



NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2013

25 years of clinical trials



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The NHMRC Clinical Trials Centre at the University of Sydney, now 25 years old, runs large multicentre investigator-initiated clinical trials, undertakes research with national and international trial groups, and contributes expertise to trials run by others. It also:

- takes a lead in proposing new directions for clinical research in Australia, particularly research aligned with national policy and clinical practice
- participates in translational research, from bench to bedside
- conducts methodological research in relation to clinical trials
- reviews and synthesises evidence from completed trials, and is at the forefront of developments in methods, such as prospective meta-analysis
- supervises postgraduate students in all of these areas
- offers postgraduate degrees in clinical trials research
- runs short courses to train people for Australian medical research.

The CTC also offers health technology and diagnostic test assessments, economic analyses, biostatistical design and analysis, and automated central randomisation services.

Core funding is provided by the 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 Chris O'Brien Lifehouse on Missenden Road.

This report covers the CTC's achievements for 2013.



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Directors' report

This year, 2013, marks an important milestone for us. It is now over a quarter-century since the CTC was established. We started operations in late 1988, with an initial grant of \$250 000 and a commitment to ongoing funding from the NHMRC and provision of facilities and services from the University of Sydney. By the end of the first full year, the CTC had 17 staff and was conducting and collaborating in large trials in cardiovascular disease and cancer, common diseases where small improvements make major differences to health.

Our initial objectives were: to promote and help coordinate large-scale collaborative clinical trials throughout Australia; to provide a consultative service for smaller clinical trials in design and analysis; to provide an educational resource to help clinical investigators run their own trials, to assist practitioners evaluate trial results for clinical decision making and to initiate appropriate academic courses; and to develop and promote research in clinical trials methodology and research aimed at improving the impact of clinical trial results on medical practice.

These initial goals still largely reflect the philosophy of CTC today. Over our first 25 years there have been many examples of research that has changed clinical practice and health outcomes.

Highlights of first 25 years

In cardiovascular disease, a long-standing research focus for us has been prevention. Treatments that reduce the risk of cardiovascular events can benefit many thousands of Australians. The LIPID coronary disease prevention study, completed in 1998, was then the largest trial undertaken in Australia. Its results, that statin therapy reduced mortality in people with average cholesterol levels, had a major impact on health and on treatment guidelines in Australia and elsewhere. Cost-effectiveness analyses showed that the treatment and the trial itself were both economically worthwhile, and long-term follow-up has shown that the treatment is safe. LIPID is also a contributor to the ongoing 20-year-old Cholesterol Treatment Trialists' Collaboration, an international prospective meta-analysis collaboration, now comprising 27 trials and 170 000 patients, co-founded and co-coordinated by the CTC. It has delivered precise and convincing evidence on the benefits of statin therapy.

The FIELD fenofibrate study, 1997–2005, was a trial of a potential treatment for coronary disease risk, but fenofibrate was unexpectedly shown to be very effective in preventing vascular complications of diabetes. In 2013 fenofibrate was approved by the Therapeutic Goods Administration for diabetic retinopathy and has been approved in the EU and USA for co-prescription with statin therapy for dyslipidaemia.

Both LIPID and FIELD are yielding new insights into the risk factors, biomarkers and mechanisms of cardiovascular disease as we continue to follow up patients and analyse biological samples in relation to later clinical events. FIELD is also exploring mechanisms of diabetes affecting eye disease, kidney disease and foot ulcers.

The CTC has played a significant role in the assessment of treatment strategies for acute coronary syndromes over many years in collaboration with international trialists of the VIGOUR organisation. More recently, in trials of venous thrombosis, we showed in ASPIRE that aspirin is an inexpensive and effective long-term treatment for preventing recurrent deep-vein thrombosis. The cost of the trial is likely to be overtaken within two years by national savings in thrombosis treatment prevented.

Clinical trials in cancer have involved collaboration with many cancer cooperative groups—trials in prevention, surgical treatment, chemotherapy and novel targeted therapies. Examples include the international IBIS trial with the ANZ BCTG where for women at risk, breast cancer incidence was reduced by a third after five years of tamoxifen, a reduction that was maintained over 10 years of follow-up, the SNAC trial, in collaboration with the RACS, of minimally invasive sentinel node biopsy management instead of routine axillary clearance surgery for early breast cancer. The newer treatment results in better quality of life and has now become the standard of care.

continued...

HISTORICAL

Controlled clinical trials are the most scientifically valid way to evaluate new treatments for patients and can also be used to evaluate any form of intervention aimed at treating or preventing disease and improving health.

Controlled clinical trials can be used not only to identify significant, real advances in medical care but also to identify ineffective therapies which may have appeared promising in uncontrolled studies.

Large-scale clinical trials are of important value in directing small, but humanly worthwhile, improvements in treatment.

— John Simes, 1988



The promise of individualised treatment was realised by the international CO.17 trial in collaboration with AGITG, a biomarker study in which colorectal cancer tumours responded to cetuximab chemotherapy only if they did not have a K-ras mutation. International guidelines now recommend patients have genetic testing so that only susceptible tumours are treated, sparing other patients an ineffective treatment, with potential cost saving of many millions of dollars worldwide.

Provision for biological and genetic studies is an integral part of the design of our cancer trials. Similarly, most of our trials now include data collection for prospectively planned cost-effectiveness analyses.

Our neonatal trials began in 2001 with INIS, evaluating the use of immunoglobulin to prevent later disability or death in newborn infants with infection. Immunoglobulin has been recommended in clinical practice on the basis of some evidence, but the INIS trial showed conclusively in 2011 that it did not make a difference, with the result that patients could avoid unnecessary treatment and hospitals could save its cost.

Notable among our recent achievements is the BOOST II neonatal study, published in 2013, which addressed the long-standing question of the optimal supplemental oxygen target concentration for premature infants. The trial's higher target resulted in better short-term survival outcomes than a lower target for currently used oximeters. The impact of this on practice still awaits the assessment of long-term outcomes with further follow-up and confirmation by combined analysis

of international data from over 5000 infants in this and similar trials.

We have had leading roles in international meta-analysis collaborations in cardiovascular disease and neonatology for many years and other areas more recently. As well, we coordinate reviews on clinical evidence for the Cochrane Collaboration and undertake systematic reviews of new medical technology for the Australian government. Allied to this is our important research interest in developing methods for evaluating clinical tests.

Clinical evidence from systematic reviews must be comprehensive to minimise bias, so these analyses depend on public trial registration. The Australian New Zealand Clinical Trials Registry based at the CTC is the realisation of an early aspiration. Launched in 2005, the ANZCTR now has about 9000 registered clinical trials helping inform ongoing trials research and as a resource for reviews of trial evidence.

Trial design has diversified since 1988 as research has sought ways of reaching objectives while minimising cost and expense. Refinements in methods developed here and elsewhere improve the way we conduct our own trials and are shared in the teaching and consultation activities of our biostatistics group. Building capacity for Australian expertise in the design and conduct of clinical trials is an important activity. The new postgraduate program in clinical trials research is now well established.

In 2013, we received over \$20 million in grant funding from public and charitable sources. This is the first year of our current five-year NHMRC program grant for advancing the

evidence base in national priority areas for health, the third such grant received by the CTC, but the first for a collaborative undertaking (with the Boden Institute of Obesity, Nutrition, Exercise & Eating Disorders). The grant is supporting multidisciplinary collaborative research focusing on diseases with substantial mortality and morbidity.

We have had to anticipate and respond to changes in the landscape of clinical trials over 25 years, both global and national. Our objectives from 1988 have been achieved and developed into new questions, new methods, new ways of conducting trials, and new ways of using trial evidence to improve health outcomes.

The next 25 years

There are exciting and challenging times ahead in clinical trials research. There has been an explosion of new knowledge about patient and disease characteristics based on the human genome, with novel targeted therapies and more individualised therapeutic strategies. Costs of health care are continuing to rise and regulatory challenges continue. In such an environment, clinical trials research will be even more important in identifying the most effective and cost-effective treatments. But more efficient trial design and governance will be required to ensure this system is sustainable and remains competitive—with greater use of adaptive designs, the need for more efficient trial operations embedded in the health care system and the ability to work effectively with clinical trial networks integrated into health care.

After the MJA summit on the future of clinical trials in 2012, a group of leading Australian clinical researchers came together as an interim committee to lead formation of the Australia Clinical Trials Alliance (ACTA), with the purpose of cooperating on common issues affecting investigator-initiated trials in Australia. These issues relate to funding, advocacy, identifying gaps in research, sharing infrastructure (such as biobanks and biostatistical expertise), translating research into clinical practice and sustaining the health system. We are pleased to be part of this exciting new venture, to be formalised in 2014, designed to benefit research, the health care system and patients.

On the positive side, methodological and technological advances will allow us to administer our trials more efficiently and potentially better ways of doing research can be investigated by integrating trials seamlessly with electronically recorded clinical care, at much lower cost than the current model of separate research.

Well-conducted randomised controlled trials remain the best way of determining the efficacy of new treatments. There will be challenges in integrating research with basic science and clinical care, requiring new methods and new partnerships. We will be part of the solutions by generating new evidence, and interpreting, combining and applying the evidence to improve health outcomes.

CTC Executive



John Simes, director



Anthony Keech, deputy director



Wendy Hague, clinical trials program director



Kim Russell-Cooper, general manager

TIMELINE

1996: Mallett Street



1988

- CTC sets up offices in 5 uncarpeted rooms in the basement of the Edward Ford Building, University of Sydney, with two staff.

1990

- International tPA/streptokinase mortality trial completed.

1992

- The CTC starts collaborating with the AGITG.
- CTC establishes and collaborates with the Australian New Zealand Germ Cell Trials Group (ANZ GCTG).
- Randomisation of over 9000 patients in the LIPID trial completed.

1994

- National Cancer Trials Registry is set up to disseminate information about current cancer trials.

1996

- The CTC outgrows its offices and moves to Mallett Street in Camperdown.

1998

- The LIPID trial completed and published.
- FIELD diabetes trial launched by the Minister for Health.



- Cochrane's Prospective Meta-Analysis Methods Group founded and based at the CTC.



Dr Michael Spence, Vice-Chancellor, University of Sydney

2000

- Biostatistics Collaboration of Australia founded.



1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

1989

- CTC establishes statistical and randomisation centre for the ANZ BCTG.
- CTC expands to 10 rooms and 17 staff.

1991

- The first GUSTO trial opens for recruitment.
- The first of regular short courses on clinical trials presented.

1993

- First GUSTO international trial closed and published, with 2287 patients in Australia and 41 021 internationally.
- CTC pioneers dynamic balanced randomisation.

1995

- Collaboration with the NSW Cooperative Oncology Group (NCOG) on investigator-initiated cancer trials.
- The CTC and the National Breast Cancer Centre initiate a collaborative review group for the Cochrane Collaboration.



1999

- International Clinical Trials Symposium, 'Improving health care in the new millennium'.
- VIGOUR collaboration founded with CTC as regional centre for international coronary trials.



2001

- CTC publishes first in a series of studies of trade-offs and preferences in cancer treatment.
- INIS, CTC's first neonatal trial, begins in collaboration with NPEU.



2002

- International Clinical Trials Symposium.



- ANZGOG established.
- 5-year NHMRC program grant for CTC research team awarded.
- SNAC trial begun after patients' concerns about complications of breast cancer surgery.

2004

- Australian Lung Cancer Trials Group (ALTG) formed, and CTC's first lung cancer trials begin.

2007: Mallett St and MFB



2006

- Biostatistical meta-analysis settles the controversy about radiotherapy after mastectomy, finding that it is beneficial.
- CTC researchers devise a strategy for evaluating diagnostic tests, which becomes the basis for guidelines used by the Medical Services Advisory Committee on Medicare funding for new tests.


2008

- 5-year NHMRC program grant for CTC research team awarded.
- Symposium: '20 years of clinical trials'.
- CO.17 investigators identify K-ras gene mutation as target for cetuximab.

2010

- Health economics group is formally set up at the CTC.

2012

- ASPIRE shows that aspirin is an inexpensive way to prevent recurrent thrombosis.
- 
- New evidence from BOOST II helps to establish the optimum oxygen level for newborns.
 - CTTC results—27 trials, 174 000 patients—even people at low risk benefit from lipid-lowering treatment.
 - Laboratory studies in diabetes established at the CTC.
 - Sydney Catalyst: the Translational Cancer Research Centre of Central Sydney and Regional NSW founded: director, John Simes.

2002

2003

2004

2005

2006

2007

2008

2009

2010

2011

2012

2013

2005

- The national Australian Clinical Trials Registry formally established at the CTC
- First prospective meta-analysis of the CTTC—14 trials, 90 000 patients—shows conclusively that statin drugs reduce risk.
- FIELD trial—with nearly 10 000 patients with diabetes—completed and published.

2007

- ANZ GCTG and APUG amalgamate to form ANZUP.
 - *Interpreting and reporting clinical trials* published by AMPCo.
 - *Communicating prognosis and issues surrounding the end of life* report published and becomes the basis for Australian guidelines.
 - International Clinical Trials Symposium.
- 
- International Clinical Trials Symposium 2007
- Cooperative trials Group for Neuro-Oncology (COGNO) established.
 - PARIS meta-analysis shows aspirin prevents pre-eclampsia, benefiting mother and baby.

2011

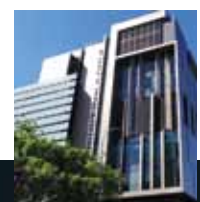
- INIS shows that intravenous immunoglobulin does not benefit infants with infections.
- Master of Clinical Trials enrolls its first students.
- MAPPiNO shows that NO does not improve lung function in premature infants.

2009

- Fenofibrate shown to reduce amputation in type 2 diabetes.

2013

- CTC's 5-year collaboration with the Boden Institute (BIONE) and Macquarie University formally begins.
- Australian Clinical Trials Alliance established by clinical trial leaders to advance investigator-initiated trials research.
- The CTC's trials group move to Lifehouse, a new multidisciplinary centre for integrated cancer care and research.



2013: Lifehouse

Oncology research

The CTC's oncology group of over 40 staff work with national cancer collaborative groups to conduct trials and associated research that will improve the outcomes of people with various cancers. These collaborations develop new concepts into working trials. The trials result in high-level evidence which is translated into standards for cancer treatment and prevention.

The CTC works collaboratively as coordinating centre or collaborating sponsor with the Australasian Gastro-Intestinal Trials Group, the Australia New Zealand Gynaecological Oncology Group, Australian and New Zealand Urogenital and Prostate Cancer Trials Group, Australasian Lung Cancer Trials Group and the Cooperative Trials Group for Neuro-Oncology. The CTC is the statistical centre for the Australian and New Zealand Breast Cancer Trials Group and conducts the SNAC breast cancer trials with the Royal Australasian College of Surgeons.

Some recent achievements are described in these pages.

In 2013 the CTC's oncology group embarked on ways to improve processes working with these collaborators and others, including research nurses, data managers and pharmacists, international counterparts, such as the NCIC CTG in Canada, the Medical Research Council in the UK and the European Organisation for Research and Treatment of Cancer; funders, such as Cancer Australia, the NHMRC and the Cancer Institute; and commercial partners. The quest for these improvements has come in the context of the busy day-to-day running of these important cancer trials. The studies address clinical questions not only about advancing treatments, but also on quality of life, cost issues and translational biological substudies.

In its research outcomes, the group and its collaborators had a bumper year, publishing 48 journal papers and delivering 40 research presentations at major international conferences, 18 of these at the American Society of Clinical Oncology Annual Meeting. Some were substudies on biomarkers, quality-of-life or economics analyses, some were some early notifications of trials in progress, and some were final results of completed trials.



Burcu Vachan, oncology program manager, and Sonia Yip, oncology senior translational research fellow and manager



Martin Stockler, co-director of the CTC's oncology trials



CANCER GROUPS

Gastrointestinal cancer (AGITG)

The CTC has been conducting trials with the Australasian Gastro-Intestinal Trials Group since the early 1990s. In that time the collaboration has published nearly 80 articles in scholarly journals and presented over 130 study findings at national and international conferences.

In 2013, the group presented final results of ATTAX3, an Australian trial of adding panitumumab to standard chemotherapy as a treatment for advanced oesophagogastric cancer, a cancer associated with poor prognosis. Panitumumab is a human monoclonal antibody targeting the epidermal growth factor receptor. It has had some success as a treatment for colorectal cancer, but this trial showed that the treatment did not benefit patients with oesophagogastric cancer. The results of the LAP07 pancreatic cancer trial were also presented, similarly showing that radiotherapy in addition to standard chemotherapy did not improve outcomes. Both these trials will spare future patients ineffective additional treatments as the search for better treatments goes on.

A new trial for 2013, ASCOLT, is testing the efficacy of aspirin in reducing recurrence in people who have already had surgery and treatment for colorectal cancer.



Professor John Zalcborg, chair of AGITG

Aspirin is safe and inexpensive and appears to have anticancer properties. The study will also measure survival and find out the characteristics of patients who benefit most.

At the other end of the trial lifecycle is the MAX colorectal cancer trial, which was the first AGITG-CTC international trial, completed in 2009. MAX was part of a recent meta-analysis of 7 trials totalling 3178 patients examining the effect of adding bevacizumab, a monoclonal antibody, to chemotherapy treatment.¹⁸¹ The new analysis was large enough to show the effects in subgroups, including 426 patients aged 75 years or over, and confirmed that this group did benefit from bevacizumab treatment. This finding is important because elderly patients have been underrepresented in clinical trials. Tumour tissue from MAX trial patients is being analysed in relation to biomarkers for prognosis and prediction of how treatment affects individual patients (p. 15).¹¹²

DANIELLE FERRARO

The Kristian Anderson Award, which provides funding to support a clinician to research an aspect of personalised medicine in the area of bowel cancer, was presented to Dr Danielle Ferraro, clinical research fellow for the gastrointestinal and lung trial groups.

She is investigating use of cetuximab and panitumumab in colorectal cancers. These drugs are effective for only some patients' tumours. Dr Ferraro aims to produce a test that gives clinicians more accurate information about which patients would benefit from these drugs, which will spare other patients their side-effects.





Associate Professor Paul Mitchell, president of ALTG

Lung cancer (ALTG)

The Australasian Lung Cancer Trials Group was formed in 2004, the same year the first of its trials with the CTC were initiated. Trials have been conducted in non-small-cell lung cancer and mesothelioma.

Mesothelioma is a form of lung cancer caused by exposure to asbestos and is usually only detected when it is advanced. New drugs for treatment after initial chemotherapy are badly needed. A new agent, BNC105P, which targets the blood vessels in tumours, suppressing tumour growth, was recently tested for efficacy and safety by ALTG investigators.¹⁰² Unfortunately, it did not live up to its promise. It was not effective on its own, but may act to improve the delivery of other treatment, so future investigations will examine combinations with chemotherapy drugs.

Another drug that acts against blood vessel growth, cediranib, was investigated in an ALTG collaborative trial with the National Cancer Institute of Canada Clinical Trials Group.⁸³ This study found that the drug did not improve the survival of people with non-small-cell lung cancer.

Recent studies on patients' preferences in trade-offs between survival and chemotherapy treatment in lung cancer have been published or presented at international meetings (p. 14).^{88,93}

Gynaecological cancer (ANZGOG)

Since 2000, the Australia New Zealand Gynaecological Oncology Group, whose trials are coordinated at the CTC, has been the lead group for trials in ovarian cancer, cervical cancer, and cancer of the uterus, vulva and vagina. The group aims to initiate and conduct trials covering surgery, drug treatments and radiation, as well as biological research and quality-of-life studies. Most importantly, research questions reflect the needs of patients. The group also emphasises engagement of patients and their families with the research process.

The ANZGOG-CTC Symptom Benefit trial is an open international quality-of-life study, which is measuring subjective improvement as well as the tumour response in women who have palliative



Kate Sawkins, operations associate oncology program manager for ALTG and COGNO



Dr Alison Brand, chair of ANZGOG

chemotherapy after ineffective platinum chemotherapy for advanced ovarian cancer. The Australian investigators recently published a substudy of the relationships among expectations, hope, and depression in the participants. They found that if women’s hopes were not fulfilled, they were more likely to become depressed. This has implications for the way that clinicians communicate with these patients.¹³²

The collaboration undertook a substudy of the Australian Ovarian Cancer Study, looking at physical symptoms, coping styles and quality of life in the last year of life of women whose cancer had recurred.¹¹¹ The findings are important for patients and their doctors who have to make decisions about treatment and supportive care at the end of life.

Anne Long, clinical research fellow, and Professor Ian Davis, chair of ANZUP

Urogenital cancer (ANZUP)

The CTC is coordinating centre for the trials of the Australian and New Zealand Urogenital and Prostate Cancer Trials Group, formed 5 years ago to meet a need to improve treatment of bladder, kidney, testicular and prostate cancers through clinical trials research.

The successful completion in 2013 of Accelerated BEP, the pilot trial of an accelerated chemotherapy regimen for testicular cancer, showed that the treatment was safe, feasible and active, leading the way for a new large international trial to obtain high-level evidence on definitive treatment for men with testicular cancer, particularly those at high risk. This trial, which will be led by ANZUP and the CTC, is currently being initiated. An Australia-wide survey of current patterns of management of this disease by medical oncologists⁵³ indicated a need for evidence-based

guidelines, expected to be the end result of the new trial.

An essential precursor to any new clinical trial is a thorough review of the current evidence on the clinical question. This is the case for a new phase 3 trial of a treatment regimen for bladder cancer, BCG+MMC, expected to open in 2014. CTC and ANZUP researchers undertook a systematic review and meta-analysis of available evidence on the effect of intravesical (that is, introduced directly into the bladder) chemotherapy added to standard therapy. This review recommended that a further trial was warranted but that only some stages of bladder cancer were responsive to the treatment. The treatment will now be tested in the new trial, with participation in the trial limited to patients who have these specific tumours.





Professor Mark Rosenthal,
chair of the COGNO
Scientific Advisory
Committee

Tumours of the brain and nervous system (COGNO)

The Cooperative Trials Group for Neuro-Oncology (COGNO) is a relatively young collaborative investigator group. It was established in 2007 in response to a need for a coordinated, structured approach to the management of large-scale, multicentre brain cancer trials in Australia.

COGNO's annual scientific meeting in 2013 was its first stand-alone conference. This annual event is a forum where current work by local and international research leaders is presented and where ideas for new trials are conceived. So far there have been few trials in this area. Foundation work by COGNO researchers has included determining the current status of treatment in Australia. The first Australia-wide study of patterns of care for glioblastoma, published in the *Asia-Pacific Journal of Clinical Oncology*,²⁸ and another study on care for medulloblastoma, presented at the American Society of Clinical

Oncology, both found variations in aspects of treatment, pointing to specific needs for future clinical trials on treatment strategies.

The CABARET trial is an ongoing study of treatment for glioblastoma, an aggressive brain cancer. Glioblastoma that recurs after initial treatment currently does not have standard treatment. The trial investigated bevacizumab, a monoclonal antibody that inhibits the growth of new blood vessels in tumours, with or without carboplatin chemotherapy. The preliminary results, that adding carboplatin to bevacizumab did not result in clinical benefit compared with bevacizumab alone, were presented at the meeting of the American Society of Clinical Oncology. This study is also providing data for substudies and exploratory analyses, including the benefits of continuing versus stopping bevacizumab after disease progression, and a validation of the criteria for assessing tumour response.

Diana Winter,
CABARET data manager, and
Ann Livingstone, associate
oncology program manager,
COGNO and ALTG



Breast cancer

The CTC is the statistical and randomisation centre for the Australia and New Zealand Breast Cancer Trials Group, doing methodological research, statistical design of new studies, management of quality of life and cost-effectiveness protocols, systematic reviews of data quality and analyses of current trials.

CTC statisticians and oncologists recently published data from an early ANZ BCTG trial to test trade-offs in quality of life and survival with two different chemotherapy regimens for advanced breast cancer.⁸⁵ The investigators assessed patients' quality of life while on chemotherapy and also assessed side-effects associated with treatments. They found that the more toxic but also more effective regimen was associated with more improvement in progression-free survival adjusted for quality-of-life score than the lesser toxic but also less effective therapy.

The methods used, of weighting quality-of-life assessment by patients to obtain global scores and integrating weighted scores with survival outcomes, were methods initially developed by CTC statisticians and their colleagues in the past. When applied to this breast cancer trial, the methods provided a complete picture of the balance of benefit and harm, and are recommended for use in future trials where trade-offs of toxicity with tumour response and survival exist.



Chee Lee, clinical lead in oncology research



Sarah Chinchin, operations associate oncology program manager and mentor.

HISTORICAL



SENTINEL NODE BIOPSY VERSUS AXILLARY CLEARANCE (SNAC)

SNAC was a trial to compare the outcomes of sentinel lymph node biopsy compared with axillary node clearance in early breast cancer. Axillary node clearance, a more invasive procedure, often results in arm swelling (lymphoedema).

SNAC was notable in that it arose directly from concerns of patients, who felt that lymphoedema was underestimated by the medical profession. At the National Breast Cancer Conference in 1998, those present recommended that researchers collect and report evidence on lymphoedema and the different surgical options for early breast cancer.

SNAC began in 2001 as a collaboration between the Royal Australasian College of Surgeons and the CTC with funding from the Medical Benefits Fund and the Department of Health and Ageing. It was completed in 2005 after very rapid recruitment, which was partly attributed to the interest of consumers in this question.

The investigators reported that, after one year, women who did not have an axillary clearance had less arm swelling. Arm swelling increased over time. Patients are still being followed up for lymphoedema and other effects of surgery, and data from the trial will contribute to a prospective meta-analysis of recurrence of breast cancer after the trial treatments.

HISTORICAL



If the major purpose of the trial is to help decide which treatment strategy is more likely to benefit the patient, then it is important to take into account the advantages and disadvantages of each of the therapies from the patient's perspective.... For example, a treatment which offers an additional 3 months survival may not be preferred if it is at the expense of considerable side-effects from therapy.

— John Simes,
Statistics in Medicine, 1985

Cancer studies that address patients' circumstances and psychological needs

Most clinical trials in cancer investigate novel treatment regimens to maximise survival and quality of life. However, most trials also generate data that can be analysed to find the best ways of meeting the psychosocial needs of patients. This is used in studies of, for example, how oncologists can predict and communicate likely survival in the context of uncertainty, and how much treatment individual patients will freely endure for survival.

Survival and prognosis

People with advanced cancer often want information about their expected survival time, and those wanting information prefer to receive estimates for the possible worst-case, typical and best-case scenarios rather than receive a single number estimate of median survival.⁸² It is difficult for oncologists to estimate and explain survival time in a meaningful way. In a study recently published in the *Journal of Clinical Oncology*, CTC researchers and their colleagues examined the accuracy and usefulness of oncologists' estimates of survival time for patients with mixed incurable cancers.⁸¹ Although the actual estimates were not accurate, they were useful and accurate as a basis for estimating worst-case, typical and best-case scenarios. For patients requesting information on their likely survival time, presenting this information as three scenarios should improve patient understanding and help with decision making and planning.

Preference studies

The CTC and its collaborative groups have a reputation for useful observational studies investigating attitudes to chemotherapy from the patient's point of view—that is, asking patients to articulate the increase in survival that would make their chemotherapy worthwhile.⁸⁸ Two of these studies by ALTG (p. 10) and the CTC, one eliciting patients' preferences and the other eliciting clinicians' preferences, were presented at the World Conference on Lung Cancer in October 2013. The patients, who had non-small-cell lung cancer, indicated that chemotherapy was worthwhile for moderate improvements in survival. Clinicians' preferences were similar but less varied. These investigators also sought to find out patients' preferred and actual levels of involvement in decision making. Their preferences were varied but stable, prompting the conclusion that clinicians should talk to patients and consider their preferences for involvement in decision making when discussing chemotherapy treatment for lung cancer.

For advanced ovarian cancer, the standard treatment is infusion of chemotherapy drugs. However, in terms of acting on the tumour, delivering chemotherapy directly into the abdomen would be ideal because it exposes the tumour to a higher concentration of drugs. This is not commonly done in Australia because of concerns about side-effects and inconvenience. ANZGOG and CTC investigators (p. 10) have completed a trial to determine the feasibility of this method, looking at survival, complications, quality-of-life measures and patients' preferences in trade-offs between survival and quality of life.⁸

Patients judged treatment worthwhile for a survival improvement of months, but their responses were tempered by the greater toxicity and inconvenience of this method. Preference studies such as this are recommended in all treatment trials, because they can help determine the acceptability and likely uptake of the regimens.

Translational research in cancer

Translational research aims to integrate all phases of medical research, from scientific innovation in the laboratory through various phases of clinical trials to ways of implementing research findings in clinical practice. This integration speeds the long pathway between scientific discoveries and their practical use to improve the outcomes for patients.

The CTC has a close relationship with Sydney Catalyst: the Translational Cancer Research Centre of Central Sydney and Regional NSW. This consortium brings together teams of clinicians and researchers from more than 20 member organisations. Its offices and staff are co-located with the CTC and CTC director John Simes is founding and current program director of Sydney Catalyst.

During 2013 Sydney Catalyst celebrated important milestones, including a growth in membership (from just over 200 in 2012 to more than 330 at the end of 2013), a highly successful International Translational Cancer Research Symposium in May with over 120 participants, more than 500 publications, close to \$45 million in competitive funding from a subset of members and good progress against important flagship projects in lung and pancreatic cancers.

Clinical trials and translational research

Patients enrolled in clinical trials receive the best treatments for their particular disease, but individual patients may respond differently depending on the individual characteristics of their tumours, including the proteins expressed by the DNA in the tumour. Drugs that act against protein expression, such as monoclonal antibodies, are used in cancer treatment, but some patients may benefit from the treatment and some may not. There are many unknowns in the use of these promising anticancer agents.

Most of the CTC's clinical trials include analysis of tumour tissue and blood samples in laboratory studies that compare the tumour and blood characteristics with the individual response to treatment. Ultimately, this information should improve treatment planning, allowing clinicians to test patients and identify who would benefit from particular drugs.

Detecting such tissue and blood biomarkers to predict a patient's response to a therapy is a focus of the laboratory studies associated with the CTC's clinical trials. For example, the monoclonal antibody tested in the completed MAX trial, bevacizumab, which acts against vascular endothelial growth factor, is now included in initial therapy regimens for metastatic colorectal cancer because it improves patient outcomes. It is known to bind to and inactivate one kind of vascular endothelial growth factor, but the drug's action against its targets is complex and so far survival benefits have been modest. Current research focuses on examining tumour tissue for biomarker subtypes in the light of known patient responses to bevacizumab.¹¹²

GENOMIC CANCER CLINICAL TRIAL INITIATIVE (GCCTI)

The GCCTI is a 3-year program to support the national cooperative cancer clinical trials groups, including those described in these pages, in developing trial protocols testing new drugs whose molecular target may be common to different cancer sites. The process will cover generating and prioritising ideas, developing these concepts and making applications for national and international grants.

The GCCTI aims to develop at least one new protocol per year. In 2013 the group held the first of its annual concept workshops.

The program is funded by Cancer Australia and managed by the CTC, with chief investigator Martin Stockler, clinical leads Chee Lee and Katrin Sjoquist, and senior translational fellow Sonia Yip, in partnership with independent consulting group ZEST Health Strategies.

Katrin Sjoquist, clinical lead for GCCTI, and research student Aflah Roohullah



Cardiovascular research

Cardiovascular disease is the underlying cause of more than 1 in 5 deaths in Australia. Research evidence in this area, when translated into prevention and treatment, can therefore make a big difference to health. In recent years, the death rate has been declining.

The CTC aims to undertake trials aimed at improving treatments, evaluating best available therapies and addressing areas where individuals at high risk are currently untreated. The CTC has been responsible for coordinating nine large cardiovascular trials in Australia. Seven of these were international collaborative trials of treatments for acute coronary syndromes, and two, LIPID and FIELD, were prevention trials designed and implemented in Australia and New Zealand. In total, the CTC randomised 26 565 of the patients enrolled these trials.

With improvements in methods and interpretation, meta-analysis of the results of all trials with the same entry criteria and measured outcomes have become an alternative to large randomised trials. If meta-analyses are prospectively planned, they provide the same strength of evidence of a large trial but are easier to initiate and manage.

The CTC co-coordinates the Cholesterol Treatment Trialists' Collaboration, a prospective meta-analysis group set up in the early 1990s by the CTC and the Clinical Trial Service Unit at Oxford. The group is now analysing data from 27 cholesterol-lowering trials totalling nearly 170 000 people.

LIPID

Biomarkers of cardiovascular risk in the LIPID study

The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) study showed that statin treatment reduced the risk of a second or further coronary event in people with heart disease. Blood samples collected over the first 6 years of the trial are being analysed to shed light on how biomarkers are related to heart disease risk.

For example, it has been thought that statins reduce cardiovascular risk by reducing LDL cholesterol, but more recently that other mechanisms are also important. The LIPID study investigators assessed Lp-PLA₂,

an enzyme found in blood vessel plaque. They found that pravastatin treatment reduced Lp-PLA₂ levels, and this accounted for much of the reduction in subsequent heart attacks.¹⁵⁹

Other analyses showed that lipoprotein a⁹⁸ and troponin¹⁶⁰ levels were significant risk factors for future cardiovascular events.

More of these biomarker analyses are ongoing or yet to come. The LIPID Australian and New Zealand investigators are collaborating with scientists from Germany, Sweden and the United States.

HISTORICAL



LIPID had a large investigator group, seen here at their final meeting in Palm Desert, USA in 1998





LIPID: AN EARLY CTC LARGE-SCALE MULTICENTRE TRIAL

The LIPID trial of cholesterol-lowering treatment with pravastatin was a major achievement of the CTC in its early days. The trial recruited patients who had recently had a coronary event but had normal cholesterol levels. Over 9000 patients from 87 hospitals in Australia and New Zealand were randomised between 1990 and 1992 and then followed up for 6 years.

The treatment significantly and cost-effectively reduced mortality and major cardiovascular events. Overall mortality was reduced by 23% and coronary heart disease death by 24%. Clinical evidence from LIPID enabled subsidy for pravastatin treatment through the Pharmaceutical Benefits Scheme in 1999 and change in the Australian treatment guidelines.

Blood samples were collected from patients at entry to the trial and during the trial. Research is now focusing on what the blood samples can tell us about coronary heart disease.

The LIPID group is also analysing data on deaths and cancers in the patients over 16 years of follow-up.

Fenofibrate Intervention and Event Lowering in Diabetes (FIELD)

Patients from the completed FIELD trial are still being followed up through regular questionnaires and data linkage.

The investigators are also using blood samples taken during the trial and its follow-up to study the effects and mechanisms of fenofibrate treatment and to determine biological and genetic markers of the risk of various manifestations of cardiovascular disease and diabetes complications.

Action of fenofibrate in mice

Fenofibrate was originally described as a PPAR- α agonist, acting on blood lipids to reduce the risk of vascular diseases. A substudy of the FIELD trial in 2010 unexpectedly showed that fenofibrate dramatically reduced the risk of amputation, leading the investigators to look for further mechanisms of action of fenofibrate.

Since then animal and laboratory studies to tease out this effect have been done. In a study by Rajamani and colleagues, the blood flow in the hind limbs of diabetic mice was reduced in a simulation of blood vessel damage. Then fenofibrate treatment ameliorated the effect, restoring blood to the extremities and allowing the paws to move. Associated tissue studies revealed that fenofibrate appeared to promote new blood vessel formation. Molecular pathway studies are ongoing.

High bilirubin equals low amputation risk

People with diabetes have a higher-than-normal risk of amputation of toes or feet due to blood vessel disease. As an early step in finding a way of reducing this risk, FIELD investigators tested bilirubin in the blood as a possible predictive marker. Bilirubin is known to have antioxidant

and anti-inflammatory properties which may protect the blood vessels. The investigators found a significant association between lower bilirubin levels and higher risk, raising the hypothesis that bilirubin may protect against amputation.²⁶

Is HDL cholesterol linked to poor glucose control in diabetes?

HDL (good) cholesterol is often low in people with type 2 diabetes and may be low years before diabetes becomes apparent. The FIELD team are investigating whether HDL biology contributes to the development and progression of type 2 diabetes. Initial results, presented at the meeting of the Cardiac Society of Australia and New Zealand, suggest that levels of HDL cholesterol and its components are directly related to slowing diabetes progression, a finding that is being further explored for full publication in the near future.

HISTORICAL



A LARGE INTERNATIONAL TRIAL TO REDUCE RISK OF CARDIOVASCULAR COMPLICATIONS OF DIABETES

FIELD was a double-blind placebo-controlled trial of the use of fenofibrate to reduce the risk of coronary heart disease in people with type 2 diabetes, chaired by CTC deputy director, Anthony Keech. The trial was conducted in Australia, New Zealand and Finland. It was initiated in the late 1990s, began recruiting patients in early 1998, and its five-year follow-up was completed in October 2005.

A feature of the trial was that its wide entry criteria allowed the results to be generalised to a population of typical patients with diabetes consulting general practitioners.

The main results showed that fenofibrate did not significantly reduce risk of myocardial infarction or death from coronary disease, but it did have a significant effect on other cardiovascular disorders, notably amputations and the need for laser treatment for retinal disease. The finding that fenofibrate

appeared to prevent microvascular disease, led to new directions of research examining the reasons and mechanisms. On the basis of these results (and another study), the Australian Therapeutic Goods Administration approved fenofibrate for diabetic retinopathy in December.

Also, during the trial, evidence emerged from other trials around the world that statin therapy reduced the risk of cardiovascular disease, and many patients, especially in the active fenofibrate group, started taking statins as well as their study drug. This was considered to cause potential confounding likely to result in underestimation of the benefit of fenofibrate treatment. CTC researchers developed a novel statistical method to adjust treatment effects for use of other medication. The approach can be applied to other long-term trials where differential changes in usual care between treatment arms occur unexpectedly.

Diabetes and vascular disease

Type 2 diabetes is an increasing health burden in Australia and worldwide. Often, the diagnosis of type 2 diabetes is made only when symptoms occur, after many years of high blood glucose. Type 1 diabetes, which often presents in childhood and requires daily insulin injections, affects over 122 000 Australians and is increasing in incidence. Both forms of diabetes can irreversibly damage the kidneys, blood vessels, nerves, heart and eyes. Investigators at the CTC and their clinical co-workers continue to seek ways to predict and prevent diabetes, to reduce the destructive consequences of diabetes and to use technology to improve diabetes care. The international FIELD trial, 1997–2005, is still providing data for blood marker and other substudies. FIELD is now joined by REMOVAL, which aims to test the use of metformin, a type 2 diabetes medication, for preventing blood vessel damage in adults with type 1 diabetes.

Many research efforts are focusing on earlier diagnosis and prevention of diabetes and its complications. At the CTC, these range from laboratory-based cell and animal model studies to the new T4DM and FAME1-EYE clinical trials.

REMOVAL: a new trial of an old drug

Metformin is a common, inexpensive and usually well-tolerated drug used for blood glucose control in type 2 diabetes. It also reduces cardiovascular complications and reduces insulin resistance, which can also be a feature of type 1 diabetes. A new international type 1 diabetes trial is being conducted to discover whether metformin can slow or



Karen Bracken, T4DM trial project manager

prevent atherosclerosis. During 3 years of metformin treatment or placebo, participants are having scans to assess changes in their blood vessels and heart.

Testosterone for the prevention of diabetes mellitus (T4DM)

Low testosterone levels are often associated with lower motivation to exercise, lower muscle mass and with a higher risk of type 2 diabetes. The T4DM trial is recruiting 1500 middle-aged men who have low testosterone levels and prediabetes, that is, higher than normal blood glucose levels, to see whether treating them with a weight-loss diet and testosterone supplements over 2 years can prevent progression to full-blown diabetes.

The men are initially screened on the basis of their waist circumference and then screened again by blood tests for testosterone levels and blood glucose. Investigators expect to screen 24 000 Australian men during recruitment. The study design and progress to date were presented in 2013 at the World Diabetes Conference.

Fenofibrate and Microvascular Events (FAME1-EYE)

Irreversible vision loss is a most feared complication of diabetes. The FIELD type 2 diabetes trial showed that the lipid-modifying drug fenofibrate was effective against vision-threatening diabetic damage to retinal blood vessels in the eye. Laboratory studies have backed up these findings and shown how the drug works. In a study published in 2013, it was shown that in mice with type 1 diabetes, fenofibrate, administered orally or by injection, reduced inflammation and leakage from the blood vessels in the eye.²⁹

Now a major new trial is investigating the use of fenofibrate tablets to protect the vision of people with type 1 diabetes who have early diabetic retinal damage. Investigators from the CTC, the University of Melbourne and Westmead Hospital in Sydney are collaborating in the FAME1-EYE study, a 3-year double-blind, placebo-controlled trial of daily fenofibrate for 450 adults with type 1 diabetes

continued...



Andrzej Januszewski, diabetes laboratory research fellow, with Alicia Jenkins, professor of diabetes molecular medicine and telehealth

Should the results prove positive, an existing, low-cost, well-tolerated treatment to reduce the personal and economic burden of the complications of type 1 diabetes could rapidly be translated into clinical practice world-wide.

Using technology to improve health care in remote areas

The diabetes group has extended its research into telehealth, a model of patient care that can improve health care access, particularly in rural and remote areas. Whereas in cities the death rate from diabetes-related causes has dropped in recent years, it has remained stable at about 45 deaths per 100 000 among people living in regional and remote areas. Type 2 diabetes is especially prevalent among people in Aboriginal communities, and retinal eye disease is a common complication.

The Telehealth Eye and Associated Medical Services (TEAMSnet) collaboration has embarked on a program to use internet and mobile technologies to provide eye examinations and coordinated diabetes and heart care to indigenous Australian people. Patients and consumers may be ahead of health care professionals in the use of new technology.¹⁸ The diabetes study is recruiting participants from 3 Aboriginal communities in the Northern Territory. The research group will monitor and analyse images of the retina via telecommunication channels and will also evaluate education, coordination of medical care, patient preferences and clinical decision making. The group has already obtained valuable insights into telehealth: care delivered by a virtual team can optimise health outcomes, telehealth supports shared decision making. These findings were presented at the 2013 meeting of the Australian Diabetes Society.

Laboratory research

RNA-based analysis for prediction of islet death

Blood glucose levels are normally tightly regulated by insulin released from beta cells in the pancreas. Insulin lowers blood glucose levels and enables the body's cells to utilise and store the energy in glucose. By the time type 1 diabetes is diagnosed, over two-thirds of the pancreatic beta cells have been killed by inflammation and immune attack, usually over several years. Beta cell death also contributes to the progression of type 2 diabetes glucose-control treatment from diet and exercise alone, to tablets, to insulin injections.

RAPID is a laboratory study searching for biomarkers that may allow diabetes to be predicted before the damage is done and to monitor the efficiency of protective treatments. A class of RNA (genetic) molecules (microRNAs) regulating gene expression are being investigated as potential markers of beta cell damage. The RAPID investigators have developed a method to identify microRNAs as markers of pancreatic cell death.⁴⁰ They are continuing to analyse levels of various microRNAs in the blood, with the eventual goal of a blood test that could detect loss of pancreatic cells before the clinical onset of diabetes or monitor treatments to slow down damage to the pancreas.



Clinical trials and meta-analyses in neonatology

The NeOProM meta-analysis

Although oxygen treatment for premature babies has been in use for 60 years, the best level of oxygen to prevent death and disability is still not known.

Different levels of oxygen, even though they may differ by only a few percentage points, have different benefits and harms. Too much oxygen may cause vision loss; too little oxygen may lead to death from lung disease. Although several trials have been completed, testing this question properly requires at least 5000 participants, which is beyond the resources of any single trial group. Instead, five trial groups are cooperating in a prospective meta-analysis, called NeOProM, started in 2003 and now nearing completion.

The CTC's BOOST II trial is following up 1055 infants born very prematurely in Australia and New Zealand over two years. In BOOST II they were randomly allocated to 85–89% or 91–95% oxygen saturation.¹⁰ Recruitment to the trial was stopped after an analysis of data from BOOST II and other NeOProM trials showed better survival up to 36 weeks in the group that received the higher oxygenation level. This was published in the *New England Journal of Medicine*.¹⁰ Recommendations on the best range of oxygen saturation await a full 2 years of follow-up and the NeOProM study analysis.



Lisa Askie, investigator for neonatal studies and head of the CTC's systematic reviews and health technology assessment group



William Tarnow-Mordi (foreground), investigator for BOOST II with Alpana Ghadge, manager of BOOST II

HISTORICAL



For decades, the optimum range of oxygenation was, and remains to this day, unknown. Unfortunately, the uncertainty continues and the question of what is the optimal oxygen saturation range for preterm infants is a moving target. ...

The oxygen story highlights the potential for unanticipated, adverse consequences when clinical practices are changed only on the basis of anecdotal, observational and nonrandomised evidence.²

— Lisa Askie,
Current Opinion in Pediatrics

HISTORICAL



INTERNATIONAL NEONATAL IMMUNOTHERAPY STUDY (INIS)

The CTC's first trial in neonatal medicine was INIS, conceived in the late 1990s, started in 2001, and over 6 years recruiting nearly 3500 infants from 9 countries.

INIS was a trial of polyvalent IgG immunoglobulin added to antibiotic therapy for newborn infants with serious infection. This was then a standard regimen for preventing later death and disability, a consequence of infection.

The trial showed that the additional immunoglobulin did not make a difference, evidence that is saving babies from an ineffective treatment and also saving its substantial cost.



Lucille Sebastian, manager of APTS, with Adrienne Kirby (foreground) and John Simes, CTC director (background)

Australian Placental Transfusion Study (APTS)

APTS is an open multicentre CTC trial which will eventually have 1600 participants—babies born more than 10 weeks early.

It will determine whether a 60-second delay in clamping and cutting the cord can improve the baby's blood flow to the brain and gut, reduce the need for donor blood, and reduce rates of infection, retinopathy, poor growth, death and disability in babies born more than 10 weeks early.

Lactoferrin Infant Feeding Trial (LIFT)

Does lactoferrin reduce mortality and morbidity in very low birth weight infants?

Exciting recent evidence suggests that bovine lactoferrin, an inexpensive antimicrobial, antioxidant, anti-inflammatory dairy protein, substantially reduces sepsis, extending the benefits of probiotics.

LIFT brings together an international research team and parents committed to clinical trials to improve survival without disability in newborn babies. A cost-effectiveness analysis is also planned to capture completely the potential cost-effectiveness and societal benefits of lactoferrin in preventing major morbidity.

LIFT is an investigator-initiated trial, funded by NHMRC, which has established a new partnership with the internationally respected Vermont Oxford Network, USA.

WINNER Centre encompasses perinatal and neonatal trials at the CTC.



Health economics

The economic impacts of ill-health can extend beyond the health system to affect family incomes, welfare payments, taxation revenue and special education.

Potential to save costs beyond the health system

The health economics group is collaborating on the LIFT neonatal trial (p. 22). The economic evaluation includes developing a model of the relationship between improved cognitive outcomes in childhood and educational attainment.

CTC MAX colorectal cancer trial

Economic evaluations are an important part of assessments of new treatments and technologies; they must be shown to be value for money as well as effective. This is especially important for cancer treatments, where costs have been rising dramatically.

In Australia the cost per prescription has quadrupled in the past decade while expenditure by the Pharmaceutical Benefits Scheme has increased even more. It is important that trials of new cancer drugs incorporate cost-effectiveness analyses to inform governments and other bodies making decisions about reimbursement.

In the AGITG MAX trial of combined treatment for advanced colorectal cancer (p. 9), data were collected during the trial for a study determining the cost effectiveness of adding a monoclonal antibody, bevacizumab, to chemotherapy. This was the first study to collect patient data as part of a prospectively

designed economic study built into a phase III trial. Costs were analysed in relation to survival and quality of life. The regimen was found to be excessively expensive in proportion to its benefit. This lack of cost-effectiveness could change if new biomarkers for treatment benefit allow targeted treatment.²⁴

Costs and quality-of-life impacts of prostate cancer screening in Australia

Screening the general population or people without symptoms for cancer adds to health costs but is generally not worthwhile and may even be harmful. But for people at high risk, the trade-off between the potential benefits, harms and financial costs may favour testing.

For example, a recently published study looked at prostate cancer screening in Australia.⁹⁰ The current test used is a prostate-specific antigen (PSA) blood test, followed by more tests and possibly surgery if the test is positive. The costs of testing and treatment are high, especially when multiplied by the many middle-aged men who would be tested with universal screening. CTC statisticians and health economists developed a decision model to estimate the net benefit and cost of PSA screening versus no screening. They found that for the 1% of men who were at very high risk of prostate cancer, screening was cost-effective, but for others, the cost would be over \$100 000 per quality-adjusted life year saved. What is needed now is a way of identifying each man's level of risk.

continued...

WORKFORCE AND POVERTY STUDIES

The health economics group has in recent years carried out extensive research on the relationships between income, poverty, employment and various aspects of ill-health. These studies have been based on a model developed in collaboration with groups at the University of Canberra, University of Sydney and University of Queensland. Recent studies have focused on specific chronic health conditions associated with premature retirement and loss of income, including arthritis,¹²⁵ psychiatric disorders,^{119,121} and cardiovascular disease.^{118,123} People with a chronic health condition are less likely to be employed than healthy people, and multiple conditions lead to greater costs from lower labour force participation, lower income, lower taxation revenue and higher government benefits.

In a related strand of this research, Emily Callander and the group have developed a new way of conceiving poverty—the Freedom Poverty Measure—a multidimensional poverty scale, which incorporates income, health and education status to measure disadvantage. Ill-health is a major contributor to low living standards. The measure was used to explore the associations between chronic conditions and poverty, and it was found that arthritis, back problems and mental and behavioural disorders affected living standards most. Of people with a chronic condition, 18% were poor by this definition, compared with only 4% of those without a chronic condition.²⁰

...Health economics (continued)

Treatment of obesity

A randomised trial by the Boden Institute of Obesity, Nutrition, Exercise & Eating Disorders (BIONE) at the University of Sydney in collaboration with colleagues in the UK and Germany showed that referral to Weight Watchers produced greater weight loss, over 12 months, than attending a primary practitioner for a similar period.

BIONE researchers and CTC health economists recently undertook cost-effectiveness analyses of the two approaches to weight loss. The Weight Watchers program was found to be more cost-effective on several health economic measures, such as dollars per kilogram lost, even though it involved more visits and more travel. Outside the trial setting, the cost of such a commercial program would currently be borne by the individual, and in Australia, the cost of the primary practitioner would be covered by Medicare. The commercial program was cost-effective when modelled from the point of view of the health system.⁴⁶

This analysis was extended in a model that extrapolated the trial data to project the outcomes for patients over a lifetime, finding that the commercial program continued to be more effective and less costly than primary care for improving the health of people who are overweight or obese.



**Fergus Tai, Kylie Hunter and Henry Ko,
of the Australian New Zealand Clinical
Trials Registry**

HISTORICAL



AUSTRALIAN NEW ZEALAND CLINICAL TRIALS REGISTRY (ANZCTR)

Medical evidence can be distorted if results of clinical trials are published selectively. Nearly three decades ago, John Simes demonstrated this using the example of cancer trials to 'illustrate an approach to reviewing the clinical trial literature, which is free from publication bias, and demonstrate the value and importance of an international registry of all clinical trials'.

In 1994 the CTC established a national registry of clinical trials in cancer, known as the NCTR, coordinated by Davina Ghersi, funded by the New South Wales Cancer Council, and affiliated with the Australian Cochrane Centre. The CTC's registry group was then working with other groups, such as the Register of European Cancer Trials, the Register of UK Cancer Trials, and PDQ (Physician Data Query) in the USA, aspiring to make trial registration comprehensive and international. In the mid-1990s, information in the register was public, but distributed by newsletter. In 1998, the register passed 200 trial records, and in 1999 a website was set up.

In 2005, trial registration received a boost when the editors of many prestigious medical journals made prior registration mandatory for publication of results. The new Australian registry, with an Australia-wide advisory board, was established very quickly with funding from the NHMRC. It extended to all Australian research involving human participants and covered interventions such as pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment strategies, rehabilitation strategies and complementary therapies. The Australian registry was one of the first to be recognised as a primary registry by the World Health Organisation.

Since 2005, the registry has continued to be developed by a team at the CTC, with ongoing funding from the NHMRC. By the end of 2013, 8755 trials were registered and the registry website had advanced in ease of use and linkage with other registries. In September, the ANZCTR manager, Lisa Askie, was appointed as a member of the WHO International Clinical Trials Registry Platform advisory committee. The Australian registry is advancing and is well connected with international developments in trial registration, contributing to its original aims of universal registration of clinical trials.



Combining evidence for better clinical care

The best unbiased evidence on a particular aspect of clinical care is generally found in results of a systematic review of available research results. Systematic reviews with meta-analysis of trial results also estimate the effects of treatment more precisely than their constituent trials and may have enough data to show whether treatment effects vary in different subgroups. Published systematic reviews assist clinicians in evidence-based decision making.

An improvement on basing a systematic review on trial results is to reanalyse the data in an individual-participant-data meta-analysis. Such analyses have some of the advantages of a single large trial: better statistical precision in the results, the ability to show effects in subgroups of participants, and secondary hypothesis testing.

In prospective meta-analyses, trial investigators cooperate, often across national borders, to design their trials with future combined analysis in mind. Designs are harmonised in terms of entry criteria, sample size calculations and the choice and definition of trial endpoints agreed to in the meta-analysis protocol, before any results are known.

CTC authors conduct systematic reviews and individual-patient-data meta-analyses for peer-reviewed journals in various topic areas, such as neonatal disorders, cardiovascular disease^{9,171} cancer,^{65,84} and trial methodology.¹²⁷

Systematic reviews for the Cochrane Collaboration

The Cochrane Library is a database that contains high-quality, independent evidence from systematic reviews on a range of clinical questions to inform health-care decision-making. Its work is done by specialist groups around the world that prepare, maintain and peer-review these reviews, independent of commercial support. These reviews add value to trials already done by combining existing results and also take account of the quality of their methods and conduct, for example, by examining the risk of bias in each study.

The Cochrane Breast Cancer Group, which coordinates, edits and facilitates the publication of reviews on all aspects of breast cancer and recruits and trains new contributors, is based at the CTC. The group apply their content and methodological expertise to ensure that the protocol for conducting each review is rigorous and will lead to a comprehensive assessment of the current state of evidence.

In 2013, the group produced five new reviews—on chemotherapy, surgery, rehabilitation and detection of breast cancer—plus updates with new evidence of previously published reviews. They also facilitated the formulation of new protocols on aspects of surgery, radiotherapy, yoga and acupuncture.

HISTORICAL



COCHRANE BREAST CANCER GROUP

John Simes and Davina Ghersi established the Cochrane Breast Cancer Group, a registered review group of the Cochrane Collaboration, at the CTC in 1996. In 2001, the group received a major boost in funding from the US Department of Defense, which enabled it to conduct a portfolio of systematic reviews addressing clinically relevant questions in advanced breast cancer. Nicholas Wilcken was the key person in seeing these reviews to completion and getting review findings into clinical practice guidelines internationally.

Nicholas Wilcken and Annabel Goodwin now lead the Cochrane Breast Cancer Group. The group has a moderate sized portfolio of clinically relevant reviews (70 reviews and protocols) and has strong consumer involvement at every level of the editorial process.

Davina Ghersi and John Simes



New medical technology: how do we know that it is effective and affordable?

In Australia, medical procedures are mainly funded by taxpayers. Therefore, the government requires evidence that new procedures and technologies are worth paying for and will benefit patients. Decisions are made by the Minister for Health on the advice of the Medical Services Advisory Committee.

The health technology assessment team at the CTC undertakes systematic reviews of new procedures being proposed for public funding. These are major reports that aggregate and evaluate evidence for safety, effectiveness and cost-effectiveness.

Over the past twelve months, the health technology assessment team has performed a review of the clinical effectiveness of cervical cancer screening technologies for the National Cervical Screening Program Renewal and prepared assessments of the use of fiducial markers for radiotherapy in prostate cancer, cone beam computed tomography for dental imaging, and MRI screening for women at high risk of breast cancer.

Diagnostic testing as part of a clinical pathway that leads to the best outcome for the patient

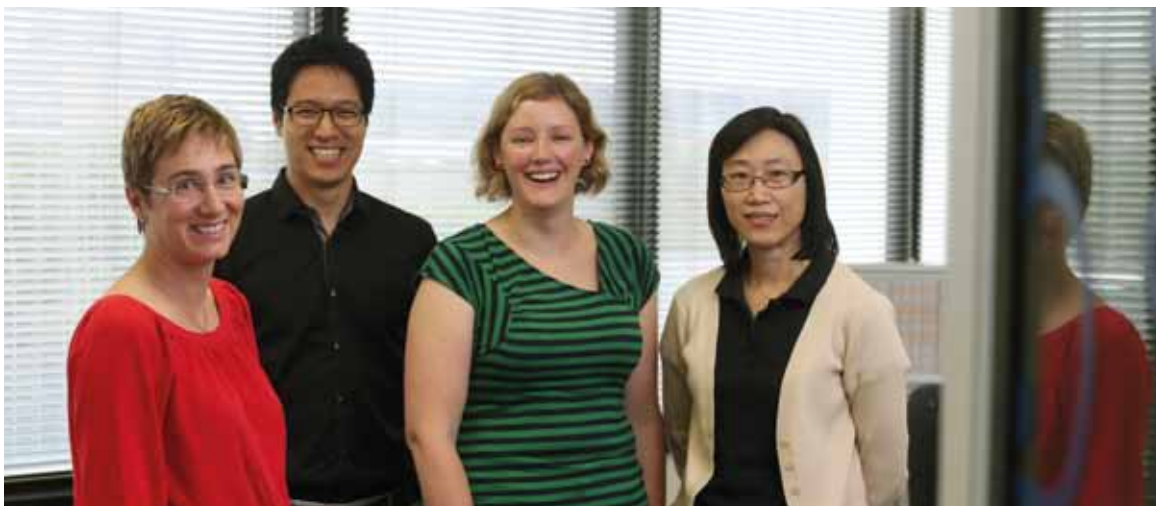
Evaluation of diagnostic medical tests is different from trialling drugs and interventions in that a test does not affect health outcomes directly. Therefore, evaluation of tests has to include consideration of the doctors' decisions and treatments that follow test results. The process as a whole must improve health, reduce costs or make health care delivery more efficient. Tests can only be justified if there is evidence of eventual benefit.

In the past decade, many advances have been made in test evaluation, much of it from the CTC. An example is development of a radiological sign distinguishing spinal stenosis from other causes of back pain. The concept, that nerve roots sink under gravity in the normal spine but do not move in the stenosed spine, was observed and shown to distinguish stenosis in 2010. The research group has now begun to examine the clinical pathway.⁶ They asked 'Does the sign provide clinical

information that can be used in treatment decisions and so improve health outcomes?' in a study of 118 patients attending a hospital clinic for back pain. The results suggested that the sign could help in identifying patients who might benefit from decompression surgery. Recent studies have been validating the test, through examining the biological mechanisms of the effect in animals⁴ and in humans.⁵

The CTC's Sally Lord is a member of the Test Evaluation Working Group of the European Federation of Clinical Chemistry and Laboratory Medicine, which has been developing a framework that considers the whole clinical pathway after laboratory testing for disease biomarkers.⁶⁴ This is a concern of funding bodies, which want to see a benefit from expensive laboratory tests, and patients, who may be harmed by overdiagnosis and overtesting.

A group at the CTC prepares assessments of new technologies for the Medical Services Advisory Committee of the Department of Health. Left to right: Samara Lewis, Henry Ko, Briony Jack and Elizabeth Seil.



Methodology

Biostatistical expertise applied to CTC trials and beyond

CTC biostatisticians are responsible for design, data analysis and validation of the analysis of trials initiated and conducted by the CTC and its collaborative groups.

They also travel to various hospitals and universities in Sydney and elsewhere in Australia to take part in research studies in diverse clinical fields: Indigenous health, gynaecology, pregnancy and birth, cancers, radiology, psychiatry, heart disease, nutrition and health service delivery. Over 50 such studies were published during 2013.

Urogynecology

Statisticians have collaborated with a group at the University of Western Sydney examining the demographic associations with and physical causes of perineal tearing during childbirth. They analysed data from over half a million births in New South Wales. Severe tearing often requires later surgical attention. It occurs during nearly 2% of Australian births, a rate that is increasing, especially in male births.¹¹³



Val Gebski, head of biostatistics

Psychiatry

Psychiatrists at Nepean Hospital in Sydney have been investigating obsessive-compulsive disorders in several studies.¹¹⁻¹⁴ Statistical methods have been used to classify various manifestations of this disorder and to create models relating thoughts to symptoms.¹¹ Factor analysis has been used to distinguish taboo thoughts from other kinds of obsessive-compulsive disorders and to identify other characteristics, such as substance abuse and hostility, that are associated with taboo thoughts.¹²

Emergency services

The Head Injury Retrieval Trial is comparing care by a team that includes a doctor trained in emergency care with standard paramedic care for people rescued from accidents by helicopter. People with head injury often suffer from lack of oxygen and blood loss, and medical practitioners are able to provide more advanced procedures

than paramedics. The CTC is working with Careflight on the study of cases from the Ambulance Service of New South Wales. The study design has to allow for the many individual factors that characterise serious accidents and injuries.⁴⁸

CTC biostatisticians have collaborated with emergency staff at Royal Prince Alfred Hospital, Sydney, on several studies of service delivery. They compared vital sign assessments at the scene of the injury and in the emergency department, with the aim of improving triage systems.³⁷ Triage of trauma patients at the site of injury by ambulance services is essential to ensure that patients who need it go to trauma centres but less critically injured patients do not overload specialist hospital systems. They have also used statistical modelling to predict risk in injured patients³⁵ and have analysed the costs of injury, particularly in elderly patients.³⁶

HISTORICAL



CTC biostatisticians Elaine Beller and Val GebSKI take a break with Professor Paul Glasziou at the meeting of the International Society for Clinical Biostatistics and the Society for Clinical Trials, Brussels, in 1991.

A BETTER RANDOMISATION METHOD

One of the first new methods developed by the CTC biostatistics group, in the early 1990s, was dynamic balancing, an improvement on then current ways of randomising patients to trials. The method resolved the disadvantages of selection bias and imbalance in the treatment arms. The CTC author group said that:

'Imbalances in the numbers of patients receiving each treatment within individual subgroups can result in confounding bias. ...Dynamic balancing is an intuitively simple, easily implemented scheme for use in centrally randomised trials. The method provides the trial coordinator with a greater degree of control over imbalances at all levels of stratification.'

— Signorini et al. *Statistics in Medicine*, 1993



Methodological research

Research on ways to improve the design and conduct of clinical trials has always been central to the CTC's activities. This includes incorporating quality-of-life and cost-effectiveness studies into the design of trials⁹² and biostatistical studies that critically analyse current methods and propose new ones.

Statistics-based guidance for systematic reviewers

When the benefit of a trial treatment becomes apparent early, and this is confirmed by statistical analysis, the trial may be stopped early.

There are standard statistical procedures for this. But these calculations may overestimate the benefit of the treatment. When the results are combined with other trials in a systematic review, such overestimation might influence the combined evidence. Whether truncated trials should be included in systematic reviews and meta-analyses has been widely debated. CTC biostatisticians Manjula Schou and Ian Marschner undertook a mathematical analysis of data from 515 trials, considering possible estimation bias and also the effect of information weights used to aggregate the estimates in meta-analyses.¹²⁷ Finding that the combined evidence was not biased by data from truncated trials, they concluded that early stopping of clinical trials due to treatment benefit was not an important source of bias and recommended that systematic reviewers continue to include all trials in their calculations.



David Espinoza and Andrew Martin

Multistate survival models in clinical trials

Survival of a trial patient without having the disease outcome is good for the patient, but causes challenges in time-to-event statistical analyses. A new method extrapolates information on events during a trial to predict possible later events.⁶⁶ Biostatisticians used data from the LIPID study (p. 16) to demonstrate the method, which estimates the hazard ratio, overall survival and the benefit of treatment. Ongoing long-term follow-up of LIPID patients for many years after the end of the trial will provide an opportunity for later validation of this method.

HISTORICAL



BIostatISTICS FOR BREAST CANCER

Professor John Simes and Professor Val Gebski have conducted and overseen statistical work for the Australia and New Zealand Breast Cancer Trials Group (p. 13) continuously for 25 years.

Recently, researchers have used methods established by past CTC methodologists for assessing quality of life and treatment trade-offs to achieve authoritative approaches to balancing toxicity and survival.⁸⁵



Rachel O'Connell, Val Gebski, Jodie Gonzalez-Jennings, Elizabeth Barnes, Anne-Sophie Veillard, Simone Marschner, from the biostatistics group

HISTORICAL



THE BCA MEETS THE NEED FOR BIOSTATISTICIANS IN AUSTRALIA

The founding of the BCA was an initiative coordinated by the CTC in the late 1990s. A shortage of biostatisticians in Australia was formally identified in 1999 in a review by the national Public Health Education and Research Program (PHERP). But such a specialised degree was beyond the wherewithal of any one university. In September 1999, representatives of universities, government departments and industry met to plan a postgraduate coursework program in biostatistics delivered by distance education by a consortium of (then) 6 universities.

The Department of Health and Aged Care provided seed funding for the BCA to launch the new courses and two subsequent rounds of funding, finishing in 2010. The BCA is now self-funding, via a capitation fee per unit of study enrolment. An office was established at the CTC, run by the executive officer, Erica Jobling, and enrolments began in 2001. Since then, around 300 students have graduated, 170 of these with a Master of Biostatistics.

Since its inception, the BCA has developed into one of Australia's most successful examples of a multi-institutional approach to addressing a critical skills shortage. In particular, it has delivered in high-quality innovative programs beyond what would be feasible in any single institution. The key elements of the BCA's success have been the critical mass from Australia's most influential biostatistics groups together with a robust system of governance and ongoing review.

Education

Masters degree in clinical trials research

As part of its education and training activities to improve the quality and scope of randomised trials in Australia, the CTC developed a postgraduate program in clinical trials research. Courses have been offered by Sydney Medical School since 2011.

The program leads to formal qualifications from the University of Sydney in the design, conduct and interpretation of clinical trials.

The first students graduated in 2013, nine with a Master of Clinical Trials (Research) and two with a graduate diploma.

The program is coordinated by Adrienne Kirby, with directors Anthony Keech and Val GebSKI, and is a major teaching commitment for many of the CTC's academic staff.



BCA graduation at the University of Sydney

Biostatistics Collaboration of Australia

The BCA is currently a consortium of seven universities providing a well-defined path for the training of senior biostatisticians for clinical research.

In 2013, there were 282 active students at the semester 2 census date. The BCA convened an external curriculum review to assess the relevance, completeness and standards of its current curriculum and recommend any changes. The reviewers interviewed former and current students, employers and potential employers, and representatives of industry and academia.

CTC biostatisticians are active in teaching and coordinating BCA courses. In 2013, Rachel O'Connell coordinated 'Advanced clinical trials'. Elizabeth Barnes and Lucy Davies coordinated 'Principles of statistical inference'.

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	Coordinating centre and collaborator
	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 Multidisciplinaire en Oncologie (GERCOR), National Cancer Centre, Singapore, 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)	
Australasian Lung Cancer Trials Group (ALTG)	Collaborative group for lung cancer trials: Australia, New Zealand	Coordinating centre and collaborator
	International collaborations: NVALT (Netherlands), NCIC CTG (Canada)	
Australasian Society of Thrombosis and Haemostasis	Professional group undertaking thrombosis trials: Australia, New Zealand	Coordinating centre and collaborator
Australia New Zealand Gynaecological Oncology Group (ANZGOG)	Collaborative group for gynaecological cancer trials: Australia, New Zealand	Coordinating centre and collaborator
	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)	
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 Multidisciplinaire 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 and collaborator
Australian New Zealand Breast Cancer Trials Group (ANZ BCTG)	Collaborative group for breast cancer trials: Australia, New Zealand	Statistical centre for group, including randomisation
	International collaborations: International Breast Cancer Study Group (IBCSG), Breast International Group (BIG), International Breast Cancer Intervention Study (IBIS)	
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
Boden Institute of Obesity, Nutrition, Exercise & Eating Disorders,	Research institution: Australia	Collaborator

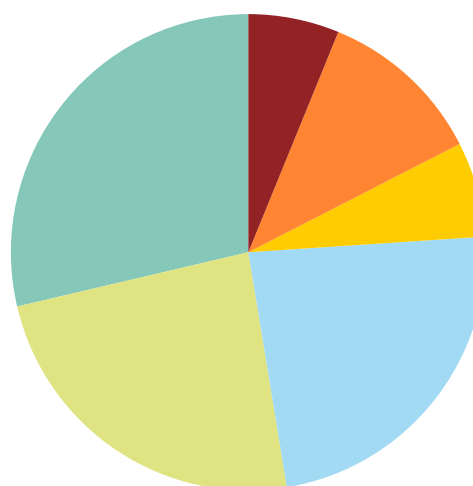
GROUP	NATURE OF GROUP	CTC ACTIVITY
Clinical Trial Development Unit (CTDU)	Partnership with the Centre for Biostatistics and Clinical Trials, Peter MacCallum Cancer Institute: Australia	Trial operation and statistical support for cancer trials
Cochrane Collaboration Breast Cancer Group	Collaborative group undertaking systematic reviews of trial evidence: international	Editorial 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 and collaborator
	International collaborations: European Organisation for Research and Treatment of Cancer (EORTC)	
Early Prevention of Obesity in Children (EPOCH) collaboration	Prospective meta-analysis collaboration: international	Data coordination centre
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
Heart Foundation	Nongovernment organisation: Australia	Cardiovascular research
INSPIRE	Meta-analysis: ASPIRE and WARFASA (Italy)	Member
International Neonatal Immunotherapy Study (INIS) Study 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	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
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
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



GROUP	NATURE OF GROUP	CTC ACTIVITY
Prospective Pravastatin Pooling (PPP) project	Collaborative group: international	Coordinating centre
RNA-based Analysis for Prediction of Islet Death (RAPID)	Collaborative group: Australia	Collaborator
REMOVAL trial group	Collaborative group: international	Coordinating centre and collaborator
Royal Australasian College of Surgeons (RACS)	Professional society undertaking trials of surgery: Australia and New Zealand	Coordinating the SNAC trials in breast cancer with the RACS
Sydney Catalyst	Consortium for translational research in cancer	Collaborator
Trans-Tasman Radiation Oncology Group (TROG)	Collaborative group: Australia and New Zealand	Collaborator
T4DM trial group	Collaborative group: Australia	Coordinating centre and collaborator
Star Child Health	Meta-analysis collaboration: international	Member
University of Melbourne Department of Medicine	Research institution: Australia	Collaborator on diabetes studies
WINNER Centre for Newborn Research	Collaboration for international neonatal trials: Australia	Collaborator

Funding

FUNDER	
National Health and Medical Research Council	7,105,094
Australian Research Council	220,202
Cancer Australia	3,526,895
Cancer Council	316,101
Cancer Institute New South Wales	2,084,412
Collaborative investigator groups	34,652
Other research grants	2,046,277
Overseas research grants	1,605,594
Other Australian public funding	1,253,451
Research infrastructure grants	2,260,027
Pharmaceutical industry, primarily for trials	2,798,621
Consulting	422,622
Student Fees	141,832
Other	966,101
	24,781,881



- National Health and Medical Research Council
- Cancer Australia, Cancer Institute NSW and Cancer Council
- Other public funding
- Overseas research grants
- Pharmaceutical industry
- Other

Current CTC trials

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
NEONATAL DISORDERS			
Trials in start-up			
LIFT: Lactoferrin infant feeding trial <i>CTC-led study</i>	Infants born weighing under 1500 g	1100	–
Current trials			
APTS: Australian placental transfusion study <i>CTC-led study</i>	Neonates born before 30 weeks' gestation	1600	657
Trials in follow-up			
BOOST II: Benefits of oxygen saturation targeting <i>CTC-led study</i>	Neonates born before 28 weeks' gestation	1200	1135
CARDIOVASCULAR AND DIABETES			
Trials in start-up			
FAME1-EYE: Fenofibrate and microvascular events in type 1 diabetes <i>CTC and University of Melbourne</i>	Adults with type 1 diabetes and some thickening of the macula of the eye	450	–
Current trials			
REMOVAL: Effects of metformin added to insulin on atheroma progression <i>University of Glasgow and NHS-led, and CTC study</i>	Adults with type 1 diabetes at risk of cardiovascular disease	90 (ANZ): 500 (international)	52 (ANZ): 441 (international)
T4DM: efficacy of adding testosterone to a lifestyle program to prevent progression to type 2 diabetes <i>University of Adelaide and CTC study</i>	Men with prediabetes and low testosterone	1500	109
Trials in follow-up			
FIELD: Fenofibrate intervention and event lowering in diabetes <i>CTC-led study</i>	Patients with type 2 diabetes	8000	9795
LIPID: Long-term intervention with pravastatin in ischaemic disease <i>CTC-led study</i>	Patients with a history of coronary heart disease	9000	9014
ONCOLOGY PROGNOSIS STUDY			
Current trials			
iTool: Evaluating a web-based tool for estimating and explaining prognosis <i>CTC study</i>	Patients with incurable cancer who attend clinics of participating oncologists and who want information about life expectancy	70 patients; 70 oncologists	40 patients; 6 oncologists



TRIAL	PARTICIPANTS	TARGET	ACCRUAL
BREAST CANCER (COLLABORATING WITH RACS)			
Current trials			
SNAC 2: Sentinel node biopsy versus axillary clearance <i>RACS and CTC study</i>	Women with operable breast cancer, stratified by factors including age and tumour size	1012	298
Trials in follow-up			
SNAC 1: Sentinel node biopsy versus axillary clearance <i>RACS and CTC study</i>	Women with a single operable breast tumour <3 cm, stratified by factors including age and tumour size	1000	1088
GASTROINTESTINAL CANCER (COLLABORATING WITH AGITG)			
Trials in start-up			
ASCOLT: Aspirin for Dukes C and high-risk Dukes B colorectal cancers <i>National Cancer Institute (Singapore)-led, AGITG and CTC study</i>	Patients with colorectal cancer who have completed surgery and other treatment	200 (Australia); 2660 international	–
Current trials			
A La CART: Australian phase III randomised trial of laparoscopy-assisted resection compared with open resection <i>AGITG and CTC study</i>	Patients with primary rectal cancer	470	315
CO.23: BBI608 and supportive care compared with placebo and supportive care for colorectal carcinoma <i>NCIC-CTG-led AGITG and CTC study</i>	Patients with advanced colorectal carcinoma	275 (ANZ); 650 (international)	42 (ANZ)
DOCTOR: Phase 2 trial of preoperative cisplatin, 5-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer <i>AGITG and CTC</i>	Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy	150	72
GAP: Phase 2 study of gemcitabine and NAB-paclitaxel <i>AGITG and CTC</i>	Patients with resectable pancreas cancer	50	28
ICECREAM: Irinotecan cetuximab evaluation and cetuximab response evaluation among mutants <i>AGITG- and CTC-led international study</i>	Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation	100	40
IMPACT: Phase 2 trial using genomic sequencing and protein expression to direct first-line treatment <i>Garvan, AGITG and CTC</i>	Patients with metastatic pancreatic cancer	20	1
INTEGRATE: Phase 2 trial comparing regorafenib and placebo <i>AGITG and CTC-led international</i>	Patients with advanced oesophagogastric cancer	150	135
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer <i>MRC-led, AGITG and CTC</i>	Patients with fully resected stage III colorectal cancer	225 (ANZ); 9500 (international)	213 (ANZ); 6144 (international)
TOPGEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer <i>AGITG- and CTC-led international study</i>	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	98 (stage 1)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Trials in follow-up			
Adjuvant GIST: Adjuvant imatinib mesylate versus no further therapy after complete surgery (AG0403, EORTC 62024) <i>EORTC-led, AGITG and CTC</i>	Patients with resected gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ)	81 (ANZ); 908 (international)
Advanced GIST: Relation between dose and clinical activity of imatinib mesylate (AG0102, EORTC 62005) <i>EORTC-led, AGITG and CTC</i>	Patients with unresectable or metastatic malignant gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ); 600 (international)	116 (ANZ); 946 (international)
ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases <i>AGITG and CTC study</i>	Patients with confirmed resectable liver metastases and no other disease	200	9
EORTC liver metastases: Oxaliplatin, 5-fluorouracil and leucovorin versus surgery for resectable colorectal cancer liver metastases (EORTC 40983) <i>EORTC-led, AGITG and CTC</i>	Patients with colorectal cancer with resectable liver metastases	330 (international)	35 (ANZ); 364 (international)
LAP07: Randomised multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib <i>GERCOR-led, AGITG and CTC</i>	Patients with locally advanced adenocarcinoma of the pancreas	60 (ANZ); 900 (international)	32 (ANZ); 442 (international)
PAN1: Phase II study evaluating potential predictive biomarkers in treatment of locally advanced and metastatic pancreatic cancer <i>AGITG and CTC</i>	Patients with confirmed metastatic pancreatic adenocarcinoma	80	13
PETACC 6: Addition of capecitabine to preoperative oxaliplatin chemoradiotherapy and postoperative oxaliplatin chemotherapy for rectal cancer (AG0707R) <i>EORTC (PETACC)-led, AGITG and CTC</i>	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) <i>OCTO-led, AGITG and CTC</i>	Patients with colon cancer treated by surgery	120 (ANZ); 1892 (international)	219 (ANZ); 1952 (international)
REGISTER: Multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response <i>AGITG- and CTC-led international study</i>	Patients with gastrointestinal stromal tumour not suitable for curative surgery	80	47
TACTIC: Phase 2 trial of panitumumab, cisplatin and gemcitabine <i>AGITG and CTC</i>	Patients with biliary tract cancer	45	48

GYNAECOLOGICAL CANCER (COLLABORATING WITH ANZGOG)

Current trials

ICON 8: Dose-fractionated chemotherapy compared with 3-weekly chemotherapy for ovarian cancer <i>MRC-led ANZGOG and CTC study</i>	Women with ovarian, fallopian tube or primary peritoneal cancer.	145 (ANZ); 1485 (international)	3 (ANZ); 794 (international)
ANZGOG-1103: Phase I-II BNC105P combination study <i>ANZGOG- and CTC-led international study</i>	Women with partly platinum-sensitive ovarian cancer in first or second relapse	Phase 1: up to 24 (international)	15



TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer (ANZGOG-0902) <i>ANZGOG- and CTC-led international study</i>	Women with locally advanced cervical cancer	780 (international)	68 (ANZ); 195 (international)
PARAGON: Phase II study of anastrozole in gynaecological cancers (ANZGOG-0903) <i>ANZGOG- and CTC-led international study</i>	Women with potentially hormone-responsive gynaecological cancers	350 (international)	175 (ANZ); 58 (international)
PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with pelvic radiation alone in high-risk endometrial carcinoma <i>DGOG-led, ANZGOG and CTC study</i>	Women with advanced endometrial carcinoma	120(ANZ); 670 (international)	121 (ANZ); 671 (international)
REZOLVE: Phase II study to evaluate the safety and potential palliative benefit of intraperitoneal bevacizumab <i>ANZGOG and CTC study</i>	Women with symptomatic ascites due to advanced chemotherapy-resistant ovarian cancer	16 [*]	1
Symptom benefit: Does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG-0701) <i>ANZGOG- and CTC-led international study</i>	Women with platinum-resistant or refractory ovarian cancer	200 (ANZ); 800 (international)	126 (ANZ); 439 (international)
Trials in follow-up			
CALYPSO <i>GINECO-led, ANZGOG and CTC</i>	Women with platinum sensitive relapsed ovarian cancer	974 (international)	71 (ANZ) 976 (international)
GOG182 <i>GOG-led, ANZGOG and CTC</i>	Women with advanced stage (FIGO III-IV) epithelial ovarian or primary peritoneal carcinoma.	4200 (international)	184 (ANZ), 4312 (international)
GOG199 <i>GOG-led, ANZGOG and CTC</i>	Women at high risk of ovarian cancer	800 (international)	83 (ANZ), 800 (international)
ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy <i>MRC-led, ANZGOG and CTC</i>	Women with platinum-sensitive relapsed ovarian cancer	400 (international)	17 (ANZ); 486 (international)
ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy <i>MRC-led, ANZGOG and CTC</i>	Women with epithelial ovarian cancer who had not received systemic antitumour therapy	1444 (international)	76 (ANZ); 1450 (international)
OVAR 16: Pazopanib versus placebo for ovarian cancer <i>AGO-led, ANZGOG and CTC</i>	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	900 (international)	65 (ANZ); 940 (international)
SCOTROC 4: Multicentre trial of carboplatin flat dosing vs inpatient dose escalation in first-line chemotherapy <i>SGCTG-led, ANZGOG and CTC</i>	Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum-taxane therapy	1300 (international)	64 (ANZ); 937 (international)
EORTC55041 Tarceva <i>EORTC-led, ANZGOG and CTC</i>	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	830 (international)	41 (ANZ), 830 (international)
TRIPOD (ANZGOG-0601) <i>ANZGOG and CTC</i>	Women with optimally debulked stage III cancer of the ovary, peritoneum and fallopian tube.	35-100	39

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
GENITOURINARY CANCER (COLLABORATING WITH ANZUP)			
Trials in start-up			
BCG+MMC: Phase III trial of adding mitomycin C to BCG as adjuvant intravesical therapy for bladder cancer <i>ANZUP and CTC study</i>	Patients with high-risk, non-muscle-invasive bladder cancer	500	–
P3BEP: Phase III trial of accelerated versus standard BEP (ANZUP 1302) <i>ANZUP, ANZGOG and CTC study</i>	Patients with intermediate and poor-risk metastatic germ-cell tumours	Phase 1: 90 (ANZ); 150 (international) Phase 2: 350	–
Trials in follow-up			
Chemo & cognition: Cognitive function and treatment for testicular cancer (ANZGCTG 0106) <i>ANZUP and CTC</i>	Patients being treated and followed up for testicular cancer	154	151
Eversun: Phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901) <i>ANZUP and CTC</i>	Patients starting first-line systemic therapy for advanced renal cell carcinoma	55	55
SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05) <i>MRC-led, ANZUP and CTC</i>	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ); 1656 (international)	1711
LUNG CANCER (COLLABORATING WITH ALTG)			
Current trials			
NITRO: phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for advanced non-small-cell lung cancer (ALTG 06/003) <i>ALTG and CTC</i>	Patients with advanced non-small-cell lung cancer	500	350
Trials in follow-up			
BR.26: Phase III trial of PF-804 in patients with incurable, non-small-cell lung cancer (ALTG 09/002) <i>NCIC-led, ALTG and CTC</i>	Patients with stage IIIB or IV non-small-cell lung cancer	180	88
B2P2M2: phase II trial of BNC105P as second-line chemotherapy for pleural mesothelioma (ALTG 09/004) <i>ALTG and CTC</i>	Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy	60	30
PACT in NSCLC: Preferences for adjuvant chemotherapy in non-small-cell lung cancer <i>ALTG and CTC observational study</i>	Patients, surgeons and oncologists	200	122
BRAIN CANCER (COLLABORATING WITH COGNO)			
Current trials			
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC 26053-22054) <i>EORTC-led, COGNO and CTC</i>	Patients with non-1p/19q- deleted anaplastic glioma	100 (ANZ); 748 (international)	54 (ANZ); 542 (international)
Trials in follow-up			
CABARET: Phase II study of carboplatin and bevacizumab in recurrent glioblastoma multiforme <i>COGNO and CTC</i>	Patients aged 18 years and over with recurrent grade IV glioma after radiotherapy and temozolomide chemotherapy	122 (part 1); 60 (part 2)	122 (part 1); 48 (part 2)
SEED: Self-reported evaluation of the adverse effects of dexamethasone <i>COGNO and CTC</i>	Patients with brain tumours or brain metastases or advanced cancer using steroids	50 patients, 50 caregivers	66 patients, 66 caregivers



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Dirkje W Sommeijer, MD, PhD, clinical research fellow, AGITG and ANZGOG

Sonia Yip, BSc(hons), PhD, oncology senior translational research fellow and manager

Cooperative Trials Group for Neuro-Oncology

Jenny Chow, AssocDip, executive officer

Yi Feng, administrative assistant, BE(aeronautical)(hons)

Hannah O'Riley, BSc(hons), administrative assistant

Karen Miranda, trial coordinator and monitor, oncology





In April, Jenny Chow received a Faculty of Medicine award for exceptional performance

Neonatal trials

William O Tarnow-Mordi, MRCP(UK), FRCPCH, coordinator of neonatal trials and head, WINNER Centre for Newborn Research

INIS and APTS trials

Lucille Sebastian, BSc(hons), PhD, project manager

Rebecca Brown, BSc(hons), clinical trials assistant

Caitlin van Holst Pellekaan, BMedSc(hons), data manager

BOOST II trial

Alpana Ghadge, BSc, MSc, PhD, GradCert TradeMarksLawPract, project manager

LIFT trial

Alpana Ghadge, BSc, MSc, PhD, GradCert TradeMarksLawPract, project manager

Rebecca Brown, BSc(hons), clinical trial assistant

Cardiovascular trials

FIELD follow-up

Li Ping Li, BMed, GradCertDM, project manager

San Yip Chan, administrative assistant

Sandra Healey, BA(hons), GradDipFA, RN, substudy coordinator

ASPIRE

Rebecca Mister, BSc, MSc, project manager

Rebecca Brown, BSc(hons), clinical trial assistant

Caitlin van Holst Pellekaan, BMedSc(hons), data manager–study monitor

LIPID follow-up

Helen Pater, BAppSc, project manager

Diabetes trials

REMOVAL

Helen Pater, BAppSc, project manager

T4DM

Karen Bracken, BEc, MPH, project manager

Caitlin van Holst Pellekaan, BMedSc(hons), data manager–study monitor

Quality assurance

Phillipa Smith, BPharm(hons), MSc, head of quality assurance

Karen Wilkinson, DipTeach, BA, PostgradDip Psychol, MRQA, clinical trials auditor

Clinical data management

Mark Maclean, BA, DCR(T), CM, head
Salma Fahridin, BAppSc(HIM), MHlthSc, clinical data coordinator

Liam Murphy, BSc, clinical data coordinator

Michelle M Parry, BSc, PhD, clinical data project manager

Lindsay Stevens, BSc, clinical data coordinator

Site management

Rebecca Mister, BSc, MSc, head

Diabetes molecular medicine and telehealth

Alicia J Jenkins, MB BS, MD, FRACP, FRCP, professor of diabetes and vascular medicine

Sven-Erik Bursell, PhD, professor of telehealth

Anandwardhan A Hardikar, BSc, MSc, PhD, associate professor, Australian Future Fellow (ARC)

Andrzej S Januszewski, MD, PhD, senior research fellow

Mugdha Joglekar, BSc, MSc, PhD, Juvenile Diabetes Research Foundation research fellow

Daniel Calandro, BSc, research assistant

Veronica Dy, PhD, clinical trial assistant

Thomas McCorquodale, BSc, clinical trial assistant

Sarang Satoor, BSc, MSc, research fellow

Systematic reviews and health technology assessment

Lisa M Askie, BN, MPH, PhD, director, and principal research fellow

Jenny Chow, AssocDip, executive officer

Henry CH Ko, BEng(Med)(hons), PhD, research fellow

Sally J Lord, MB BS, DipPaed, MS, FRACGP, epidemiologist and research fellow

Health technology assessment

Briony Jack, PhD, project manager

Samara Lewis, BA/BSc(hons), PhD, project manager

Elizabeth Seil, BA(hons), MSc(HTA), project officer

Anna Stoklosa, BA, MA, PhD, research fellow

Sally Wortley, BHlthSc(hons), MPH, Grad Cert Hlth Econ, project officer

Cochrane breast cancer review group

Melina Willson, BSc (hons)/BA, PhD, managing editor

Fergus Tai, BAppSc, DipIT, MPH, trials search coordinator

Australian New Zealand

Clinical Trials Registry

Kylie E Hunter, BA, BA(hons), project officer

William YT Ooi, MHlthSc, BAppSc, project officer





Health economics

Deborah J Schofield, BSpPath, GradDipComp, PhD, professor
 Emily J Callander, BA, PhD, research fellow
 Hannah Carter (Verry), BEc, health economist
 Michelle Cunich, BEc, MEc, PhD, economist
 Sharyn Lymer, BA, BPTHy, MBIostat, PhD, research fellow
 Rupendra N Shrestha, MSc, PhD, research fellow

Biostatistics and consulting

Val J GebSKI, BA, MStat, professor and principal research fellow
 Jodie Gonzalez-Jennings, administrative officer
 H Malcolm Hudson, BSc(hons), PhD, honorary professor
 Ian C Marschner, BSc(hons), PhD, professor

Senior biostatisticians

Karen Byth (Wilson), BSc(hons), MSc, PhD, DIC, CStat RSS, senior lecturer
 Adrienne C Kirby, BSc(hons), MSc, senior lecturer
 Andrew J Martin, BA, MA, GradDip, PhD, AStat, senior lecturer
 Rachel L O'Connell, BMath, MMedStat, PhD, research fellow

Research fellow

Elizabeth H Barnes, BAppSc, MStat

Biostatisticians

Luke Buizen, BSc
 Lucy Davies, BSc, MSc
 Mark W Donoghoe, BSc(hons)
 David Espinoza, BSc(hons)
 Emma Gibbs, BSc, MSc
 Kristy Mann, BScAgr(hons), MBIostat
 Simone Marschner, BSc(hons), MSc
 Anne-Sophie Veillard, BSc, MSc

Biostatistics Collaboration of Australia (BCA)

Erica Jobling, executive officer
 Kew Flood, administrative officer

Information systems

Infrastructure

Dinh Tran, BMath, MCompSc, infrastructure manager
 Asanka Perera, BSc, computer systems officer
 Ha Le, BCST, desktop support officer
 Ryan Sausa, BE, computer systems officer
 Thuyen Vu, BSc, computer systems officer

Database administration

Anh Tai Nguyen, BMath, database administrator

Software development

Colin Sutton, BSc, MSc, IT systems development manager
 Seshu Atluri, BE, software engineer

Business administration

Kim Russell-Cooper, BA(hons), MBA, general manager
 Lily Cakir, receptionist
 Mira Mikulic, receptionist
 Lia Sherwood, BBIomedSc, MSc, grants and contracts coordinator

Finance

Paul Smyth, BCom, CPA, finance manager
 Agnes Ho, MPracAcc, CPA, finance officer
 Maki Joseph, DipEd, finance officer
 Carlos Sterling, BEng, MBA, finance officer

Human resources

Cynthia Carr, BEd(HRD), human resources and administration manager
 Suzanne Everett, BSW, human resources and administration coordinator

Mark Maclean, head, clinical data management

Publications

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

Research students

Daniel Calandro, BSc
 Venu Chalasani, MB BS, FRACP
 Ryan Farr, BSc, MPhil
 Jordan Fulcher, BSc(Med), MB BS
 Deme Karikios, BSc, MB BS, FRACP
 Kushwin Rajamani, MB BCH
 Ru-Dee Ting, MB BS, FRACP
 Boris Waldman, BSc
 Wilson Wong, BSc(hons)

Academic staff

Lisa M Askie, BN, MPH, PhD, associate professor and principal research fellow
 Elizabeth H Barnes, BAppSc, MStat, research fellow
 Karen Byth, BSc(hons), MSc, PhD, DIC, CStat RSS, senior lecturer
 Emily J Callander, BA, PhD, research fellow
 Hannah Carter (Verry), BEc, research associate
 Michelle Cunich, BEc, PhD, economist
 Val J GebSKI, BA, MStat, professor and principal research fellow
 Wendy Hague, MB BS, MBA, PhD, senior research fellow
 Anandwardhan A Hardikar, BSc, MSc, PhD, associate professor and Australian Future Fellow (ARC)
 Andrzej S Januszewski, MD, PhD, senior research fellow
 Alicia J Jenkins, MB BS, MD, MRCP, FRACP, FRCP, professor
 Anthony C Keech, MB BS, MSc, FRACP, FCSANZ, principal research fellow and professor
 Adrienne C Kirby, BSc(hons), MSc, senior lecturer
 Henry Ko, BEng(Med)(hons), PhD, research fellow
 Chee K Lee, MB BS(hons), MMedSc, MBIostat, PhD, FRACP, senior research fellow
 Sally (Sarah) J Lord, MB BS, DipPaed, MS, FRACGP, senior research fellow
 Sharyn Lymer, BA, BPTHy, MBIostat, PhD, research fellow
 Ian C Marschner, BSc(hons), PhD, professor
 Andrew J Martin, BA, MA, GradDip, PhD, AStat, senior lecturer
 Rachel L O'Connell, BMath, MMedStat, PhD, senior research fellow
 Deborah J Schofield, BSpPath, GradDipComp, PhD, professor

Rupendra N Shrestha, MSc, PhD, research fellow
 R John Simes, BSc(Med)(hons), MB BS(hons), MD, SM, FRACP, senior principal research fellow and professor
 Katrin M Sjoquist, BSc(Med), MB BS, MClint(R), FRACP, clinical research fellow
 Martin R Stockler, MB BS(hons), MSc, FRACP, professor
 Anna Stoklosa, BA, MA, PhD, research fellow
 Sonia Yip, BSc(hons), PhD, senior research fellow

Honorary associates of the CTC

Associate Professor Meera R Agar, COGNO scientific advisory committee
 Dr Andrew Barbour, PI, DOCTOR and GAP trials (AGITG)
 Dr Sally Baron-Hay, ANZGOG executive
 Dr Andrew Berry, BOOST II safety and data monitoring committee chair
 Dr Andrew Biankin, PI, LAP07 trial (AGITG)
 Dr Alex Boussioutas, Gastric trial (AGITG)
 Dr Timothy Brighton, PI, ASPIRE trial
 Dr Ian Campbell, PI, SNAC 2 trial
 Professor Christopher Christophi, AGITG management committee
 Dr Yu Jo Chua, PI, PAN1 trial (AGITG)
 Professor Alan Coates, Biostatistics
 Professor Forrester Cockburn, BOOST II trial Safety and Data Monitoring Committee
 Ms Melinda Cruz, LIFT study
 Dr Andrew Davidson, PI, NITRO trial (ALTG)
 Associate Professor Ian D Davis, PI, SORCE trial and chair, ANZUP
 Dr Andrew Dean, PI, ICON8 trial
 Dr Jayesh Desai, PI, REGISTER trial (AGITG)
 Professor Catherine D'Este, BOOST II trial Safety and Data Monitoring Committee
 Dr Pei Ni Ding, Oncology
 Dr Katherine Drummond, COGNO management committee
 Dr John Eikelboom, co-PI, ASPIRE and PREDICT trials
 Dr Jonathan Fawcett, co-PI, ATTACHE trial (AGITG)
 Dr Kathryn Field, PI, CABARET trial (COGNO)
 Ms Marcia Fleet, COGNO management committee
 Dr Matthew Foote, COGNO management committee
 Dr Michael Friedlander, ANZGOG executive and PI, GOG182, TRIPOD, OVAR16, Symptom Benefit and PARAGON trials

Professor Sanjeev Galande, Diabetes, Molecular Medicine and Telehealth
 Professor Alexander Gallus, ASPIRE trial management committee
 Dr Davina Ghersi, Australian New Zealand Clinical Trial Registry advisory committee and CTC adjunct professor
 Professor P Grantley Gill, PI, SNAC trials
 Dr David Goldstein, PI, LAP07 trial, co-PI, ATTACHE trial, AGITG board
 Dr Andrew M Haydon, PI, SCOT trial (AGITG)
 Dr Sandra Hayes, ECHO study
 Professor Dickon Hayne, PC4 trial, ANZUP
 Dr Elizabeth Hovey, COGNO executive
 Dr H Malcolm Hudson, Biostatistics
 Dr Monika Janda, COGNO scientific advisory committee
 Dr Michael Jefford, SCOT trial (AGITG)
 Dr Lindy Jeffree, COGNO scientific advisory committee
 Dr Terrance Johns, COGNO management committee
 Dr David J Joseph, COGNO scientific advisory committee
 Dr Andrew Kneebone, AGITG
 Dr Eng-Siew Koh, COGNO management committee
 Dr Dusan Kotasek, Adjuvant GIST study
 Dr Danette Langbecker, COGNO scientific advisory committee
 Ms Robyn Leonard, COGNO management committee
 Dr Trevor Leong, PI, TOP GEAR, Gastric trial (AGITG)
 Dr Helen Liley, PAEAN study
 Dr Kerrie McDonald, COGNO scientific advisory committee
 Dr Sue-Anne McLachlan, PACT in SCLC (ALTG)
 Associate Professor Peter Meikle, LIPID and FIELD studies
 Dr Michael Michael, PI, TOPGEAR trial (AGITG)
 Dr Linda Mileshekin, ANZGOG executive, PI, PORTEC-3 and OUTBACK trials
 Professor Michael J Millward, PI, BR26 trial (ALTG)
 Associate Professor Paul Mitchell, ALTG
 Dr Paul Nguyen, ANZUP
 Professor Anna Nowak, PI, CATNON trial (COGNO)
 Dr Robert Padbury, AGITG
 Dr Nicholas J Petrelli, AGITG
 Associate Professor Timothy J Price, PI, PETACC6 trial (AGITG)

Dr Kushwin Rajamani, FIELD study
 Dr David T Ransom, PI, SCOT and ARCTIC trials (AGITG)
 Dr Danny Rischin, ANZGOG executive
 Dr Aflah Roohullah, AGITG
 Dr Mark Rosenthal, COGNO chair
 Dr Gail Ryan, COGNO scientific advisory committee
 Associate Professor Eva Segelov, PI, ICECREAM, QUASAR2 and SCOT trials (AGITG)
 Dr Shomik Sengupta, ANZUP
 Dr Catherine Shannon, OVAR 2.21 (ANZGOG)
 Dr Jennifer A Shannon, PI, TACTIC trial (AGITG)
 Dr Bernard M Smithers, Gastric trial (AGITG)
 Dr Benjamin Solomon, PI, BR24 trial (ALTG)
 Dr Allan Spigelman, Sydney Catalyst
 Dr Nigel A Spry, PI, LAP07 trial (AGITG)
 Dr Andrew R Stevenson, PI, A La CART (AGITG)
 Associate Professor David Sullivan, LIPID and FIELD trial management committees
 Dr Christopher Sweeney, ANZUP
 Associate Professor Niall Tebbutt, PI, ATTAX, ATTAX2, ATTAX3 and MAX trials (AGITG)
 Associate Professor Damien Thomson, co-PI, Aprepitant trial (ANZUP) and ANZUP germ-cell subcommittee
 Dr Andrew Tonkin, BiomarCare, LIPID study chair
 Dr Paul Vasey, PI, SCOTROC4 trial (ANZGOG)
 Dr Michelle Vaughan, ANZGOG executive, PI ICON6
 Dr Euan Walpole, PI, SCOT trial (AGITG)
 Dr Neil Wetzig, co-PI, SNAC trial
 Dr Louise Wigston (Nott), CO.23 trial (AGITG)
 Associate Professor Nicholas Wilcken, ANZ BCTG
 Dr Kathryn Williams, FIELD study
 Professor Gary Wittert, PI, T4DM trial
 Dr Desmond Yip, SCOT (AGITG)
 Professor John Zalcborg, AGITG chair



Staff activities

Supervision of research degrees in 2013

Lisa Askie

Angela Carberry: PhD

Anthony Keech

Jordan Fulcher: PhD

Jason Harmer: PhD

Kushwin Rajamani: PhD

Ru-Dee Ting: PhD

John Simes

Claudia Dobler: PhD

Jordan Fulcher: PhD

Michelle Cunich

Thomas Lo: PhD

Val Gebiski

Farnoush Noushi: PhD

Anandwardhan Hardikar

Ryan Farr: PhD

Wilson Wong: MPhil/PhD

Michael Williams: PhD

Andrzej Januszewski

Daniel Calandro: MPhil

Alicia Jenkins

Paul Benitez Aguirre: PhD

Daniel Calandro: MPhil

Yoon Hi Cho: PhD

Ben Ma: PhD

Jon Noonan: PhD

Kushwin Rajamani: PhD

Harris Schlen: PhD

Ru-Dee Ting: PhD

Chee Lee

Amira Elmadahm: PhD

Sally Lord

Amira Elmadahm: PhD

Andrew Martin

Claudia Dobler, PhD

Deme Karikios, PhD

Deborah Schofield

Hannah Carter (Verry): PhD

Deme Karikios: PhD

Rupendra Shrestha

Hannah Carter (Verry): PhD

Martin Stockler

Deme Karikios: PhD

Degrees awarded in 2013

Belinda Kiely: PhD, The art of oncology:

communicating survival expectancy to patients with cancer

Katrin Sjoquist: MClint (R)

Anna Stoklosa: PhD, The concept of evidence in health technology assessment

External committees

Lisa Askie

Antenatal Magnesium IPD International Collaboration (AMICABLE) individual patient data collaboration steering committee

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 advisory committee

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

Anthony Keech

CAMELLIA-TIMI 61 executive committee (lead investigator)

Cholesterol Treatment Trialists' Collaboration (CTTC) (joint coordinator and convenor)

Fenofibrate and Microvascular Events (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



Program Grant investigators

Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk (FOURIER) executive 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 grant review panel

PLoS Medicine editorial board

REMOVAL trial steering committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

John Simes

Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) scientific advisory committee

Aspirin to Prevent Recurrent Venous Thrombo-embolism (ASPIRE) trial management committee (chair)

Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee, operations executive committee, MAX trial management committee

Australian New Zealand Clinical Trials Registry (ANZCTR) policy advisory committee

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

International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolic (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

Sentinel Biopsy versus Axillary Clearance (SNAC) trial management committee
Sydney Catalyst governing council and scientific advisory committee

Trials associate editor

Elizabeth Barnes

Biostatistics Collaboration of Australia teaching committee

Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee

DOCTOR trial management committee (AGITG)

Outback trial management committee (ANZGOG)

Jenny Chow

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

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

Val GebSKI

Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and MAX, TOPGEAR, IMPACT, PAN-1, ATTACHE, ATTAX3, TACTIC, DOCTOR, ICECREAM and REGISTER trial management committees and group statistician

Australasian Kidney Trials Network advisory board

Australia and New Zealand Breast Cancer Trials Group (ANZ BCTG) scientific advisory committee, GALA, LATER SORBET and NeoGem trial management committees, and group statistician

Australian and New Zealand Urogenital and Prostate Cancer Trials Group ANZUP scientific advisory committee and Accelerated BEP and EVERSUN trial management committees and group statistician

Australian New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee, CALYPSO trial management committee, PARAGON and OUTBACK trial management committees, and group statistician

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) safety and data monitoring committees

Biostatistics Collaboration of Australia steering and teaching committees

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

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

NSW Health Central Sydney Area ethics committee clinical trials subcommittee

SNAC trial management committee

T4DM trial management committee

Trans Tasman Radiation Oncology Group (TROG) scientific committee, publications committee, and group statistician

Alpana Ghadge

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

Lactoferrin Infant Feeding Trial (LIFT) 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 and A La CaRT trial management 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

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

International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolic (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

Anandwardhan Hardikar

Experimental Diabetes Research special issue on non-coding RNAs, chief guest editor
Islet Society, Stockholm, Sweden, vice-president

Lifestyle Interactions in Fenofibrate and the Epigenome (FIELD-LIFE), co-investigator
NHMRC Grant Review Panel member for diabetes/ obesity/ stem cell panels, Project Grant Assigners Academy member, Translational Research Faculty member

Non-coding RNAs in Endocrinology, editor-in-chief

RNA-based Analysis for Prediction of Islet Death (RAPID), principal investigator

Pancreatic islet biology book editor, Springer series 'Regenerative medicine'

Visiting faculty, Indian Institute of Science Education Research, Pune, India

Alicia Jenkins

Australian Diabetes Society council member and treasurer

Insulin For Life Australia, Insulin for Life global and Insulin For Life USA board member

International Diabetic Federation Life For a Child program board member

REMOVAL study of metformin in type 1 diabetes, co-principal investigator and Australian lead

TEAMSNET telehealth initiative principal investigator

Adrienne Kirby

Australian Placental Transfusion Study (APTS) management committee

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

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

Faculty of Medicine, University of Sydney postgraduate coursework committee

Improving Delivery of Secondary Prophylaxis for Rheumatic Heart Disease trial management committee

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

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

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

Ann Livingstone

Cancer Institute NSW Neuro-oncology Group (NSWOG)

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

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee and operational executive committee.

Sally Lord

Protocol Advisory Committee (PASC) for Medical Services Advisory Committee

European Federation of Clinical Chemistry and Laboratory Medicine Test Evaluation Working Group

Andrew Martin

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee

BLOCADE safety data monitoring committee

ONTRAC, ProCare, INTEGRATE, EPOCH, NeuHorizons, LIFT and EVERSUN trial management committees

Julie Martyn

Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee, operations executive committee and ICON-6, ICON-7, PORTEC-3 and OVAR-16 international steering committees and TRIPOD, Symptom Benefit, PORTEC-3 and Outback trial management committees

Gynecological Cancer Intergroup (GCI) harmonisation and statistics committee (chair)

Danielle Miller

Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee and TOPGEAR trial management 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-Embolic (INSPIRE) steering committee

Rachel O'Connell

D-Health (a study of vitamin D and health) trial management committee

PARAGON and Symptom Benefit trial management committees (ANZGOG)

PAN-1, TACTIC and TOPGEAR trial management committees (AGITG)

Kate Sawkins

Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive committee, and CABARET, CATNON and SEED trial management committees

Biostatisticians, Anne-Sophie Veillard and Rachel O'Connell



Deborah Schofield

Advisory Board for Pain Australia advisory board
Australian Research Council College of Experts
Garvan Institute Centre for Clinical Genomics, strategic advisory board
Health Workforce Australia technical advisory group
International Health Workforce Collaborative
International Journal of Microsimulation health editor
NSW Ministerial Advisory Committee on Ageing
Sydney Health Policy Network steering committee
Westmead International Network for Neonatal Education and Research (WINNER Centre) advisory committee

Lucille Sebastian

Australian Placental Transfusion Study (APTS) management committee and echocardiography substudy management committee
HSP 90 inhibitor study (HSP90) management committee
PAEAN management committee

Katrin Sjoquist

Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee, alumni committee (chair), future faculty fellow
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and operations executive committee, Symptom Benefit trial management committee, PARAGON trial management committee
Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and operations executive committee, Upper GI working party, PAN1 trial management committee (CTC clinical lead), INTEGRATE trial management committee (CTC clinical lead) and international trial management group, ATTACHE, ATTAX3 and TACTIC trial management committees

Martin Stockler

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee and operations executive
Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee (convenor)
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research 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
National Health and Medical Research Council grant review panels for oncology
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 University of Sydney Medical Program 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
Cooperative Trials Group for Neuro-Oncology (COGNO) operations executive

Anne-Sophie Veillard

ATTAX3 trial management committee

Kate Wilson

Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee, scientific advisory committee and annual scientific meeting committee, and MAX, QUASAR2, PETACC6, A La CaRT, GAP, DOCTOR, ICECREAM and ATTACHE trial management committees.

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

ARCS Australia Annual Scientific Congress organising committee
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive and biological subcommittee, and GAP, IMPACT, INTEGRATE trial management committees
Australian and New Zealand Urogenital and Prostate Group (ANZUP) scientific advisory committee, renal cell subcommittee, germ cell subcommittee, translational subcommittee, and EVERSUN, SORCE
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and cervix working group
Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee
Sydney Cancer Conference co-chair
Sydney Catalyst: Translational Cancer Research Centre of Central Sydney and Regional NSW scientific advisory committee, operations executive committee and T1 working group

Regular academic teaching

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

Anthony Keech

Royal Prince Alfred Hospital cardiology training, and clinical tutor
Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
Master of Clinical Trials, University of Sydney (coordinator)

John Simes

Decision analysis, Master of Public Health and Master of Medicine, University of Sydney

Elizabeth Barnes

Basic sciences in oncology, NSW Health Education Training Institute
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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
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Publications

Journal articles by CTC authors

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