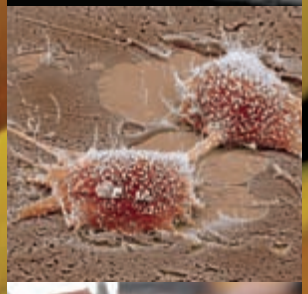
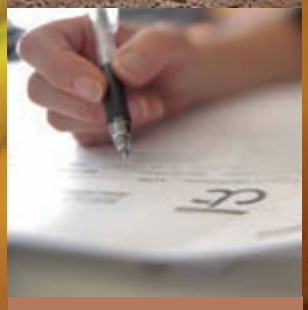
NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2011





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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.

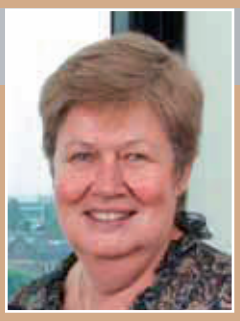
Our research collaborations, which include groupings within the CTC, across Australia and internationally, lead to better coordination of research projects, leverage the different contributions of experts in various fields of research and thus maximise the research effort. The exchange of ideas and the 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.

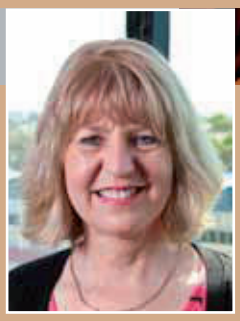
For example, cancer clinical research in Australia relies on investigators across the country who conceive, initiate and conduct trials in areas of need. We work closely with eight Australian cancer cooperative trial groups. These, in turn, have working relationships with 14 international cancer groups. They currently have nearly 50 trials in recruitment or in follow-up, with many more in development.

John Simes

Anthony Keech



Wendy Hague



Kim Russell-Cooper

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 triallists 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 implemention 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.

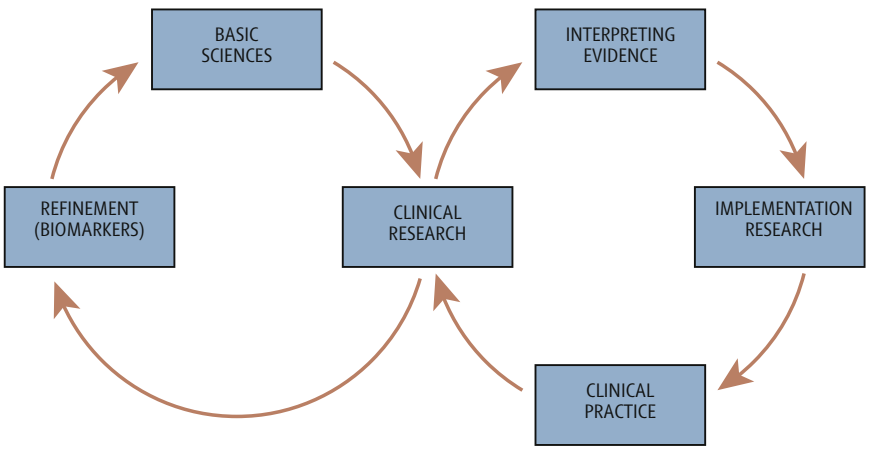
Biospecimens are stored in biobanks for the future, because knowledge and technology are developing rapidly, and new research ideas may come about during the course of a trial running over several years.

Extensive new laboratory-based studies in heart disease and diabetes have been initiated on the basis of biological data derived from two large completed heart disease prevention trials, LIPID (p. 5) and FIELD (p. 8).

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

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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 Michael Solomon (director, Surgical Outcomes Research Centre (SOuRCe), University of Sydney)

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

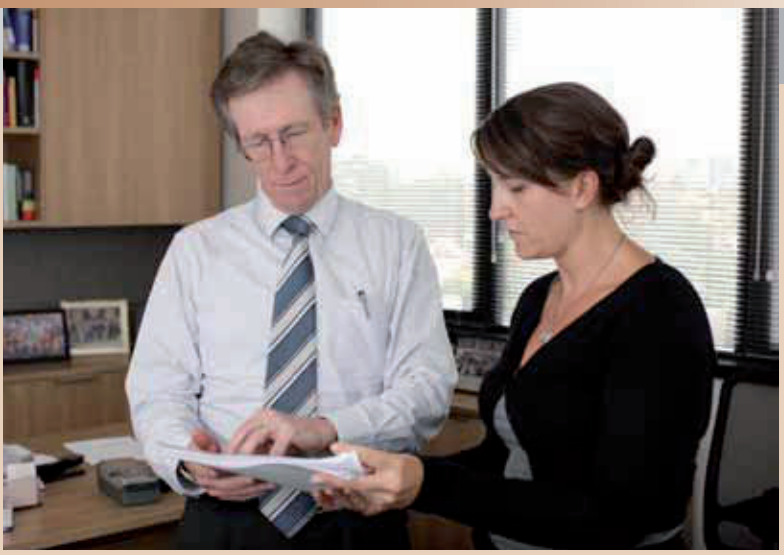
In 2011, Sydney Catalyst: the Translational Cancer Research Centre of Central Sydney and Regional NSW was established with funding from the Cancer Institute NSW. The CTC is one of the collaborators in this program, and Professor John Simes, CTC director, is to be responsible for its leadership and direction.

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



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

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.

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

Alicia Jenkins, Anand Hardikar, Surya Sutanto, Stephen Twigg, Anthony Keech, Susan McLennan, Wilson Wong

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.

COLLABORATIONS

Professor James Best,
University of Melbourne

Professor Stephan Blankenberg,
University Heart Centre, Hamburg

Dr Andrzej Januszweski,
University of Melbourne

Professor Alicia Jenkins,
University of Melbourne

Professor Markku Laakso,
University of Kuopio

Associate Professor Susan McLennan,
Sydney Medical School

Professor John Simes, CTC

Dr Helen Speirs,
University of New South Wales

Professor Stephen Twigg,
University of Sydney

Professor Russell Scott,
Christchurch Hospital

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.

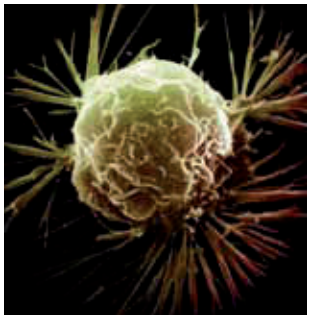
Most of the recent advances in cancer care in Australia can be attributed to collaborative group trials. Recognition of this has resulted in national efforts to build the capacity of the groups, to develop common infrastructure and to improve the efficiency of their activities, mainly with funds from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



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Breast cancer cell (scanning electron micrograph)

CTC collaboration with the 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.

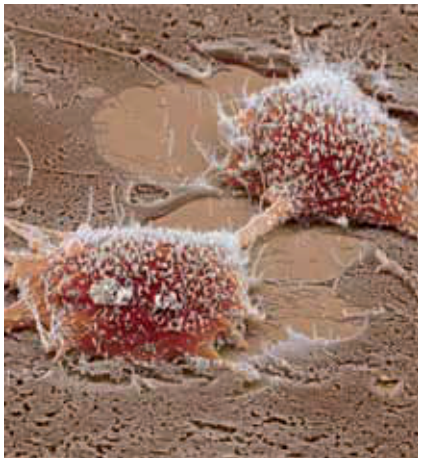
GABRIELLE VOINOT/LOOK AT SCIENCE/SCIENCE PHOTO LIBRARY

John Zalcberg, AGITG chair (with colleagues), chairing the AGITG annual general meeting

Clinical trials to find better treatments for people with gastrointestinal cancers

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 Multidisciplinarie en Oncologie (GERCOR), the Trans-Tasman Radiation Oncology Group (TROG), and in the United States, the Eastern Cooperative Oncology Group (ECOG) and the the National Surgical Adjuvant Breast and Bowel Project (NSABP).



STEVE GSHMEISSNER/SCIENCE PHOTO LIBRARY

Scanning electron micrograph of a colorectal cancer cell dividing

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, GOFURTGO, 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.

Jay Griffiths, Amy Boland, Jennifer Thompson, oncology staff working with ANZUP

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

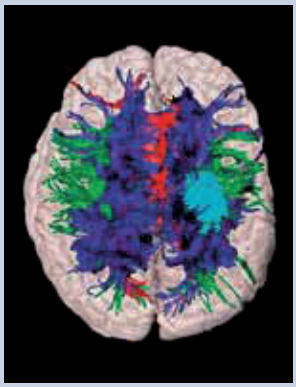
Kate Sawkins, Alan Lucas, Bhagwant Sekhon, Bea Tomes and Trevor France, supporting brain cancer trials at the CTC (Ann Livingstone on leave)

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*



SOVEREIGN, ISM/SCIENCE PHOTO LIBRARY

Coloured three-dimensional diffusion tensor imaging scan in top view through the brain, showing a glioblastoma brain cancer tumour (light blue) among the normal orientation of bundles of white matter nerve fibres

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 leukopenia 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 leukopenia 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.

Martin Stockler and Belinda Kiely

Patients differ in their response to biological agents such as bevacizumab, depending on the genetic status of their tumours. The MAX triallists 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.

Anthony Keech, chair of the FIELD management committee

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

AJ PHOTO/SCIENCE PHOTO LIBRARY

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.

John Simes, Lucille Sebastian, William Tarnow-Mordi, Wendy Hague, Lisa Askie and Alpana Ghadge are responsible for the CTC's contributions to neonatal research

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.

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

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

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.'

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.

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

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.'

Methodology: research and biostatistics outreach

Val Gebski became an honorary Fellow of the Royal Australian and New Zealand College of Radiologists in October 2011

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.

Christopher Brown, research fellow in biostatistics

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.

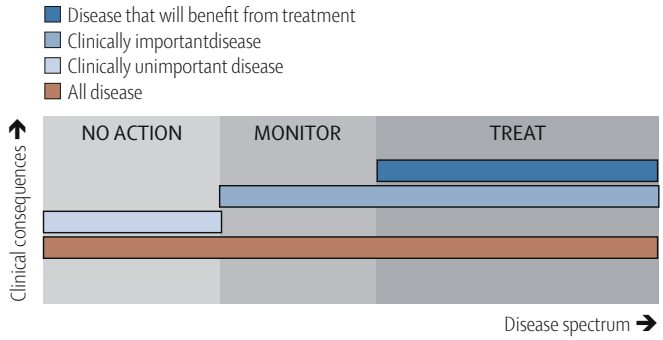
Collaboration between the University of Sydney and the University of Amsterdam on evaluation of medical tests

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 systemrequires 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.

The CTC's systematic reviews and health technology assessment team: Sally Lord, Toby Gould, Samara Lewis, Henry Ko, Lisa Askie, Lukas Staub, Melina Willson, William Ooi, Kylie Hunter, Fergus Tai, Thuyen Vu

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.

The Cochrane Breast Cancer Review Group contributed to publication of this review on breast cancer treatment in 2011

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.

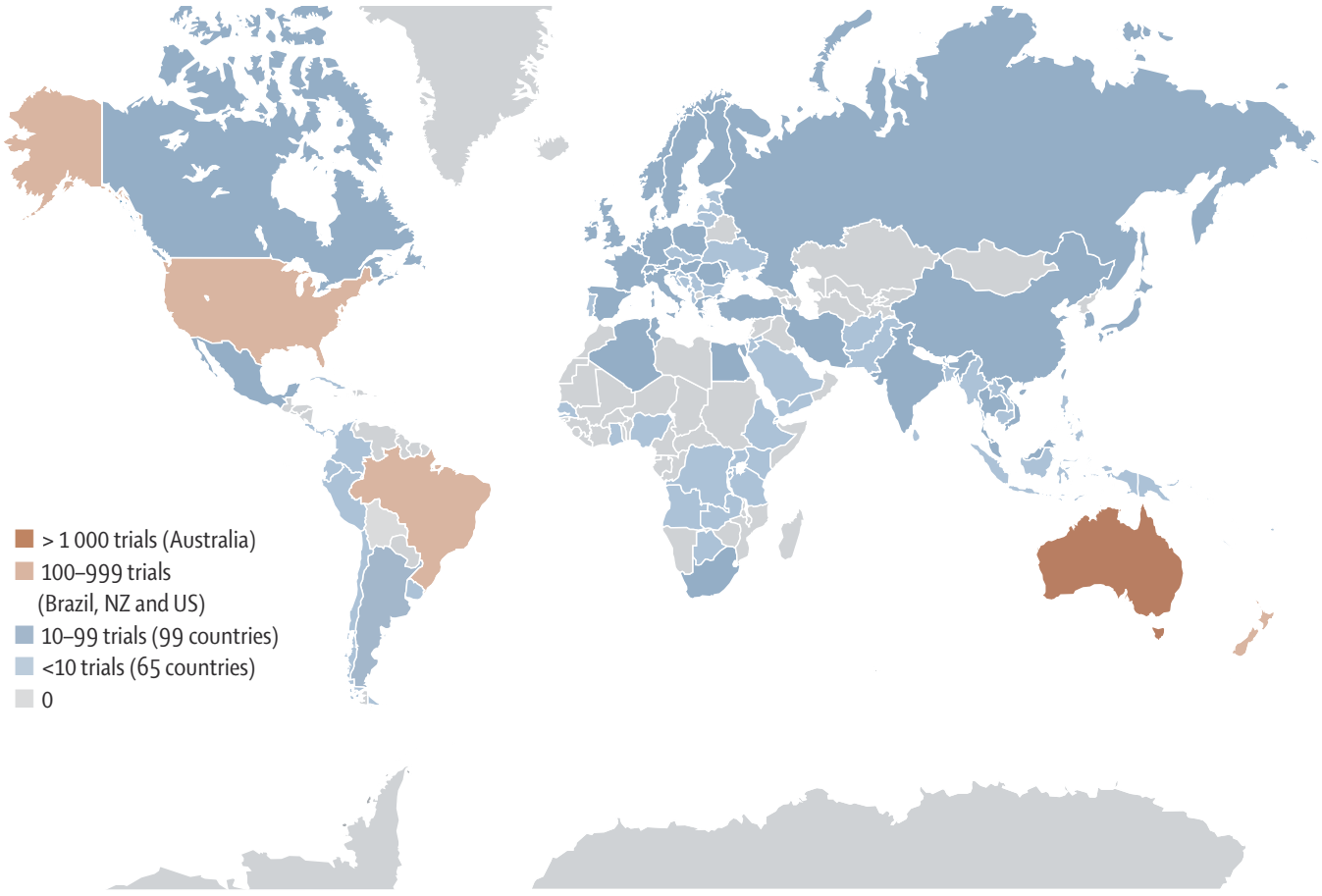
ANZCTR: a national resource

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.

ANZCTR: countries of recruitment



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.

Deborah Schofield, professor, and chair of health economics

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 eonomic 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.

Hannah Verry and Rupendra Shrestha, health economists

COLLABORATIONS

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.

GROUP	NATURE OF GROUP	CTC ACTIVITY
Australasian Gastro-Intestinal Trials Group (AGITG)	Collaborative group for gastrointestinal cancer trials: Australia, New Zealand 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) , Groupe Coopérateur Multidisciplinarie en Oncologie (GERCOR), 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)	Coordinating centre
Australasian Lung Cancer Trials Group (ALTG)	Collaborative group for lung cancer trials: Australia, New Zealand	Coordinating centre
	International collaborations: NVALT (Netherlands), NCIC CTG (Canada)	
Australasian Society of Thrombosis and Haemostasis	Professional group undertaking thrombosis trials: Australia, New Zealand	Coordinating centre
Australia New Zealand Gynaecological Oncology Group (ANZGOG)	Collaborative group for gynaecological cancer trials: Australia, New Zealand International collaborations: Dutch Gynaecologic Oncology Group (DGOC), Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens (GINECO), Gynecological Cancer Intergroup (GCIG), International Gynaecological Cancer Intergroup (IGCI), Gynecologic Oncology Group (GOG), Medical Research Council (MRC), Scottish Gynaecologic Cancer Trials Group (SGCTG)	Coordinating centre
Australian and New Zealand Urogenital and Prostate Clinical Trials Group (ANZUP)	Collaborative group for cancer of the genitourinary system: Australia, New Zealand. International collaborations: Cancer Research UK (CRUK), European Organisation for Research and Treatment of Cancer (EORTC), Groupe Coopérateur Multidisciplinarie en Oncologie (GERCOR),Institute of Cancer Research (ICR), National Cancer Research Institute (NCRI), Swedish & Norwegian Testicular Cancer Project (SWENOTECA), and Wales Cancer Trials Unit (WCTU)	Coordinating centre
Australian New Zealand Breast Cancer Trials Group (ANZ BCTG)	Collaborative group for breast cancer trials: Australia, New Zealand International collaborations: International Breast Cancer Study Group (IBCSG), Breast International Group (BIG), International Breast Cancer Intervention Study (IBIS)	Statistical centre for group, including randomisation
Australian New Zealand Clinical Trials Registry (ANZCTR)	National register of clinical trials: Australia, New Zealand and international	Coordinating centre
Biostatistics Collaboration of Australia	Universities undertaking postgraduate education in biostatistics: Australia	Coordinating centre
Cholesterol Treatment Trialists' Collaboration (CTTC)	Investigators of cholesterol treatment trials: Australia, New Zealand, United Kingdom, United States, Italy	Coordination of meta-analyses in heart disease
Clinical Trial Development Unit (CTDU)	Partnership with the Centre for Biostatistics and Clinical Trials, Peter MacCallum Cancer Institute: Australia	Trial operation and statistical support for cancer trials
Cochrane Collaboration Breast Cancer Group	Collaborative group undertaking systematic reviews of trial evidence: international	Editoral base
Cochrane Prospective Meta-Analysis Methods Group	Collaborative group undertaking systematic reviews of trial evidence: international	Coordinating centre
Cooperative Trials Group for Neuro-Oncology (COGNO)	Collaborative group for brain cancer trials: Australia	Coordinating centre
Early Prevention of Obesity in Children (EPOCH) collaboration	Prospective meta-analysis collaboration: international	Data coordination centre

GROUP	NATURE OF GROUP	CTC ACTIVITY
European Organisation for Research and Treatment of Cancer (EORTC)	International collaborative group	Collaborator through Australian groups
Fenofibrate and Event-Lowering in Diabetes (FIELD) Study Investigators	Collaborative group for FIELD diabetes trial genetic, molecular and follow-up substudies: Australia, New Zealand, Finland, Germany	Coordinating centre
INSPIRE	Meta-analysis: ASPIRE and WARFASA (Italy)	Member
International Neonatal Immunotherapy Study (INIS) Group	Collaborative group for INIS trial: Australia, New Zealand, Europe, Argentina	Regional coordinating centre
Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group	Collaborative group for LIPID cholesterol-lowering trial genetic, molecular and follow-up substudies: Australia, New Zealand, Germany	Coordinating centre
Medical Services Advisory Committee (MSAC) and Department of Health and Ageing	Government: Australia	Provide assessments of new technologies and other research services
Menzies Research Institute and Charles Darwin University	Research institution: Australia	Collaborator
Meta-analysis collaboration (AMICABLE)	Meta-analysis collaboration: international	Collaborator
Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPiNO) collaboration	Meta-analysis collaboration: international	Data coordination centre
Heart Foundation	Nongovernment organisation: Australia	Cardiovascular research
National Perinatal Epidemiology Unit (NPEU), University of Oxford	Research institution: UK	Collaborator on the INIS neonatal trial
Neonatal Oxygenation Prospective Meta-analysis (NeOProM) collaboration	Prospective meta-analysis collaboration: international	Coordinating centre
NSW Cancer Council	Cancer Epidemiology Research Unit	Collaborator
NSW Cooperative Oncology Group (NSWOG)	Collaborative group: New South Wales	Coordinating centre
Perinatal Antiplatelet Review of International Studies (PARIS) collaboration	Meta-analysis collaboration:international	Co-coordinating centre
Prenatal repeat corticosteroid international individual-patient-data study group: assessing the effects using the best level of evidence (PRECISE) collaboration	Meta-analysis collaboration: international	Collaborator
Prevention of Ventilator Induced Lung Injury Collaborative Study Group (PreVILIG)	Meta-analysis collaboration: international	Data coordination centre
Primary Care Cancer Trials Group (PC4)	Collaborative group: Australia	Collaborator
Primary Coronary Angioplasty versus Thrombolysis (PCAT)	Meta-analysis collaboration: international	Co-coordinating centre
Prospective Pravastatin Pooling (PPP) project	Collaborative group: international	Coordinating centre
Royal Australasian College of Surgeons (RACS)	Professional society undertaking trials of surgery: Australia and New Zealand	Coordinating the SNAC trials in breast cancer
Sydney Catalyst	Consortium for translational research in cancer	Collaborator
Trans-Tasman Radiation Oncology Group (TROG)	Collaborative group: Australia and New Zealand	Collaborator
Star Child Health	Meta-analysis collaboration: international	Member
VIGOUR group	Collaborative group for trials in heart disease: 40 countries	VIGOUR leader

CURRENT CTC TRIALS

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
NEONATAL DISORDERS			
Current trials			
APTS: Australian placental transfusion study	Neonates born before 30 weeks' gestation	1600	101
Trials in follow-up			
BOOST II: Benefits of oxygen saturation targeting	Neonates born before 28 weeks' gestation	1200	1135
CARDIOVASCULAR DISORDERS			
Pending trials			
REMOVAL: Effects of metformin added to insulin on atheroma progression *University of Glasgo and NHS-led, and CTC trial*	Adults with type 1 diabetes at risk of cardiovascular disease	90 (ANZ): 500 (international)	
Trials in follow-up			
ASPIRE: Aspirin to prevent recurrent venous thromboembolism	People who have had 6 months of treatment with warfarin for a venous thromboembolism	1200 (international)	689 (Australasia); 722 (international); 1225 (INSPIRE meta-analysis)
FIELD: Fenofibrate intervention and event lowering in diabetes	Patients with type 2 diabetes	8000	9795
LIPID: Long-term intervention with pravastatin in ischaemic disease	Patients with a history of coronary heart disease	9000	9014
BREAST CANCER (COLLABORATING WITH RACS)			
Current trials			
SNAC 2: Multicentre randomised trial of sentinel node biopsy versus axillary clearance *RACS and CTC study*	Women with operable breast cancer, stratified by various factors, including age and tumour size	1012	218
Trials in follow-up			
SNAC 1: Sentinel node biopsy versus axillary clearance *RACS and CTC study*	Women with operable breast cancer, stratified by various factors, including age and tumour size	1000	1088
GASTROINTESTINAL CANCER (COLLABORATING WITH AGITG)			
Pending trials			
GAP: Phase 2 study of gemcitabine and NAB-paclitaxel *AGITG and CTC study*	Patients with resectable pancreas cancer	50	
ICECREAM: Irinotecan Cetuximab Evaluation and Cetuximab Response Evaluation Among Mutants *AGITG and CTC study*	Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation	100	
IMPACT: Phase 2 trial using genomic sequencing and protein expression to direct first-line treatment *Garvan, AGITG and CTC study*	Patients with metastatic pancreatic cancer	90	
INTEGRATE: Phase 2 trial comparing regorafenib and placebo *AGITG and CTC-led international study*	Patients with advanced oesophagogastric cancer	150	
TACTIC: Phase 2 trial of panitumumab, cisplatin and gemcitabine *AGITG and CTC study*	Patients with biliary tract cancer	45	
Current trials			
A La CART: Australian phase III randomised trial of laparascopy-assisted resection compared with open resection *AGITG and CTC study*	Patients with primary rectal cancer	470	54
ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases *AGITG and CTC study*	Patients with confirmed resectable liver metastases and no other disease	200	1
DOCTOR: Phase 2 trial of preoperative cisplatin, 5-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer *AGITG and CTC study*	Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy	150	35

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
LAP07: Randomised multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib for pancreatic cancer *GERCOR-led, AGITG and CTC study*	Patients with locally advanced adenocarcinoma of the pancreas	60 (ANZ); 900 (international)	26 (ANZ); 423 (international)
PAN1: Phase II study evaluating potential predictive biomarkers in treatment of locally advanced and metastatic pancreatic cancer *AGITG and CTC study*	Patients with confirmed metastatic pancreatic adenocarcinoma	80	
REGISTER: Multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response *AGITG and CTC study*	Patients with gastrointestinal stromal tumour not suitable for curative surgery	80	44
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer *MRC-led, AGITG and CTC study*	Patients with fully resected stage III colorectal cancer	225 (ANZ): 9500 (international)	89 (ANZ): 2827 (international)
TOP GEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer *AGITG and CTC study*	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	34
Trials in follow-up			
Advanced GIST: Relation between dose and clinical activity of imatinib mesylate (AG0102, EORTC 62005) *EORTC-led, AGITG and CTC study*	Patients with unresectable or metastatic malignant gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ): 600 (international)	116 (ANZ); 946 (international)
ATTAX 3: Phase 2 trial of docetaxel, cisplatin and fluoropyrimidine with or without panitumumab for oesophagogastric cancer (AG0607OG) *AGITG and CTC study*	Patients with metastatic or locally recurrent oesophagogastric cancer	100	77
C07: 5-fluorouracil plus leucovorin compared with oxaliplatin with 5-fluorouracil + leucovorin for stages II and III carcinoma of the colon *NSABP-led, AGITG and CTC study*	Patients with resected stage II or stage III colon carcinoma	150	134
CO.20: Phase III study of BMS-582664 with cetuximab versus placebo with cetuximab *NCIC CTG-led, AGITG and CTC study*	Patients with metastatic colorectal carcinoma previously treated with combination chemotherapy	370 (ANZ); 750 (international)	416 (ANZ); 686 (international)
EORTC liver metastases: Oxaliplatin, 5-fluorouracil and leucovorin versus surgery for resectable colorectal cancer liver metastases (EORTC 40983) *EORTC-led, AGITG and CTC study*	Patients with colorectal cancer with resectable liver metastases	330 (international)	35 (ANZ); 364 (international)
PETACC 6: Addition of capecitabine to preoperative oxaliplatin chemoradiotherapy and postoperative oxaliplatin chemotherapy for rectal cancer (AG0707R) *EORTC (PETACC)-led, AGITG and CTC study*	Patients with locally advanced rectal cancer	135 (ANZ); 1090 (international)	127 (ANZ); 1094 (international)
Quasar 2: Phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer (AG0107CR) *OCTO-led, AGITG and CTC study*	Patients with colon cancer treated by surgery	120 (ANZ); 1892 (international)	219 (ANZ); 1952 (international)

GYNAECOLOGICAL CANCER (COLLABORATING WITH ANZGOG)

Pending trials			
ANZGOG 1013: Phase I–II BNC105P combination study *ANZGOG study*	Women with partly platinum-sensitive ovarian cancer in first or second relapse	134 (international)	
PARAGON: Phase II study of anastrozole in gynaecological cancers *MRC, ANZGOG and CTC-led international study*	Women with potentially hormone-responsive gynaecological cancers	100 (ANZ)	
Current trials			
PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with with pelvic radiation alone in high-risk endometrial carcinoma *GCIG-led, ANZGOG and CTC study*	Women with advanced endometrial carcinoma	200 (ANZ); 600 (international)	89 (ANZ); 499 (international)

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*	Women with locally advanced cervical cancer	780	21 (ANZ); 28 international
Symptom benefit: does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG 1103) *ANZGOG and PoCoG study*	Women with platinum-resistant or refractory ovarian cancer	800	95
Trials in follow-up			
TRIPOD: Phase II trial of intraperitoneal chemotherapy (ANZGOG 0601) *ANZGOG and CTC study*	Women with ovarian and related cancers	35–100	39
ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy *MRC-led, ANZGOG and CTC study*	Women with with platinum-sensitive relapsed ovarian cancer	400 (international)	17 (ANZ); 486 (international)
ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy *MRC-led, ANZGOG and CTC*	Women with epithelial ovarian cancer who had not received systemic antitumour therapy	100	76
SCOTROC 4: Multicentre trial of carboplatin flat dosing vs intrapatient dose escalation in first-line chemotherapy *SGCTG-led, ANZGOG and CTC*	Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum–taxane therapy	150 (ANZ); 1300 (international)	64 (ANZ); 937 (international)
Prospective study of risk-reducing salpingo-oophorectomy and longitudinal CA-125 screening (GOG 199) *GOG-led, ANZGOG and CTC*	Women aged >30 at genetic risk of ovarian cancer	250	83

GENITOURINARY CANCER (COLLABORATING WITH ANZUP)

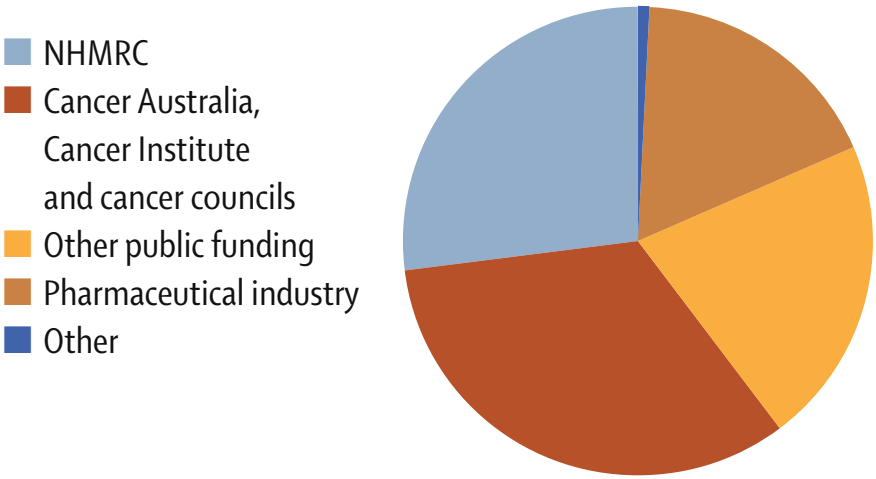
Current trials			
Aprepitant for germ cell chemotherapy: 7-day aprepitant schedule to prevent chemotherapy-induced nausea and vomiting (ANZGCTG 0801) *ANZUP and CTC study*	Patients receiving cisplatin-based chemotherapy for germ cell tumours	50	50
Chemo & cognition: Cognitive function and treatment for testicular cancer (ANZGCTG 0106) *ANZUP and CTC study*	Patients being treated and followed up for testicular cancer	154	141
Eversun: Phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901) *ANZUP and CTC study*	Patients starting first-line systemic therapy for advanced renal cell carcinoma	55	38
SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05) *MRC-led, ANZUP and CTC study*	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ); 1656 (international)	88 (ANZ); 901 (international)
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*	Patients with intermediate and poor-risk advanced germ-cell tumours (and selected good-risk tumours)	25	45

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*	Patients with stage IIIB or IV non-small-cell lung cancer	180	65
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*	Patients with advanced non-small-cell lung cancer	500	202
Trials in follow-up			
B2P2M2: phase II trial of BNC105P as second-line chemotherapy for pleural mesothelioma (ALTG 09/004) *ALTG and CTC study*	Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy	60	6

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
BR.29: Cediranib versus placebo for patients receiving paclitaxel and carboplatin for non-small-cell lung cancer (ALTG 09/001) *NCIC CTG-led, ALTG and CTC study*	Patients with stage IIIB or IV non-small-cell lung cancer	100	75
BRAIN CANCER (COLLABORATING WITH COGNO)			
Pending trials			
Phase II study of acetazolamide plus dexamethasone versus dexamethasone for cerebral oedema in high-grade glioma *COGNO and CTC study*	Patients with high-grade glioma requiring new dexamethasone or dose increase due to progressive or recurrent disease	86	
Phase II study of psycho-educational intervention in patients with primary brain tumour *PoCoG-led and COGNO study*	Patients with confirmed primary brain tumours	60	
Current trials			
Cabaret: phase II study of carboplatin and bevacizumab in for glioblastoma multiforme *COGNO and CTC study*	Patients with recurrent grade IV glioblastoma multiforme following radiotherapy and temozolomide chemotherapy	120	86
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC 26053-22054) *EORTC-led COGNO and CTC study*	Patients with non-1p/19q- deleted anaplastic glioma	100 (ANZ); 748 (international)	31
Phase III trial of temozolomide and short-course radiation versus radiation alone (TROG 08.02) *COGNO, TROG and CTC study*	Elderly patients with new glioblastoma multiforme	100 (ANZ); 500 (international)	41 (ANZ); 251 (International)
SEED: Self-reported evaluation of the adverse effects of dexamethasone *COGNO and CTC study*	Patients with brain tumours or brain metastases or advanced cancer using steroids	50 patients, 50 caregivers	13
Trials in follow-up			
LGG: Phase III study of primary chemotherapy with temozolomide versus radiotherapy (TROG 06.01, EORTC 22033-26033) *EORTC, COGNO, TROG and CTC study*	Patients with low-grade glioma, stratified for genetic 1p loss	100 (ANZ); 466 (international)	36 (ANZ); 466 (international)

CTC's research funding



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- 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 Trialists 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 Study (IBIS-II) international steering committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-embolism (INSPIRE) steering committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee (chair)
- Kanyini GAP Polypill Study safety and data monitoring committee (chair)
- 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 Axillary 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 (ASPAC) 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 Trialists' 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 IPD International Collaboration (AMICABLE) individual patient data collaboration steering committee
- 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

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, B2P2M2 trial management committee
- Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee, operational executive committee; CABARET trial management committee; SEED trial study management committee

Mark Chatfield

- Accelerated BEP trial management committee
- Aprepitant trial management committee
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee

Alan Coates

- *Annals of Oncology* editorial board
- APHINITY study interface committee
- Australasian Gastro-intestinal Trials Group (AGITG) safety and data monitoring committee (chair)
- Early Breast Cancer Trialists' Collaborative Group steering committee
- International Breast Cancer Study Group (IBCSG) foundation council
- International Breast Cancer Study Group scientific committee (co-chair)

Jenny Chow

- Cancer Institute NSW Neuro-oncology Group (NSWOG), COGNO operations executive, management committee, annual scientific meeting organising committee, COSA executive officers network

Xanthi Coskinas

- Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee, operational executive committee; NITRO trial management committee, B2P2M2 trial management committee, PACT in NSCLC 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, ATTAX3, TACTIC, DOCTOR, and REGISTER trial management committees
- ANZ BCTG scientific advisory committee
- ANZGOG Research Advisory Committee and PARAGON and OUTBACK trial management committees
- ANZUP scientific advisory committee and Accelerated BEP and EVERSUN 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-Instestinal Trials Group (AGITG); Australian New Zealand Gynaecological Oncology Group (ANZGOG); 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
- SNAC trial management committee

Alpana Ghadge

- Benefits of Oxygen Saturation Targeting (BOOST) II trial management committee
- Westmead international update management committee

Wendy Hague

- Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee
- Australasian Gastro-Intestinal Trials Group (AGITG) trials operations committee
- Australia New Zealand Gynaecological Oncology Group (ANZGOG) 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 SNAC 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
- Gynecological 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 Mister
- Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (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 committee
- 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
- Australian Placental Transfusion Study (APTS) management committee
- Australian Placental Transfusion Study echocardiography substudy management committee
- B2P2M2 trial management committee
- Cancer Australia Clinical Trials Development Unit (CTDU) site performance subcommittee

Katrin Sjoquist
- 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 opera tions 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, PAN1 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, operations executive and Accelerated BEP, Aprepitant, Chemo & Cognition 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 GMP3/4 (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, PAN1 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

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

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 (co-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

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

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

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 (course coordinator)

Project management in clinical trials: development, leadership and problem solving, Master of Clinical Trials Research, 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

PUBLICATIONS

JOURNAL ARTICLES

Adams EJ, Cox JM, Adamson BJ, **Schofield DJ.** Truncated careers in nuclear medicine technology: increased job control may improve retention. *Australian Health Review* 2011; 35(2): 124–129.

Aebi S, Sun Z, Braun D, Price KN, Castiglione-Gertsch M, Rabaglio M, Gelber RD, Crivellari D, Žgajnar J, Snyder R, Karlsson P, Simoncini E, Gusterson B, Viale G, Regan MM, **Coates AS,** Goldhirsch A. Adjuvant chemotherapy and tamoxifen in postmenopausal patients with node-negative breast cancer: Long-term follow up on IBCSG Trial IX. *Annals of Oncology* 2011; 22: 1981 – 1987.

Ananda S, Nowak AK, Cher L, Dowling A, **Brown C, Simes J,** Rosenthal MA, and for the Cooperative Trials Group for Neuro-Oncology (COGNO). Phase 2 trial of temozolomide and pegylated liposomal doxorubicin in the treatment of patients with glioblastoma multiforme following concurrent radiotherapy and chemotherapy. *Journal of Clinical Neuroscience* 2011;18(11): 1444–1448.

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Brown A, **Gebski V,** Beldham-Collins R, Hardcastle-Fowler T, Do V, Turner S. Gold seed fiducial markers for prostate radiation therapy: describing prostate motion. *Radiographer* 2011; 58(3): 57–61.

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Callander E, Schofield D, Shrestha R. Multi-dimensional poverty in Australia and the barriers ill health imposes on the employment of the disadvantaged. *Journal of Socio-Economics* 2011; 40(6): 736-742.

Callander 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 8 Nov 2011.

Callander EJ, Schofield DJ. Emergency department workforce models: What the literature can tell us. *Emergency Medicine Australasia* 2011; 23(1): 84–94.

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Changsirivathanathamrong D, Wang Y, Rajbhandari D, Maghzal GJ, Mak WM, Woolfe C, Duflou J, **Gebski V,** Dos Remedios CG, Celermajer DS, Stocker R. Tryptophan metabolism to kynurenine is a potential novel contributor to hypotension in human sepsis. *Critical Care Medicine* 2011; 39(12): 2678-2683.

Chen JY, Hruby G, **Stockler MR,** Patanjali N, Bucci J, Perez G, Loadsman JA, Sheehan E. Patient-reported outcomes of prostate high-dose-rate brachytherapy boost comparing an outpatient and inpatient protocol: A two-center chronologic cohort study. *Brachytherapy* 2011; 10(6): 454-460.

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Colleoni M, Giobbie-Hurder A, Regan MM, Thürlimann B, Mouridsen H, Mauriac L, Forbes JF, Paridaens R, Láng I, Smith I, Pienkowski T, Wardley A, Price KN, Gelber RD, **Coates AS,** Goldhirsch A, for the BIG 1-98 Collaborative and International Breast Cancer Study Groups. Analyses adjusting for selective crossover show improved overall survival with adjuvant letrozole compared with tamoxifen in the BIG 1-98 study. *Journal of Clinical Oncology* 2011; 29(9): 1117-1124.

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de Boer SP, **Barnes EH,** Westerhout CM, **Simes RJ,** Granger CB, Kastrati A, Widimsky P, de Boer MJ, Zijlstra F, Boersma E. High-risk patients with ST-elevation myocardial infarction derive greatest absolute benefit from primary percutaneous coronary intervention: results from the Primary Coronary Angioplasty versus Thrombolysis (PCAT)-2 Collaboration. *American Heart Journal* 2011; 161(3): 500–507. e1.

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Dietz HP, Franco AV, Shek KL, **Kirby A.** Avulsion injury and levator hiatal ballooning: two independent risk factors for prolapse? An observational study. *Acta Obstetricia et Gynecologica Scandinavica.* Published online 4 Nov 2011.

Dobson R, **Barnes E,** Tyrrell K, Hosking B, Larsen J, Besier R, Love S, Rolfe P, Bailey J. A multi-species model to assess the effect of refugia on worm control and anthelmintic resistance in sheep grazing systems. *Australian Veterinary Journal* 2011; 89(6): 200–208.

Drury PL, **Ting R, Zannino D,** Ehnholm C, Flack J, Whiting M, Fassett R, Ansquer JC, Dixon P, Davis TM, **Pardy C,** Colman P, **Keech A.** Estimated glomerular filtration rate and albuminuria are independent predictors of cardiovascular events and death in type 2 diabetes mellitus: the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study. *Diabetologia* 2011; 54(1): 32–43.

Ellingson K, Muder RR, Jain R, Kleinbaum D, Feng PJ, Cunningham C, Squier C, Lloyd J, Edwards J, **Gebski V,** Jernigan J. Sustained reduction in the clinical incidence of methicillin-resistant *Staphylococcus aureus* colonization or infection associated with a multifaceted infection control intervention. *Infection Control and Hospital Epidemiology* 2011; 32(1): 1–8.

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