NHMRC CLINICAL TRIALS CENTRE THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2014



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The NHMRC Clinical Trials Centre at the University of Sydney conducts 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 2014.



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CTC EXECUTIVE

John Simes, director Anthony Keech, deputy director Wendy Hague, clinical trials program director Kim Russell-Cooper, general manager

Directors' report

Translational research

The Clinical Trials Centre collaborates with investigators on major trials and undertakes research and education in trials methodology. Increasingly, we are cooperating with diverse individuals and organisations in integrated translational research programs, which promise to reduce the time taken to render scientific discoveries into health outcomes. At the CTC, our research is planned with the full research pathway in mind.

For example, in translational cancer research, the CTC works closely with its fellow members of Sydney Catalyst. This consortium brings together teams of researchers and clinicians from 6 institutes and 8 hospitals, over 400 people in all, across New South Wales. Its research program encompasses three linked processes: T1, new knowledge from the laboratory or scientific setting; T2, testing in humans; and T3, using results of clinical studies in clinical practice and decision making.

The CTC is also a member of Sydney Research, a cluster of the major academic health institutions and tertiary hospitals in the Sydney health district, which form a broadly based precinct as a foundation for research growth and excellence. In 2014, the group established its strategic objectives, which include integrating research into every aspect of healthcare practice.

Beyond the research pathway

The Australian Clinical Trials Alliance (ACTA) was formally launched at the ACTA Summit in March 2014. ACTA aims to be the national peak body to support and represent the investigator networks that conduct clinical trials in areas of need. The CTC has been deeply involved in the formation of ACTA and its current initiatives, including an international symposium to be held in Sydney in October 2015. Its longer-term objectives, include: first, bringing networks together to share expertise and develop strategies for boosting the capacity of Australian clinicians to answer important clinical questions; second, coordinating or supporting projects that help streamline the process of starting and running well-designed clinical trials; and third, driving policy development aimed at making 'public-good' clinical trials more central to health care in Australia in order to produce better health outcomes at lower cost.

Achievements by the CTC and its collaborators

Within the CTC itself, many individual projects make up a major research effort. Our main areas of interest are cancer, diabetes, cardiovascular disease and neonatal disorders, in a context of collaboration with others. In oncology, the process of choosing trial questions starts with concepts developed from real-world health care needs by networks of practising clinicians. The CTC works with major Australasian cancer investigator networks: gastrointestinal (AGITG), lung (ALTG), urogenital (ANZUP), gynaecological (ANZGOG), brain (COGNO) and and breast (ANZBCTG). These established

groups have annual scientific meetings at which gaps in research are discussed and practicable responses developed, resulting in new rials that meet real-world needs.

Diabetes is Australia's fastest growing chronic disease and a focus of a large part of CTC's research. The FIELD trial had shown that fenofibrate prevented progression of retinopathy, setting the scene for current studies in type 1 and type 2 diabetes: the FAME1-Eye trial (type 1 diabetes) and the work of the virtual Centre for Research Excellence in Health Services Research (type 2 diabetes). Clinical investigations are conducted in tandem with genetic and molecular experiments on the mechanisms and markers of diabetes risk.

In cardiovascular disease, the recent publication of the results of the INSPIREsstudy on aspirin to prevent thrombosis attracted worldwide media attention. INSPIRE, a prospective pooled analysis of the CTC's ASPIRE trial and the Italian WARFASA study, gave us clear evidence that aspirin, an inexpensive treatment available everywhere, could prevent recurrent thrombosis in patients who cannot or do not want to take long-term anticoagulants.

New multicentre trials in neonatology were launched in 2014. Among these, PAEAN is a trial of erythropoietin added to standard treatment for newborns with brain damage from birth hypoxia. It continues one of CTC's research interests: improving the prospects of neonates at risk. The trial has been planned in cooperation with a parallel US trial, so if the treatment is found to be effective, the results will be evidence enough to rapidly translate into worldwide standard treatment. CTC is now a leading source of experts in clinical trials methodology for Australia. We contribute to health research organisations throughout Australia and internationally though representation on committees of peak bodies such as ACTA and NHMRC, cancer council committees, trial steering and management committees, and executive roles on investigator networks.

Our research methodology capability in biostatistics is widely shared through an active consultancy enterprise in which statisticians apply their knowledge to research programs in various Sydney hospitals, in addition to their extensive teaching commitments and educational masterclasses and workshops. They are among the CTC academics who teach the Master of Clinical Trials program and continue to be part of the national Biostatistics Collaboration of Australia's postgraduate program.

The work of the health economics group is highly regarded, especially in an environment where demonstrated cost-effectiveness of health care interventions is essential.

The CTC has been active for many years in the Cochrane Collaboration's work of obtaining and disseminating high-quality evidence to guide clinical decision making. Achievements by the Cochrane Breast Cancer Group were recognised when the Cochrane Library rated this team, based at the CTC, as one of its best and most productive groups. Their proficiency and relevance were reflected in the current high impact factor of their published reviews. The Australian New Zealand Clinical Trials Registry, established in 2005, recently reached 10,000 trials registered. For each trial, information on the research plan, eligibility of patients, the drug or intervention, and much more, are available for anyone to view. Among its many benefits to researchers, clinicians and patients, the registry is a significant contributor to research transparency.

Contributors to CTC successes

Patients, or study participants, have an essential role in all our trials. The CTC's policies recognise the central place of participants in research. Patient representatives are consulted when trials are being planned, often via a specific consumer advisory panel. We aim to communicate the results of trials to participants, and inform them of this commitment as part of the initial consent to participate in a trial.

The NHMRC and other government entities continue to award substantial grants to the CTC in a highly competitive environment. The NHMRC program grant to the CTC's collaboration with the Boden Institute enables important research studies to be integrated with trials funded from industry and other sources. We are grateful to our collaborators , among them the investigator networks, and funders, such as the pharmaceutical companies which provide almost half of our trials funding.

CTC research and education achievements depend on over 200 academic staff, professional staff and honorary associates. Their knowledge, experience, tenacity and representation in the wider clinical research community are behind our continuing successes.

National and international landmark trials



Oncology trials

The CTC's oncology group works in partnership with Australia's leading cancer collaborative investigator groups. The CTC is the coordinating centre for the:

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

Through these groups, the CTC has links to other groups in Australia and internationally (see p.31).

The oncology group coordinates trials of treatments for various cancers: gastrointestinal, lung, urogenital, gynaecological, brain and breast. Most trials are designed to answer a primary clinical question, such as whether one treatment is better than another. Treatments range across surgery, chemotherapy, radiation therapy and targeted agents, and more often are multidisciplinary treatments. However, the knowledge arising from a trial is much more: the data are applied to studies about health-related quality of life, cost-effectiveness of treatments, studies of tissue markers in individuals that predict their responses to specific treatment, and others.

The oncology group has grown rapidly in recent years to a team of over 50. Such a large group engaged with many colleagues around the world presents administrative challenges. In 2014, the management team was reorganised to form two streams—development and operations—with the aims of focusing on fast development of concepts into working protocols and maximising efficiency in trial operation. The group has also been working hard on increasing engagement and involvement with their many associates in investigator networks and at trial sites, including more streamlined web-based communications for training, initiation of trial sites, and access to documents and information.

The group currently has over 60 trials in start-up, currently recruiting, or with patients in followup. In 2014, the CTC's oncology researchers published 35 articles in peer-reviewed journals and presented 60 studies at national and international conferences.



Burcu Vachan, Oncology program manager

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Cancer biomarker studies lead to personalised treatment and better understanding of treatment targets

The search is on for biological markers that will predict how well individual patients will react to different kinds of treatment. Ultimately, patients can be given the treatment most likely to control their particular type of tumour and be spared treatments not likely to help them.



Sonia Yip, the CTC's senior translational research fellow, provides scientific expertise in development of biological studies for clinical trials and works closely with all five collaborative groups. She also convenes workshops in concept development for trials and translational studies. This is the age of personalised medicine: specific cancer therapies have been found to benefit some patients and not necessarily all, and patients respond to treatments to different degrees and in different ways. The search is on for biological markers that will predict how well individual patients will react to different kinds of treatment. Ultimately, patients can be given the treatment most likely to control their particular type of tumour and be spared treatments not likely to help them.

C017

Since the landmark findings of the CO.17 cetuximab trial in 2008, routine genetic testing of colorectal tumours for KRAS mutations can indicate which patients are unlikely to benefit from cetuximab treatment. These results were a major step forward for the treatment of advanced colorectal cancer and have been followed by many new questions. Why was cetuximab also ineffective for some of the patients in the group with nonmutated tumours? Is it because other biomarkers also affect their response to treatment? Analyses from the CO.17 trial population recently showed for the first time that another biomarker, epirequlin mRNA

expression, also predicts whether cetuximab will improve survival.⁷⁵

ICECREAM

In ICECREAM, a current trial of cetuximab, potential trial participants with advanced colorectal cancer are screened to classify them according to genetic markers. Only those patients with tumours that are considered genetically susceptible to cetuximab are eligible for the trial. They are then randomly allocated to cetuximab alone or cetuximab with chemotherapy.²⁵⁹ The study will reveal whether cetuximab works best alone or with chemotherapy and will also provide high-quality data on the activity of cetuximab. Patients are being recruited from Australia, the UK, Spain and Italy.

IMPACT

Pancreatic cancer is a disease very much in need of new effective treatments. Most people with metastatic cancers of the pancreas do not survive to 5 years. Pancreatic tumours are biologically diverse, so a new approach is to group patients according to their molecular tumour type and use different targeted treatments depending on the type.¹²⁶ The Individualised Molecular Pancreatic Cancer Therapy (IMPACT), is a trial assessing the



feasibility of such personalised treatment in patients with recurrent or metastatic pancreatic cancer.^{179,181} IMPACT will test tumours for several molecular biomarkers with the aim of developing effective personalised treatment strategies. Patients will be randomised to standard gemcitabine chemotherapy or one of three targeted treatments, depending on the results of tumour testing. IMPACT is a multidisciplinary collaboration between Sydney Catalyst, the Australasian Gastro-Intestinal Trials Group, the Garvan Institute of Medical Research, which houses the Australian Pancreatic Cancer Genome Initiative (APGI), and the CTC. The pilot stage of the trial has been funded by Sydney Catalyst.

The importance of biomarkers in the trials of the CTC and its collaborative groups can be seen in the results now flowing from renal cell,¹⁸⁷ lung⁴⁴ and colorectal cancer trials.^{65,77,128,184} All these biomarker studies pinpoint the biological characteristics of patients that predict whether treatment will be individually worthwhile or not. They also increase knowledge about specific genetic and cellular processes and pathways that interact with treatments, leading the way for future research.

Benefiting patients through national and international brain cancer trials

The most common brain tumours of adults are gliomas. High-grade gliomas, including glioblastoma multiforme, are aggressive and difficult to treat and most patients live less than a few years. This type of cancer is therefore an important target for new and better treatments.

COGNO, the CTC's newest cancer collaboration, is now well established, with an active trials program, a growing membership, and productive working relationships with various international research groups. COGNO's main aim is to conduct investigator-initiated and collaborative group trials addressing important clinical questions in patients with brain tumours.

CABARET

In 2014, COGNO–CTC completed its second trial of treatment for glioblastoma multiforme. The trial, CABARET, has tested bevacizumab, a monoclonal antibody that is known to improve patient outcomes in brain and other types of cancers. It targets a vascular endothelial growth factor (VEGF), thus attacking the blood supply nourishing the tumour. The trial is comparing bevacizumab alone with bevacizumab added to standard chemotherapy in over 100 Australian patients. The results of the trial will be published in 2015.

In the second stage of CABARET, surviving patients are continuing to be followed up after their disease has progressed, with half of them randomised to continuing bevacizumab to see whether this leads to better outcomes than stopping treatment.

A recently published review of a similar question for the Cochrane Library found that, for people with newly diagnosed and recurrent glioblastoma, bevacizumab did not improve overall survival but prolonged the period that they remained well.⁷⁹ Whether this situation makes a difference to quality of life remained unclear, underlining the need for more evidence from clinical trials.



Dr Kathryn Field, CABARET study chair 'It is time that patientreported quality of life measures and benefits be included as co-primary endpoints in the targets of clinical trials for patients with recurrent ovarian cancer.'

'For most of these patients the aim of treatment is palliation. The primary endpoint of clinical trials has traditionally been progression-free survival, but arguably measuring the impact of treatment on symptoms for these patients is equally if not more important.'

> Michael Friedlander, principal investigator for the Symptom Benefit study and member of the ANZGOG board of directors

Does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer?

Most women with ovarian cancer have advanced-stage disease when their cancer is first discovered and most will develop recurrent disease. Many of these women are primarily concerned with relief of symptoms and improvement in quality of life, but most clinical trials focus more on tumour responses to chemotherapy and survival.

Symptom Benefit is an international collaborative trial attempting to address this inconsistency and lay groundwork for future trials. It is measuring the effect of palliative chemotherapy on symptoms suffered by women with ovarian cancer that has progressed after chemotherapy. Stage 1 of the study has aimed, first, to comprehensively describe the symptom burden, and second, to assess the how well symptoms are measured by current methods. With this knowledge, the investigators are constructing the optimal instrument for measuring subjective symptom benefit in trials of palliative chemotherapy for recurrent ovarian cancer.

The first part of the study has been published.^{50, 80} The women reported pain, fatigue, abdominal bloating and discomfort, sleep disturbance, bowel problems, nausea and vomiting, shortness of breath, poor appetite, urinary symptoms, weight changes and emotional problems. Some symptoms mentioned by patients, such as anxiety and insomnia, were usually not reported by the doctors. The findings show how important it is to ask patients to rate their symptoms themselves.

Embedded in this trial was the development of a general questionnaire instrument for measuring patient-reported outcomes, the 'Measure of Ovarian Symptoms and Treatment',⁸⁰ which is being validated in stage 2 of the study.

Symptom Benefit, one of the ANZGOG-CTC trials, had its origin in a meeting in 2004 of the Gynecological Cancer Intergroup, the international network of investigators. The trial questions arose from discussion about gaps in the treatment of advanced ovarian cancer. It is now making a difference to many of the 200,000 women with a diagnosis of ovarian cancer each year.



PHOTOSTOCK-ISRAEL/SCIENCE PHOTO LIBRARY

Continuing the work on improving survival after prostate cancer in two new ANZUP trials

Prostate cancer is the most common cancer in Australian men and has become an important target for Australian research efforts.

Better detection and improvements in treatment driven by research evidence have increased survival over the past 20–30 years. Now, over 90% of men with prostate cancer survive for more than 5 years, but there are still about 3000 deaths a year.

EZARAD and ENZAMET

ANZUP and CTC, in collaboration with international groups, have opened two trials of a new hormone therapy that promises to improve survival of men with prostate cancer—ENZARAD and ENZAMET.

In these trials a new second-generation nonsteroidal anti-androgen drug, enzalutamide, which blocks the action of male hormones, is being compared with a conventional anti-androgen drug. It is hoped that early use of enzalutamide will reduce residual androgen-receptor signalling that might promote growth of the tumour.

In the ENZARAD trial, men with localised prostate cancer are receiving enzalutamide or a conventional anti-androgen drug for two years, during which time they also have 8 weeks of radiotherapy. It is expected to take two years to recruit 800 men, who will then be followed up after treatment for another 5¹/₂ years.

ENZAMET is attempting to prolong survival in men with prostate cancer that has spread after earlier treatment. The trial will have 1100 participants. Men will be recruited from Australia, New Zealand, USA, Canada, UK, and Ireland.

In both trials, tumour tissue and blood will be analysed to find biomarkers related to prognosis and that predict the effect of treatment in individual patients.



ENZARAD and ENZAMET

'These two trials aim to answer the basic questions that patients and their doctors face every day in the clinic: what is the best way of treating men with prostate cancer?

They will be two of the largest trials in prostate cancer and people around the world are already intensely interested in them and what their outcomes might be.'

> Professor Ian Davis, co-chair of ENZAMET



Xanthi Coskinas, development associate oncology program manager for ENZARAD and ENZAMET trials

New treatments for gastrointestinal cancers

The CTC's collaboration with AGITG initiates and conducts research into treatments for gastrointestinal cancers at locations from the oesophagus to the rectum.

INTEGRATE

In Australia, there are about 3,400 new cases a year of cancer at the junction between the oesophagus and the stomach. This is treated with surgery and chemotherapy, with or without radiotherapy. There are no current proven treatments after failure of chemotherapy, and about 2,400 people die each year. INTEGRATE is a trial of a promising new treatment, regorafenib, an inhibitor of enzymes involved in tumour growth. The drug is known to improve survival in patients with other gastrointestinal tumours. INTEGRATE recruited 152 patients across 54 centres in four countries, and was completed recently. Results will be presented and published in 2015.

A LA CART

A La CaRT is a current trial determining whether laparoscopic surgery, or keyhole surgery, in the hands of qualified surgeons is equivalent to open surgery for rectal cancers in terms of the immediate effects of the surgery and longer-term recurrence, survival and quality of life.

Laparoscopic surgery has many advantages—a short time in hospital, smaller scars and fewer postoperative complications. It may be as good as open surgery in the long term. For rectal cancers, the advantages of laparascopic surgery over open surgery have not been reliably measured until now. This Australian-led trial will provide high-quality evidence of laparoscopic versus open rectal resection. The trial will also collect information on surgical complications, patientrated quality of life and long-term clinical outcomes. Standardisation of practices and training of surgeons



John Simes, AGITG group coordinator, with Tim Price, chair of AGITG

are key parts of the trial, so it is also expected to improve the quality of rectal cancer treatment in Australia and New Zealand, an important extra benefit for these and future patients.

RECENTLY COMPLETED TRIALS

In 2014, several investigator-initiated gastrointestinal cancer studies conducted by the AGITG and the CTC were brought to a conclusion and results published or presented.^{103,} ^{184, 208, 247, 265, 266} Many of the new and current studies have been testing antibody treatments that target specific genetic pathways. These agents may be combined with chemotherapy or given if chemotherapy treatment has not stopped tumours from growing. For example, TACTIC was a phase Il trial in biliary tract cancer, a rare disease with a relatively low survival, usually treated with surgery. In this trial, panitumumab antibody treatment was added to the optimal standard chemotherapy. It was the first Australian trial selecting patients for expected treatment success on the basis of KRAS genetic status. TACTIC screened patients with biliary tract tumours and recruited 48 patients with KRAS wild-type tumours. The net clinical benefit of the combination treatment at 12 weeks was over 80%. The new antibody treatment was well tolerated and is promising, although this was a small, unrandomised trial and data on survival are still to come. The preliminary results were presented in late 2014.247

SYDNEY CANCER CONFERENCE

John Simes, CTC director, and Sonia Yip, oncology translational senior research fellow, with Professor Ian Frazer, director of research at the Translational Research Institute in Brisbane, at the Sydney Cancer Conference in November. Sonia Yip was co-convenor of the conference and Ian Frazer a keynote speaker. The conference covered T1–T3 translational research: bench-tobedside and evidence into practice.



Lung cancer, the leading cause of cancer deaths in Australia

Lung cancer is the fourth most common cancer and the leading cause of cancer death, killing over 8000 Australians in 2012. Over 60% of patients have advanced disease when it is found. New treatment options are needed. The ALTG-CTC collaboration completed two important lung cancer trials in 2014.

NITRO

NITRO was a large phase III trial of giving patients nitroglycerin through a patch along with one of the standard chemotherapy regimens for advanced nonsmall-cell lung cancer. Nitroglycerin is commonly used to dilate blood vessels and improve blood flow in heart patients. In the NITRO study, patients were randomly allocated to chemotherapy alone or chemotherapy with a patch. The biological rationale for the treatment was that nitroglycerin would lead to better delivery of the chemotherapy through improving blood perfusion and oxygenation and other potential mechanisms. The trial closed early after a median follow-up of 18 months, when an interim analysis showed that patients did not benefit.¹⁸⁶

BR.26

Treatment options are needed for patients with advanced non-small-cell lung cancer after progression of their disease with standard chemotherapy. The BR.26 trial investigated the effect of dacomitinib, a new oral antibody treatment. Patients on dacomitinib had a longer period without symptoms such as cough, breathlessness and pain, but also had more treatment side-effects. Overall, their survival was no better than for those on placebo. But the treatment did appear to improve survival in patients with a particular genetic marker, *KRAS* wild-type, indicating a direction for future research.⁴⁴

ALTG is dedicated to reducing the incidence, morbidity and mortality of lung and other thoracic cancers and improving the quality of life of these patients, carers and families. The group is also taking the lead in establishing an international group to facilitate thoracic cancer research worldwide.

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Oncology clinical research fellows, Felicia Roncolato and Anne Long

Clinical fellows

The CTC's collaborative oncology research program relies on the contributions of its clinical research fellows and clinical leads, most of them practising oncologists spending a period in their careers on research in areas of individual interest, including new treatments, clinical trial methods, meta-analysis and quality of life.

Research fellows and senior fellows share their clinical expertise and take the lead in developing overviews of current clinical evidence and therapy. They add value to the findings of clinical trials, developing new ideas, pursuing substudies, writing and presenting trial research and setting the CTC's trials in the context of current health care.^{82, 126, 127, 128, 217, 243, 244}

Research fellows are central to the quality, completeness and efficiency of the CTC's integrated oncology research program.



Katrin Sjoquist, CTC clinical lead for gastrointestinal and gynaecological cancer trials

Trials to reduce arm symptoms after surgery for early breast cancer (SNAC)

New results from the SNAC breast cancer trial were published in October.¹⁴⁹ 1088 women with early breast cancer in Australia and New Zealand took part in the trial, which compared two methods of detecting whether their cancer had spread. Half had sentinel-lymph-node based management and half had routine axillary clearance of lymph nodes.

The women who had removal and examination of a sentinel lymph node had less subsequent arm swelling over 3 years than women who had the more invasive procedure.

In both groups, arm swelling increased over the first two years, but the women who had only the sentinel-node operation had a significantly smaller increase, about 3% compared with about 6% for those who had the axillary clearance. The women's arm movement was affected after the operation, epecially in the group having a full clearance, but it was almost back to normal after 6 months and remained virtually unchanged on average over the 3 years.

Patients are still being followed up, and the analysis of 5 years of data will soon be published. The investigators have also been recruiting women with larger tumours and multiple tumours for the SNAC2 trial. The aim is to find out whether the risk of cancer recurrence is the same after sentinel-node biopsy as after full node clearance. If so, the sentinelnode procedure will become standard practice for all women with low-risk early breast cancer.

Trial participants have a central place in our clinical trials

Trials could not happen without the many patients who volunteer to participate. For many of these people, the motivation is altruistic. The trial treatment might not benefit them personally, but they know that the results may change treatment and help other patients in the future.

Trial patients have the reassurance that no matter which treatment they receive, they are getting the latest treatments and the best available medical care. In general, patients on trials do better than patients not on trials.

Consumer advisory panels (CAPs) are generally part of the organisational structure of each clinical trial, investigator group or collaborative group. They contribute to the planning and conduct of our clinical trials to ensure that the consumer perspective is incorporated from the time a trial is first planned until the final results are published. Consumer panels comprise people who have some connection with the disease area; they may have volunteered to take part in a trial in the past or had family experience with the illness in question. They may advocate for the patient group, identify gaps in research, contribute to clinical trial policy, advise on recruitment and retention of participants, review trial proposals, and contribute to developing documents and communications for trial participants to make sure that they will be understandable. They also bring their individual skills and insights to the whole process. The CTC appreciates the commitment of trial patients. The groups at the CTC make particular efforts to provide participants with regular updates during long trials, and also to convey



results to participants in language they understand.



JAMES KING-HOLMES/SCIENCE PHOTO LIBRARY



Lucille Sebastian, manager of the PAEAN and APTS trials

Preventing complications of preterm birth is an important theme in the CTC's research program, which has included successful trials such as INIS and BOOST II, and international meta-analyses, such as PARIS and NeoProM. About a million babies worldwide are born before 30 weeks each year. Many die or face disability, with risks of neuromotor delay, low IQ, sensory, learning, and behavioural problems, diabetes, and hypertension.



ELISABETH SCHNEIDER/LOOK AT SCIENCES/SCIENCE PHOTO LIBRARY

Neonatal trials

Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy (PAEAN)

The current standard treatment for infants deprived of oxygen during birth and suffering brain injury is controlled whole-body cooling. Even with treatment, up to half of these infants have permanent disabilities or die. Outcomes may be devastating for families and are costly for the health system so further treatments that can work synergistically with cooling and improve outcomes for these children are needed.

Erythropoietin, better known perhaps as a performance enhancer in competitive sport, works by different mechanisms from cooling and could lead to a further improvement in developmental outcomes, including cerebral palsy. PAEAN, a double-blind placebo-controlled trial to test this hypothesis, began in 2014. Full-term infants who show signs of brain damage immediately after birth are randomised to treatment with erythropoietin or placebo in addition to wholebody cooling. Long-term improvements in child health are important, so these children will be assessed for development when they are 2 years old.

PAEAN investigators are also collaborating with the Cerebral Palsy Alliance and collecting further information on possible causes, predictors or preventions of cerebral palsy.

The investigators are cooperating with another trial group in the United States. The groups have agreed to harmonise their trial design and share data in a planned meta-analysis. If the results from both trials are positive, the evidence obtained is likely to translate into a rapid change in clinical practice worldwide.

Does placental transfusion prevent death and disability in very preterm infants?

The Australian Placental Transfusion Study (APTS) is an investigator-initiated study evaluating deferred clamping of the umbilical cord when infants are born more than 10 weeks early to improve blood flow to their brain and gut at the time of birth.

Current practice is to clamp the cord immediately after birth so that the infant may quickly be attended by a clinician. However, preterm infants are at risk of problems like anaemia and respiratory distress, which may lead to childhood disability. If the umbilical cord is left unclamped for a few minutes after the birth, some of the blood from the placenta passes to the baby (placental transfusion), increasing the infant's blood volume and increasing blood flow to the lungs and other organs.

The optimum time for clamping the cord is unclear¹³³ APTS has been established to answer this question. It is the largest ever randomised controlled trial of placental transfusion in very preterm infants. It will determine whether giving a placental transfusion at birth, by deferring clamping and cutting the cord, improves systemic blood flow and prevents ischaemia–reperfusion injury to the brain and gut and also reduces the need for donor blood, and thus reduces sepsis, retinopathy, poor growth, mortality, morbidity and disability.

This group of babies are being followed up and will be assessed for disability up to 3 years of age. The follow-up assessments will use costeffective parent-report methods.

This large multicentre trial is recruiting infants from Australia, New Zealand, France, Pakistan, the United State and the United Kingdom and has recruited the largest number of participants in the preterm population of any study to date.

Preventing complications from preterm birth is an important theme in the CTC's research program, which has included previous successful trials such as INIS and BOOST II, and international meta-analyses, such as PARIS and Neoprom. About a million babies worldwide are born before 30 weeks each year. Many die or face disability, with risks of neuromotor delay, low IQ, sensory, learning, and behavioural problems, diabetes, and hypertension.

Milk protein to reduce mortality in infants with low birthweight (LIFT and LEAP)

Preterm infants with very low birthweight are at high risk of infection and other problems, which may lead to childhood disability or death. They receive insufficient lactoferrin, an antimicrobial, antioxidant, anti-inflammatory iron-binding milk protein, from breast milk in their first month, resulting in suboptimal protection. The Lactoferrin Infant Feeding Trial (LIFT) is investigating whether adding lactoferrin to feeds for newborns at risk will reduce infection and its consequences.

LIFT

LIFT Is an international investigatorinitiated Australian-led trial recruiting 1500 infants from Australia, New Zealand and the United States. Parents have an integral role in the conduct of the study; they are part of the management group, help prepare study materials, promote recruitment, and disseminate results.

A cost-effectiveness analysis of the intervention and its outcomes is planned. The treatment is inexpensive and could potentially have benefit worldwide, even in countries where cost is a major consideration.

LEAP

The Lactoferrin Evaluation in Anaemia in Pregnancy (LEAP) trial aims to use lactoferrin to help infants through treatment of anaemia in pregnant women. Pregnant women can develop iron-deficiency anemia because of the growing fetus and the higher volume of blood circulating in a woman's body. Anaemia is associated with preterm birth, low birthweight and developmental problems. The rate is 12% in Australia, but up to 40% in Indigenous Australians and over 50% in low-income countries. The current standard treatment is iron, which has common adverse side-effects. and although it corrects the mother's anaemia, there is no evidence that it improves the outcomes for the infants.

In the LEAP study, lactoferrin from cow's milk will be compared with oral iron treatment, first to see whether it improves anaemia in women who are not pregnant. If it is safe and effective, it will then be given to pregnant women. The effect of treatment on the infant's birthweight and iron levels will be assessed. 'Iron sulphate is currently the standard first line of defence against anemia but it is suboptimal and has a host of negative side effects. For example, it is poorly absorbed, causes inflammatory problems, and poses a risk of accidental overdose and death in children if not safely stored.'

Lactoferrin, a natural protein found in breast and cow's milk, in the treatment of iron deficiency anemia in pregnancy, could protect infants from a host of severe health problems.'

William Tarnow-Mordi, professor of neonatal medicine





Alpana Ghadge, manager of the LIFT and LEAP trials

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Anthony Keech and Jordan Fulcher, who led the CTTC study of statins for women

'These results resolve a major uncertainty about the value of treating women with statin therapy, and reinforce the need for recommendations to be included in national and international guidelines'.

> Anthony Keech, co-coordinator of the international Cholesterol Treatment Trialists' Collaboration

Cardiovascular trials

Statin treatment reduces the risk of cardiovascular disease in women

In Australia more than 11,500 women die of a heart attack or stroke every year.

It has long been known that statin medications prevent cardiovascular events in people at risk. Women tend to develop cardiovascular disease later in life than do men, so have been underrepresented in most statin trials.

A large international meta-analysis by the Cholesterol Treatment Trialists' Collaboration used the power of many studies combined to show conclusively that statin treatment reduces the risk of cardiovascular disease in women.

The research assessed the effect of statins in 46,675 women and 127,474 men who had taken part in 27 clinical trials, including the CTC's LIPID trial (Long-Term Intervention with Pravastatin in Ischaemic Disease). It is the largest such database of statin trial data in the world.

Overall, statin treatment reduced the risk of a major vascular event (heart attack, stroke, cardiac death, and the need for coronary revascularisation, stenting or bypass surgery) by 21% for each 1 mmol/L reduction in LDL cholesterol. The percentage risk reductions were similar in women and men, irrespective of any history of cardiovascular disease.

There has been a recent worldwide shift towards recommending treatment with statins to people without existing cardiovascular disease but with a sufficiently high risk of future disease. The results of this study will reassure doctors that these risk-based guidelines for treatment can be applied to men and women equally.

The study was an initiative of the Clinical Trials Centre and the Clinical Trial Service Unit & Epidemiological Studies Unit (CTSU), University of Oxford. The current metaanalysis is one of a series of analyses of this data set, first planned in 1994. The work was funded by the NHMRC, the UK Medical Research Council (MRC), the British Heart Foundation (BHF), and the European Community Biomed Program.

Women with diabetes benefit from fenofibrate treatment

Fenofibrate, available since the mid-1970s, is used to lower levels of blood fats (triglycerides) and small dense LDL or 'bad' cholesterol, and increase levels of HDL or 'good' cholesterol. High triglycerides along with high LDL is a common blood lipid profile in people with type 2 diabetes.

The CTC's FIELD study investigated the effect of fenofibrate treatment on prevention of cardiovascular events in nearly 10,000 patients in Australia, New Zealand and Finland. It was the first study to show that fenofibrate significantly reduced rates of diabetes complications such as eye and kidney damage and amputations.

In late 2014, the FIELD investigators completed a sex-specific analysis (of 3657 women and 6138 men with type 2 diabetes) and found that fenofibrate appears to be as effective in women as in men³⁸. This new evidence is especially important for clinical practice because previous trials have either not included women or the numbers have been too small to generate meaningful results.

Participants in the trial took 200 mg of fenofibrate daily for an average of 5 years. The researchers found that fenofibrate reduced levels of adverse blood fats, total, LDL, and non-HDL cholesterol, and apolipoprotein B, more in women than in men, independent of menopausal status and whether they started taking statins. Fenofibrate reduced the risk of cardiovascular death, stroke, or a carotid or coronary revascularisation by 30% in women and 13% in men. The low rates of side-effects of fenofibrate were similar in men and women.

'The finding is good news for Australian women, who have a higher prevalence of cardiovascular disease than men. The study shows fenofibrate reduced the risk of dying from cardiovascular disease, or having a stroke or other adverse cardiovascular event, by 30 per cent in women and 13 per cent in men.'

Anthony Keech, chair of the FIELD trial





Studies from the LIPID dataset

The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) study showed that statin treatment reduced the risk of a further coronary event in people with heart disease. Many years on from the main trial, the LIPID dataset of over 9000 patients is still answering questions about coronary heart disease.

The LIPID Australian and New Zealand investigators are collaborating with scientists from Germany, Sweden and the United States in studies of how molecular biomarkers are related to heart disease risk, and potential prediction of events by biomarker levels.

A recent substudy showed that the baseline troponin level was an independent predictor of a higher risk of myocardial infarction and other cardiovascular events, such as heart failure and stroke.¹⁵⁰ An increase in the troponin level in the first year of the trial was also associated with risk.

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'The treatment effect of aspirin is less than with warfarin or other new-generation direct thrombin inhibitors. But aspirin represents a useful treatment option for patients who are not candidates for anticoagulant drugs for anticoagulant drugs because of the expense or the associated increased risk of bleeding. Aspirin will be ideal in many countries where prolonged anticoaqulant treatment is too expensive. This could mean a saving of millions of healthcare dollars worldwide.'

> John Simes, chair of the INSPIRE meta-analysis collaboration

Aspirin lowers the risk of recurring blood clots in the INSPIRE study

A CTC international collaborative meta-analysis has provided clear, consistent evidence that low-dose aspirin reduces the risk of venous blood clots in people who are at risk because they have already suffered a blood clot¹²⁵.

Most people who have had a blood clot in a leg vein (deep-vein thrombosis) or an embolism (where the clot blocks the blood flow) have anticoagulant drug treatment (such as warfarin) for at least 6 months, first to dissolve the clot and then to prevent it happening again. Long-term anticoagulant drugs require frequent regular blood tests and adjustments to the dosage. Also, there is a risk that the treatment could cause bleeding in some patients. For people who are not able to cope with this, the viable alternative of taking regular aspirin is a great benefit.

The results come from INSPIRE, a combined analysis of the CTC's ASPIRE study and the WARFASA study in Italy. ASPIRE was completed in 2012 and showed that the aspirin treatment reduced the incidence of vascular events, but the number of patients was not sufficient to estimate the effects of treatment on individual types of event or in subgroups of patients.

ASPIRE had 822 participants from Australia, New Zealand, Singapore, India and Argentina, followed up for an average of 3 years, and WARFASA another 402 patients followed up for at least 2 years.

The combined analysis showed that 100 mg aspirin a day compared with placebo reduced the risk of further blood clots in the veins by more than a third. Those with a higher risk, such as men and those at an older age, were more likely to benefit. Treatment was safe, with no significant bleeding associated with aspirin treatment

INSPIRE was planned and a protocol developed before the results of the two trials were known, a method that can provide the highest-quality, least biased evidence. This, in addition to the rigorous expert statistical analysis, vouch for the validity of these results.

John Simes, Rebecca Mister, Adrienne Kirby and Wendy Hague, CTC members of the INSPIRE international steering committee. Wendy Hague, clinical trials program director, was also manager of the LIPID study.



What can be done about diabetes?



Retinal pictures from the outback can be viewed in Sydney. Sven Erik Bursell and Alicia Jenkins at the CTC

Diabetic retinopathy: new Centre for Research Excellence

Indigenous Australians with diabetes are at high risk of various complications, such as loss of vision and and kidney and cardiovascular disease. Optimum treatment requires coordinated care, and this can be challenging in rural and remote Australia.

A diabetes research team based at the CTC is setting up the collaborative virtual Centre for Research Excellence in Health Services Research to improve the health of Indigenous people in remote areas using modern electronic communication methods.

The main goal of the new centre is to detect potential diabetic eye disease early and streamline decisions on treatment to improve prevention, detection and treatment of vascular complications of diabetes. Teleretinal imaging will be used to assess risk of diabetic eye disease and cardiovascular disease. The telehealth service is expected to reduce the impact of chronic disease in Indigenous communities, reduce costs for health care associated with chronic diseases and reduce the health care disparity gap.

The new centre will have three main components:

- Electronic decision support systems and retinal imaging software for managing diabetic eye disease, diabetes and cardiovascular disease embedded into local Indigenous health care facilities, with remote retinal picture reading, electronic referral and electronic reporting;
- 2. Shareable resources for administration, data registry and repository, biostatistics services and training of health professionals. These facilities will be accessible for new collaborative national and international diabetes research projects; and

The prevalence of diabetes is increasing alarmingly throughout the world. It is predicted that in 15 years, 340 million people will have diabetes. People with diabetes have a higher risk of heart attack, stroke, peripheral vascular disease, amputation, renal disease and eye disease. The factors that promote type 2 diabetes—obesity, inactivity, smoking and others—also independently contribute to cardiovascular disease. The incidence of type 1 diabetes, which most often starts in childhood, is also increasing.

The CTC is part of worldwide efforts to understand the mechanisms of diabetes development and complications and improve the treatment of diabetes. Its research covers the full pathway from molecular and genetic laboratory studies through the phases of clinical trials to delivery of clinical services for type 1 and type 2 diabetes.

CENTRE FOR RESEARCH EXCELLENCE COLLABORATION

- Anthony Keech, Alicia Jenkins, Sven-Erik Bursell and Val Gebski from the CTC
- Tim Henderson, Alice Springs
 Hospital
- Alex Brown, South Australian Health and Medical Research Institute, University of Melbourne
- Jamie Craig, Flinders University
- Louise Maple-Brown, Menzies School of Health Research
- Kerin O'Dea, University of South Australia

 training the next generation of doctor-researchers in Indigenous health by engaging postdoctoral fellows, PhD students and others to undertake clinical and research projects.

The new centre will integrate care for diabetes, eye disorders and cardiovascular disease for all life stages, build workforce capacity for high-quality health care delivery and research, develop new knowledge, build networks for guideline-based care, and expedite translation of new findings into practice and policy in Australia and other countries.

Members of the national research team are collaborating to share their vast experience and expertise in relevant areas of health care. They are research leaders in Indigenous health, diabetes, cardiovascular disease, ophthalmology, telehealth services and biostatistics.

The work is part of current efforts in the Northern Territory to develop a health information technology infrastructure to support diabetes management, funded by the NHMRC and the Fred Hollows Foundation.

Potential prevention of diabetic eye disease and other disorders of small blood vessels

CTC's completed FIELD trial, with nearly 10,000 patients, unexpectedly showed that fenofibrate slowed the development of disease of the small blood vessels, including eye and kidney disease, in people with type 2 diabetes. These results, and subsequent animal studies, have led to new ideas about the mechanisms of fenofibrate and other benefits it might have.

In the new FAME1-Eye trial, CTC researchers and their colleagues will be determining whether the benefit of fenofibrate in retarding diabetic retinal eye disease is similar in people with type 1 diabetes. Patients will be randomised to fenofibrate or placebo and followed up for 3 years with regular comprehensive assessments of their eye and general health. In parallel with the clinical study, CTC laboratory teams are investigating microRNAs, specific regulatory molecules that are markers of vascular damage in diabetes.

Daniel Calandro and Andrzej Januszewski



In both type 1 and type 2 diabetes, genetic and environmental factors influence the risks of developing small-blood-vessel disease, but how these factors interact is not well understood. FIELD LIFE, an extension of FIELD in the laboratory, is examining blood levels of microRNAs and DNA damage. Laboratory results and risk factors are being compared in 2000 patients who participated in the FIELD trial.

The CTC is also leading a telehealthbased initiative for diabetic retinopathy screening, cardiovascular risk assessment and patient education, with 600 Indigenous participants in the Northern Territory.

Cell replacement therapy for type 1 diabetes

InsulIn from the pancreas is essential for controlling blood glucose levels. In type 1 diabetes, an auto-immune disease, T cells and other cells attack the insulin producing cells of the pancreas, so people with type 1 diabetes need an alternative source of insulin, usually through multiple daily injections. Transplantation of pancreatic cells is an effective temporary treatment for type 1 diabetes, but not feasible for all patients with type 1 diabetes because donor pancreatic cells are scarce. Embryonic cells, adult stem cells and other cell types are being considered as an alternative source of insulin.¹⁰

The CTC's Diabetes and Islet Biology group are leading research to understand the molecular and genetic processes involved in insulin production and to find ways of increasing insulin gene expression in tissues other than the pancreas. In work so far on cells from mice and humans with diabetes, the group has found that gallbladder epithelial cells can produce insulin. They have shown that gallbladder cells have promise as an alternative to pancreas, are readily available and can be grown in the laboratory. 'Living with type 1 diabetes is extraordinarily challenging, requiring the acquisition and maintenance of a complex set of practical skills and the ability to manage the behavioural and psychological impacts of having a chronic medical condition. Engaging with, supporting and learning with and from people with type 1 diabetes are central to delivering quality care. The skills are complex and not necessarily intuitive.'

Alicia Jenkins, professor of diabetes and vascular medicine at the CTC, and head of the CTC's diabetes research

Sarang Satoor, Wilson Wong, Mugdha Joglekar and Anandwardhan Hardikar, diabetes and islet biology group



Professional diabetes education advanced by two new books



An important new book for diabetes clinicians and scientists, *Lipoproteins in Diabetes Mellitus*, details the many changes wrought by insulin resistance and diabetes mellitus on lipid and lipoprotein metabolism. The editors have brought together a panel of international diabetes scholars to describe in detail the place of vascular complications of diabetes and the ways of studying and treating them. The lead editor of the book, Professor Alicia Jenkins, says

'It is our sincerest hope that the clinicians who care for patients with insulin resistance and diabetes mellitus and the basic science researchers who explore mechanisms of vascular damage and protection will

find this treatment of the issues covered herein timely and relevant and that it will significantly impact patient care in a positive and lasting way.'

Alicia Jenkins is chair of the working group for *Enhancing your Consulting Skills*, an education resource for trainees in adult endocrinology and other interested health professionals. This resource has been published by the National Diabetes Services Scheme and Diabetes Australia, with lead author, Dr Jennifer Conn. It has already had several print runs.

The book teaches techniques that healthcare professionals can use to help people with type 1 diabetes develop the cognitive, practical and social skills that enable them to optimally self-manage their chronic medical condition in everyday life. Mental health problems, like depression, anxiety and eating disorders are more common in people with diabetes. The book addresses the skills required to identify and respond to such mental health issues.

The CTC's T4DM trial coordination team, Caitlin van Holst Pellekaan and Sandra Healey, with trial manager Karen Bracken



RECRUITMENT TO THE T4DM DIABETES STUDY

The T4DM study is investigating whether adding testosterone treatment to a diet and lifestyle intervention can reduce the risk of type 2 diabetes in men at high risk of developing diabetes due to overweight, low testosterone and impaired glucose tolerance.

To enrol 1500 study participants, it was estimated that 24,000-30,000 men need to be screened, a recruitment challenge. Approaches to maximising the number of men screened ranged from a major national media launch on state-based and national TV to grassroots promotion at local shopping centres and workplaces, as well as social media.

The T4DM group reviewed the recruitment strategies used in the first year and presented their results to the Society for Clinical Trials.¹⁷³ In the first year, over 13,000 unique visitors visited the website and 28% went on to access the screening questionnaire, most doing so within 2 weeks of the initial media launch. Others heard about the study from subsequent mainstream media stories. Mass media was the most effective tool, with grassroots approaches delivering relatively small returns for effort.

www.diabetesprevention. org.au Quality and leadership in clinical research best evidence, best policy, best practice



New procedures and technologies must be shown to work so that patients receive effective treatment and public funding is not wasted.

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.

The Medical Services Advisory Committee uses evidence from systematic reviews to advise the Minister for Health.

'We would like to take this opportunity to congratulate you on achieving consistently high standards in the reviews we have screened from [the group]'

> Toby Lasserson, senior editor, Cochrane editorial unit

Breast cancer reviews in the Cochrane Library

The Cochrane Library is the online resource of medical evidence accessible to clinicians and people all over the world. It allows clinicians to make informed treatment decisions and patients to receive optimal treatments.

The Cochrane Breast Cancer Group, based at the CTC, develops Cochrane systematic reviews. The group coordinates a large team of medical and radiation oncologists, breast surgeons, statisticians and consumer advocates, who act as authors, editorial board members and referees. This multidisciplinary make-up helps to ensure that reviews cover aspects of treatment most relevant to patients. The group endeavours to disseminate review findings as widely as possible, and its work is used by clinical practice guideline developers such as Cancer Australia and the National Institute for Health and Care Excellence in the UK.

In 2014, the group was rated as one of its best performers by Cochrane, acknowledging consistently highquality work. Reviews published by the group in 2011 or 2012 were cited, on average, nearly 12 times in 2013 (impact factor 11.6).

KEY COCHRANE REVIEWS PUBLISHED IN 2014

Reviews published in 2014: 'Partial breast irradiation for early breast cancer', 'Trastuzumab-containing regimens for metastatic breast cancer' and 'Surgery versus primary endocrine therapy for operable primary breast cancer in elderly women'.

Reviews to ensure that new medical technologies are effective and affordable

As an example of evidence in action, in April 2014 the Medical Services Advisory Committee recommended a major change to cervical cancer prevention in Australia. It was recommended that five-yearly testing for the human papilloma virus (HPV) replace the current two-yearly Pap tests for cervical cancer and that screening start at age 25 rather than 18.

The decision was based on a systematic review by the CTC's health technology assessment team with researchers at the University of New South Wales and clinical experts. They had presented evidence to MSAC that the new HPV test would be more clinically effective and costeffective than the current test. Using it in screening is likely to reduce the occurrence of cervical cancer by at least 15%.

Over the past twelve months, the health technology assessment team has also prepared two major assessments of the use of MRI and positron emission tomography imaging techniques to assist in surgery and treatment planning for women with locally advanced or metastatic breast cancer.

The ANZCTR's 10,000th registered trial aims to improve mental health and coping of new parents

A new trial called 'Baby Steps' was the 10,000th trial to be registered on the Australian and New Zealand Clinical Trials Registry (ANZCTR), in operation since 2005 at the CTC. The trial is assessing a program of interactive internet and text messaging to help distressed new parents cope with baby care and improve their wellbeing. As an example of our registered trials, it reflects the reality that clinical trials are not just tests of drugs, but can look at many aspects of health care.

This is a significant milestone for the registry. Registration of all clinical trials is important to health, as it is a way of disclosing all current research involving humans. It gives everyone the right to know what research is being done and whether any results might be missing from published science.

The registry also improves the efficiency and value of trials research, by minimising duplication of research and reducing bias in the evidence used by medical professionals as a basis for choosing treatments.

There are trial registries in several countries, but the Australian registry was one of the first to be endorsed by the World Health Organisation. It has played an integral role in the worldwide initiative to make research information publicly available. With funding from the NHMRC and Therapeutic Innovation Australia, the registry is a valuable and free resource which enables patients and health professionals to access information about clinical trials taking place across all areas of health: new drugs, treatments, therapies, preventive measures, surgical procedures, lifestyle, rehabilitation strategies, complementary therapies and new medical devices.

Data from the registry is also uploaded to other websites, such as the consumerfriendly Australian Cancer Trials site. Access to such information helps patients find suitable trials, which ultimately contributes to better health outcomes for all Australians. The ANZCTR is freely available at www.anzctr.org.au 'Clinical trials are the part of the research process through which consumers, governments and companies can be assured that new drugs, treatments and medical devices that are developed are effective and safe. 'NHMRC believes in the

value of registering clinical trials and promotes transparency in and the reporting of NHMRC-funded outcomes. Transparency helps to ensure accountability and high standards in research— which ultimately results in better outcomes for the beneficiaries of medical discoveries.'

> Warwick Anderson, Chief Executive Officer, National Health and Medical Research Council

Further transparency of clinical trial information is an ongoing topic of concern and discussion among researchers, particularly those who undertake meta-analyses using data from individual patients in multiple clinical trials. How can trial data be shared responsibly and economically without violating research integrity or patients' privacy? This was the subject of a recent article by the CTC's head of systematic reviews and health technology assessment, Lisa Askie, and her colleagues in government and industry.¹⁸



Ryan Sausa and Kylie Hunter, ANZCTR

EPOCH research questions

- Do interventions implemented in the first year of life prevent obesity?
- Do they influence weight status and behaviour at 18-24 months of age?

Obesity in children, which is becoming more common, is thought to begin very early, depending on infant feeding practices, parents' eating habits and other family factors. Metabolic and behavioural patterns are often established in the first few years of life.

How can we prevent obesity in young children?

There have been strong arguments for starting preventive action early. but there have been no published trials to guide the design, content and implementation of effective interventions that target infants. The Early Prevention of Obesity in CHildren (EPOCH) Collaboration is an Australian and New Zealand group conducting research into this question.

The collaboration comprises CTC experts in meta-analysis methodology and the investigators of four trials of obesity prevention strategies commencing before age 6 months. In general, evidence from randomised controlled trials can be more powerful when synthesised in an individual-participant-data prospective meta-analysis. In these analyses, the hypotheses, analysis methods and selection criteria are specified before the results of the individual trials are known. This method minimises publication and selection bias. Specific statistical techniques are used to account for differences between trials and missing data.

The EPOCH research plan is completely transparent and was in fact published in 2010 before the analysis was done. Now the 2-year analysis has been completed and preliminary results were presented at the annual scientific meeting of the Australian and New Zealand Obesity Society in October.¹⁷⁰

Data were obtained from 2196 women and infants. Active interventions were moderately effective in reducing body mass index, prolonging breast feeding and reducing TV viewing, but did not affect sleeping patterns, physical activity, or the proportion of children who were overweight or obese. Further analysis will determine the longer-term effects of the intervention at 3.5 and 5 years of age.

<image>

The research has pushed knowledge boundaries in terms of the individual trials and the use of innovative analysis methods. The information obtained will guide decisions on investment in child health services to provide universal access to programs that are the most effective in reducing the prevalence of childhood obesity and associated harmful effects on health over the short and long term.

Kylie Hunter with Lisa Askie, head of CTC's systematic reviews and health technology assessment group

Health economics

Workforce studies

Keeping experienced, older workers in the labour force benefits the national economy, and thus is a concern to governments. Labour force participation is entwined with health status. CTC health economists, with their national collaborators. use Health&WealthMOD2030, an influential microsimulation model based on the Australian Bureau of Statistics Surveys of Disability, Ageing and Carers, to model health, labour force participation, personal incomes and savings, and so measure the economic impacts of ill-health leading to early retirement in Australia.

For example, diabetes is a national health priority and a common reason for early retirement. An economic modelling study estimated the overall dollar costs of diabetes at hundreds of millions.¹¹¹ Better diabetes prevention would not only improve the health of the population but also the fiscal health of the country. In another modelling study, prevention of depression through group therapy was estimated to have economic benefits, with higher income for the individuals and a saving to the government of several million dollars in tax collected and expenditure avoided.142

CTC health economists work with the Boden Institute on weight loss research

Overweight is not just a health risk for the individual, but is a growing burden on health-care resources. It may be worthwhile for governments to subsidise weight-loss initiatives. To ensure that public funding for is not wasted, the costs and costeffectiveness of new interventions can be assessed within the framework of a clinical trial.

The health economics team and the Boden Institute of Obesity, Nutrition, Exercise & Eating Disorders recently compared standard care by primary care providers and referral to Weight Watchers for their economic potential.⁵¹ Although the cost of the Weight Watchers program was higher initially, in the long run, it led to greater weight loss at lower cost than standard GP care. The results of the study suggest that referral to commercial weight loss programs might be a highly cost-effective approach for doctors to consider for those at high risk of weight-related health problems, although outside the trial setting, the cost of such a commercial program would be borne by the individual, and in Australia, the cost of the primary practitioner would be covered by Medicare.

Radiotherapy

Intensity modulated radiation therapy (IMRT) is a new radiotherapy technique that allows a high radiation dose to the target tumour while minimising the dose to surrounding structures. It requires more resources initially and has longer planning and treatment times than the established alternative—conformal radiotherapy. An economic study under the auspices of the Trans Tasman Radiation Oncology Group (TROG) estimated the long-term effectiveness and cost-effectiveness of IMRT versus



Deborah Schofield, professor, and leader of national health economics workforce studies

conformal radiotherapy for prostate cancer, accounting for quality of life, complications of radiation therapy and tumour control.²⁸ IMRT was estimated to be both more effective and less costly overall than conformal radiotherapy, but differences were quite small and dependent on the assumptions used.

A problem with this (and assessment of rapidly evolving technologies generally) is that clinical trial evidence on the new treatment's long-term effects would take years to gather, but evidence for funding decisions is needed now. The researchers used their best methods to extrapolate from the information available and used a decision analysis model with sensitivity analyses to reach conclusions that also highlight the areas where more evidence is needed.

Biostatisticians collaborate with international and national groups



'The value of CTC biostatisticians is in providing clinicians not just with statistical results but also key concepts with respect to interpretation of study results and innovative study designs. They are a conduit between statistical methods and clinical relevance.'

> Val Gebski, professor of biostatistics

The CTC has been synonymous with methodological expertise in international trials and trial groups since 1988. CTC biostatisticians have long experience in leading the conception, design, analysis or interpretation of data in large complex studies conducted by national and multinational investigator groups.

For example, the CTC's biostatistics group is the statistical centre for the European Network of Gynaecological Oncological Trial Groups (ENGOT), which brings together 19 trial groups from 14 countries. The collaboration is particularly relevant for academic clinical trials and can draw in international capability for translational research. A large dispersed group such as this is needed to recruit sufficient patients for research on rare diseases.

AURELIA TRIAL

In 2014, CTC clinicians and biostatisticians led a substudy of the European AURELIA trial. It examined the important question of how adding the drug bevacizumab to chemotherapy affects symptoms and other aspects of quality of life for women with advanced ovarian cancer.¹²⁹ Bevacizumab slows the growth of blood vessels and retards tumours, but has several side-effects. This study showed that the treatment did more than just delay the recurrence of the disease; it also improved quality of life, providing evidence for using this treatment in practice.

ANZBCTG

The CTC has had a 27-year association with the Australia and New Zealand Breast Cancer Trials Group (ANZBCTG), as its statistical centre. The group recently published the main results of the NeoGEM trial, which found that a change to the chemotherapy regimen did not improve the the efficacy and safety of pre-surgery chemotherapy for women with locally advanced breast cancer.⁹³

Biostatisticians beyond the CTC

Statistical methodology is a necessary aspect of most clinical research projects. CTC statisticians lend their expertise to research programs in other institutions in Sydney and elsewhere. For example, the group have worked with the emergency departments in Sydney hospitals and ambulance trauma teams in analyses supporting research to improve emergency services.^{37, 41, 83} Another series of studies involves methodological work with gynaecologists at Nepean Hospital to explore female pelvic organ prolapse across a range of aspects, from women's perceptions of bother,^{136, 139, 141} through clinical assessment of the problem³⁹ to predicting the success of repair surgery.¹⁰⁶ These investigations are all different in terms of research question and design, requiring knowledge and versatility from the statistician.



Biostatistics group. Back row: David Espinoza, Malcolm Hudson, Luke Buizen, Jodie Gonzalez Jennings, Elizabeth Barnes, Emma Gibbs, Lucy Davies, Ian Marschner, Chee Lee, Rachel O'Connell, Valérie Garès. Front row: Andrew Martin, Val Gebski, Kirsty Mann, Mark Donoghoe

Master classes in methodology

The biostatistics team run high-quality master classes, lasting between one day and a week, on a variety of statistical methodology topics. In 2014 they conducted a practical master class in time-to-event analysis, which covered sophisticated and complex techniques used to analyse follow-up data in clinical trials.

The statistical group is also involved in developing and delivering the critical appraisal component of the highly successful Basic Sciences in Oncology for oncology trainees for their professional clinical accreditation.

.....

Ian Marschner

Biostatistics Collaboration of Australia

The BCA is an initiative of a collaborative group of biostatistical experts from around Australia. It has a postgraduate program in biostatistics by distance education provided by a consortium of seven Australian universities. In 2014, 314 students were enrolled, 170 of them new in 2014, and 32 successfully completed their courses. The BCA coordinating office is supported by the CTC.

The report for an external review of the program in 2014 concluded that 'The review panel found the BCA curriculum to be well-designed and keenly supported by stakeholders.' In another evaluation, when the program was included in the University of Adelaide review of coursework studies in the schools of population health, medical sciences and medicine, it was alone in receiving a commendation.

CTC statistician Elizabeth Barnes continues to coordinate and teach 'Principles of statistical inference', now co-coordinated by Lucy Davies.

Masters degree in clinical trials research

The CTC is at the forefront in knowledge and expertise in clinical trials. CTC's researchers are well qualified to pass on their skills in a postgraduate program leading to formal qualifications in the design, conduct and interpretation of clinical trials. The Master of Clinical Trials Research program is taught by CTC academic staff and leads to degrees from the Faculty of Medicine at the University of Sydney.

Students complete the course with a solid understanding of research methodologies, clinical trials literature and the clinical trials process, including design, regulations, and statistical and ethical considerations.

The program is delivered 100% online, including lectures, discussion forums and supplementary notes. It is coordinated by Adrienne Kirby, Val Gebski and Anthony Keech.

'This is an excellent course for anyone embarking on a career in clinical research. The comprehensive curriculum of trial design ... provides a solid foundation for the planning and execution of clinical studies. It also adds a further layer of sophistication when analyzing and critiquing the current literature.'

Ru-Dee Ting, clinical research fellow, Department of Cardiology, St Michael's Hospital, University of Toronto

'The Master of Clinical Trials Research program has provided me with an excellent scientific education for clinical research. It has ... enabled me to pursue my goals without being confined to a rigid campus-based lecture schedule. I was able to manage my time and studies around running my private practice and yet still receive the regular support and feedback that I needed ... Without this flexible, remote learning platform my research and PhD aspirations would not have been possible.'

Craig Moore, chiropractor in private practice



MASTER OF BIOSTATISTICS GRADUATE

Patrick Schober took the BCA program from the Netherlands. His background is in anesthesiology and emergency medicine.

'The BCA program allowed me to study next to my regular work at my own pace. The learning objectives are clear, units and course material are highly relevant, and online discussions with fellow students as well as excellent and timely feedback by instructors made studying biostatistics an enjoyable experience. I am proud of completing this program, which has provided the necessary skills to perform adequate analyses of medical research data.'

Patrick Schober

How an idea becomes a plan for a trial

One-day concept development workshops are a popular educational initiative of the CTC. These workshops help clinical and scientific investigators develop their ideas into a proposal for a clinical trial or translational research study. The investigators refine their idea into a suitable aim, objectives, population, interventions, study design, outcome measures, sample size, analysis plan and funding strategy, which can be used for a funding application and protocol.

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
ONCOLOGY INVESTIGATOR GROUPS		
Australasian Gastro-Intestinal Trials Group (AGITG)	Collaborative group for gastrointestinal cancer trials: Australia, New Zealand International collaborations: Cancer Clinical Trials Unit Scotland (CACTUS), Eastern Cooperative Oncology Group (ECOG), European Organisation for Research and Treatment of Cancer (EORTC), European Study Group for Pancreatic Cancer (ESPAC), Groupe Coopérateur Multidisciplinarie en Oncologie (GERCOR), National Cancer 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)	Coordinating centre and collaborator
Australasian Lung Cancer Trials Group (ALTG)	Collaborative group for lung cancer trials: Australia, New Zealand International collaborations: NVALT (Netherlands), NCIC CTG (Canada)	Coordinating centre and collaborator
Australia New Zealand Gynaecological Oncology Group (ANZGOG)	Collaborative group for gynaecological cancer trials: Australia, New Zealand International collaborations: Dutch Gynaecologic Oncology Group (DGOC), Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens (GINECO), Gynecological Cancer Intergroup (GCIG), International Gynaecological Cancer Intergroup (IGCI), Gynecologic Oncology Group (GOG), Medical Research Council (MRC), Scottish Gynaecologic Cancer Trials Group (SGCTG)	Coordinating centre and collaborator
Australian and New Zealand Urogenital and Prostate Clinical Trials Group (ANZUP)	Collaborative group for cancer of the genitourinary system: Australia, New Zealand. International collaborations: Cancer Research UK (CRUK), European Organisation for Research and Treatment of Cancer (EORTC), Groupe Coopérateur Multidisciplinarie en Oncologie (GERCOR),Institute of Cancer Research (ICR), National Cancer Research Institute (NCRI), Swedish & Norwegian Testicular Cancer Project (SWENOTECA), and Wales Cancer Trials Unit (WCTU)	Coordinating centre and collaborator
Australian New Zealand Breast Cancer Trials Group (ANZ BCTG)	Collaborative group for breast cancer trials: Australia, New Zealand International collaborations: International Breast Cancer Study Group (IBCSG), Breast International Group (BIG), International Breast Cancer Intervention Study (IBIS)	Statistical centre for group, including randomisation
Cooperative Trials Group for Neuro-Oncology (COGNO)	Collaborative group for brain cancer trials: Australia International collaborations: European Organisation for Research and Treatment of Cancer (EORTC)	Coordinating centre and collaborator
RACS-SNAC collaboration	Collaboration with Royal Australasian College of Surgeons on SNAC trials: Australia	Coordinating centre and collaborator
Trans-Tasman Radiation Oncology Group (TROG)	Collaborative group: Australia and New Zealand	Collaborator
COLLABORATIONS FOR META-ANALYSIS		
Antenatal Magnesium IPD International Collaboration (AMICABLE)	Meta-analysis collaboration: international	Collaborator
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

GROUP	NATURE OF GROUP	CTC ACTIVITY
Cochrane Collaboration Breast Cancer Group	Collaborative group undertaking systematic reviews of trial evidence: international	Editoral base
Cochrane Prospective Meta-Analysis Methods Group	Collaborative group undertaking systematic reviews of trial evidence: international	Coordinating centre
Cord Clamping and other Measures to Influence Placental Transfusion at Preterm Birth (CCPTP)	Prospective meta-analysis collaboration: international	Collaborator
Early Prevention of Obesity in Children (EPOCH) collaboration	Prospective meta-analysis collaboration: international	Data coordination centre
INSPIRE (International Trials of Aspirin to Prevent Recurrent Venous Thrombo- Embolism_	Meta-analysis: ASPIRE and WARFASA (Italy)	Member
Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPiNO)	Meta-analysis collaboration: international	Data coordination centre
Neonatal Oxygenation Prospective Meta- analysis (NeOProM) collaboration	Prospective meta-analysis collaboration; international	Coordinating centre
Perinatal Antiplatelet Review of International Studies (PARIS) collaboration	Meta-analysis collaboration:international	Co-coordinating centre
Prenatal repeat corticosteroid international individual-patient-data study group: assessing the effects using the best level of evidence (PRECISE) collaboration	Meta-analysis collaboration: international	Collaborator
Prevention of Ventilator Induced Lung Injury collaborative study group (PreVILIG)	Meta-analysis collaboration: international	Data coordination centre
Star Child Health	Meta-analysis collaboration: international	Member
OTHER COLLABORATIONS		
Australasian Society of Thrombosis and Haemostasis (ASTH)	Professional group undertaking thrombosis trials: Australia, New Zealand	Coordinating centre and collaborator
Australian Clinical Trials Alliance (ACTA)	Advocacy body for investigator-initiated trials groups: Australia	Founding member
Australian New Zealand Clinical Trials Registry (ANZCTR)	National register of clinical trials: Australia, New Zealand and international	Coordinating centre
Biostatistics Collaboration of Australia (BCA)	Universities undertaking postgraduate education in biostatistics: Australia	Coordinating centre
Clinical Trials Transformation Inititative (CTTI)	Advocacy body for clinical trials: international	Member
RNA-based Analysis for Prediction of Islet Death (RAPID)	Collaborative group: Australia	Collaborator
Sydney Catalyst	Consortium for translational research in cancer	Collaborator
ORGANISATIONS		
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

Current CTC trials

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
NEONATAL DISORDERS			
Trials in start-up			
LEAP: Lactoferrin evaluation in anaemia in pregnancy CTC-led study	Pregnant women with anaemia	900	
PAEAN: Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy <i>CTC-led</i> study	Newborn infants with signs of brain damage	300	
Current trials			
APTS: Australian placental transfusion study CTC-led study	Neonates born before 30 weeks' gestation	1600	916
LIFT: Lactoferrin infant feeding trial CTC-led study	Infants born weighing under 1500 g	1100	143
Trials in follow-up			
BOOST II: Benefits of oxygen saturation targeting CTC-led study	Neonates born before 28 weeks' gestation	1200	1135
CARDIOVASCULAR DISORDERS			
Current trials			
Trials in follow-up			
FIELD: Fenofibrate intervention and event lowering in diabetes CTC-led study	Patients with type 2 diabetes	8000	9795
LIPID: Long-term intervention with pravastatin in ischaemic disease CTC-led study	Patients with a history of coronary heart disease	9000	9014
DIABETES			
Trials in start-up			
e-PREDICE: Early prevention of diabetes complications in people with hyperglycaemia in Europe and Australia International study, BIONE and CTC	Adults with hyperglycaemia	100 (Australia); 3000 (international)	
FAME1-Eye: Fenofibrate and microvascular events in type 1 diabetes CTC-led study	Adults with type 1 diabetes and nonproliferative retinopathy	450	
Current trials			
Performance of closed-loop artificial pancreas at home compared with best available technology St Vincents Hospital, Melbourne, JDRF, Medtronic, CTC study	People with type 1 diabetes	24	
REMOVAL: Effects of metformin added to insulin on atheroma progression University of Glasgow and NHS-led, and CTC study	Adults with type 1 diabetes at risk of cardiovascular disease	90 (ANZ); 500 (international)	60 (ANZ); 429 (international)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
T4DM: efficacy of adding testosterone to a lifestyle program to prevent progression to type 2 diabetes University of Adelaide and CTC study	Men with prediabetes and low testosterone	1500	
TEAMSnet: using internet and mobile technologies for coordinated diabetes and heart University of Melbourne, Fred Hollows Foundation, AMSANT, CERA, CTC study	Indigenous people from remote and rural Australian communities	600	600
ONCOLOGY			
Current trial			
iTool: Evaluating a web-based tool for estimating and explaining prognosis CTC study	Patients with incurable cancer who attend clinics of participating oncologists and who want information about life expectancy	70 patients; 70 oncologists	130 patients; 28 oncologists
BREAST CANCER (COLLABORATING WITH RACS)			
Current trial			
SNAC 2: Sentinel node biopsy versus axillary clearance RACS and CTC study	Women with operable breast cancer, stratified by factors including age and tumour size	1012	
Trials in follow-up			
SNAC 1: Sentinel node biopsy versus axillary clearance RACS and CTC study	Women with a single operable breast tumour <3 cm, stratified by factors including age and tumour size	1000	1088
GASTROINTESTINAL CANCER (COLLABORATING WIT	H AGITG)		
Trials in start-up			
ACTICCA-1: Phase III trial of adjuvant gemcitabine and cisplatin chemotherapy compared with observation AIO (Germany)-led, AGITG, and CTC study	Patients with biliary tract cancer after resection	440 (international)	
CONTROL NETS: phase II open-label trial of lutetium-177 octreotate added to capecitabine and temozolomide for neuroendocrine tumours AGITG and CTC study	Patients with pacreatic or midgut neuroendocine tumous	165	
InterAACT: phase II open-label trial comparing cisplatin plus 5-fluorouracil versus carboplatin plus paclitaxel for anal cancer Cancer Research UK, AGITG and CTC study	Patients with locally recurrent or metastatic anal cancer	80 (international)	
Current trials			
ALT GIST: Imatinib alternating with regorafenib compared to imatinib alone for GIST AGITG, EORTC study	Adults with previously untreated metastatic gastrointestinal stromal tumours	240	0 (ANZ); 0 (international)
ASCOLT: Aspirin for Dukes C and high-risk Dukes B colorectal cancers National Cancer Institute (Singapore)-led, AGITG and CTC study	Patients with colorectal cancer who have completed surgery and other treatment	200 (ANZ); 2660 (international)	21 (ANZ); 550 (international)
DOCTOR: Phase II trial of preoperative cisplatin, 5-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer AGITG and CTC	Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy	150 registered; 60 randomised	104 registered; 52 randomised
ICECREAM: Irinotecan cetuximab evaluation and cetuximab response evaluation among mutants AGITG- and CTC-led international study	Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation	100	81

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
IMPACT: Phase II trial using genomic sequencing and protein expression to direct first-line treatment Garvan, AGITG, CTC and Sydney Catalyst	Patients with metastatic pancreatic cancer	20	1
TOPGEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer AGITG- and CTC-led international study	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	120 (stage 1) 35 (stage 2)
Trials in follow-up			
A La CART: Australian phase III randomised trial of laparoscopy-assisted resection compared with open resection AGITG and CTC study	Patients with primary rectal cancer	470	475
Adjuvant GIST: Adjuvant imatinib mesylate versus no further therapy after complete surgery (AG0403, EORTC 62024) EORTC-led, AGITG and CTC	Patients with resected gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ)	85 (ANZ); 946 (international)
Advanced GIST: Relation between dose and clinical activity of imatinib mesylate (AG0102, EORTC 62005) EORTC-led, AGITG and CTC	Patients with unresectable or metastatic malignant gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ)	116 (ANZ)
ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases AGITG and CTC	Patients with confirmed resectable liver metastases and no other disease	200	8
CO.23: BBI608 and supportive care compared with placebo and supportive care for colorectal carcinoma NCIC-CTG-led AGITG and CTC study	Patients with advanced colorectal carcinoma	275 (ANZ); 650 (international)	78 (ANZ); 282 (international)
GAP: Phase II study of gemcitabine and NAB-paclitaxel for pancreas cancer AGITG and CTC	Patients with resectable pancreas cancer	50	42
INTEGRATE: Phase II trial comparing regorafenib and placebo for oesophagogastric cancer AGITG and CTC -led international	Patients with advanced oesophagogastric cancer	150	152
LAP07: Multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib GERCOR-led, AGITG and CTC	Patients with locally advanced adenocarcinoma of the pancreas	60 (ANZ); 900 (international)	32 (ANZ); 442 (international)
PETACC 6: Addition of capecitabine to preoperative oxaliplatin chemoradiotherapy and postoperative oxaliplatin chemotherapy for rectal cancer (AG0707R) EORTC (PETACC)-led, AGITG and CTC	Patients with locally advanced rectal cancer	135 (ANZ); 1090 (international)	127 (ANZ); 1094 (international)
Quasar 2: Phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer (AG0107CR) OCTO-led, AGITG and CTC	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 AGITG- and CTC-led international study	Patients with gastrointestinal stromal tumour not suitable for curative surgery	80	47
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer MRC-led, AGITG and CTC	Patients with fully resected stage III colorectal cancer	225 (ANZ): 9500 (international)	213 (ANZ); 6144 (international)
TACTIC: Phase II trial of panitumumab, cisplatin and gemcitabine AGITG and CTC	Patients with biliary tract cancer	45	48

TRIAL	PARTICIPANTS	TARGET	ACCRUAL		
GYNAECOLOGICAL CANCER (COLLABORATING WITH ANZGOG)					
Trials in start-up					
ECHO: Exercise during chemotherapy for ovarian cancer ANZGOG and CTC study	Women with newly diagnosed ovarian cancer starting treatment	500			
Current trials					
ANZGOG-1103: Phase I–II BNC105P combination study ANZGOG- and CTC-led international study	Women with partly platinum-sensitive ovarian cancer in first or second relapse	Phase 1: up to 24 (international)	15		
ICON 8: Dose-fractionated chemotherapy compared with 3-weekly chemotherapy for ovarian cancer MRC-led ANZGOG and CTC study	Women with ovarian, fallopian tube or primary peritoneal cancer.	145 (ANZ); 1485 (international)	70 (ANZ); 1566 (international)		
Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer (ANZGOG-0902) ANZGOG- and CTC-led international study	Women with locally advanced cervical cancer	780 (international)	112 (ANZ); 506 (international)		
OVAR.21: Noninferiority phase III trial of bevacizumab + gemcitabine and carboplatin compared with bevacizumab + doxorubicin and carboplatin GCIG-led, ANZGOG and CTC study	Women with recurrent cancer sensitive to platinum-based treatment	654 (international)	48		
PARAGON: Phase II study of anastrozole in gynaecological cancers (ANZGOG-0903) ANZGOG- and CTC-led international study	Women with potentially hormone- responsive gynaecological cancers	350 (international)	283 (international)		
REZOLVE: Phase II study to evaluate the safety and potential palliative benefit of intraperitoneal bevacizumab DGOG-led, ANZGOG and CTC	Women with symptomatic ascites due to advanced chemotherapy-resistant ovarian cancer	26	11		
Symptom benefit: Does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG-0701) ANZGOG- and CTC-led international study	Women with platinum-resistant or platinum-refractory ovarian cancer	200 (ANZ); 800 (international)	144 (ANZ); 945 (international)		
Trials in follow-up					
CALYPSO: Phase III trial comparing pegylated liposomal doxorubicin and carboplatin vs paclitaxel and carboplatin GINECO-led, ANZGOG and CTC	Women with platinum-sensitive relapsed ovarian cancer	974 (international)	71 (ANZ); 976 (international)		
GOG182 GOG-led, ANZGOG and CTC	Women with advanced stage (FIGO III-IV) epithelial ovarian or primary peritoneal carcinoma.	4200 (international)	184 (ANZ), 4312 (international)		
GOG199 GOG-led, ANZGOG and CTC	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 MRC-led, ANZGOG and CTC	Women with platinum-sensitive relapsed ovarian cancer	400 (international)	17 (ANZ); 486 (international)		
ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy MRC-led, ANZGOG and CTC	Women with epithelial ovarian cancer who have not received systemic antitumour therapy	1444 (international)	76 (ANZ); 1450 (international)		
OVAR 16: Pazopanib versus placebo for ovarian cancer AGO-led, ANZGOG and CTC	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	900 (international)	65 (ANZ); 940 (international)		
PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with with pelvic radiation alone in high-risk endometrial carcinoma ANZGOG- and CTC-led international study	Women with advanced endometrial carcinoma	120 (ANZ); 670 (international)	122 (ANZ); 688 (international)		

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
SCOTROC 4: Multicentre trial of carboplatin flat dosing vs intrapatient dose escalation in first-line chemotherapy SGCTG-led, ANZGOG and CTC	Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum–taxane therapy	1300 (international)	64 (ANZ); 937 (international)
Tarceva: Erlotinib after standard treatment for ovarian cancer (EORTC55041)	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	830 (international)	41 (ANZ), 830 (international)
TRIPOD: Phase II trial of intraperitoneal chemotherapy with paclitaxel and cisplatin (ANZGOG-0601) ANZGOG and CTC	Women with optimally debulked stage III cancer of the ovary, peritoneum and fallopian tube.	35–100	39

GENITOURINARY CANCER (COLLABORATING WITH ANZUP)

Trials in start-up				
BL 12: Phase II trial comparing nab-paclitaxel with paclitaxel ANZUP and CTC study	Patients with metastatic urinary tract cancer and previous platinum therapy	199 (ANZ)		
Pain Free TRUS B: Phase III trial of methoxyflurane with periprostatic local anaesthesia to reduce discomfort of transrectal ultrasound-guided prostate biopsy ANZUP and CTC study	Men scheduled to undergo first TRUS biopsy of the prostate	420 (ANZ)		
Current trials				
BCG+MMC: Phase III trial of adding mitomycin C to BCG as adjuvant intravesical therapy for bladder cancer ANZUP and CTC study	Patients with high-risk, non-muscle-invasive bladder cancer	500	22	
ENZAMET: phase III trial of enzalutamide in androgen- deprivation therapy for metastatic prostate cancer ANZUP and CTC study	Men with metastatic prostate cancer	1100	90	
ENZARAD: phase III trial of enzalutamide in androgen- deprivation therapy for localised prostate cancer ANZUP and CTC study	Men with high-risk localised prostate cancer	800	34	
P3BEP: Phase III trial of accelerated versus standard BEP (ANZUP 1302) ANZUP, ANZGOG and CTC study	Patients with intermediate and poor-risk metastatic germ-cell tumours	Stage 1: 90 (ANZ); 150 (international) Stage 2: 350	4 (ANZ)	
Trials in follow-up				
Accelerated BEP: Feasibility study of accelerated BEP for advanced germ cell tumours ANZUP and CTC study	Patients with advanced germ-cell tumours	Up to 50	45	
Chemo & cognition: Cognitive function and treatment for testicular cancer (ANZGCTG 0106 ANZUP and CTC study)	Patients being treated and followed up for testicular cancer	154	151	
Eversun: Phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901) ANZUP and CTC study	Patients starting first-line systemic therapy for advanced renal cell carcinoma	55	56	
SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05) MRC-led, ANZUP and CTC	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ); 1656 (international)	168 (ANZ); 1711 (international)	
LUNG CANCER (COLLABORATING WITH ALTG)				

Trials in start-up

BR.31: Phase III study of adjuvant MEDI4736	Patients with resected primary stage IB IB	200 (ANZ);
NCIC-led, ALTG and CTC	(>4 cm), II or IIIA non-small-cell lung cancer	1100 (international)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Trials in follow-up			
BR.26: Phase III trial of PF-804 for non-small-cell lung cancer (ALTG 09/002) NCIC-led, ALTG and CTC	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) ALTG and CTC	Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy	60	30
NITRO: Phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for non-small-cell lung cancer (ALTG 06/003) ALTG and CTC	Patients with advanced non-small-cell lung cancer	500	372
PACT in NSCLC: Preferences for adjuvant chemotherapy in non-small-cell lung cancer ALTG and CTC observational study	Patients, surgeons and oncologists	200	122
BRAIN CANCER (COLLABORATING WITH COGNO)			
Trials in start-up			
VERTU: Veliparib, radiotherapy and temozolomide in unmethylated MGMT glioblastoma COGNO and CTC	Patients with newly diagnosed resected glioblastoma with unmethylated MGMT promoter gene	120	
ACED: Phase II study of acetazolamide + dexamethasone v dexamethasone alone for cerebral oedema COGNO and CTC	Adults with recurrent or progressive high- grade glioma, who require dexamethasone or dose increase for cerebral oedema	84	
Current trials			
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC 26053-22054) EORTC-Ied, COGNO and CTC	Patients with non-1p/19q-deleted anaplastic glioma	100 (ANZ); 748 (international)	74 (ANZ); 662 (international)
Trials in follow-up			
CABARET: Phase II study of carboplatin and bevacizumab in recurrent glioblastoma multiforme COGNO and CTC	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 COGNO and CTC	Patients with brain tumours or brain metastases or advanced cancer using steroids	50 patients, 50 caregivers	66 patients, 66 caregivers

Funding

CTC undertakes investigator-initiated trials in collaboration with academic partners or clinical trial groups. Studies supported by research grants from industry are published independently of their funders in order to uphold CTC's core commitment to integrity and transparency in research.



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

Health technology assessment

- Briony Jack, PhD, project manager Mark Ayson, MB ChB, GradDipPH, project
- officer Adam Irving, MSc, BEconSc(hons), project officer
- Samara Lewis, BA/BSc(hons), PhD, project manager
- Elizabeth Seil, BA(hons), MSc(HTA), project officer
- Anna Stoklosa, BA, MA, PhD, research fellow

Cochrane breast cancer group

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

Ava Grace Tan-Koay, BSc(hons), MAIT, MPH, trial search coordinator

Australian New Zealand Clinical Trials Registry

Kylie E Hunter, BA, BA(hons), project officer Ryan Sausa, BE, computer systems officer Thuyen Vu, BSc, computer systems officer Ava Grace Tan-Koay, BSc(hons), MAIT, MPH, 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 Malcolm Hudson, BSc(hons),

PhD, honorary professor

Ian C Marschner, BSc(hons), PhD, professor Senior hiostatisticians

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 fellows

Elizabeth H Barnes, BAppSc, MStat Valérie Garès, PhD

Biostatisticians

Luke Buizen, BSc

Lucy Davies, BSc, MSc

Mark W Donoghoe, BSc(hons)

David Espinoza, BArch(hons), 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

Ha Le, BIT, computer systems officer Asanka Perera, BSc, computer systems 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
- Libby Cregan, administration assistant
- Philip Jones, DipLib, administration assistant 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

Publications

Rhana Pike, BA, MA, GradCert, ELS, CMPP

Research students

Daniel Calandro, BSc Ryan Farr, BSc, MPhil Jordan Fulcher, BSc(Med), MB BS, FRACP Deme Karikios, BSc, 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, BEc, research associate Matthew Chan, MB BS, research fellow, Manju Chandrasegaram, MBChB, FRACS, research fellow

- Michelle Cunich, BEc, PhD, economist Valerie Gares, PhD, research fellow
- 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
- Mustafa Khasraw, MBChB, MD, MRCP, FRACP, senior research fellow
- 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, MSc, 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
- Felicia Roncolato, MBChB, research fellow

- Aflah Roohullah, MBChB, MClinTRes, FRACP, 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, MClinTRes, FRACP, senior research fellow
- Martin R Stockler, MB BS(hons), MSc, FRACP, professor
- Anna Stoklosa, BA, MA, PhD, research fellow Annette Tognela, LLB/BSc, MB BS, research fellow
- Sonia Yip, BSc(hons), PhD, senior research fellow

Honorary associates of the CTC

- Dr Hany Abed, cardiovascular group
- Associate Professor Meera R Agar, COGNO scientific advisory and management committees
- 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
- Dr Matthew Chan, oncology
- Dr James Chen COGNO



Information systems infrastructure group: Ha Le, Thuyen Vu, Dinh Tran and Ryan Sausa (Asanka Perera absent)

- 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 Professor Paul de Souza, oncology Dr Andrew Dean, PI, ICON8 trial Dr Javesh Desai, PI, REGISTER trial (AGITG) Professor Catherine D'Este, BOOST II trial Safety and Data Monitoring Committee Dr Pei Ni Ding, Oncology Associate Professor Katherine Drummond, COGNO scientific advisory and management committees 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 scientific advisory and management committees 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 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, BCG+MMC trial, ANZUP Dr Elizabeth Hovey, COGNO operations executive and management committee and chair, scientific advisory committee Dr H Malcolm Hudson, Biostatistics Dr Michael Jefford, SCOT trial (AGITG) Dr Lindy Jeffree, COGNO scientific advisory committee Dr Terrance Johns, COGNO scientific advisory and management committees Dr Andrew Kneebone, AGITG Dr Eng-Siew Koh, COGNO executive and management committee, deputy chair, scientific advisory committee Dr Dusan Kotasek, Adjuvant GIST study Dr Danette Langbecker, COGNO scientific
- Dr Danette Langbecker, COGNO scient advisory committee

- Ms Robyn Leonard, COGNO scientific advisory and management committees
- 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 Linda Mileshkin, ANZGOG executive,
- PI,PORTEC-3 and OUTBACK trials Professor Michael J Millward, ALTG operations executive, scientific advisory and management committees; PI, BR26 trial
- Associate Professor Paul Mitchell, ALTG scientific advisory and management committees, chair, operations executive,
- Dr Paul Nguyen, ANZUP
- Professor Anna Nowak, COGNO scientific advisory committee, PI, CATNON trial
- Oei, JL, BOOSTII and TORPIDO2 trials
- 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
- Professor Mark Rosenthal, COGNO chair; COGNO operations executive, scientific advisory and management committees
- 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, ALTG scientific
- advisory committee, PI, BR24 trial 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 Ben Tran, BL12 study (ANZUP)
- 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 Helen Wheeler, COGNO scientific advisory committee
- Dr Louise Wigston (Nott), CO.23 trial (AGITG) Associate Professor Nicholas Wilcken, Cochrane Breast Cancer Group Dr Kathryn Williams, FIELD study
- Dr Scott Williams, ENZARAD trial (ANZUP) Professor Gary Wittert, PI, T4DM trial Dr Desmond Yip, SCOT, ALT GIST (AGITG) Professor John Zalcberg, AGITG chair

Staff activities

Supervision of research degrees in 2014

Anthony Keech Jordan Fulcher, Jason Harmer, Claudia Boubeta, Ming Pan

Lisa Askie

Jacquelyne Lam

Michelle Cunich Thomas Lo

Val Gebski Alan Garner, Farnoush Noushi

Anandwardhan Hardikar Ryan Farr, Wilson Wong, Michael Williams

Andrzej Januszewski

Daniel Calandro

Alicia Jenkins

Paul Benitez Aguirre, Erin Bell, Daniel Calandro, Yoon Hi Cho, Ben Inja, Joanne Lee, Ben Ma, Claudia Boubeta, Ming Pan, Jon Noonan, Harris Schlen, Karin Schwartz, Caroline Traill

Chee Lee

Amira Elmadahm

Sally Lord

Amira Elmadahm

Andrew Martin Deme Karikios

Martin Stockler

Lesley Chim, Deme Karikios, Michaela Smith, Puma Sundaresan

William Tarnow-Mordi

Claudia Boubeta, Ming Pan

Degrees awarded in 2014

- Matthew Chan, MB BS, FRACP, Master of Clinical Trials Research
- Andrzej Januszewski, MD, PhD, Master of Clinical Trials Research
- Ru-Dee Ting, Ru-Dee Ting, MB BS, FRACP, PhD, Master of Clinical Trials Research

External committees

John Simes

- Australia and New Zealand Breast Cancer Trials Group (ANZBCTG) scientific advisory committee
- Australian Clinical Trials Alliance (ACTA) founding member and chair, governance working group.



Belinda Kiely, senior clinical research fellow in oncology, was awarded a Peter Bancroft prize from the University of Sydney in September for her PhD thesis, 'Estimating and communicating prognosis in advanced cancer'.

- ASPIRE and INSPIRE steering committees (chair)
- Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee, operations executive committee
- Australian New Zealand Clinical Trials Registry (ANZCTR) policy advisory committee
- Cochrane Breast Cancer Group editor
- Cholesterol Treatment Trialists Collaboration (CTTC) (joint coordinator)
- Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee (deputy chair), management committee, operations executive
- BOOST II and LIFT trial management committees (neonatal)
- FIELD management committee, executive, and cost-effectiveness subcommittee IMPACT trial management committee (co-
- Kanyini GAP Polypill Study safety and data monitoring committee (chair)
- LIPID management committee, executive, and biomarker subcommittee
- Clinical Trials Centre management review committee and scientific advisory committee
- SNAC trial management committee

Sydney Catalyst governing council and scientific advisory committee (director) *Trials* associate editor

Anthony Keech

chair)

- Australian Clinical Trials Alliance (ACTA) founding members
- CAMELLIA-TIMI 61 executive committee (lead investigator)

- Cholesterol Treatment Trialists' Collaboration (CTTC) (joint coordinator and convenor)
- Clinical Trials Centre research committee (chair)
- FAME-1 diabetes trial steering committee (chair)
- FIELD management committee (principal investigator and study chairman), and quality-of-life and cost-effectiveness, ophthalmology, and scientific substudies committees
- Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk (FOURIER) executive committee
- International Journal of Cardiology editorial board
- LIPID study management committee and executive
- National Health and Medical Research Council grant review panel
- New South Wales state ethics committee
- PLoS Medicine editorial board
- REMOVAL trial steering committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Lisa Askie

- AMICABLE, MAPPINO, PARIS, PRECISE, and PreVILIG collaboration steering committees
- Australian Clinical Trials Alliance network profiling expert working group
- Australian New Zealand Clinical Trials Registry operational executive committee
- BOOST-II trial management committee
- Cancer Australia Australian cancer trials expert user group
- Clinical Trials Centre research committee and neonatal executive committee
- Cochrane Collaboration prospective metaanalysis methods group (convener), neonatal collaborative review group, handbook advisory group and individual patient data methodology group
- CONSORT-C, PROMPT and SPIRIT-C advisory committees
- EPOCH and NeOProM collaborations, chair
- German Clinical Trials Registry and Pan African Clinical Trials Registry scientific advisory committees
- International Forum for Standards for Research in Children sample size and data safety monitoring subcommittee
- NHMRC assigners academy, NHMRC Australian Clinical Trials website editorial panel, large-scale clinical trials grant review panel, national ethics application form advisory group, research translation faculty, scholarships review panel
- PLOS ONE academic editor

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- PRISMA-IPD reporting standard working group
- Use of magnesium sulphate for preterm infant neuro-protection guideline development panel
- World Health Organization International Clinical Trials Registry Platform advisory committee and best practice group

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)

Karen Bracken

BCG+MMC trial management committee T4DM study steering committee

Jenny Chow

Cancer Institute NSW Neuro-oncology Group (NSWOG), Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive, annual scientific meeting organising committee, Clinical Oncology Society of Australia (COSA) executive officers network and associated working groups

Alan Coates

- Australasian Gastro-Intestinal Trials Group (AGITG), chair, independent data and safety monitoring committee,
- International Breast Cancer Study Group (BCSG), co- chair, scientific committee,

Xanthi Coskinas

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations and scientific advisory committee, ENZARAD and ENZAMET trial management committees

Val Gebski

- Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and MAX, TOPGEAR, IMPACT, PAN-1, GAP, 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, ELIMINATE, GALA, LATER, NeoGem and PROSPECT 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; 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 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 and T4DM trial management committees
- Trans Tasman Radiation Oncology Group (TROG) scientific committee, publications committee, and group statistician

Alpana Ghadge

- BOOST II, LIFT and LEAP trial management committees
- Westmead international update management committee

Wendy Hague

- ASPIRE, INSPIRE, and LIPID management committees (cardiovascular)
- 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
- APTS, BOOST II, LEAP and PAEAN management committees (neonatal) SNAC 1 and SNAC 2 trial management committees
- T4DM trial management committee

Anandwardhan Hardikar

- Islet Society, Stockholm, Sweden, vicepresident
- 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

- RAPID study principal investigator
- Pancreatic islet biology book editor, Springer series 'Regenerative medicine'
- Visiting faculty, Indian Institute of Science Education Research, Pune, India

Alicia Jenkins

- Insulin For Life Australia, Insulin for Life global and Insulin For Life USA board member
- International Diabetes Federation Life For a Child program board member
- REMOVAL metformin study, co-principal investigator and Australian lead
- TEAMSNET telehealth initiative principal investigator

Adrienne Kirby

- APTS and BOOST II management committees (neonatal)
- 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
- **INSPIRE** steering committee
- LIPID management committee
- Randomised Trial on Surgical Treatment for Otitis Media in children Living in Remote Australian Communities trial management committee
- Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Chee Lee

- Genomic Cancer Clinical Trials Initiative (GCCTI)
- Study of Olaparib Clinical Effect (SOLACE0 trial management committee

Ann Livingstone

- Australasian Lung Cancer Trials Group (ALTG) operations executive and scientific advisory committees
- Cancer Institute NSW Neuro-oncology Group (NSWOG)
- Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees

Sally Lord

- Protocol advisory subcommittee (PASC) for Medical Services Advisory Committee
- European Federation of Clinical Chemistry and Laboratory Medicine test evaluation working group
- NHMRC grant review panel member for clinical trials panel

Ian Marschner

- Australasian Gastro-Intestinal Trials Group (AGITG) independent data and safety monitoring committee
- APTS trial independent data and safety monitoring committee
- Biostatistics Collaboration of Australia steering committee

Kristy Mann

T4DM trial management committee APTS management committee

Andrew Martin

- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee
- BCG-MMC, CHEST, EPOCH, EVERSUN, INTEGRATE, LEAP, LIFT, ONTRAC, P3BEP and ProCare trial management committees

Julie Martyn

Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and operations executive committee

Danielle Miller

- Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee and IMPACT and TOPGEAR trial management committee
- Sydney Catalyst operations committee and executive committee

Rebecca Mister

ASPIRE and INSPIRE management committees (cardiovascular)

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)
- PAEAN trial management committee (neonatal)

Kate Sawkins

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

Deborah Schofield

- 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

- Pharmacodynamic effects of the heat shock protein 90 (Hsp90) inhibitor AUY922 in high-risk, localised prostate cancer (HSP 90 inhibitor study) trial management committee
- IMPACT trial management committee (AGITG)
- Interdisciplinary Maternal Perinatal Australasian Collaborative Trials (IMPACT) Network operational subcommittee
- PAEAN trial management committee and APTS management committee and echocardiography substudy management committee (neonatal)

Katrin Sjoquist

- Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee, alumni committee (chair), faculty member
- Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and operations executive committee, Symptom Benefit and PARAGON trial management committees, REZOLVE co-chair
- Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and operations executive committee, Upper & Lower GI working parties, CONTROL-NETS, IMPACT, TACTIC, INTEGRATE trial management committees (CTC clinical lead) and international trial management group,

Genomic Cancer Clinical Trials Initiative (GCCTI)

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 and NITRO trial management committee

Kate Wilson

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

Nicole Wong

Australasian Gastro-Intestinal Trials Group (AGITG) and Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations executive committees, and ATTACHE, LAP07, SCOT, ATTAX 3, PAN1, TACTIC, and Accelerated BEP, Aprepitant, P3BEP, SORCE and EVERSUN trial management committees

Sonia Yip

- ARCS Australia Annual Scientific Congress organising committee
- Australasian Gastro-Intestinal Trials Group (AGITG) operations executive, scientific advisory committee and biological subcommittee, AGITG-NCIC-CTG correlative research committee, and ALT-GIST, ASCOLT, 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, ENZAMET and ENZARAD, P3BEP trial management committees, ENZAMET and ENZARAD translational research steering committee
- Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and cervix working group, REZOLVE trial management committee.
- Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee

Sydney Cancer Conference 2014 co-convenor

Sydney Catalyst scientific advisory committee, operations executive committee and T1/T2 working group

Regular academic teaching

John Simes

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

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)

Lisa Askie

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

Elizabeth Barnes

ACORD faculty

- Principles of statistical inference, Biostatistics Collaboration of Australia (coordinator)
- Statistical principles and clinical trials, Master of Clinical Trials Research, University of Sydney (coordinator)
- Controlled clinical trials, School of Public Health, University of Sydney (co-coordinator)

Mark Donoghoe

Basic sciences in oncology, Health Education and Training Institute

David Espinoza

Critical appraisal of evidence, Master of Clinical Trials Research, University of Sydney

Val Gebski

- Basic sciences in oncology, NSW Cancer Council
- Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
- Radiation oncology training, RACR trainees, Westmead Hospital, NSW Cancer Council

Wendy Hague

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

Deme Karikios

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

Evidence-based medicine in the clinical years, and Oncology and palliative care, University of Sydney Medical Program

Adrienne Kirby

- Master of Clinical Trials, University of Sydney (course coordinator)
- Trial design and methods, Master of Clinical Trials, University of Sydney (coordinator)

Chee Lee

- ACORD faculty Global biomarker studies, Master of Clinical
- Trials, University of Sydney

Sally Lord

Biomarker studies, Master of Clinical Trials, University of Sydney

Decision analysis, Master of Public Health, University of Sydney

Kristy Mann

Advanced systematic reviews, Master of Clinical Epidemiology, University of Sydney

Andrew Martin

ACORD faculty

- Decision analysis (coordinator) and Controlled clinical trials (coordinator), School of Public Health, University of Sydney
- Interpretation of trial analyses (coordinator), Master of Clinical Trials, University of Sydney

Rebecca Mister

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

Rachel O'Connell

Advanced trial design, Master of Clinical Trials, University of Sydney

Katrin Sjoquist

ACORD faculty

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

Martin Stockler

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

Anne-Sophie Veillard

Trial design and methods, Master of Clinical Trials, University of Sydney

Sonia Yip

- Global biomarker studies, Master of Clinical Trials, University of Sydney (coordinator)
- Problem-based learning in the clinical years, University of Sydney Medical Program

Publications

Books

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Conference presentations

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- 173. Bracken K, Hague W, Wittert G. Recruiting to an Australian prevention study through mainstream media, social media and local promotion: lessons learnt. Society for Clinical Trials 35th Annual Meeting; 18–21 May 2014; Philadelphia.
- 174. Caudwell-Hall J, Kamisan Atan I, Martin A, Guzman Rojas RA, Langer SE, Shek C, Dietz HP. Intrapartum predictors of pelvic floor trauma. 24th World Congress on Ultrasound in Obstetrics and Gynecology; 14–17 September 2014; Barcelona.
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