespecified cardiovascular events and mortality led to new Australian and international guidelines.

Now, 15 years after the close of the trial, patients are still being followed up for long-term effects of their trial treatment via questionnaires collecting data on their medication for cardiovascular disease and their smoking and diabetes status. Data are available for about 95% of the surviving cohort. Trial researchers have also obtained data from linkage with death and cancer registers, and for a subset of patients, from hospital admission data.

The LIPID investigators had the foresight to obtain consent from patients for their blood to be used in future analysis. Blood collections were repeated at intervals over the course of the trial. These samples are now providing important new biological data which can be related to individual risk of cardiovascular events and the effects of pravastatin treatment on risk. The original group of investigators has expanded to include scientists in Germany, where blood samples have been analysed for biomarkers for cardiovascular disease.

The collaboration now focuses on relating levels and changes of various blood components to trial outcomes. This involves work by the laboratory scientists and local biostatisticians, who have developed new models of risk and prediction.

Preliminary results of these studies were presented at the meeting of the American Heart Association in November. It was found that adding some biomarker levels (brain natriuretic protein, cystatin C, D-dimer and troponin I) to a conventional risk model significantly improved the estimation of the risk of a recurrent heart attack. Patients above the top quartile of risk were identified as priority candidates for more intensive treatment.

LIPID STUDY GROUP

Professor Andrew Tonkin, Monash University, Melbourne (chair)
Professor Stefan Blankenberg, University Heart Centre, Hamburg
Associate Professor David Colquhoun, Greenslopes Hospital, Brisbane
Professor Paul Glasziou, Bond University, Gold Coast
Dr Wendy Hague, CTC
Dr David Hunt, Melbourne
Professor Anthony Keech, CTC
Ms Adrienne Kirby, CTC
Professor Paul Nestel, Baker IDI, Melbourne
Professor John Simes, CTC
Associate Professor David Sullivan, Royal Prince Alfred Hospital, Sydney
Professor Peter Thompson, Sir Charles Gairdner Hospital, Perth
Professor Malcolm West, University of Queensland
Professor Harvey White, Auckland City Hospital
WHO’S WHO AT SYDNEY CATALYST

SCIENTIFIC ADVISORY COMMITTEE

Professor John Simes, program director
Professor Michael Boyer (medical director, Chris O’Brien Lifehouse, Royal Prince Alfred Hospital)
Professor Mathew Vadas (executive director, Centenary Institute of Cancer Medicine & Cell Biology, University of Sydney)
Professor Rob Sutherland (director, Kinghorn Cancer Centre, Garvan Institute of Medical Research)
Professor Mathew Vadas (executive director, Centenary Institute of Cancer Medicine & Cell Biology, University of Sydney)
Professor Rob Sutherland (director, Kinghorn Cancer Centre, Garvan Institute of Medical Research)
Professor Phyllis Butow (director, Centre for Medical Psychology and Evidence-based Decision-making (CeMPEd), University of Sydney)
Scientific Advisory Committee, 2011

GOVERNING COUNCIL MEMBERS

Professor Andrew Biankin (head, Pancreatic Cancer Research, Garvan Institute of Medical Research)
Professor Jane Young (Cancer Epidemiology, School of Public Health, University of Sydney)
Associate Professor Martin Stockler, (Oncology program co-director,)
Dr Sonia Yip (senior translational research fellow, Sydney Catalyst)
Mr John Newsom (Cancer Voices Australia)

Sydney Catalyst: a CTC collaboration

In 2011, Sydney Catalyst: the Translational Cancer Research Centre of Central Sydney and Regional NSW was established with funding from the Cancer Institute NSW. The CTC is one of the collaborators in this program, and Professor John Simes, CTC director, is to be responsible for its leadership and direction.

In Australia, many millions of dollars, and worldwide, billions, are spent on cancer research. Usually, many years pass before laboratory discoveries reach clinical practice. Novel therapies must be tested in various phases of clinical trials and the results integrated into evidence that can be used in treatment guidelines and adopted by clinicians.

Translating new knowledge into improved outcomes quickly requires cooperation and collaboration among many people and institutions with specialised expertise.

Sydney Catalyst is a consortium covering the full spectrum of cancer research and clinical practice: basic biosciences, molecular biomarker discovery, descriptive research, clinical trials, psychosocial research and implementation research of best evidence-based care into practice. It brings together outstanding teams of researchers and clinicians with the aim of improving cancer health outcomes for people affected by cancer. It exists as a virtual centre,

The inaugural Sydney Catalyst planning meeting for members at the University of Sydney in October
Connecting researchers from a range of different disciplines and groups to work together to achieve specific objectives and goals. The consortium aims to ensure that discoveries are rapidly implemented into evidence-based practice.

The research falls into two areas, theme 1 (T1) and theme 2 (T2):

T1: developing therapeutic strategies using patient and cancer biomarkers and linking the biosciences, clinical trials and individualised care.

T2: increasing the use of evidence-based care in practice, for example, by building more effective models for providing effective cancer care and closing the gap between the evidence and practice.

Specific goals for the near future are to:

• build partnerships and facilitate and increase collaboration.
• develop and undertake major research initiatives across the spectrum of cancer research, including laboratory research, clinical research and implementation research.
• increase expertise, career development and research capacity through professional development and educational opportunities for both clinicians and researchers.

The consortium has established the governance and organisational structure needed to help support members to achieve its goals.

John Simes, director, and Danielle Miller, research manager, Sydney Catalyst

MEMBER GROUPS AND HOSPITALS, 2011

Asbestos Diseases Research Institute (ADRI)
ANZAC Research Institute (includes Dendritic Cell Biology and Therapeutics Group)
Bathurst Base Hospital
Cancer researchers from University of Sydney (includes Cancer Epidemiology and Services Research group (CESR), Cancer Nursing Research Unit (based at SCC), the Centre for Medical Psychology & Evidence-based Decision-making (CeMPED), NHMRC Clinical Trials Centre, Surgical Outcomes Research Centre (SOuRCe), Institute of Medical Physics (School of Physics))
Canterbury Hospital
Centenary Institute
Coffs Harbour Base Hospital
Concord Repatriation General Hospital
Cunningham Centre for Palliative Care, St. Vincent’s Hospital
Dubbo Base Hospital
Melanoma Institute Australia
North Coast Cancer Institute, Coffs Harbour Hospital
Orange Hospital
Royal Prince Alfred (RPA) Hospital
St. Vincent’s Hospital (includes the Sacred Heart Hospice)
Sydney Cancer Centre/the Chris O’Brien Lifehouse at RPA (includes Department of Radiation Oncology)
The Kinghorn Cancer Centre, Garvan Institute
Wagga Wagga Base Hospital

INVESTIGATOR GROUPS

Current collaborating partner groups include: AGITG, ALTG, ANZBCTG, ANZGOG, ANZUP, COGNO, PC4, and PoCoG
Unlocking genetic factors predicting type 2 diabetes complications

Diabetes and its complications have been linked to various genes through genome-wide association studies over the past decade.

New CTC research is identifying genetic contributions to the complications of diabetes; these include heart disease, stroke, eye disease and kidney disease. Another research question is whether genetic ageing is accelerated by diabetes.

Scientists are analysing single-nucleotide polymorphisms (SNPs) from targeted areas on the chromosomes of control subjects without diabetes and 5000 patients from the completed FIELD trial (p. 16). Biostatisticians at the CTC will use the eventually very large dataset to analyse the genetic patterns in relation to diabetes risk and complications and to resolve other questions about diabetes. The answers may be a step in the process of personalising clinical medicine.

Patients in the FIELD trial provided blood samples and gave consent for their blood to be used in scientific studies to benefit future diabetes patients. The blood has been stored for analysis at the FIELD study laboratories in Sydney and Adelaide.

A large project like this demands the skill and knowledge of a diverse group of people. Professor Tony Keech from the CTC is chairing the group, just as he has chaired the FIELD trial over the past 10 years. Other members of the team have expertise in the biochemical basis of diabetes, atherosclerosis, genetics and diabetes, and the relationships among diabetes, chromosomes and ageing.
Clinical trials in oncology: they need Australia-wide networks of people with diverse but complementary skills

Because many research questions relate to relatively rare events, high-quality trials require large numbers of participants, recruited from many hospital centres. In Australia, multicentre trials in oncology are made possible by national networks of investigators, each specialising in a tumour site or system. These investigators propose research questions, explore the feasibility of answering each research question with a trial, and then develop the concept into a trial.

Members of these collaborative groups represent the disciplines involved in clinical research and treatment, including statisticians, data managers, research nurses, trial coordinators, medical oncologists, surgeons, radiation oncologists, scientists and pathologists. Each project needs the expertise of many people through the process of protocol development, funding, ethics approval, site selection, recruitment, data collection, analysis and publication.

Most of the recent advances in cancer care in Australia can be attributed to collaborative group trials. Recognition of this has resulted in national efforts to build the capacity of the groups, to develop common infrastructure and to improve the efficiency of their activities, mainly with funds from Cancer Australia and the Cancer Institute NSW.

The CTC works collaboratively as sponsor, coordinating centre or supporting consultant with five of these specialised oncology research groups:

- Australasian Gastro-Intestinal Trials Group (AGITG)
- Australia New Zealand Gynaecological Oncology Group (ANZGOG)
- Australasian Lung Cancer Trials Group (ALTG)
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
- Cooperative Trials Group for Neuro-Oncology (COGNO)

and the Royal Australasian College of Surgeons.

The CTC also provides randomisation and statistical support to the Australia & New Zealand Breast Cancer Trials Group (ANZ BCTG) and trial concept development support to the Primary Care Cooperative Cancer Clinical Trials Group (PC4).

CTC collaboration with the Royal Australasian College of Surgeons in trials of treatment early breast cancer

The Sentinel Node versus Axillary Clearance (SNAC) trial was the first, large, Australasian prospective assessment of the risk of lymphoedema after surgery for early breast cancer. The trial compared sentinel node biopsy of selected lymph nodes with clearance of axillary nodes in women with tumours smaller than 3 cm. Short-term results showed that arm swelling was less in the group having only sentinel node biopsy. Both treatment groups had moderate limitations in arm movement over the first 6 months, which then recovered to near normal levels. The results showed that for women with small tumours, sentinel node biopsy was a viable alternative to axillary clearance. The patients are being followed up so that long-term effects can be measured. Outcomes at 3 years will shortly be published.

In SNAC 2, the investigators are recruiting women with large or multiple tumours in a more extensive trial with similar questions, which will allow any differences in subgroups of women to be analysed.
Gynaecological cancer trials in Australia

The Australia New Zealand Gynaecological Oncology Group (ANZGOG), a network of investigators, supports collaborative research to improve outcomes for women with gynaecological tumours, that is, all cancers involving the female reproductive system. The CTC ANZGOG team collaborates with ANZGOG in developing new concepts into functioning trials and obtaining funding. Together they encourage clinicians and researchers to participate and publish results widely. Nine trials are recruiting or in follow-up and more are in development.

ANZGOG was formed in 2000 and soon after that allied itself with the Gynecological Oncology Group (GOG) in the United States and also became a member of the Gynecological Cancer Intergroup (GCIG).

OUTBACK CERVIX CANCER TRIAL

Outback is a flagship study for ANZGOG. It is investigating the effect of adding further chemotherapy to standard chemoradiation for patients with high-risk cervix cancer. This is widely acknowledged to be the most important unanswered question in cervix cancer treatment. The concept was first proposed by Associate Professor Linda Mileshkin at the 2008 Annual Scientific Meeting. She has championed the concept ever since and, with the efforts of the team at the CTC, has secured funding from the National Cancer Institute to support the participation of GOG and another US cooperative group, RTOG, so that American patients can join the trial.

Linda Mileshkin, chair of the Outback study

Thirteen sites in Australia-New Zealand and 15 in the US have now been activated.

CERVIX CANCER RESEARCH NETWORK

Outback is also the first study for the Cervix Cancer Research Network, which aims to help institutions in developing countries participate in high-quality academic clinical trials. Dr Julie Martyn, ANZGOG manager, has conducted site visits in India and Thailand to assess their capacity to participate in trials such as Outback.
The Australasian Gastro-Intestinal Trials Group is a not-for-profit company that facilitates clinical trial research into cancers of the oesophagus, stomach, liver, gall bladder, pancreas and bowel. Members can propose new concepts for trials, which may then be developed by the group in collaboration with the CTC, the coordinating and statistical centre for the AGITG since its inception in 1991. Over 20 years, the collaboration has produced 51 peer-reviewed journal articles and over 100 conference presentations.

The CTC collaborates with various international cooperative groups, allowing patients from the Australasian region to participate in clinical trials of international significance. These include the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), the European Organisation for Research and Treatment of Cancer (EORTC), European Study Group for Pancreatic Cancer (ESPAC), Oxford Clinical Trials Office, Oxford University (OCTO), Pan-European Trials in Alimentary Tract Cancer (PETACC), the UK Medical Research Council (MRC), Cancer Clinical Trials Unit Scotland (CACTUS), Groupe Coopérateur Multidisciplinaire en Oncologie (GERCOR), the Trans-Tasman Radiation Oncology Group (TROG), and in the United States, the Eastern Cooperative Oncology Group (ECOG) and the National Surgical Adjuvant Breast and Bowel Project (NSABP).

The trials are not commercially driven and aim to improve the treatment of people with gastrointestinal cancers. In 2011, work from the AGITG and CTC, with their collaborators, generated new results from ABC, C07, C0.17, Da VINCI, ESPAC3, G0FURTGO, IG9401, MAX, and SCOT trials.
Urogenital cancers (ANZUP trials)

Research in urogenital and prostate cancers is carried out in collaboration with the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). ANZUP was formed in 2008 by amalgamation of the Australian and New Zealand Germ Cell Trials Group and the Australian Prostate and Urogenital Cancer Group.

ANZUP aims to minimise the effect of prostate and other urogenital cancers on the community in terms of survival, incidence and quality of life, through research and education and by providing patients and carers with support.

In 2011, the group presented results at international oncology conferences, for Accelerated BEP, a study of the feasibility and tolerability of a dose-dense treatment regimen for germ cell cancer, and EVERSUN, a trial of the effect of alternating two drugs: one an anti-angiogenic therapy, the other an anti-mTOR targeted therapy (sunitinib or everolimus) in patients with renal cell cancer.

Lung cancer (ALTG trials)

Lung cancer is a common cancer with a poor prognosis, making it the leading cause of cancer death in both men and women in Australia. It has been listed by the Australian Government as a disease causing a significant burden in terms of morbidity, mortality and health care costs.

The CTC undertakes trials in lung cancer in collaboration with the Australasian Lung Cancer Trials Group (ALTG), a multidisciplinary organisation dedicated to reducing the incidence, morbidity and mortality of lung and thoracic cancer and improving the quality of life of lung and thoracic cancer patients in Australia and New Zealand. The group has several trials near completion, in progress and in development. In 2011, the group presented results from the Maintenance Thalidomide in Mesothelioma (MATES) trial, a collaboration with Dutch investigators which examined the effect on survival of adding thalidomide to maintenance chemotherapy. These preliminary results showed that thalidomide treatment was safe, but survival was not significantly longer. Secondary studies on patient preferences and survival estimation arising from ALTG trials were also presented.

Tumours of the brain and nervous system (COGNO trials)

The CTC is a partner in the trials of the Cooperative Trials Group for Neuro-Oncology (COGNO), an Australian organisation concerned with clinical trials to improve outcomes for people affected by brain tumours. Members are researchers and clinicians involved in various disciplines that touch on this area.

Trials can be evaluations of current therapies, new treatments or supportive interventions for brain tumours. Beyond the trials, the group aims to promote integrated laboratory substudies, and also to engage members of the medical and scientific community who might participate in the research process. The group is currently conducting a major
Brain cancers are not common; only 7 in 100,000 people in Australia are diagnosed with a brain tumour each year, but the emotional and economic burden for patients and their families is great. The average person-years of life lost has been estimated at 12 years per patient, much higher than the 3 years average for all cancers.

About half of the brain tumours diagnosed in Australia are glioblastoma multiforme, an aggressive disease which is resistant to most chemotherapy. Radiotherapy plus a period of temozolomide chemotherapy results in some improvement in survival, but the blood-brain barrier is an obstacle to delivery of the drug to the tumour. Better treatment for this cancer is keenly sought.

COGNO researchers conducted a phase 2 trial adding pegylated liposomal doxorubicin (PLD) to the standard treatment. Doxorubicin is known to kill glioma cells, and its formulation as PLD allows it to cross the blood-brain barrier relatively effectively. In this trial, survival did not increase significantly, although the trial showed that the combination of the two chemotherapy drugs was well tolerated by patients.

*Ananda et al. Journal of Clinical Neuroscience*

Contribution to an international study and two locally developed trials. In 2011, its trial of doxorubicin added to temozolomide for glioblastoma multiforme was completed and results published.

COGNO was formed in 2007 and is now firmly established and flourishing. Each year, a national scientific meeting has given members the opportunity to plan, to propose new research questions, and to learn about current research.

In 2011, COGNO received two important grants from Cancer Australia, one to fund the group and the other for its CATNON study.
**Highlights of published research**

**PREDICTION AND PROGNOSIS**

**Can CA-125 predict response to treatment?**

Cancer antigen 125 (CA-125), is an indicator of tumour activity. When patients are being treated with chemotherapy for ovarian cancer, if the level of CA-125 goes down, the doctor may assume that the chemotherapy is having an effect. However, some have questioned whether early changes in the level of CA-125 in response to chemotherapy predict the patient’s condition several months down the track. This was tested in a study done by the CALYPSO international trial group, based on statistical analysis led by CTC researchers. They found that the level of CA-125 was not a good predictor of the effect of treatment and recommended that doctors should not rely on this as an indication for ceasing treatment.

The CALYPSO trial was a Gynecologic Cancer InterGroup trial, led by GINECO in France, with participating researchers Belgium, Italy, Germany, Denmark, and Australia and New Zealand (ANZGOG). This secondary study was published in the *Journal of the National Cancer Institute*.

**Prognostic nomograms for ovarian cancer and breast cancer**

Patients with advanced ovarian cancer are varied, and it has been difficult to predict their progression-free survival time. A tool that predicts the effect of platinum-based chemotherapy in individual patients has been developed and validated (see http://roconline.ctc.usyd.edu.au). It is a step toward improving information about prognosis for patients and will be useful for stratifying patients for future clinical trials. The analysis used data from the CALYPSO trial.

Breast cancer patients are similarly mixed with respect to their characteristics, their tumours and their survival times. A study used data from three large Australian and New Zealand trials as a starting point for a statistical model for breast cancer prognosis. It has the potential to improve predictions of survival and decisions about treatment for patients undergoing anthracycline chemotherapy. The nomogram derived from the model is available online at http://advancedonline.ctc.usyd.edu.au.

**Side-effects of chemotherapy can predict individual progression-free survival**

CALYPSO study researchers hypothesised that leucopenia and sensory neuropathy, common toxic side-effects of paclitaxel chemotherapy, would reflect susceptibility to the treatment, and therefore patients with these side-effects would also survive longer without recurrence of their disease. This indeed happened during the trial: development of neuropathy and increasing severity of leucopenia were each associated with longer survival in patients whose treatment included paclitaxel. An implication of these findings is that dosages of chemotherapy might be personalised for individual patients on the basis of toxic effects early in the treatment regimen.

**NEW RESULTS FROM THE MAX COLORECTAL CANCER STUDY**

The MAX study, an AGITG- and CTC-initiated international trial completed and published in 2010, showed that adding bevacizumab to capecitabine therapy improved progression-free survival of patients with advanced colorectal cancer. A recent detailed analysis of data from the subgroup of patients aged 75 years or over, published in *Annals of Oncology*, has found that the combination of bevacizumab and capecitabine is a safe, convenient and effective regimen for older patients. Older people are often not included in clinical trials, so their representation in MAX has resulted in useful evidence. A separate analysis, also published in *Annals of Oncology*, confirmed that bevacizumab treatment is associated with a modest increase in the risk of arterial thromboembolism. Further substudies, on quality of life and psychological issues, are in progress.
Patients differ in their response to biological agents such as bevacizumab, depending on the genetic status of their tumours. The MAX trialists have been examining the effect of the mutation status of genes in predicting survival and response to treatment. A study published in the Journal of Clinical Oncology showed that KRAS and BRAF gene mutation status did not affect the patients’ response to treatment, but that BRAF gene mutation status was prognostic for survival. Additional analyses on patients’ tissue samples and linkage of their results with trial results are ongoing.

DAVINCI TRIAL

The DaVINCI trial was a comparison of single-agent (irinotecan) and combination (irinotecan and 5-fluorouracil) chemotherapy treatments for recurring advanced colorectal cancer. Rates of progression-free survival and overall survival slightly favoured the combination treatment. Patients on combination treatment fared better in terms of side-effects. However, there is still a place for the single-agent treatment for some patients, depending on their vulnerability to certain side-effects and their preferences. Full results were published in the European Journal of Cancer.

AWARD FOR CANCER RESEARCH

Belinda Kiely, medical oncology research fellow, received a Young Investigator Award from the Conquer Cancer Foundation of the American Society of Clinical Oncology for her project, ‘Evaluating an iTool to estimate and explain survival time scenarios to people with advanced cancer’.

Belinda and her colleagues developed a web-based tool (iTool) to help cancer specialists describe three scenarios for survival time based on the estimated median survival for a group of similar patients. This is an extension of her work more generally in prognosis, prediction and communication in advanced cancers, especially in breast cancer.

OESOPHAGEAL CANCER META-ANALYSIS CONFIRMS THE BENEFITS OF TREATMENT BEFORE OPERATION

Oesophageal carcinoma is treated with surgery, usually, but not always, preceded by chemotherapy or chemoradiotherapy. A meta-analysis published in The Lancet assessed whether these treatments increased perioperative mortality and compared the benefits of chemotherapy and chemoradiotherapy. Patients who had one of these treatments before surgery had significantly longer survival than those having surgery alone. The benefit of chemoradiotherapy was slightly greater than that for chemotherapy alone.
FIELD data answering clinical questions about diabetes and heart disease

The FIELD (Fenofibrate Intervention and Event Lowering in Diabetes) trial investigated the use of fenofibrate to modify blood lipids and reduce the risk of coronary heart disease in people with type 2 diabetes. FIELD was an international collaboration among investigators from Australia, New Zealand and Finland, and enrolled 9795 patients. The main results were published in 2005, but the immense FIELD dataset is still being analysed to answer questions about diabetes and cardiovascular disease.

For example, a substudy published in 2011 by Sullivan and the FIELD investigators examined the relationships between the type of glucose-controlling medication diabetes patients were taking when they enrolled in the FIELD study, their subsequent cardiovascular risk and how this was related to their lipid-modifying treatment with fenofibrate. The study showed apparent differences in the risk of cardiovascular events associated with oral hypoglycemics but they were largely abolished by adjustment for the severity of diabetes and patients’ risk factors.

Patients with the metabolic syndrome—generally high blood pressure, a large waist, low HDL (good) cholesterol and high triglycerides—are more likely to develop diabetes and in addition may have a higher risk of cardiovascular events. The FIELD investigators analysed data from FIELD and showed that people with diabetes who did not have the metabolic syndrome had a lower risk of cardiovascular events, but that high blood pressure or a combination of low HDL cholesterol with high triglycerides led to a higher risk. The findings were published in Cardiovascular Diabetology.

Follow-up of patients in FIELD continues, and, as well, blood samples from patients are now being analysed in a major new genetic and molecular studies program (p. 8).
New findings from neonatal trials

Collaboration is more than formal agreements within trials and projects. Cooperation among different groups across countries and across trials improves the efficiency of trials research and aids trialists in their decision making, ultimately to deliver the best evidence of treatments for patients.

In neonatal research, international cooperation among research groups is a way of overcoming two obstacles, first, that most neonatal risk is associated with prematurity and less than 1% of all births in developed countries are very premature, and, second, that treatment effects may be subtle. Individual trials, with close cooperation among the trial groups, together with planned prospective meta-analysis of the data, are features of the CTC’s neonatal research.

**BOOST II: oxygen levels for premature babies**

An example is the BOOST-II trial, whose objective is to determine the best level of blood oxygen to aim for in very premature infants to prevent later disability. The precise optimal level of oxygen is still not known. BOOST II is one of several recent trials comparing a higher range of blood oxygen saturation level (91–95%) with a lower range (85–89%).

Investigators for the Australasian and UK BOOST II trials were faced with the need for unexpected decisions and changes after the announcement of results from a similar trial, SUPPORT, in the United States showed slightly higher mortality in the group of babies on the lower level of oxygen saturation. At the time, three trials, in Australia, Canada and the UK, were continuing, using a new software algorithm associated with improved targeting and greater separation in saturations between randomised groups, which closely resembles algorithms used in many oximeters globally. After separate reviews of each trial, the data monitoring committees independently found no reason to discontinue recruitment. Subsequently a joint safety analysis of mortality at 36 weeks gestation was undertaken by the UK and the combined Australian and New Zealand data monitoring committees by pooling their trials with SUPPORT. The high target showed significant increased survival to 36 weeks gestation in all infants and in a subgroup of infants enrolled after introduction of the revised software. As a result, both trials closed recruitment. However, follow-up of all infants is continuing and a full follow-up will provide evidence on the effects of the oxygen saturation on disability and death at 2 years. Substantive reports of hospital outcomes will also follow. Until longer-term survival and disability are known, it is considered prudent not to target the lower range in infants born before 28 weeks gestation. The two BOOST II data monitoring committees have asked that this advice be widely and rapidly disseminated. This advice does not represent a standard of care, and may change when the primary outcomes of disability-free survival are reported in all NeOProM trials (p. 18), by 2014.
neoPRom InteRnAtIonAl CoLLAboRAtIon on oxygen foR bAbIeS

A prospective meta-analysis of all five neonatal oxygen targeting trials, totalling approximately 5000 patients, is planned. The trialists will share individual-patient data in a formal association called the NeOProM Collaboration. Using such fine-grained data, rather than simply aggregating the results of the trials, improves the power of the analysis and extends its scope for detailed subgroup analyses. The protocol for this project has been published (Askie et al. in BMC Pediatrics), and results are expected after completion of all member trials, in 2014.

INIS trial’s new evidence will spare sick babies an unnecessary treatment

Newborns are deficient in endogenous immunoglobulin and so may be relatively unable to fight infection. Neonatal infection may lead to subsequent infection, various disabilities and possibly death. Adding immunoglobulin to their antibiotics had been shown in meta-analyses of various prior trials to reduce these risks, but the trials were small and their quality varied. To test this question, the International Neonatal Immunotherapy Study (INIS) enrolled 3493 infants with neonatal infection (1398 in Australia or New Zealand) from 9 countries, who were randomly assigned to receive infusions of either immunoglobulin or matching placebo.

Despite the earlier evidence, the immunoglobulin infusions were not effective. After 2 years, the rates of disability, death and adverse events were the same in the two randomised groups. Immunoglobulin is expensive, being obtained from human donors, and is administered by intravenous infusion, so this therapy is not without risk. The evidence from this large, well-designed and conducted trial will allow hospitals, doctors, and their patients to avoid unnecessary treatment.

The trial completed follow-up in 2010 and the results were published in the New England Journal of Medicine in 2011.

Could lactoferrin prevent anaemia, prematurity and neonatal sepsis?

In October, a workshop for 50 participants from India and Australia was held at the Postgraduate Institute for Medical Education and Research, Chandigarh, India, to examine the evidence for lactoferrin—a low cost anti-inflammatory, antioxidant, antimicrobial and iron-containing dairy protein—in the prevention of iron-deficiency anaemia in pregnancy and prevention of sepsis in newborn infants at high risk. The workshop was jointly funded by the Australia India Strategic Research Fund and the Indian Department of Biotechnology. As a result of the information shared, applications are planned for multicentre randomised trials to address these important questions.
Clinical trial operations

One of the advantages the CTC brings to clinical trial operations is its three central cross-trial teams, in data management, site management and quality assurance. These are the horizontal functions in a matrix management structure. Together, these expert teams ensure that systems and processes are harmonised across all the CTC’s trials and bring efficiency and operational excellence to all the varied trials coordinated by the CTC.

Phillipa Smith and Karen Wilkinson, quality assurance specialists, ensure and promote the high quality of the CTC’s trials, through development of standard operating procedures, training, and central and on-site audit programs.

Michelle Cummins, Mark Maclean and Salma Fahridin, from the clinical data management team (Liam Murphy not shown). The data management group facilitates optimum data quality and accuracy for each study through developing and maintaining standards and systems.

Rebecca Mister, head of site management, ensures that the CTC has common processes across all trials with respect to ethics and regulatory applications, site feasibility, intervention logistics, and central and on-site monitoring.
Postgraduate course in clinical trials up and running

In 2011, the CTC launched its postgraduate course in clinical trials research offered by Sydney Medical School at the University of Sydney, and 23 students enrolled.

The course responds to a need for formal qualifications among doctors, researchers, health care professionals, study coordinators and others working in clinical research.

Students will complete the course with a solid understanding of research methods, clinical trials literature and the clinical trials process, including design, protocol development, doses of treatment, and statistical and ethical considerations.

Students have the option of obtaining a masters degree, a graduate certificate or graduate diploma or studying individual units. All teaching is online, including lectures, tutorials, discussion forums and supplementary notes, so geography is no barrier to enrolment.

Dr Mateya Trinkaus, a medical oncologist from Toronto, is a student in the Master of Clinical Trials course. Mateya says: ‘This course in clinical trials research has complemented my clinical training and will consolidate my experience in research, allowing me to lead the design and conduct of trials in the future.’

BCA graduate, Dr Robin Turner

‘The masters provided training in the application of statistics to public health and epidemiological research and broadened the statistics skills I had gained during my PhD. I found the courses to be well designed and enjoyed being taught by leaders in the field across a range of universities. ‘I am now a research fellow in Biostatistics in the Screening and Test Evaluation Program at the Sydney School of Public Health. The skills learnt during the masters have been essential to my ongoing research and career.’

Postgraduate courses in biostatistics

The Biostatistics Collaboration of Australia’s postgraduate coursework program is serving the need for qualified biostatisticians in Australia and elsewhere. The program is run by a consortium of Australian universities and administered from the CTC’s premises.

www.bca.edu.au
Methodology: research and biostatistics outreach

Macquarie University and CTC have now formally joined forces and obtained funding to build a cutting-edge methodological research program. This will leverage the expertise of both teams of biostatisticians and enable the group to undertake more ambitious projects.

The CTC biostatisticians undertake methodological research to advance the design and conduct of clinical trials, particularly in methods of analysis of repeated measures and time-to-event outcomes with competing risks, systematic review methods, methods for combining quality-of-life outcomes with efficacy measures and combining evidence using prospective meta-analysis.

As well, responsibility for sound design and data analysis in the CTC’s trials generally falls to the biostatisticians, who work in collaboration with clinicians and others to maintain the high quality of this research. This expertise means that triallists working with the CTC are reassured that optimal study designs and state-of-the-art analysis methods underpin their research.

In 2011, members of the biostatistics group were co-authors on over 50 journal articles and 70 peer-reviewed conference presentations.

Statistical predictions of risk

Computational methods in epidemiology

Statistical modelling to assess the risk of clinical events is an important area of epidemiology. Models are used to identify individuals at risk and to guide interventions for reducing risk. Some risk factors are additive, but some are multiplicative, making the calculations complex. Biostatisticians at the CTC and Macquarie University have developed a model accounting for this complexity based on stratified additive Poisson regression. The model was applied to heart attacks in a large clinical trial. Results were published in Computational Statistics and Data Analysis.

Early spread of endometrial cancer

In the LACE trial, a method of multiple cross-validation analysis was used to find a level of the cancer biomarker, CA-125, that would predict early spread of endometrial cancer. A cut-off level of 30 U/mL identified a group of patients with an increased risk. Patients with high CA-125 thus appear to have a one in three risk that the cancer has spread, but if the CA-125 is normal, the chance that the endometrial cancer is limited to the uterus is over 85%. CA-125 measurement may be a useful investigation in comprehensive surgical staging in the management of apparent early-stage endometrial cancer.
Collaboration between the University of Sydney and the University of Amsterdam on evaluation of medical tests

Clinical trials are designed to measure treatment effects, but they also provide valuable information to improve our understanding of the biology and natural history of disease. CTC epidemiologists Sally Lord and Lukas Staub explore how trial data can be used to improve the classification of disease to guide treatment decisions. This work has important implications for medical testing.

Their recent study was done in collaboration with world leaders in the field of medical test research, Professor Les Irwig from the Screening and Test Evaluation Program (STEP), School of Public Health, University of Sydney, and Professor Patrick Bossuyt from the Biomarker and Test Evaluation (BiTE) research program at the University of Amsterdam. They published a paper in the BMJ which explains how information from clinical trials can be used to improve the design and interpretation of test accuracy studies.

When a test is used to guide treatment decisions, studies measuring its accuracy in distinguishing trial-defined classifications of disease will provide clinicians with more relevant information than traditional measures of test accuracy for detecting the presence of all disease.

Development and evaluation of medical tests to guide personalised treatment decisions is a challenging new field that requires the integration of clinical trials research, medical test research, clinical expertise, and patient and community values. The advantage of this collaborative effort is to be able to share ideas, perspectives and skills with leading researchers working in complementary fields.

A new test is worthwhile if it detects diseases that will benefit from treatment (reprinted from BMJ, with permission)

Reviews of new procedures and technologies considered for public funding

In Australia, new medical procedures and technologies are funded by the taxpayer on the basis of evidence that they are safe, effective and cost-effective. Decisions are made by the Minister for Health and Ageing, advised by the Medical Services Advisory Committee (MSAC).

A team at the CTC takes part in systematically reviewing the evidence for some of these new procedures and preparing reports for the committee. The evaluators are supported by an expert advisory group comprising clinical experts nominated by the department, and MSAC representatives. MSAC makes a recommendation to the Minister on the basis of the report.

The Department of Health and Ageing recently committed to a new open, transparent and integrated system guiding how Medicare funding decisions are made. This system requires decision analytic protocols that define the decision options or questions that agreement to fund will be based on. The evaluation team at the CTC was active throughout 2011 in developing and completing such protocols across a wide range of technologies. Clinical experts are nominated by the department and the evaluation team consult widely with these experts during the development of each protocol.
Cochrane Collaboration

The Cochrane Collaboration is an international organisation of more than 28,000 health care professionals, practising physicians, researchers and consumers.

The collaboration aims to provide high-quality information about the effectiveness of health care interventions. They search for research evidence, formally appraise it and publish the results as Cochrane (systematic) reviews. The CTC is the home of: 1. the Cochrane Breast Cancer Review Group, which coordinates, edits and facilitates the publication of breast cancer reviews; and 2. the Prospective Meta-Analysis Methods Group, an expert group for methodological development and advice.

Interest in undertaking Cochrane reviews is generated at the annual Cochrane Colloquia, through networks of editors and authors, and through the Cochrane Centres.

When a topic in breast cancer is accepted, the CTC’s Cochrane group works with the author team by helping to flesh out their initial proposal and providing specialised advice (such as clinical, statistical and consumer contributions) at the conceptualisation phase and at protocol and review stages. New Cochrane topics registered with the group reflect the diversity of authors: they are from many countries including Austria, Brazil, Canada, China, Italy and the UK. Recently appointed editors have come from the UK, USA and Italy.

Depending on their knowledge and experience, some author groups may require more support than others. One aim of the team at the CTC is to help new authors gain the appropriate skill set in developing Cochrane reviews so that they are interested in continuing with other Cochrane projects, and in general, building up the levels of expertise.

In 2011, the Cochrane Breast Cancer Group facilitated the publication of 7 protocols, 2 reviews, 3 review updates and 4 amended reviews for the Cochrane Library and received input from the Cochrane Methods Group.

The Cochrane Breast Cancer Review Group contributed to publication of this review on breast cancer treatment in 2011.
ANZCTR: a national resource

The Australian New Zealand Clinical Trials Registry (ANZCTR), administered from the CTC, is a public, searchable online database that provides information on trials being conducted in Australia, New Zealand and some other countries. The average number of trials registered each year has increased steadily since 2006; now 6065 trials are registered.

The ANZCTR, together with other international trials registries, ensures that all relevant evidence can be accessed in determining best practice in health care. The ANZCTR can also help improve the efficiency and value of clinical trials research undertaken in Australia by helping improve trial participation and planning new trials in priority areas.

The ANZCTR is also a resource for research to underpin policy decisions. For example, a study by researchers from the University of Sydney (including the CTC) published in the *Medical Journal of Australia* showed that in 2009, there was significant variation in the number of trials according to the type of cancer, with some cancers being underrepresented relative to their burden of disease; for example, 7% of cancer trials were in lung cancer, even though lung cancer, of all cancers, is responsible for the greatest burden of disease.
Health economics is an important aspect of today’s clinical research

In a tight fiscal environment, it is vital that we capture the financial costs and benefits of implementing new medical treatments. These costs and benefits may go beyond those in the health care system. There are often impacts on areas such as productivity, the costs of providing care, and flow-on costs to the tax and welfare systems. Taking a cross-portfolio approach by including these societal costs leads to more-complete assessments and thus more efficient allocation of resources in the health system.

The health economics team, with their national collaborators, are developing large-scale microsimulation models to analyse national productivity losses and the associated economic impacts of chronic conditions leading to early retirement. They are providing critical evidence about the cross-system influences of health interventions.

In collaboration with NATSEM (University of Canberra) and the Sydney School of Public Health (University of Sydney), the health economics group pioneered the development of Health&WealthMOD, a microsimulation model of the economic effects of premature retirement due to illness and their costs for individuals and government (funded by an Australian Research Council linkage grant with Pfizer Australia as an industry partner). This work has placed Australia at the forefront of this emerging field, which is fundamental to ensuring that health-care funding is sustainable, families have adequate income and labour force participation is maximised.

The University of Queensland has joined the collaboration (funded by another ARC linkage grant with Pfizer Australia) to extend the work to a new microsimulation model for projecting economic impacts up to the year 2030. This model captures important trends, such as the rapid rise in the prevalence of diabetes. The findings from these studies have been published in highly regarded journals including the British Journal of Psychiatry, Pain, the International Journal of Cardiology and Spine.

Whether publicly or privately funded, advances in health care must be shown to be affordable as well as effective. Economic evaluations are an important aspect of assessments of new treatments and technologies, including the CTC’s trials and systematic reviews of evidence. The CTC relies on its health economics team to establish whether effective new treatments are also value for money.
The CTC works with organisations around the world in collaborations that lead to better health outcomes in Australia and internationally. New collaborations are continually sought and then consolidated in research projects benefiting the health of Australians and others.

### Collaborations

<table>
<thead>
<tr>
<th>GROUP</th>
<th>NATURE OF GROUP</th>
<th>CTC ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australasian Gastro-Intestinal Trials Group (AGITG)</td>
<td>Collaborative group for gastrointestinal cancer trials: Australia, New Zealand</td>
<td>Coordinating centre</td>
</tr>
<tr>
<td></td>
<td>International collaborations: Cancer Clinical Trials Unit Scotland (CACTUS), Eastern Cooperative Oncology Group (ECOG), European Organisation for Research and Treatment of Cancer (EORTC), European Study Group for Pancreatic Cancer (ESPAC), Group Coopérateur Multidisciplinaire en Oncologie (GERCOP), National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), National Surgical Adjuvant Breast and Bowel Project (NSABP), Medical Research Council (MRC), Oxford Clinical Trials Office, Oxford University (OCTO), Pan-European Trials in Alimentary Tract Cancer (PETACC)</td>
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<td>Australasian Lung Cancer Trials Group (ALTG)</td>
<td>Collaborative group for lung cancer trials: Australia, New Zealand</td>
<td>Coordinating centre</td>
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<td>International collaborations: NVALT (Netherlands), NCIC CTG (Canada)</td>
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<tr>
<td>Australasian Society of Thrombosis and Haemostasis</td>
<td>Professional group undertaking thrombosis trials: Australia, New Zealand</td>
<td>Coordinating centre</td>
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<tr>
<td>Australia New Zealand Gynaecological Oncology Group (ANZGOG)</td>
<td>Collaborative group for gynaecological cancer trials: Australia, New Zealand</td>
<td>Coordinating centre</td>
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<td>International collaborations: Dutch Gynaecologic Oncology Group (DGO), Group d’Investigateurs Nationaux pour l’Étude des Cancers Ovaïriens (GINECO), Gynecological Cancer Intergroup (GCIG), International Gynaecological Cancer Intergroup (IGCI), Gynecologic Oncology Group (GOG), Medical Research Council (MRC), Scottish Gynaecologic Cancer Trials Group (SGCTG)</td>
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<td>Australian and New Zealand Urogenital and Prostate Clinical Trials Group (ANZUP)</td>
<td>Collaborative group for cancer of the genitourinary system: Australia, New Zealand</td>
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<td>International collaborations: Cancer Research UK (CRUK), European Organisation for Research and Treatment of Cancer (EORTC), Group Coopérateur Multidisciplinaire en Oncologie (GERCOP), Institute of Cancer Research (ICR), National Cancer Research Institute (NCRI), Swedish &amp; Norwegian Testicular Cancer Project (SWEnOTeca), and Wales Cancer Trials Unit (WCTU)</td>
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<td>Australian New Zealand Clinical Trials Registry (ANZCTR)</td>
<td>National register of clinical trials: Australia, New Zealand and international</td>
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<td>Biostatistics Collaboration of Australia</td>
<td>Universities undertaking postgraduate education in biostatistics: Australia</td>
<td>Coordinating centre</td>
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<td>Cholesterol Treatment Trialists’ Collaboration (CTTC)</td>
<td>Investigators of cholesterol treatment trials: Australia, New Zealand, United Kingdom, United States, Italy</td>
<td>Coordination of meta-analyses in heart disease</td>
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<td>Clinical Trial Development Unit (CTDU)</td>
<td>Partnership with the Centre for Biostatistics and Clinical Trials, Peter MacCallum Cancer Institute: Australia</td>
<td>Trial operation and statistical support for cancer trials</td>
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<td>Cochrane Collaboration Breast Cancer Group</td>
<td>Collaborative group undertaking systematic reviews of trial evidence: international</td>
<td>Editorial base</td>
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<td>Cochrane Prospective Meta-Analysis Methods Group</td>
<td>Collaborative group undertaking systematic reviews of trial evidence: international</td>
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<td>Cooperative Trials Group for Neuro-Oncology (COGNO)</td>
<td>Collaborative group for brain cancer trials: Australia</td>
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<td>Early Prevention of Obesity in Children (EPOCH) collaboration</td>
<td>Prospective meta-analysis collaboration: international</td>
<td>Data coordination centre</td>
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<td>GROUP</td>
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<td>CTC ACTIVITY</td>
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<td>European Organisation for Research and Treatment of Cancer (EORTC)</td>
<td>International collaborative group</td>
<td>Collaborator through Australian</td>
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<td>groups</td>
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<tr>
<td>Fenofibrate and Event-Lowering in Diabetes (FIELD) Study Investigators</td>
<td>Collaborative group for FIELD diabetes trial genetic, molecular and follow-up substudies: Australia, New Zealand, Finland, Germany</td>
<td>Coordinating centre</td>
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<td>INSPIRE</td>
<td>Meta-analysis: ASPIRE and WARFASA (Italy)</td>
<td>Member</td>
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<td>International Neonatal Immunotherapy Study (INIS) Group</td>
<td>Collaborative group for INIS trial: Australia, New Zealand, Europe, Argentina</td>
<td>Regional coordinating centre</td>
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<td>Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group</td>
<td>Collaborative group for LIPID cholesterol-lowering trial genetic, molecular and follow-up substudies: Australia, New Zealand, Germany</td>
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<td>Medical Services Advisory Committee (MSAC) and Department of Health and Ageing</td>
<td>Government: Australia</td>
<td>Provide assessments of new technologies and other research services</td>
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<td>Menzies Research Institute and Charles Darwin University</td>
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<td>Collaborator</td>
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<td>Meta-analysis collaboration (AMICABLE)</td>
<td>Meta-analysis collaboration: international</td>
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<td>Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPINO) collaboration</td>
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<td>Heart Foundation</td>
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<td>Cardiovascular research</td>
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<td>National Perinatal Epidemiology Unit (NPEU), University of Oxford</td>
<td>Research institution: UK</td>
<td>Collaborator on the INIS neonatal trial</td>
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<td>Neonatal Oxygenation Prospective Meta-analysis (NeOProM) collaboration</td>
<td>Prospective meta-analysis collaboration: international</td>
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<td>NSW Cancer Council</td>
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<td>Perinatal Antiplatelet Review of International Studies (PARIS) collaboration</td>
<td>Meta-analysis collaboration: international</td>
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<td>Prenatal repeat corticosteroid international individual-patient-data study group: assessing the effects using the best level of evidence (PRECISE) collaboration</td>
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<td>Prevention of Ventilator Induced Lung Injury Collaborative Study Group (PreVILIG)</td>
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<td>Primary Care Cancer Trials Group (PC4)</td>
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<td>Primary Coronary Angioplasty versus Thrombolysis (PCAT)</td>
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<td>Prospective Pravastatin Pooling (PPP) project</td>
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<td>Professional society undertaking trials of surgery: Australia and New Zealand</td>
<td>Coordinating the SNAC trials in breast cancer</td>
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<td>VIGOUR group</td>
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## CURRENT CTC TRIALS

### NEONATAL DISORDERS

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<th>Trial</th>
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<th>Participants</th>
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<tbody>
<tr>
<td>APTS: Australian placental transfusion study</td>
<td>Neonates born before 30 weeks’ gestation</td>
<td>1600</td>
<td>101</td>
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<tr>
<td>BOOST II: Benefits of oxygen saturation targeting</td>
<td>Neonates born before 28 weeks’ gestation</td>
<td>1200</td>
<td>1135</td>
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### CARDIOVASCULAR DISORDERS

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<th>Pending trials</th>
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<th>Participants</th>
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<td>REMOVAL: Effects of metformin added to insulin on atheroma progression</td>
<td>Adults with type 1 diabetes at risk of cardiovascular disease</td>
<td>90 (ANZ); 500 (international)</td>
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<td>ASPIRE: Aspirin to prevent recurrent venous thromboembolism</td>
<td>People who have had 6 months of treatment with warfarin for a venous thromboembolism</td>
<td>1200 (international) 689 (Australasia); 1225 (INSPIRE meta-analysis)</td>
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<tr>
<td>FIELD: Fenofibrate intervention and event lowering in diabetes</td>
<td>Patients with type 2 diabetes</td>
<td>8000</td>
<td>9795</td>
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<tr>
<td>LIPID: Long-term intervention with pravastatin in ischaemic disease</td>
<td>Patients with a history of coronary heart disease</td>
<td>9000</td>
<td>9014</td>
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</tbody>
</table>

### BREAST CANCER (COLLABORATING WITH RACS)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Current trials</th>
<th>Target</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>SnaC 2: Multicentre randomised trial of sentinel node biopsy versus axillary clearance</td>
<td>Women with operable breast cancer, stratified by various factors, including age and tumour size</td>
<td>1012</td>
<td>218</td>
</tr>
</tbody>
</table>

### GASTROINTESTINAL CANCER (COLLABORATING WITH AGITG)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Pending trials</th>
<th>Target</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAP: Phase 2 study of gemcitabine and nab-paclitaxel</td>
<td>Patients with resectable pancreas cancer</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>ICECREAM: Irinotecan Cetuximab Evaluation and Cetuximab Response Evaluation Among Mutants</td>
<td>Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>IMPACT: Phase 2 trial using genomic sequencing and protein expression to direct first-line treatment</td>
<td>Patients with metastatic pancreatic cancer</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>INTEGRATE: Phase 2 trial comparing regorafenib and placebo</td>
<td>Patients with advanced oesophago gastric cancer</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>TACTIC: Phase 2 trial of panitumumab, cisplatin and gemcitabine</td>
<td>Patients with biliary tract cancer</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

### Current trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Target</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>A La CART: Australian phase III randomised trial of laparascopy-assisted resection compared with open resection</td>
<td>Patients with primary rectal cancer</td>
<td>470</td>
</tr>
<tr>
<td>ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases</td>
<td>Patients with confirmed resectable liver metastases and no other disease</td>
<td>200</td>
</tr>
<tr>
<td>DOCTOR: Phase 2 trial of preoperative cisplatin, S-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer</td>
<td>Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy</td>
<td>150</td>
</tr>
</tbody>
</table>
# TRIAL

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAP07: Randomised multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib for pancreatic cancer</td>
<td>Patients with locally advanced adenocarcinoma of the pancreas</td>
<td>60 (ANZ); 900 (international)</td>
<td>26 (ANZ); 423 (international)</td>
</tr>
<tr>
<td>PANI: Phase III study evaluating potential predictive biomarkers in treatment of locally advanced and metastatic pancreatic cancer</td>
<td>Patients with confirmed metastatic pancreatic adenocarcinoma</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>REGISTER: Multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response</td>
<td>Patients with gastrointestinal stromal tumour not suitable for curative surgery</td>
<td>80</td>
<td>44</td>
</tr>
<tr>
<td>SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer</td>
<td>Patients with fully resected stage III colorectal cancer</td>
<td>225 (ANZ); 9500 (international)</td>
<td>89 (ANZ); 2827 (international)</td>
</tr>
<tr>
<td>TOP GEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer</td>
<td>Patients with resectable gastric cancer suitable for these treatments</td>
<td>120 (stage 1); 632 (stage 2)</td>
<td>34</td>
</tr>
</tbody>
</table>

## Trials in follow-up

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced GIST: Relation between dose and clinical activity of imatinib mesylate (AG0102, EORTC 62005)</td>
<td>Patients with unresectable or metastatic malignant gastrointestinal stromal tumours (GIST) expressing KIT receptor</td>
<td>80 (ANZ); 600 (international)</td>
<td>116 (ANZ); 946 (international)</td>
</tr>
<tr>
<td>ATTAX 3: Phase II trial of docetaxel, cisplatin and fluoropyrimidine with or without panitumumab for oesophagogastric cancer (AG06070G)</td>
<td>Patients with metastatic or locally recurrent oesophagogastric cancer</td>
<td>100</td>
<td>77</td>
</tr>
<tr>
<td>CO7: 5-fluorouracil plus leucovorin compared with oxaliplatin with 5-fluorouracil + leucovorin for stages II and III carcinoma of the colon</td>
<td>Patients with resected stage II or stage III colon carcinoma</td>
<td>150</td>
<td>134</td>
</tr>
<tr>
<td>CO.20: Phase III study of BMS-82664 with cetuximab versus placebo with cetuximab</td>
<td>Patients with metastatic colorectal carcinoma previously treated with combination chemotherapy</td>
<td>370 (ANZ); 750 (international)</td>
<td>416 (ANZ); 686 (international)</td>
</tr>
<tr>
<td>EORTC liver metastases: Oxaplatin, 5-fluorouracil and leucovorin versus surgery for resectable colorectal cancer liver metastases (EORTC 40983)</td>
<td>Patients with colorectal cancer with resectable liver metastases</td>
<td>330 (international)</td>
<td>35 (ANZ); 364 (international)</td>
</tr>
<tr>
<td>PETACC 6: Addition of capecitabine to preoperative oxaloplatin chemotherapy and postoperative oxaloplatin chemotherapy for rectal cancer (AG0707R)</td>
<td>Patients with locally advanced rectal cancer</td>
<td>135 (ANZ); 1090 (international)</td>
<td>127 (ANZ); 1094 (international)</td>
</tr>
<tr>
<td>Quasar 2: Phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer (AG01070CR)</td>
<td>Patients with colon cancer treated by surgery</td>
<td>120 (ANZ); 1892 (international)</td>
<td>219 (ANZ); 1952 (international)</td>
</tr>
</tbody>
</table>

## Gyneaeological Cancer (Collaborating with ANZGOG)

### Pending trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANZGOG 1013: Phase I-II BNC105P combination study</td>
<td>Women with partly platinum-sensitive ovarian cancer in first or second relapse</td>
<td>334 (international)</td>
</tr>
<tr>
<td>PARAGON: Phase II study of anastrozole in gynaecological cancers</td>
<td>Women with potentially hormone-responsive gynaecological cancers</td>
<td>100 (ANZ)</td>
</tr>
</tbody>
</table>

### Current trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with with pelvic radiation alone in high-risk endometrial carcinoma</td>
<td>Women with advanced endometrial carcinoma</td>
<td>200 (ANZ); 600 (international)</td>
</tr>
</tbody>
</table>
### TRIAL PARTICIPANTS TARGET ACCRUAL

#### Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer
ANZGOG and CTC-led international study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
<th>ACCRUAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outback</td>
<td>Women with locally advanced cervical cancer</td>
<td>780</td>
<td>21 (ANZ); 28 international</td>
</tr>
</tbody>
</table>

#### Symptom benefit: does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG 1103)
ANZGOG and PCoG study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
<th>ACCRUAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom benefit</td>
<td>Women with platinum-resistant or refractory ovarian cancer</td>
<td>800</td>
<td>95</td>
</tr>
</tbody>
</table>

### Trials in follow-up

#### TRIPoD: Phase II trial of intraperitoneal chemotherapy
ANZGOG and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIPoD</td>
<td>Women with ovarian and related cancers</td>
<td>35–100</td>
</tr>
</tbody>
</table>

#### ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy
MRC-led, ANZGOG and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICON 6</td>
<td>Women with platinum-sensitive relapsed ovarian cancer</td>
<td>400 (international); 17 (ANZ); 486 (international)</td>
</tr>
</tbody>
</table>

#### ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy
MRC-led, ANZGOG and CTC

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICON 7</td>
<td>Women with epithelial ovarian cancer who had not received systemic antitumour therapy</td>
<td>100</td>
</tr>
</tbody>
</table>

#### SCOTROC 4: Multicentre trial of carboplatin flat dosing vs intrapatient dose escalation in first-line chemotherapy
SCTCG-led, ANZGOG and CTC

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCOTROC 4</td>
<td>Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum-taxane therapy</td>
<td>150 (ANZ); 1300 (international); 64 (ANZ); 937 (international)</td>
</tr>
</tbody>
</table>

#### Prospective study of risk-reducing salpingo-oophorectomy and longitudinal CA-125 screening (GOG 199)
GOG-led, ANZGOG and CTC

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective study</td>
<td>Women aged &gt;30 at genetic risk of ovarian cancer</td>
<td>250</td>
</tr>
</tbody>
</table>

### GENITOURINARY CANCER (COLLABORATING WITH ANZUP)

#### Current trials

**Aprepitant for germ cell chemotherapy: 7-day aprepitant schedule to prevent chemotherapy-induced nausea and vomiting (ANZGCTG 0801)**
ANZUP and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aprepitant for germ cell chemotherapy</td>
<td>Patients receiving cisplatin-based chemotherapy for germ cell tumours</td>
<td>50</td>
</tr>
</tbody>
</table>

**Chemo & cognition: Cognitive function and treatment for testicular cancer (ANZGCTG 0106)**
ANZUP and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemo &amp; cognition</td>
<td>Patients being treated and followed up for testicular cancer</td>
<td>154</td>
</tr>
</tbody>
</table>

**Everun: Phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901)**
ANZUP and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Everun</td>
<td>Patients starting first-line systemic therapy for advanced renal cell carcinoma</td>
<td>55</td>
</tr>
</tbody>
</table>

**SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05)**
ANZUP and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>SORCE</td>
<td>Patients with resected renal cell carcinoma at intermediate or high risk of relapse</td>
<td>250 (ANZ); 1656 (international)</td>
</tr>
</tbody>
</table>

### Trials in follow-up

**Accelerated BEP: feasibility study of accelerated BEP as first-line chemotherapy for advanced germ cell tumours (ANZGCTG 0206, ANZGOG 0603)**
ANZUP, ANZGOG and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerated BEP</td>
<td>Patients with intermediate and poor-risk advanced germ-cell tumours (and selected good-risk tumours)</td>
<td>25</td>
</tr>
</tbody>
</table>

### LUNG CANCER (COLLABORATING WITH ALTG)

#### Current trials

**BR.26: Phase III trial of PF-804 in patients with incurable, non-small-cell lung cancer (ALTG 09/002)**
NCIC-led, ALTG and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>BR.26</td>
<td>Patients with stage IIIIB or IV non-small-cell lung cancer</td>
<td>180</td>
</tr>
</tbody>
</table>

**NITRO: phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for advanced non-small-cell lung cancer (ALTG 06/003)**
ALTG and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>NITRO</td>
<td>Patients with advanced non-small-cell lung cancer</td>
<td>500</td>
</tr>
</tbody>
</table>

### Trials in follow-up

**BP2P2M2: Phase II trial of BNP105P as second-line chemotherapy for pleural mesothelioma (ALTG 09/004)**
ALTG and CTC study

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PARTICIPANTS</th>
<th>TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP2P2M2</td>
<td>Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy</td>
<td>60</td>
</tr>
</tbody>
</table>

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**NHMRC CLINICAL TRIALS CENTRE: 2011 RESEARCH REPORT**
## Current CTC trials

### Pending trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>BR 29: Cediranib versus placebo for patients receiving paclitaxel and carboplatin for non-small-cell lung cancer (ALTG 09/001)</td>
<td>Patients with stage IIIb or IV non-small-cell lung cancer</td>
<td>100</td>
<td>75</td>
</tr>
<tr>
<td>NCIC CTG-led, ALTG and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Brain Cancer (Collaborating with COGNO)

#### Pending trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II study of acetazolamide plus dexamethasone versus dexamethasone for cerebral oedema in high-grade glioma COGNO and CTC study</td>
<td>Patients with high-grade glioma requiring new dexamethasone or dose increase due to progressive or recurrent disease</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>Phase II study of psycho-educational intervention in patients with primary brain tumour PoCeG-led and COGNO study</td>
<td>Patients with confirmed primary brain tumours</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

#### Current trials

<table>
<thead>
<tr>
<th>Trial</th>
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<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabaret: phase II study of carboplatin and bevacizumab in for glioblastoma multiforme COGNO and CTC study</td>
<td>Patients with recurrent grade IV glioblastoma multiforme following radiotherapy and temozolomide chemotherapy</td>
<td>120</td>
<td>86</td>
</tr>
<tr>
<td>CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC 26053-22054) EORTC-led COGNO and CTC study</td>
<td>Patients with non-1p/19q- deleted anaplastic glioma</td>
<td>100 (ANZ); 748 (international)</td>
<td>31</td>
</tr>
<tr>
<td>Phase III trial of temozolomide and short-course radiation versus radiation alone (TRoG 08.02) COGNO, TRoG and CTC study</td>
<td>Elderly patients with new glioblastoma multiforme</td>
<td>100 (ANZ); 500 (international)</td>
<td>41 (ANZ); 251 (International)</td>
</tr>
<tr>
<td>SEED: Self-reported evaluation of the adverse effects of dexamethasone COGNO and CTC study</td>
<td>Patients with brain tumours or brain metastases or advanced cancer using steroids</td>
<td>50 patients, 50 caregivers</td>
<td>13</td>
</tr>
</tbody>
</table>

#### Trials in follow-up

<table>
<thead>
<tr>
<th>Trial</th>
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<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>LGG: Phase III study of primary chemotherapy with temozolomide versus radiotherapy (TRoG 06.01, EORTC 22033-26033) EORTC, COGNO, TRoG and CTC study</td>
<td>Patients with low-grade glioma, stratified for genetic 1p loss</td>
<td>100 (ANZ); 466 (international)</td>
<td>36 (ANZ); 466 (international)</td>
</tr>
</tbody>
</table>

### CTC’s research funding

- NHMRC
- Cancer Australia, Cancer Institute and cancer councils
- Other public funding
- Pharmaceutical industry
- Other
STAFF ACTIVITIES

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Kew Flood, administrative officer
H Malcolm Hudson, BSc(hons), PhD, honorary professor
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Biostatisticians
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David Espinosa, BSc(hons)
Marion Fournier, MSc
Kirsty Mann, BScAgri(hons)
Rachel L O’Connell, BMath, MedStat, PhD
Anne-Sophie Veillard, BSc, MSc
Merryn Voysey, GradDipMathStat, MBiostat

Biostatistics Collaboration of Australia (BCA)
Erica Jobling, executive officer
Heleen Johnson, BA, M MuseumStud

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Jenny Chow, AssoCip, executive officer
Sally J Lord, MB BS, DipPaed, MS, FRACGP, epidemiologist and research fellow
Lukas Staub, Dr med, DAS, project officer
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Sally Wortley, BUtilSc(hons), MPH, Grad Cert Hlth Econ, project officer

Cochrane breast cancer review group
Melina Willson, BSc (hons)/BA, PhD, project manager

Australian New Zealand Clinical Trials Registry
Kylie Hunter, BA, BA(hons), project officer
Henry CH Ko, BEng(Med)/hons), PhD, project officer
William Ooi, MUtilSc, BAAppSc, project officer
Fergus Tai, BAAppSc, DipIT, MPH, project officer

BUSINESS ADMINISTRATION
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Katie Doyle, receptionist (from Sep)
Jackie McGrath, receptionist (to May)
Lia Sherwood, BMEdSc, MSc, grants and contracts coordinator

Finance
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Paul Smyth, BCom, CPA, finance manager (from Dec)
Agnes Ho, MPraAcc, CPA, finance officer
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Carlos Sterling, BEng, MBA, finance officer

Human resources
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Suzanne Everett, BSW, human resources and administration coordinator

PUBLICATIONS
Rhana Pike, BA, MA, GradCert, ELS, CMPP, senior publications officer

RESEARCH STUDENTS
Prunella Blinman, BMed, FRACP
Belinda E Kiley, BMed(hons), MB BS, FRACP
Annette Kifley, MB BS, MAppStat
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Lukas Staub, Dr med, DAS
Ru-Dee Ting, MB BS, FRACP
Mateya E Trinkaus, MD, FRCP

ACADEMIC STAFF
Lisa M Askie, BN, MPH, PhD, senior research fellow and associate professor
Christopher SB Brown, BSc, M Biostat, research fellow
Karen Byth-Wilson, BSc(hons), MSc, PhD, DIC, CSat RSS, senior lecturer
Emily J Callander, BA, research officer
Andrew Cameron, BSc(hons), MB BS, clinical research fellow
Val J Gebksi, BA, MStat, principal research fellow and professor
Toby Gould, BA, BSc, MPH, associate lecturer
Wendy Hague, MB BS, MBA, PhD, senior research fellow
Anthony C Keech, MB BS, MSc, FRACP, principal research fellow and professor
Adrienne C Kirby, BSc(hons), MSc, senior lecturer
Chee K See, MB BS(hons), MMEdSc, M Biostat, FRACP, research fellow
Sally (Sarah) J Lord, MB BS, DipPaed, MS, FRACGP, research fellow
Rupendra Shrestha  
Emily Callender: PhD  
Hannah Verry: PhD  
Martin Stockler  
Prunella Blinkman: PhD  
Lesley Shan Wu Chim: PhD  
Belinda E Kiely: PhD  
Michaella Smith: PhD  

DEGREES COMPLETED IN 2011  
Christopher SB Brown: MBiostat  
Rachel O’Connell: PhD  

EXTERNAL COMMITTEES  
John Simes  
Australia & New Zealand Breast Cancer Trials Group (ANZBCTG) scientific advisory committee  
Aspirin to Prevent Recurrent Venous Thrombo-embolism (ASPIRE) trial management committee (chair)  
Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee, operations executive committee, MAX trial management committee  
Australian New Zealand Clinical Trials Registry (ANZCTR) policy advisory committee  
Cancer Clinical Trials Development Unit (CTDU) advisory committee, management committee and health economics advisory committee  
Cholesterol Treatment Trials Collaboration (CTTC) (joint coordinator)  
Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee (deputy chair), management committee, operations executive  
Benefits of Oxygen Saturation Targeting (BOOST) II trial management committee  
Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee, executive, and cost-effectiveness subcommittee  
Intensive Blood Pressure Reduction for Acute Cerebral Haemorrhage Trial (INTERACT) safety and data monitoring committee (chair)  
International Breast Cancer Intervention and Prevention of Ventilation Induced Lung Injury Collaborative Group (PREVILIG) statistical group (chair) and a VIGOUR leader  
Anthony Keech  
Asian-Pacific Society of Atherosclerosis and Vascular Disease Prevention executive committee (APSAVD) (founding member and treasurer)  
Asia-Pacific Study on CHD Risk Factor Intervention (ASPARC) management committee (principal investigator and study chair)  
BLISS study safety and data monitoring committee (chair)  
Cardiac Society of Australia and New Zealand clinical trials working group scientific committee (chair)  
Cholesterol Treatment Trials Collaboration (CTTC) (joint coordinator and convenor)  
FAME-1 diabetes trial steering committee (chair)  
Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee (principal investigator and study chairman), and quality-of-life and cost-effectiveness, ophthalmology, and scientific substudies committees  
Heart Protection Study (HPS) steering committee, executive committee (co-principal investigator)  
International Journal of Cardiology clinical trials editor  
ISIS Trials Group steering committee  
Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee, executive, and biomarker subcommittee  
National Health and Medical Research Council Academy  
NHMRC Clinical Trials Centre management review committee and scientific advisory committee  
Percutaneous Coronary Angioplasty versus Thrombolysis (PCAT) collaborative group (co-coordinator)  
Sentinel Biopsy versus Auxiliary Clearance (SNAC) trial management committee  
Trials associate editor  
Virtual Coordinating Centre for International Collaborative Cardiovascular Research (VIGOUR) statistical group (chair) and a VIGOUR leader  
Lisa Askie  
Antenatal Magnesium Sulphate prior to Preterm Birth for Neuroprotection of the Fetus infant and child national clinical practice guidelines, executive panel  
Cochrane Collaboration prospective meta-analysis methods working group (co-convenor) and methods editorial board  
Early Prevention of Childhood Obesity (EPOCH) prospective meta-analysis collaboration steering committee (chair)  
International Clinical Trials Registry Platform, World Health Organization, best practice group  
International Forum for Standards for Research in Children sample size and data safety monitoring committee subcommittee  
Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPINO) Collaboration steering group  
Neonatal Oxygen Prospective Meta-analysis (NeoProM) collaboration steering committee (chair)  
NHMRC Project Grant Review Panel for Clinical Trials  
Perinatal Antiplatelet Review of International Studies (PARIS) collaboration steering committee, writing committee (chair)  
PLoS ONE academic editor  
Prenatal Repeat Corticosteroid International IPD Study Group: Assessing the Effects using the Best Level of Evidence (PRECISE) steering committee  
Prevention of Ventilation Induced Lung Injury Collaborative Group (PREVILIG) steering committee  
Royal Prince Alfred Hospital clinical trials (ethics) subcommittee  
Systematic Reviews editorial board  

Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee, executive, and biomarker subcommittee  
National Health and Medical Research Council Academy  
NHMRC Clinical Trials Centre management review committee and scientific advisory committee  
Percutaneous Coronary Angioplasty versus Thrombolysis (PCAT) collaborative group (co-coordinator)  
Sentinel Biopsy versus Auxiliary Clearance (SNAC) trial management committee  
Trials associate editor  
Virtual Coordinating Centre for International Collaborative Cardiovascular Research (VIGOUR) statistical group (chair) and a VIGOUR leader  
Anthony Keech  
Asian-Pacific Society of Atherosclerosis and Vascular Disease Prevention executive committee (APSAVD) (founding member and treasurer)  
Asia-Pacific Study on CHD Risk Factor Intervention (ASPARC) management committee (principal investigator and study chair)  
BLISS study safety and data monitoring committee (chair)  
Cardiac Society of Australia and New Zealand clinical trials working group scientific committee (chair)  
Cholesterol Treatment Trials Collaboration (CTTC) (joint coordinator and convenor)  
FAME-1 diabetes trial steering committee (chair)  
Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee (principal investigator and study chairman), and quality-of-life and cost-effectiveness, ophthalmology, and scientific substudies committees  
Heart Protection Study (HPS) steering committee, executive committee (co-principal investigator)  
International Journal of Cardiology clinical trials editor  
ISIS Trials Group steering committee  
Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) study management committee and executive  
NHMRC Clinical Trials Centre management review committee and scientific advisory committee  
National Health and Medical Research Council training awards committee  
NSW Department of Health shared assessment committee  
PLoS Medicine editorial board  
Prospective Pravastatin Pooling (PPP) project international steering committee  
REMOVAL trial steering committee  
Royal Prince Alfred Hospital clinical trials (ethics) subcommittee  
University of Sydney College of Health Sciences board of postgraduate studies  
Virtual Coordinating Centre for International Collaborative Cardiovascular Research (VIGOUR)  
Lisa Askie  
Antenatal Magnesium Sulphate prior to Preterm Birth for Neuroprotection of the Fetus infant and child national clinical practice guidelines, executive panel  
Cochrane Collaboration prospective meta-analysis methods working group (co-convenor) and methods editorial board  
Early Prevention of Childhood Obesity (EPOCH) prospective meta-analysis collaboration steering committee (chair)  
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Perinatal Antiplatelet Review of International Studies (PARIS) collaboration steering committee, writing committee (chair)  
PLoS ONE academic editor  
Prenatal Repeat Corticosteroid International IPD Study Group: Assessing the Effects using the Best Level of Evidence (PRECISE) steering committee  
Prevention of Ventilation Induced Lung Injury Collaborative Group (PREVILIG) steering committee  
Royal Prince Alfred Hospital clinical trials (ethics) subcommittee  
Systematic Reviews editorial board
Amy Boland
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations executive committee, scientific advisory committee, and Accelerated BEP, Aprepitant and EVERSUN trial management committees

Christopher Brown
Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee, operational executive committee, NITRO trial management committee, BJP2M1 trial management committee

Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee, operational executive committee; CABARET trial management committee, ANZUP scientific advisory committee, and Accelerated BEP and EVERSUN trial management committees

Mark Chatfield
Accelerated BEP trial management committee

Alan Coates
Annals of Oncology editorial board

CABARET and CATNON trial management and scientific advisory committees, and Accelerated BEP, Aprepitant and EVERSUN trial management committees

Xanthi Coskinas
Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee, operational executive committee; NITRO trial management committee, BJP2M1 trial management committee

Trevor France
Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees, and CABARET and CATNON trial management committees

Val Gebski
AGITG scientific advisory committee and MAX, TOPGEAR, IMPACT, PAN-1, ATTACHE, TACTIC, DOCTOR, and REGISTER trial management committees

ANZ BCTG scientific advisory committee

ANZOGOG Research Advisory Committee and PARAGON and OUTBACK trial management committees

Australasian Kidney Trials Network advisory board

Biostatistics Collaboration of Australia steering and teaching committees

Crown Princess Mary Cancer Care Centre (Westmead) Radiation Oncology research committee

GCIG/GINECO GCIG intergroup study comparing pegylated liposomal doxorubicin (Caelyx) and carboplatin versus paclitaxel and carboplatin in patients with epithelial ovarian cancer trial management committee

Group statistician: Australia & New Zealand Breast Cancer Trials Group (ANZBCTG), Australasian Gastro-Intestinal Trials Group (AGITG), Australian New Zealand Gynaecological Oncology Group (ANZOGOG), Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP), Trans-Tasman Radiation Oncology Group (TROG)

Independent safety and data monitoring committees: Bevacizumab use in platinum-resistant epithelial ovarian cancer; CLASSIC (Adjuvant Chemotherapy versus Surgery in Gastric Adenocarcinoma); GAS (Effect of Spinal versus General Anaesthesia in Neonates undergoing Hernia Repair); TO2RPIDO (Targeted Oxygenation in the Resuscitation of Premature Infants and their Developmental Outcome)

LACC (Laparoscopic Surgery versus Hysterectomy in Patients with Cervical Cancer) trial management committee

LACE (Laparoscopic Surgery versus Hysterectomy in Patients with Endometrial Cancer) trial management committee

LATER, NeoGem, GALA and SORBET trial management committees

NSW Health Central Sydney Area ethics committee clinical trials subcommittee

Alpana Ghadge
Benefits of Oxygen Saturation Targeting (BOOST II) trial management committee

Westmead international update management committee

Yvonne fabrics
Australasian Gastro-Intestinal Trials Group (AGITG) trials operations committee

Australasia New Zealand Gynaecological Oncology Group (ANZOGOG) trials operations committee

Australian Placental Transfusion Study (APTS) management committee

Benefits of Oxygen Saturation Targeting (BOOST II) management committee

Cancer Australia Clinical Trials Development Unit (CTDU) program management committee and strategic advisory committee

Cancer Institute NSW infrastructure grant steering committee and human research ethics committee

Cancer Institute NSW infrastructure grant subcommittee

International Neonatal Immunotherapy Study (INIS) Australian and New Zealand management committee

International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee

Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee

Sentinel Biopsy versus Axillary Clearance (SNAC) 1 and 2 trial management committees

Adrienne Kirby
Combination Antibiotic Treatment for Methicillin Resistant Staphylococcus Aureus (CAMERA) trial management committee

Faculty of Medicine, University of Sydney postgraduate coursework committee

International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee

Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee

Randomised Trial on Surgical Treatment for Otitis Media in Children Living in Remote Australian Communities trial management committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Liping Li
FIELD outcomes and assessment committee

Ann Livingstone
Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees, and CABARET and CATNON trial management committees
Sally Lord
Protocol Advisory Committee (PASC) for Medical Services Advisory Committee
NHMRC Project Grant Review Panel for Clinical Trials
McMaster University Evidence-based Practice Center assessment of the Use of Natriuretic Peptide Measurement in the Management of Heart Failure

Julie Martyn
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee, operations executive committee and study coordinators committee
Gynaecological Cancer Intergroup (GCIG) harmonisation and statistics committee (chair)
ICON-6, ICON-7, PORTEC-3 and OVAR-16 international steering committees
TRIPOD, Symptom Benefit, PORTEC-3 and Outback trial management committees

Danielle Miller
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee
Australasian Gastro-Intestinal Trials Group (AGITG) TOPGEAR trial management committee
Cancer Australia Clinical Trials Development Unit (CTDU) program management committee and strategic advisory committee
Primary Care Collaborative Cancer Clinical Trials Group (PC4) operations team and scientific advisory committee
Sydney Catalyst operations committee and executive committee

Rebecca Mistar
Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee
International Trials of Aspirin to Prevent Recurrent Venous Thromboembolism (INSPIRE) steering committee

Rhana Pike
Australasian Medical Writers Association executive committee

Deborah Schofield
Australian Government Department of Health and Ageing Professional Programs and Services Advisory Committee (PPSAC) research and development committee, Department of Health North Coast Area Health Service workforce development plan implementation steering group
Health Workforce Australia expert reference group
Northern Rivers University Department of Rural Health advisory committee

University of Sydney School of Public Health research committee, Northern Rivers Department of Rural Health (RUDRH) research committee
University of Sydney vice-chancellor’s health strategy group for intergovernmental relations

Lucille Sebastian
International Neonatal Immunotherapy Study (INIS) Australian and New Zealand management committee
Australasian Placental Transfusion Study (APTS) management committee
Australian Placental Transfusion Study echocardiography substudy management committee
B3P2M2 trial management committee
Cancer Australia Clinical Trials Development Unit (CTDU) site performance subcommittee

Katrin Spiquist
Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee, alumni committee (chair)
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and operations executive committee, Symptom Benefit trial management committee
Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and operations executive committee, ATTACHE trial management committee, ATTAX3 trial management committee, PANI trial management committee (CTC clinical lead)

Martin Stockler
Australasian Leukaemia & Lymphoma Group safety and data monitoring committee
Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee
Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee (convenor)
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee
Australia & New Zealand Breast Cancer Trials Group (ANZ BCTG) scientific advisory committee
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee, renal cell subcommittee, germ cell subcommittee, and EVERSUN trial management committees
Cancer Council Australia national oncology education committee
Journal of Clinical Oncology editorial board
National Breast Cancer Centre eClinical Updates editorial board

National Breast Cancer Centre clinical updates advisory committee
National Breast Cancer Centre hormone therapy working group (chair) and information advisory group (chair)
National Breast Cancer Foundation Strategic research advisory panel
National Cancer Institute (NCI) Intergroup health related quality-of-life committee
National Health and Medical Research Council grant review panels for oncology and palliative care strategic grants
University of Sydney Faculty of Medicine oncology block committee (chair), EBM in GMF3/4 (chair), evidence-based medicine resource group, integrated clinical attachment committee and USMP cancer planning committee

Burcu Vachan
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations executive
Australia New Zealand Gynaecological Oncology Group (ANZGOG) operations executive
Australasian Lung Cancer Trials Group (ALTG) operations executive
Cancer Institute NSW infrastructure grant subcommittee
Cooperative Trials Group for Neuro-Oncology (COGNO) operations executive

Kate Wilson
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee, scientific advisory committee, study coordinators subcommittee (chair), annual scientific meeting committee, and MAX, Quasar 2, PETACC6, A La CaRT and SUPER trial management committees
Cancer Institute NSW infrastructure grant subcommittee

Nicole Wong
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee and ATTACHE, LAP07, SCOT, ATTAX 3, PANI and TACTIC trial management committees

Sonia Yip
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive and biological subcommittee
Australian and New Zealand Urogenital and Prostate Group (ANZUP) scientific advisory committee, renal cell subcommittee, germ cell subcommittee, and EVERSUN and SORCE trial management committees
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee
### Staff activities

**Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee**
- Sydney Cancer Conference organising committee
- Sydney Catalyst: Translational Cancer Research Centre of Central Sydney and Regional NSW scientific advisory committee, operations executive committee and T1 working party

### ACADEMIC TEACHING

- **Val Gebski**
  - Advanced clinical trials, Biostatistics Collaboration of Australia (coordinator)
  - Basic sciences in oncology, NSW Cancer Council
  - Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
  - Radiation oncology training, RACR trainees, Westmead Hospital, NSW Cancer Council

- **Wendy Hague**
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Adrienne Kirby**
  - Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
  - Understanding trials methods, and Trial methods, Master of Clinical Trials, University of Sydney (coordinator)

- **Sally Lord**
  - Advanced evaluation of diagnostic tests, and Decision analysis, Master of Public Health and Master of Medicine, University of Sydney
  - Critical appraisal, Basic sciences in oncology, NSW Cancer Council
  - Evidence-based medicine, University of Sydney Medical Program

- **Kristy Mann**
  - Basic sciences in oncology, NSW Cancer Council
  - Critical appraisal of evidence and Understanding trial methods, Master of Clinical Trials, University of Sydney

- **Andrew Martin**
  - Decision analysis, and Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

- **Rebecca Mister**
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Rachel O'Connell**
  - Advanced clinical trials, Biostatistics Collaboration of Australia (coordinator)
  - Principles of statistical inference, Biostatistics Collaboration of Australia (coordinator)

- **Burcu Vachan**
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Sonia Yip**
  - Oncology problem-based learning in the clinical years, University of Sydney Medical Program

- **Katrin Sjoquist**
  - Evidence-based medicine, University of Sydney Medical Program

- **Martin Stockler**
  - Australia & Asia-Pacific Clinical Oncology Research Development (ACORD) convenor, and international steering committee workshop (chair)
  - Making sense of cancer clinical trials for NSW medical oncology trainees (convenor)
  - Clinical epidemiology for physician trainees, Royal Prince Alfred Hospital
  - Evidence-based medicine in the clinical years, (chair and coordinator), and Oncology and palliative care (block chair), University of Sydney Medical Program
  - Medical oncology clinical training, Royal Prince Alfred Hospital
  - Patient-based measures, Master of Medicine, University of Sydney (coordinator)
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Elizabeth Barnes**
  - Basic sciences in oncology, NSW Cancer Council
  - Postgraduate training seminar program, University of Sydney
  - Principles of statistical inference, Biostatistics Collaboration of Australia
  - Understanding trials methods, Master of Clinical Trials, University of Sydney

- **Christopher Brown**
  - Advanced clinical trials, Biostatistics Collaboration of Australia
  - Basic sciences in oncology, NSW Cancer Council
  - Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

- **Mark Chatfield**
  - Advanced clinical trials, Biostatistics Collaboration of Australia
  - Controlled clinical trials, Master of Public Health and Master of Clinical Epidemiology, University of Sydney

- **Mark Donoghoe**
  - Trial methods, Master of Clinical Trials, University of Sydney

- **John Simes**
  - Decision analysis, Master of Public Health and Master of Medicine, University of Sydney

- **Anthony Keech**
  - Cardiology training, and clinical tutor, Royal Prince Alfred Hospital
  - Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

- **Lisa Askie**
  - Advanced systematic reviews, Master of Clinical Epidemiology, University of Sydney (coordinator)
  - Controlled clinical trials, Master of Public Health, University of Sydney
  - Critical appraisal of evidence, Master of Clinical Trials, University of Sydney
  - Evidence-based medicine in the clinical years, University of Sydney Medical Program

- **Val Gebski**
  - Advanced clinical trials, Biostatistics Collaboration of Australia (coordinator)
  - Basic sciences in oncology, NSW Cancer Council
  - Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
  - Radiation oncology training, RACR trainees, Westmead Hospital, NSW Cancer Council

- **Wendy Hague**
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Adrienne Kirby**
  - Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
  - Understanding trials methods, and Trial methods, Master of Clinical Trials, University of Sydney (coordinator)

- **Sally Lord**
  - Advanced evaluation of diagnostic tests, and Decision analysis, Master of Public Health and Master of Medicine, University of Sydney
  - Critical appraisal, Basic sciences in oncology, NSW Cancer Council
  - Evidence-based medicine, University of Sydney Medical Program

- **Kristy Mann**
  - Basic sciences in oncology, NSW Cancer Council
  - Critical appraisal of evidence and Understanding trial methods, Master of Clinical Trials, University of Sydney

- **Andrew Martin**
  - Decision analysis, and Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

- **Rebecca Mister**
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Rachel O’Connell**
  - Advanced clinical trials, Biostatistics Collaboration of Australia (coordinator)
  - Principles of statistical inference, Biostatistics Collaboration of Australia (coordinator)

- **Deborah Schofield**
  - Health workforce policy analysis, School of Public Health, University of Sydney

- **Burcu Vachan**
  - Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, University of Sydney

- **Sonia Yip**
  - Oncology problem-based learning in the clinical years, University of Sydney Medical Program
JOURNAL ARTICLES


Callender EJ, Schofield DJ, Shrestha RN. Freedom poverty: A new tool to identify the multiple disadvantages affecting those with CVD. International Journal of Cardiology. Published online 9 Nov 2011.


Cuban N, Beldham-Collins R, Westling J, Trotavo J, Gebski V. Evaluation of flexible and rigid (class solution) radiation therapy conformal prostate planning protocols. Medical Dosimetry. Published online 1 Apr 2011.


Lord SJ, Staub LP, Bossuyt PM, Inwig LM. Target practice: choosing target conditions for test accuracy studies that are relevant to clinical practice. *BMJ* 2011; 343: d4658.


Marschner IC, Gillett AC, O’Connell RL. Stratified additive Poisson models: computational methods and applications in clinical epidemiology. *Computational Statistics and Data Analysis*. Published online 10 Aug 2011.


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