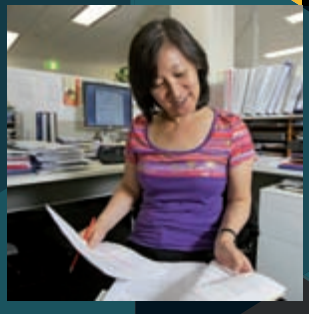
NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2012



NHMRC CLINICAL TRIALS CENTRE
UNIVERSITY OF SYDNEY
Locked Bag 77
Camperdown NSW 1450 Australia

92–94 Parramatta Road, Camperdown NSW 2050
6–10 Mallett Street, Camperdown NSW 2050
T: +61 2 9562 5000
F: +61 2 9565 1863
E: enquiry@ctc.usyd.edu.au
W: www.ctc.usyd.edu.au

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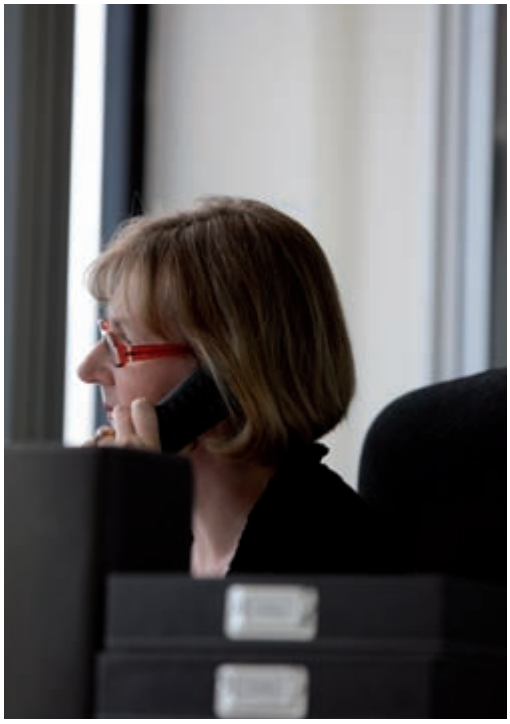
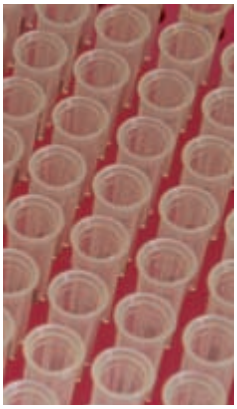




The NHMRC Clinical Trials Centre at the University of Sydney runs large multicentre investigator-initiated clinical trials, undertakes research with national and international trial groups, and contributes expertise to trials run by others. It also:

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

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

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 on Mallett Street.

This report covers the CTC's achievements for 2012.

Directors' report

2012 was a year of broad achievements, reflecting the continuing efforts of the CTC and its collaborative groups of investigators. Our activities, covering the spectrum of clinical research modalities from the laboratory to the clinic, will benefit a wide range of people: notably those with diabetes, cardiovascular disease and cancer, and newborn infants. We built capacity for future research and health care through education programs and PhD projects, several completed this year. We used systematic reviews and health economic studies to better inform practice and policy, and developed several improved methods for design and interpretation of trials. The common research themes of translation and interpretation in our program will be continued with the support of a new program grant to start in 2013.

Some of our achievements are the result of sustained research projects continuing over several years. An example is our ASPIRE study, whose results—a new use for an old drug—were published in the *New England Journal of Medicine* and presented at the American Heart Association meeting in November. We found that long-term low-dose aspirin is an effective preventive treatment for patients with unprovoked venous thrombosis who are no longer on anticoagulation. A change in practice is likely to lead to significant health benefits and savings of health care costs internationally, far exceeding the cost of this trial.

New evidence is emerging on a question occupying neonatologists for a long time: the optimal target oxygen level for premature infants. The BOOST II study has provided some of this evidence and BOOST II data is contributing to the worldwide collaboration, NeOProM, aiming to definitively and finally establish the optimum oxygen saturation target for these infants. This collaboration, led by CTC, will prospectively combine the results of the five current international neonatal trials of oxygen therapy for premature newborns. Prospective meta-analysis of data from several trials can provide more reliable evidence of treatment effects for research questions about relatively uncommon conditions or where the effects of treatment are subtle, for which vast numbers of patients may be required. Similarly, in cardiovascular disease, our LIPID trial contributes to the huge database and meta-analyses of the international Cholesterol Treatment Trialists' collaboration, co-coordinated by the CTC and the Clinical Trial Service Unit in Oxford. Its latest analysis shows that women and people at very low risk of cardiovascular events can benefit from lipid-modifying treatment.

Unbiased evidence for these and similar meta-analyses relies on the registration of all trials worldwide. The Australian New Zealand Clinical Trials Registry (since 2005 a primary registry of the WHO international network) provides public information on trials being conducted in Australia and elsewhere. In March, we welcomed the Minister for Health to the CTC to announce a major NHMRC grant to continue and develop the ANZCTR's important work, including further enhancements so that registry data can be more easily accessed by a variety of users.

Laboratory research is a major new extension of CTC activities; for example, blood samples presciently collected in the 1990s during the LIPID trial are now being analysed for relationships between blood biomarkers and later risks of coronary events. Several of these studies were presented at the 2012 American Heart Association meeting. In the FIELD trial, which recruited 9795 patients, blood samples are now being used to identify genetic contributions to the complications of diabetes. In our own oncology research and as part of the new Sydney Catalyst consortium, laboratory studies and genetic identification have become a natural companion to our clinical trials; with our collaborators, we are pushing beyond the trial to integrate the whole research pathway, from bench to bedside, with a view to accelerating the application of research to outcomes for patients. Our research aiming to close the gap between trial evidence and practice includes estimating life expectancy and communicating this to cancer patients and evaluating diagnostic tests and medical technologies.

We have had many successes, increasing knowledge and improving outcomes, but clinical trials are becoming more costly and more complex, with increasing regulatory requirements and as more trials incorporate laboratory studies and other translational aspects. We are facing up to these challenges, first, in the way we do our own research and, second, as part of national efforts to try and streamline some of these processes.

For our part, we constantly improve our methods to make trials more efficient and to maximise the evidence they produce. Clinical trials are important, not just for identifying better treatments, but for finding new uses

for current treatments and weeding out ineffective treatments — saving money and preventing harm. Trial evidence sorts out the good from the bad, and without it meaningful advances in health care will not be realised.

Externally, we contribute to the national and international debates about the future direction of research. The rising cost of health care is in part driven by the discovery of new treatments and the associated cost of clinical trials. Non-commercial trials often rely on scarce public grants, so many worthwhile projects are not undertaken. However, it should be possible to undertake more clinical trials at no extra cost to the health system by incorporating them into health care delivery. In many cases the costs are repaid when treatments proven ineffective become no longer funded, and overall, they can be more cost-effective than some treatments currently funded. To this end, in May the CTC participated in the *MJA* Clinical Trials Research Summit, at which leaders in government, industry representatives, consumer groups and health professionals met with researchers from trial investigator networks to work toward strengthening and improving investigator-initiated research in Australia. The meeting lent momentum to new ideas about integrating trials into health care, new funding models, designing studies incorporating new technologies, and building national capacity to support trials research.

As we move into 2013, we will maintain our drive to support the integration of clinical trials' research into routine health care. At the CTC we are always aware that our ultimate goal is the value of research to patients. We will continue to look at how best to use this research to answer important clinical questions, and so improve the outcomes for patients in Australia and elsewhere.

CTC executive

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

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

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

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

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

Aspirin treatment is an inexpensive way of preventing thrombosis (ASPIRE)

The international ASPIRE study was completed in 2012. It showed that patients who have had a deep vein thrombosis or pulmonary embolus can benefit from low-dose aspirin.

Recurrence is a serious risk for people who have suffered a blood clot in a leg (deep vein thrombosis) or lung (pulmonary embolism). Anticoagulant treatment, such as with warfarin, comes with the inconvenience of frequent blood tests and the risk of bleeding. Now, low-dose aspirin has been shown to be an alternative to continuing anticoagulation. It is a simple, inexpensive treatment that could prevent thousands of patients from experiencing recurrent clots each year and may lead to substantial health care savings in Australia and worldwide. It is likely that this treatment will be adopted into practice internationally.

All the 822 ASPIRE participants had suffered a deep-vein thrombosis or pulmonary embolism that occurred for no particular reason (unprovoked venous thrombosis) and had completed about 6 months of anticoagulant treatment (generally with warfarin). Participants were randomly allocated to receive either low-dose enteric-coated aspirin 100 mg daily or a matching placebo. On average, participants were followed up for three years.

John Simes, Rebecca Mister, Adrienne Kirby, Wendy Hague; CTC members of the ASPIRE executive committee

← ZEPHYR/SCIENCE PHOTO LIBRARY

The study results were consistent with the findings of an Italian study, WARFASA. The investigators of ASPIRE and WARFASA cooperated when the trial was being planned; they harmonised the protocols of both studies to have similar eligibility criteria and outcomes. The combined results of the two trials have shown clear and consistent evidence that aspirin prevents recurrent thrombosis.

ASPIRE began in 2003 as an investigator-initiated study. It was conducted by the CTC and investigators in Australia, New Zealand, India, Singapore and Argentina. National coordinating centres in India (St John's Medical College and Research Institute, Bangalore) and Argentina (Estudios Clínicos Latinoamérica International, (ECLA) Rosario) were responsible for coordinating the study in these countries. It was supported by project grants from the National Health and Medical Research Council, the New Zealand Health Research Council, the Australasian Society of Thrombosis and Haemostasis and Bayer HealthCare, Germany.

The results were published in the *New England Journal of Medicine* and presented at the Late Breaking Clinical Trials session at the American Heart Association meeting in November.[9,154]

Professor John Simes

'These results suggest that aspirin prevents about one third of recurrent blood clot events. For every 1000 patients treated for 1 year, aspirin can be expected to prevent about 20 to 30 episodes of recurrent major thrombotic events at the cost of about 3 significant bleeding episodes. '

'Many patients discontinue warfarin therapy after 6 or 12 months of treatment due to the inconvenience of regular blood tests and the increased risks of serious bleeding putting them at high risk of recurring thrombosis.

'Aspirin reduces the risk of important blood clotting events including recurrent VTE, myocardial infarction, stroke, and cardiovascular death. We now have clear evidence that aspirin benefits patients who are unable or do not wish to continue warfarin in the long term.'

—Dr Tim Brighton, co-principal investigator of ASPIRE (with Professor John Eikelboom)

Li Ping Li, manager of the FIELD trial follow-up

Ongoing studies in diabetes from FIELD data

The FIELD (Fenofibrate Intervention and Event Lowering in Diabetes) study was an international multicentre trial, initiated and coordinated by the CTC, investigating the use of fenofibrate to reduce the risk of coronary heart disease in people with type 2 diabetes. The FIELD dataset is still being used to answer questions that will benefit diabetes patients.

A major contributor to the disease burden of type 2 diabetes is stroke in its various forms, but which factors raise the risk of stroke has been controversial. For example, some studies, but not all, have shown that the risk decreases with age beyond the fifties. The large, well-documented database of the FIELD cohort, 9795 patients, allowed the investigators to analyse the factors associated with a risk of various subtypes of stroke in these patients. They found that most strokes were caused by an interruption to blood flow rather than bleeding. The cause of stroke was most commonly disease in the small arteries.Those at highest risk were older people. This detailed information on types of stroke and related risk factors will help clinicians quantify risks of stroke for individual patients.[40]

Clinical guidelines for the FIELD study drug, fenofibrate, have recommended caution in using it for patients with impaired kidney function. A substudy, published in *Diabetes Care,* assessed the benefits and safety of the drug in cases of mild or moderate renal impairment.[114] This analysis showed that using the drug did not lead to kidney disease and that it was safe for these patients, suggesting that the guidelines may be too restrictive. Another study focused on the safety of fenofibrate therapy with respect to thromboembolism, because fenofibrate raises the level of homocysteine. It was found that naturally occurring levels of homocysteine are related to risk of thromboembolism and that fenofibrate treatment was associated with a higher risk of thrombosis in patients with high homocysteine at baseline.[42]

Most of the FIELD survivors from Australia and New Zealand are still providing follow-up data through their responses to regular questionnaires and data linkage. Around 1750 Australian participants had blood samples collected late in 2012. Laboratory analyses of the samples taken during the trial and its follow-up will allow the investigators to determine biological and genetic markers of the risks of cardiovascular disease and other complications of type 2 diabetes (p.20).

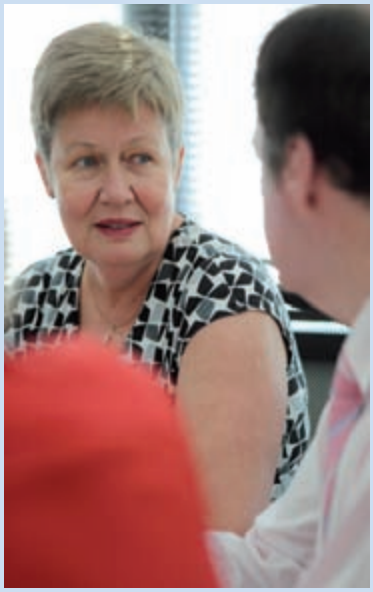
Mark Donoghoe, Rachel O'Connell and Anne-Sophie Veillard, biostatisticians for FIELD studies

LIPID (Long-term Intervention with Pravastatin in Ischaemic Disease)

Taking a statin drug to lower cholesterol to prevent heart attacks is now common in Australia and elsewhere. The CTC's LIPID study was one of the key trials providing evidence on the benefits of statin therapy and one of the largest clinical trials undertaken in Australia, involving 9014 patients from 87 hospitals in Australia and New Zealand.

Most of the survivors provided follow-up data through their responses to regular questionnaires sent to them until 2007. Mortality and cancer data have been obtained for nearly 9000 patients, 97% of the original cohort, through linkage with death and cancer registers. CTC researchers have analysed these data to assess the effect of pravastatin treatment 10 years beyond the trial by comparing the patients originally assigned pravastatin with those originally assigned placebo. The protective effect of pravastatin is still detectable, although diminishing, and there is no evidence that pravastatin increases the risk of cancer.

In addition to the main presentation of these results at the American Heart Association Scientific Sessions in Los Angeles in November,[170] the work was selected for the AHA International Forum after the abstract had been identified as one of the best submitted from Australia. A special session was dedicated to Australia to spotlight important aspects of its cardio-vascular research.



Wendy Hague, clinical trials program director and member of the LIPID Study Group

BIOMARKER STUDIES

The LIPID managing group, now including laboratory scientists, has been using blood samples collected from LIPID patients in the 1990s to investigate the associations between levels and changes of various blood components and the risk of heart disease outcomes. Various results were presented at international meetings in 2012, including the finding that midregional pro-adrenomedullin may help to identify patients at risk of future events, especially heart failure.[168]

International meta-analysis of cholesterol lowering to prevent cardiovascular events

The CTC and the Clinical Trials Service Unit at the University of Oxford have collaborated for over 20 years to operate the secretariat of the Cholesterol Treatment Trialists' Collaboration (CTTC). The purpose of the collaboration is prospective meta-analysis of data from the many patients worldwide in coronary heart disease prevention trials.

The most recent studies have analysed data from 27 trials involving 175 000 participants. Data from the LIPID study were included. A study published in *The Lancet* showed that, in people with a 5-year risk lower than 10%, statin therapy reduces the risk of major cardiovascular events, which is related to lowering the level of LDL cholesterol. Per 1000 people treated with a statin over 5 years, 11 major cardiovascular events are avoided for each 1.0 mmol/L reduction in LDL cholesterol.[73] A separate analysis showed that statin therapy did not influence the incidence of cancer or the rate of death from cancer, even among those whose LDL levels became very low.[18]

These 2012 findings, in the context of results from trials, such as LIPID, and CTTC meta-analyses over the past decade, have produced compelling evidence that lipid-lowering statin therapy reduces cardiovascular events, leading to new recommendations that clinical guidelines advocate statin treatment for patients with lower LDL cholesterol as well as those at high risk.

A joint initiative to improve health in high-priority areas

The CTC and its collaborators at the Boden Institute of Obesity, Nutrition, Exercise and Eating Disorders (BIONE) and Macquarie University will begin a new program of research in 2013, funded by a five-year program grant from the NHMRC.

It will bring together a multidisciplinary team of clinicians, epidemiologists, triallists, biostatisticians and health economists and national and international collaborative networks of investigators to tackle major health care questions in high-priority health areas.

The research program will focus on research questions promising the most benefit for future clinical practice and health policy. The research strategy focuses on diseases having significant mortality and morbidity and where advances will have substantial influence: in particular cancer, cardiovascular disease, diabetes, obesity and neonatal diseases. The program will integrate trials with translational basic science and further develop methods of assessing and applying clinical trial evidence to individual patients and to populations.

CHIEF INVESTIGATORS OF THE NEW PROGRAM

Top row: John Simes, Anthony Keech, Val Gebski and Martin Stockler
Bottom row: Ian Caterson (BIONE), Stephen Colagiuri (BIONE), Deborah Schofield and Ian Marschner (Macquarie and CTC)

The CTC's neonatal trials

Lucille Sebastian, manager of APTS

Alpana Ghadge, manager of BOOST II

The CTC's neonatal group conducts large multicentre trials covering important questions affecting the health, survival and future prospects of newborn babies. Data from these trials contribute to international meta-analyses of data from thousands of patients.

The Australian Placental Transfusion Study (APTS)

APTS is determining whether a 60-second delay in clamping and cutting the umbilical cord can improve the baby's blood flow to the brain and gut reducing the need for donor blood and reduce rates of infection, retinopathy, poor growth, death and disability in babies born more than 10 weeks early. This trial is continuing.

Benefits of Oxygen Saturation Targeting, trial II (BOOST II)

BOOST II is ascertaining which of two oxygen saturation ranges is better for very premature babies. Oxygen is the most common therapy for preterm infants. Doctors and nurses do not know the safest and most effective level of oxygenation for these babies. Higher oxygen levels may increase retinopathy of prematurity and respiratory problems, but lower oxygen levels may affect other long-term outcomes. The trial will be completed in 2013.

NEONATAL META-ANALYSES

As a member of several international collaborations in neonatology, the CTC coordinates and participates in meta-analyses designed to turn trial data into evidence. Data from several trials can be combined in an individual-patient-data meta-analysis where large numbers of patients are needed for a definitive statistical analysis. Two neonatal groups have recently published their protocols.[20,132]

Dr Lisa Askie, director of systematic reviews and a leader in meta-analyses in neonatal disorders

William Tarnow-Mordi (pictured right) attended the Patient Safety Summit of the Patient Safety, Science & Technology Movement, whose goal is 'zero preventable deaths by 2020'. He moderated the neonatal panel, and met the keynote speaker, President Bill Clinton (pictured left).

As a commitment arising from the summit, an international alliance for pulse oximetry screening in newborns will be supported by the WINNER Centre for Newborn Research and the CTC, which aim to work with others to ensure that all babies can benefit from earlier diagnosis of critical congenital heart disease, neonatal sepsis, pneumonia and pulmonary hypertension through routine pulse oximetry before discharge.

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Cancer trials

Gastrointestinal cancer (AGITG trials)

The CTC is the coordinating and statistical centre for the Australasian Gastro-Intestinal Trials Group (AGITG), a national network of gastrointestinal cancer investigators. The AGITG-CTC collaboration has now been continuing for over 20 years, improving the treatment and outcomes of people with gastrointestinal cancers, that is, cancers of the oesophagus, stomach. liver, gall bladder, pancreas and bowel. New concepts for trials are developed by this collaboration.

During 2012 the CTC's work included participating in an external review of AGITG in May, presentations and publications from completed trials, significant work with AGITG on major flagship trials, particularly INTEGRATE and TOPGEAR in gastric cancer, launching new trials, and further development of new proposals for trials opening in 2013. In 2012, 265 patients were recruited to 12 clinical trials.

A 5-year NHMRC Project Grant was obtained to support the ongoing conduct of the TOPGEAR trial, including work with international collaborators the National Cancer Institute of Canada and the European Organisation for Research and Treatment of Cancer.

In 2012, results from several major collaborative trials were published, including the international ESPAC-3 study in *JAMA*.[142] Data from the MAX trial were analysed in a substudy that showed that bevacizumab and capecitabine combined was safe, effective and well tolerated in patients aged over 75.[87] This evidence on treatment for an under-researched group will be useful for clinical practice. A collaboration of the Trans-Tasman Oncology Group with AGITG published the results of a trial comparing a short course of preoperative radiotherapy with a longer course for patients with rectal cancer; after 3 years no difference in rates of distant recurrence, survival, or late toxicity were detected.[144]

Twenty-one oral and poster presentations of current AGITG studies were presented at major international and national meetings in 2012.

Professor John Zalcberg, chairman of the Australasian Gastrointestinal Trials Group

Danielle Ferraro and Dirkje Sommejier, medical oncologists and CTC clinical research fellows for AGITG trials

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Professor Ian Davis, Monash University, is chair of ANZUP, the Australian cooperative group for urogenital trials

Urogenital cancer (ANZUP trials)

The CTC collaborates with the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). Current trials are investigating treatments for testicular, kidney and bladder cancers.

Testicular cancer, usually as germ-cell tumours, is the most common cancer in young men in Australia. Although most patients do well, many of those with intermediate- and poor-prognosis disease relapse and die despite treatment. Mechanisms of chemotherapy resistant germ-cell tumours are not well understood.

Accelerating chemotherapy by administering treatment 2-weekly rather than 3-weekly may increase cure rates without significant additional toxicity or cost. The ANZUP-CTC collaboration conducted a very successful phase II trial, Accelerated BEP, into the feasibility and tolerability of an accelerated dose-dense treatment regimen and presented the results at the American Society of Clinical Oncology meeting in 2012.[169] The results of this trial, and other evidence, supported the case for a large phase III trial of this treatment. With new funding from Cancer Australia, the trial will commence recruiting patients from Australia, the UK and the USA in 2013.

Bacillus Calmette-Guérin (BCG), an immunotherapy related to tuberculosis vaccine, is an effective treatment for bladder cancer when introduced locally into the bladder after surgery on the tumour. Some patients do not respond to this treatment, and it is uncertain whether adding chemotherapy improves their prospects. In 2012 the group published a meta-analysis of current evidence on this topic.[48] Their results indicated that adding chemotherapy to the treatment for some patients should be tested in a clinical trial. In 2013, they will commence a large phase III trial trial of adding mitomycin C to BCG as adjuvant intravesical therapy for high-risk, non-muscle-invasive bladder cancer, with initial funding from Cancer Australia.

Gynaecological cancer (ANZGOG trials)

The CTC is the coordinating centre for the Australia New Zealand Gynaecological Oncology Group (ANZGOG), the Australian investigator group for cancers involving the female reproductive system. ANZGOG is a member of the Gynecological Cancer Intergroup (GCIG), the peak international body in this field.

2012 was an outstanding year for the group, with 95% of the 386 recruited patients coming from ANZGOG-CTC home-grown trials.

The CTC and ANZGOG are collaborating on the CTC's first phase I study (ANZGOG-1103), which is adding a new investigational agent to the standard treatment of carboplatin and gemcitabine for treatment of relapsed ovarian cancer. The CTC and ANZGOG lead the OUTBACK trial, which is investigating the benefit of adding chemotherapy to standard chemoradiation treatment for high-risk cervix cancer. OUTBACK is also open to recruitment in the US, supported by the National Cancer Institute. The current status of the trial was presented in June.[189]

Symptom Benefit is another highly successful international collaboration led by ANZGOG-

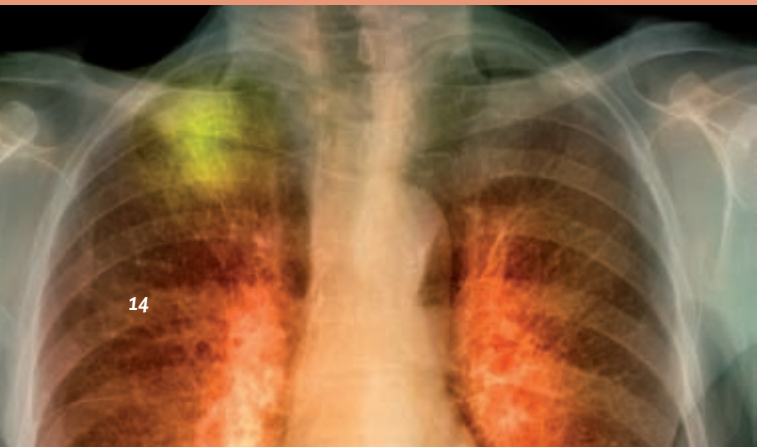
Julie Martyn, associate oncology program manager for gynaecological trials, and Kerri Carlton, trial coordinator

MANAGING CANCER TRIALS

'The diversity of my different roles (data manager, trial coordinator, manager) over the last 10 years in the therapeutic areas of early breast cancer and lung cancer has allowed me to extend my capabilities and knowledge through engagement with a wide range of staff who individually bring their own unique experience to each trial. Oncology staff come from a multitude of backgrounds, so managing these teams is a synergy of the desire to run the trial as effectively and efficiently as possible and using all our varying experience and skill sets together, to achieve a well coordinated trial.

'The most rewarding aspect since my appointment as an associate oncology program manager in 2007 is that it is a multifaceted role — including protocol development, budget forecasting, grant applications, project management, and managing teams— so I experience the life cycle of a trial from many angles with talented individuals, both CTC staff and our external collaborators.'

— Xanthi Coskinas, associate oncology program manager for lung cancer trials



CTC, with participation from nine GCIG groups, on the benefit of palliative chemotherapy in advanced ovarian cancer. PARAGON is a study of aromatase inhibitors across a range of potentially hormone-responsive gynaecological cancers, again led by ANZGOG-CTC and open internationally.

The CTC is the statistical centre for the now completed international ovarian cancer CALYPSO trial, which found that carboplatin and liposomal doxorubicin was more effective and better tolerated than the standard treatment. The new therapy has become the standard of care for patients with recurrent ovarian cancer. Statisticians and others at the CTC have continued to participate in CALYPSO substudies and methodological analyses.[1,10,37,123]

Data from CALYPSO and 13 other trials comprising nearly 17 000 patients were used in a meta-analysis to investigate how well progression-free survival predicts overall survival in patients who had platinum therapy for epithelial ovarian cancer. The two outcomes were highly correlated, indicating that progression-free survival could be used as a surrogate outcome for survival in future trials, a methodological advance that should lead to more efficient trial design.[207]

Lung cancer (ALTG trials)

The CTC collaborates with the Australasian Lung Cancer Trials Group (ALTG), the national investigator group for lung and thoracic cancer trials.

In the ALTG's homegrown flagship trial, NITRO, patients with non-small-cell lung cajncer are given a nitroglycerin patch or a placebo in addition to their chemotherapy. The effect on progression-free survival and other outcomes is being assessed. Recruitment has reached 50% in just 3 years. A prospective meta-analysis is being planned with the Netherlands Dutch Association of Chest Physicians (NVALT), which conducted a similar trial. In 2013 the ALTG-CTC team will be working with NVALT to incorporate 10 Dutch sites into the NITRO trial: the first ALTG-CTC-led international collaboration in lung cancer.

In 2012, the group presented results of a phase II trial of a vascular disrupting agent, BNC105P, for advanced malignant pleural mesothelioma. Tumours did not respond to this new treatment, so recruitment was ceased, although biomarker analyses are continuing.[192]

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Tumours of the brain and nervous system (COGNO trials)

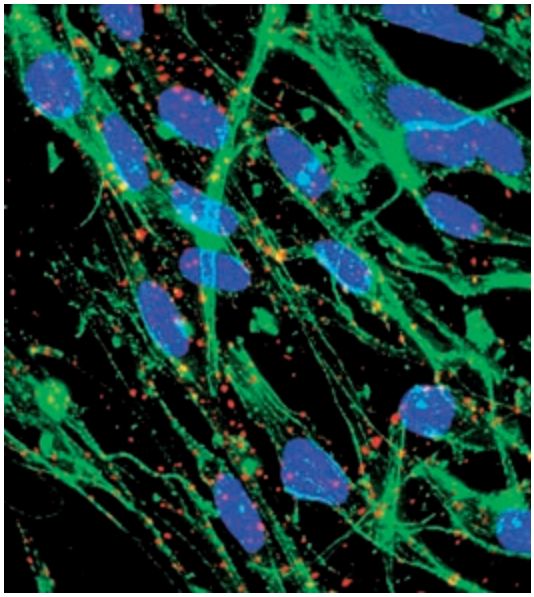
The CTC is the coordinating centre for the Cooperative Trials Group for Neuro-Oncology (COGNO).

COGNO-CTC have been conducting CABARET, a phase II study of a new treatment for glioblastoma multiforme, an aggressive malignant tumour for which there is no accepted standard management after disease progression. The study is comparing bevacizumab treatment alone with a combination of bevacizumab and carboplatin. It incorporates a prospective analysis of CogState neurocognitive testing for patients with brain tumours. Accrual to the first part of the trial is complete. The investigators presented feasibility and safety findings at several international meetings in 2012.[164,165,166]

COGNO held its annual scientific meeting in Brisbane in August. The theme was 'Neuroimaging: novel approaches for glioma', which took in sessions on neuroimaging, low-grade gliomas, translational research and comprehensive care. Included in the program was a joint symposium with the Medical Oncology Group of Australia (MOGA) on contemporary management of brain metastases.

COGNO had a concept development workshop in May, which generated ideas for new trials for the group, and a strategic planning day in December, confirming COGNO's mission and aims and laying the groundwork for the development of a plan for the next 5 years.

Dr Kathryn Field, principal investigator of CABARET (Randomised phase II study of carboplatin and bevacizumab in recurrent glioblastoma multiforme)



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Brain cancer glial cells. Glioblastomas are the most common and most aggressive form of brain tumour. They are derived from glial cells

COORDINATING CLINICAL TRIALS IN NEURO-ONCOLOGY

'Working at the CTC is a little like being a juggler, sometimes with all three balls in the air at once. No two trials are alike, and being able to coordinate a complex clinical trial is a fantastic challenge. It provides an opportunity to work with leading researchers and scientists at the forefront of their fields, with the potential to change current practice and improve outcomes for patients with cancer.

'In my role at the CTC I have been fortunate to have seen a trial from the early stage of protocol development through its lifespan. This has allowed me to develop diverse skills and knowledge which will be invaluable for future trials.'

— Kate Sawkins, oncology clinical trial coordinator, Cooperative Trials Group for Neuro-Oncology (COGNO)

Current studies in breast cancer (with RACS)

SNAC1

The SNAC1 trial is a study, now in long-term follow-up, of surgery for women with early breast cancer. It is determining whether sentinel lymph node biopsy (with axillary clearance only if the sentinel node is positive) is less damaging than immediate axillary clearance, and whether the cancer-related outcomes are equivalent. Recruitment finished in 2005, with 1088 participants.

Results from SNAC and other trials of sentinel node biopsy have been used in a decision-model analysis of the effectiveness and cost-effectiveness of this approach to diagnosis and treatment, which was published in the *British Journal of Cancer*.[121]

SNAC2

The SNAC2 trial is an extension of SNAC1. The primary objective is to determine whether sentinel-node-based management, compared with axillary clearance, increases the risk of locoregional recurrence and in particular, axillary recurrence, in any subgroup of women. This study includes women with larger tumours and those with multiple primary tumours in the same breast. SNAC2 opened to recruitment in 2006 with the target of 1012 women. The trial continues to recruit patients from almost 40 sites across Australia, New Zealand, Singapore and Hong Kong.

Costs of treatment ($) used in the decision model analysis of effectiveness and cost-effectiveness in early breast cancer[121]

AXILLARY CLEARANCE PROCEDURE	5 576
SENTINEL LYMPH-NODE PROCEDURE	4 206
AXILLARY CLEARANCE AFTER SENTINEL LYMPH NODE POSITIVE	7 771
ADJUVANT THERAPY FOR EARLY BREAST CANCER	
Radiotherapy	5 130
Chemotherapy	16 160
Endocrine therapy	10 961
Herceptin therapy	64 033
Annual follow-up	254
Physiotherapy	60
LOCAL RECURRENCE	7 658
AXILLARY RECURRENCE	24 556
DISTANT METASTASES (ANNUAL)	24 340
END OF LIFE COSTS	29 616
DEATH FROM OTHER CAUSES	8 659

Estimates of breast cancer spread are an important supplement to clinical trial data

An epidemiological study by Sally Lord and colleagues estimated the incidence of metastatic cancer developing within 5 years in women initially diagnosed with non-metastatic breast cancer. The researchers were particularly interested in women aged over 70 years and women from regional and remote areas, groups not well represented in clinical trials. They found that women were more likely to develop metastases if their disease had spread beyond the breast at diagnosis, if they were under 50, or if they lived in a lower socioeconomic area. Metastatic cancer appeared most often in the second year after their initial diagnosis.[67]

An editorial in the Medical Journal of Australia commented: 'This is the first population-based Australianreport on this subject ... and will inform discussions with Australian women newly diagnosed with breast cancer, for whom the issue of possible cancer spread is personal and vital. The article is important for its headline findings, its methods and its implications for clinical care and the collection of meaningful data.'

New research using data from clinical trials helps patients and clinical practice

PROGNOSIS

The expected survival time of patients with cancer can be uncertain, with many factors contributing, such as the size of a tumour, cancer biomarker levels, and the number of sites of metastasis.

To respond to a need for accurate and reliable information on expected survival for patients with advanced ovarian cancer, the investigators of the CALYPSO trial and CTC statisticians developed a nomogram, which assigned points for values of clinical factors in such patients treated with platinum chemotherapy. This was an extension of previous research into estimating progression-free survival time. The new nomogram, in simplified form, was validated on data from two other ovarian cancer trials. The nomogram, with 6 prognostically significant factors, was able to predict survival accurately enough to be useful to clinicians counselling patients.[65] After further validation, it may also be used to stratify patients in clinical trial analysis.

In another study on predicting survival, this time in renal cancer, CTC researchers used the knowledge that temsirolimus is an effective treatment for renal cancer and that it is also associated with increases in serum cholesterol, triglyceride, and glucose to explore the hypothesis that the two effects were related. The study used data from patients randomised to temsirolimus or interferon in the Global Advanced Renal Cell Carcinoma trial to show that increase in cholesterol (but not triglycerides or glucose) predicts the efficacy of temsirolimus in these patients.[64] Measuring the cholesterol increase may be a way to screen new treatments in clinical trials.

Continued on page 18...

Belinda Kiely, Katrin Sjoquist and Chee Lee are medical oncologists who undertake research bridging clinical trials and clinical practice

BENCH TO BEDSIDE ONCOLOGY TRANSLATIONAL RESEARCH

The CTC works in collaboration with Sydney Catalyst (p. 19) to undertake translational cancer research, in which researchers collaborate to apply laboratory discoveries to treatment and care of patients and then to improve the use of research evidence in routine clinical practice. This approach will shorten the time between new scientific discoveries and ultimately using them to improve the survival and quality of life of cancer patients.

Most trials coordinated at the CTC include an option for patients to consent to biological samples being used in specific research projects or being banked for future research. Samples of blood or tumour tissue are collected, then analysed in the laboratory for a range of individual biomarkers that may correlate with a patient's clinical outcomes or predict the response of a patient to a treatment.

In the new IMPACT trial, a collaboration with the AGITG, Sydney Catalyst, and the Australian Pancreatic Cancer Genome Initiative, patients are being screened for entry on the basis of their genetic make-up.[190] This information will be used to match individuals to specific therapies, with the hope of improving their response to treatment.

COMMUNICATION OF LIFE EXPECTANCY TO PATIENTS *(...from page 17)*

Most people with advanced cancer want to know how their illness will affect their life expectancy, a difficult task for their doctors.

Median life expectancies for various cancers are available from clinical trials, but a single point estimate of survival is not helpful for patients, especially as it does not convey the concept or the hope that an individual patient may survive much longer.

Oncologists from the CTC have been carrying out a series of studies that help clinicians to estimate how long a patient might live and explain the estimate to patients in a meaningful way.[58,59] They have proposed providing estimates of the best case, worst case, and typical scenarios for survival as a useful way of communicating life expectancy. A study presented in 2012 examined medical oncologists' estimates in relation to real survival times and concluded that the oncologists estimated these three scenarios accurately.[177,178,179] To explore the patients' side of the story, the researchers then surveyed patients attending oncology clinics, asking them how a hypothetical cancer patient would respond to information about survival. Most preferred the presentation of best case, worst case, and typical scenarios to knowing only the median survival time.[59,181]

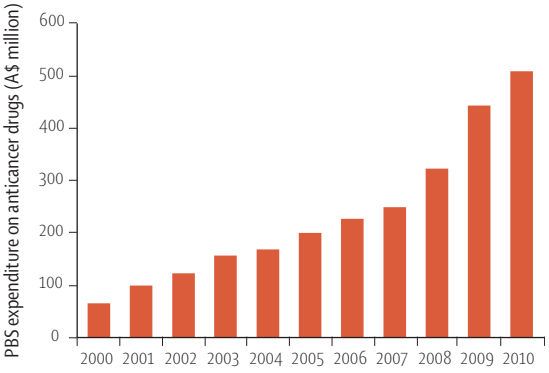
Can Australia afford new cancer treatments?

Dr Deme Karikios is undertaking research for a PhD thesis, 'The costs and effects of new anticancer drugs'.

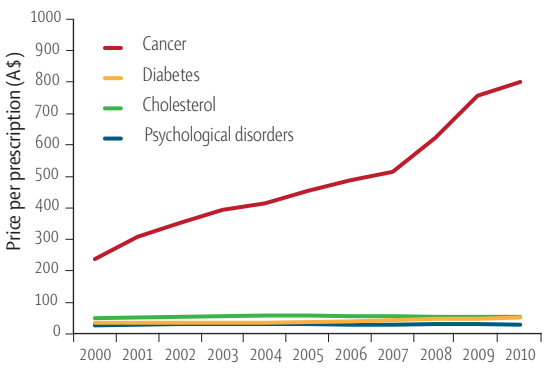
In 2012 he presented an investigation of the price of drugs over a decade.[176] He and his colleagues found that the expenditure by the Pharmaceutical Benefits Scheme had increased 8-fold and its cost per prescription had quadrupled. Such rising costs and prices may become unsustainable.

One solution to the rising costs might be better targeting of effective treatments for individual patients, a focus of current oncology research at the CTC and elsewhere.

PBS expenditure



Prescription prices



Sydney Catalyst: the Translational Cancer Research Centre of Central Sydney and Regional NSW

Sydney Catalyst is a multidisciplinary and multi-institutional endeavour, established in 2011 with core funding from the Cancer Institute NSW and based at the CTC. It brings together teams of clinicians and researchers from across NSW with the purpose of facilitating rapid translation of scientific discoveries into clinical policy and practice to improve patient outcomes.

In 2012, Sydney Catalyst commenced its T2 translational flagship program, Defining Knowledge Translation in Cancer (in lung cancer, colorectal cancer, melanoma and supportive care), and also in 2012 its first T1 translational flagship program, the IMPACT trial (Individualised Molecular Pancreatic Cancer Therapy) was highlighted in Nature news, 21 March issue. Sydney Catalyst awarded to members pilot and seed funding for four research initiatives, a full three-year PhD scholarship and several postgraduate top-up scholarships and travel and education awards. Other members were recipients of 5-year Cancer Institute NSW translational program grants.

Sadly, Sydney Catalyst lost one its founding members, Prof Rob Sutherland, FAA, AO, who died in October. He is missed by Sydney Catalyst and the oncology research community.

RAPID Study: RNA-based Analysis for Prediction of Islet Death

Most people with type 1 diabetes have lost more than 50% of their insulin-producing cells by the time they start showing any symptoms. There is therefore an urgent need to identify novel biomarkers that can help in diagnosis at even earlier stages of the disease. The aim of RAPID is to assess noncoding RNA- and micro RNA-based biomarkers of diabetes.

The knowledge gained from the RAPID study will inform medical researchers as to whether the development and progression of type 1 diabetes can be predicted, provide tests to monitor treatment strategies, and guide the development of new treatments to lessen the burden of diabetes.

The collaboration, led by Associate Professor Anand Hardikar, received an Australian Future Fellowship from the Australian Research Council in 2012.

RAPID research team Sarang Satoor, Wilson Wong, Anandwardhan Hardikar and Mugdha Joglekar

Susan McLennan, Surya Sutanto, Alicia Jenkins, Anandwardhan Hardikar, Wilson Wong, Stephen Twigg and Anthony Keech collaborating on genetic research in diabetes

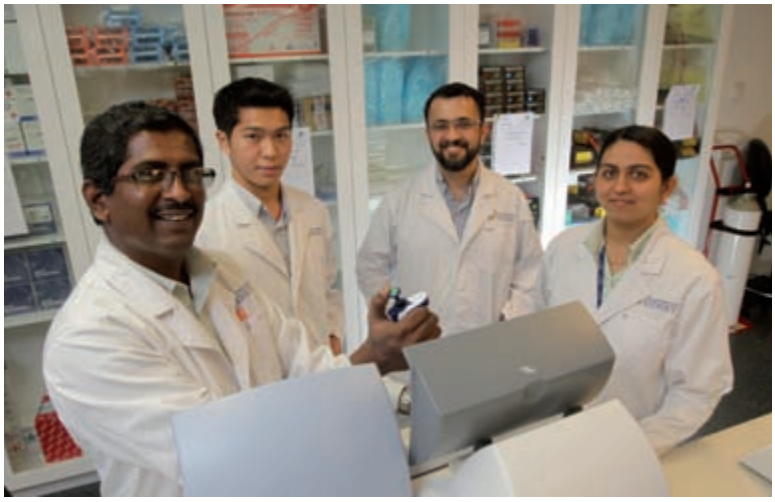
Predicting type 2 diabetes complications to improve risk assessment and treatment

New CTC research is identifying genetic contributions to the complications of diabetes, such as heart disease, stroke, eye disease and kidney disease.

Telomeres, which cap the ends of chromosomes and protect them during cell division, are the focus of this NHMRC-funded research. Telomeres tend to shorten with age, and shorter telomeres are associated with vascular risk factors, inflammation and oxidative stress, and vascular disease.

The study is investigating the relationships among genes, telomeres and diabetes by looking at DNA variation in patients from the CTC's completed FIELD trial (p.8) and, in the NHMRC-funded follow-up studies, also investigating whether the blood-fat-modifying drug fenofibrate reduces the rate of telomere shortening.

Results of a pilot study on patients with type 1 diabetes were presented at the meeting of the American Diabetes Association.[174] It was found that age-related telomere shortening was worse in people with diabetes, suggesting accelerated ageing. Telomere length correlated with the duration of diabetes, but was not related to diabetes complications or risk factors. In people without diabetes, telomere length correlated with inflammation, renal function and vascular health. Age, diabetes and C-reactive protein levels were independent determinants of telomere length.



Australian New Zealand Clinical Trials Registry

The ANZCTR is an online database that provides public information on trials being conducted in Australia, New Zealand and some other countries. Its aims are to maximise patient participation in trials, minimise unnecessary duplication of research and enable a reliable assessment of clinical research evidence by ensuring all relevant trials are known.

The Australasian registry, administered at the CTC, was one of the first World Health Organization-recognised primary registries of clinical trials.

The ANZCTR improves the efficiency and value of Australian clinical trials research by helping to increase trial participation and showing the current status of clinical research. It allows policy makers and researchers to identify potential gaps between current trials research activity and health priorities. For example, the register shows not only which trials are being conducted, but also where trial activity is deficient. A study presented in 2012 used estimates of the burden of disease in various health areas and compared these with the planned recruitment of patients in these areas.[182] Planned recruitment to asthma, obesity and diabetes trials was less than half that expected, and for asthma and obesity the number of registered trials was also lower than expected.

The number of trials registered by the ANZCTR now stands at 7500.

The Minister for Health, the Hon. Tanya Plibersek (pictured above), announced a grant of $2.1 million to the ANZCTR from the NHMRC.

The grant is enabling the registry to undertake research into the functions and use of the registry and to make access easier for a variety of users, especially patients and their families and friends.

The Minister's announcement at the CTC was attended by many. Shown with the Minister are Professor Warwick Anderson, chief executive officer, NHMRC; Associate Professor Lisa Askie, manager, ANZCTR; John Stubbs, consumer representative; Professor John Simes; Dr Michael Spence, vice-chancellor, University of Sydney

REPRESENTED ON THE ANZCTR ADVISORY COMMITTEE

- Chief Medical Officer of Australia
- University of Sydney
- International Committee of Medical Journal Editors
- Australian Health Ethics Committee
- Therapeutic Goods Administration
- National Health and Medical Research Council
- New Zealand Health Research Council
- Pharmaceutical industry
- Consumers

CTC CONTRIBUTES TO THE WORLDWIDE COCHRANE COLLABORATION

'I work closely with the joint coordinating editors on setting policies and procedures for the Breast Cancer Review Group and managing the editorial process for all its incoming Cochrane titles, protocols and reviews. The key word is collaboration, and as part of this, we provide extensive and ongoing support to our authors, who have varied experience and expertise.

'I enjoy being part of the entire Cochrane process, where we're committed to developing high-quality systematic reviews that can be used and understood by a range of people. On a daily basis, my role can vary from cross-checking that a review complies with Cochrane standards, identifying appropriate peer referees, and editing and proofreading to finally marking up a review for publication.'

— Melina Willson, manager, Cochrane breast cancer review group

Cochrane Collaboration groups at the CTC

The Cochrane Collaboration is an international organisation of more than 28 000 health care professionals, practising physicians, researchers and consumers, which is committed to providing high-quality public information about the effectiveness of health care interventions.

The CTC is the home of:

1. the C**ochrane Breast Cancer Review Group**, which coordinates, edits and facilitates the publication of reviews of evidence in breast cancer and

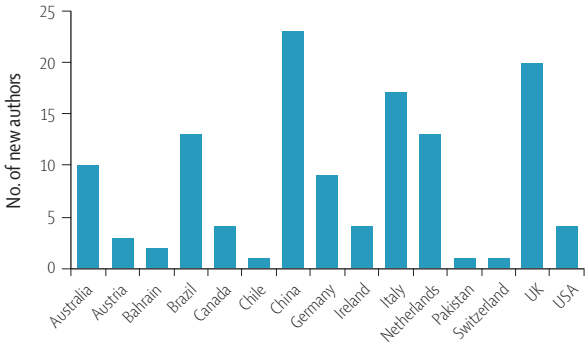
2. the **Prospective Meta-Analysis Methods Group**, an expert group for methodological development and advice.

Both groups enlist new authors from around the world who have a range of expertise and experience. They also support and train new authors to allow them to undertake systematic reviews.

In 2012, the Cochrane Breast Cancer Review Group facilitated the publication of clinically relevant and high-priority reviews, which covered (to name a few): therapies that target specific receptors on cells (for example, trastuzumab) for adjuvant therapy and

DIVERSITY OF NEW AUTHORS RECRUITED BY THE COCHRANE BREAST CANCER REVIEW GROUP IN THE PAST 2 YEARS

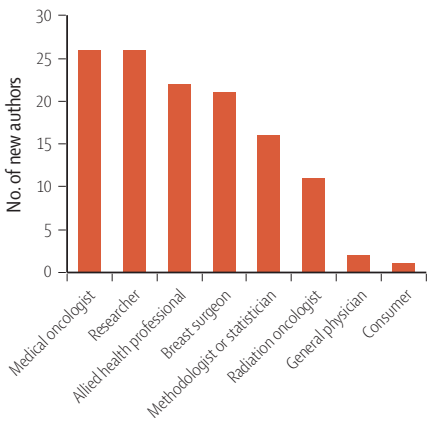
Global diversity



treatment of early breast cancer, managing chemotherapy-related side effects, new modes of delivering radiation to the breast tissue, surgical techniques to optimise wound management after breast and axillary surgery, and differing forms of survivorship care.

The review findings are integrated into national and international clinical guidelines, such as the Clinical Best Practice Guidelines in Australia, the National Institute for Health and Care Excellence in the UK, and international consensus statements, such as those of the Central European Cooperative Oncology Group for advanced breast cancer.

Diversity by discipline



Reviews of new procedures and technologies considered for public funding

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

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

During 2012, the team developed protocols for the review of several new technologies, including radiosurgery for intracranial tumours, intensity-modulated radiation therapy, image-guided radiation therapy and botulinum toxin for urinary incontinence. The team also prepared full assessments of holmium:YAG laser enucleation of the prostate (HoLEP) for the treatment of benign prostatic hyperplasia[149] and fiducial markers to guide external beam radiotherapy in prostate cancer.

Samara Lewis, Sally Lord and Sally Wortley, experts in reviews of new technology

METHODOLOGICAL GUIDANCE FOR DIAGNOSTIC TEST EVALUATION

Before a new diagnostic test is introduced into clinical practice, it must be evaluated, not just for its accuracy, but for its ability to change clinical management and ultimately improve outcomes. The pathway from a new test to better health for patients can be complex, and clinical trials of the process are not usually feasible.

Therefore, studies evaluating tests sometimes use a change in clinical management (or some other intermediate outcome, like the time to treatment) as the measure of the benefit of a test. CTC researchers in the field of diagnostic tests have reflected on the reporting of these studies and provided guidance on how this evidence should be reported.[103, 104]

PRACTICAL APPLICATION IN HEALTH AND ECONOMICS

'As an NHMRC Early Career Research Fellow I am working to build Australia's first measure of long-term multidimensional poverty. This will bring Australia in line with international best practice in this field, and will be the first time internationally that a clinically robust measure of health status— one based on the SF-36 measure of health—has been used in any measure of wellbeing.

My work has a strong focus on practical applications and will influence the way living standards are conceptualised and measured in this country.'

— Emily Callander, research fellow in health economics

Health economists: Rupendra Shrestha, Hannah Verry, Deborah Schofield and Toby Gould

Health economics: critical to translating research into practice and policy

As governments face increasing budget deficits and the global financial crisis cripples the economies of many first world nations, the competition for funding for health care increases. In this environment, a robust economic evaluation of the costs and benefits of new interventions is critical to presenting a justification for funding.

The health economics team has developed an internationally recognised research program which captures the far reaching and potentially substantial benefits of improved health not just within, but also beyond, the health system.

Over the last two years, the health economics team have completed a large scale microsimulation model to project the long-term impact (to 2030) of health on labour force participation, on family incomes and savings, and the flow-on effects for the sustainability of government finances due to impacts on taxation revenue and social security payments. The model takes account of disease trends such as the increasing prevalence of diabetes, demographic change including population ageing, policy trends such as increasing superannuation coverage and contributions, and labour trends such as rising female labour force participation. The model was developed in collaboration with NATSEM (University of Canberra), the School of Public Health (University of Sydney), and the School of Population Health (University of Queensland), and is funded by an ARC linkage grant with Pfizer Australia as an industry partner.

Capturing the personal and government economic impacts of health across society is increasingly part of clinical trials. An example is the LIFT trial, which is determining whether adding bovine lactoferrin to food reduces mortality and morbidity in infants with very low birthweight. The CTC's health economics group is assessing whether the intervention is cost-effective, including the capacity of mothers to return to the labour force if the child does not suffer a serious disability, and the impact on family income.

In 2012, the collaboration won an NHMRC Partnership Project Grant in collaboration with Carers Australia and Pfizer Australia as partner organisations to model the current and future economic impacts of becoming a carer, and Dr Emily Callander received an NHMRC Early Career fellowship to develop Australia's first measure of long-term multidimensional poverty.

The work of the team continues to be published in highly regarded journals including *Pain*,[93,94] the *International Journal of Cardiology*[96,98,99] and *Spine*.[97]

Biostatistics research

Methodological studies

CTC biostatisticians undertake methodological research to improve the design and conduct of clinical trials and to underpin predictions of risk in clinical situations.

DRILLING DOWN INTO QUALITY OF LIFE

Comparing trials of treatments for their effects on quality of life requires a single global measure of quality of life as a whole. Because many factors contribute to this, health-related quality of life is often ascertained by aggregating scores on various individual dimensions of quality of life, such as physical, psychological, social, and functional domains. The method is limited because it reduces multidimensional outcomes into a single intangible quality without systematic agreement on how they are weighted.

In a model addressing this problem, Annette Kifley and colleagues used multilevel latent variables (statistical hypothetical constructs not directly measured) to integrate and summarise health-related quality of life. They used data from a breast cancer trial in which quality of life was a key outcome. They presented their model in *Statistics in Medicine*, concluding that this approach can pinpoint wellbeing more precisely than other summary measures of quality of life.[60]

STRATIFIED ADDITIVE POISSON MODELS TO PREDICT RISK

Predicting a patient's risk of having a particular disease event is important in clinical practice. Such predictions depend on models of risk developed by biostatisticians.

Even when risk factors have been identified, it is not always clear how individual risk factors combine. Models that arrive at an overall level of risk by multiplying individual risk factors are usual in predicting cardiovascular disease, but they are troubled by artefacts caused by interactions among risk factors. So additive models have also been used. CTC biostatisticians demonstrated a method (stratified additive Poisson models) of combining multiplicative and additive components to predict risk, using data from large trials of acute myocardial infarction.[68] The method is an improvement over the multiplicative models and produced a more streamlined risk factor model by removing the need for interaction terms. The method is particularly relevant to predicting short-term mortality.

CTC BIOSTATISTICIAN ENJOYS TEACHING AND CONSULTING

'We teach the biostatistical skills required in clinical research to busy clinicians and others in this field. Although the courses are delivered online, I enjoy the regular interaction with students and being able to make a difference to their learning.

'In my current consulting role at the Kids Research Institute of the Children's Hospital Westmead, I provide advice and assistance to staff and students working in a range of areas from basic laboratory science to multicentre clinical trials. I help the researchers with many aspects of their studies, from design and data collection to analysis and interpretation of the data. I also help with presenting their results. My consulting experiences have been a very rewarding part of my career at the CTC.'

— Liz Barnes,
research fellow in biostatistics

Biostatistics and clinical trials

Responsibility for the design and data analysis of the CTC's trials lies with the biostatisticians.

CTC statisticians also collaborate with many Australian academic groups. Their work covers a wide area of health research, as illustrated by the examples described here.

The international LACE trial, led by the **University of Queensland**, compared the newer laparascopic approach and standard open abdominal surgery for endometrial cancer.[80] The CTC contributed to the trial through design and analysis of results, which showed that patients having laparascopic surgery had a much lower rate of adverse events after the surgery. If further follow-up and analysis confirm that survival is equivalent, the newer surgical approach should become the standard treatment. In the meantime, analyses of LACE data continue, answering clinical questions about risk and prediction in endometrial cancer.[63,79]

Preeclampsia is a dangerous condition of pregnancy, thought to be related to an immune response in the mother. An analysis undertaken with clinicians from **Nepean Hospital** resulted in the novel proposal that the fetal adaptive immune system may be actively involved in initiating preeclampsia.[32,162] The medical school at Nepean Hospital has also used biostatistical expertise in its studies on pelvic organ collapse, particularly after childbirth; the evidence arising is guiding surgical repair and prevention strategies.[25,26,27]

The Head and Neck Cancer Service at **Westmead Hospital** has published studies demonstrating the value of adjuvant radiotherapy for squamous cell carcinoma of the head and neck.[77,125,126]

In work with several Sydney hospitals funded by the **Dust Diseases Board**, researchers investigated factors predicting survival of patients with malignant pleural mesothelioma. They identified several factors, but especially neutrophil-to-lymphocyte ratio, a marker of inflammation, which they recommended being routinely used to stratify patients for risk level in clinical trials.[52] Health-related quality of life was also related to inflammation and survival.[53]

A study by emergency physicians at **Royal Prince Alfred Hospital** showed that introducing bias into the clinical history significantly affects the subsequent interpretation of ECGs.[21] In another study, they analysed the relationship between injury severity and resource utilisation and the relative effect of age on these costs.[28] The results, that costs increased with injury severity and that falls caused the most expensive injuries, are valuable evidence for health policy planners.

In a complex analysis with implications for health planning, Val Gebski and his colleagues from the **Centres for Disease Control and Prevention in Atlanta** investigated the effectiveness of control measures for methicillin-resistant *Staphylococcus aureus* infection (whose consequences are slow to take effect) in hospital where the interventions were implemented at different times.[36] They developed a novel step-wedge statistical model describing infection transmission.

Biostatistics group at the CTC: Andrew Martin, Anne-Sophie Veilland, Rachel O'Connell, Chee Lee, David Espinoza, Liz Barnes, Mark Donoghoe, Adrienne Kirby, Malcolm Hudson, Lucy Davies, Alan Coates and Jodie Gonzales Jennings.

Master of Clinical Trials (Research): a postgraduate course

Clinicians and health professionals are expected to have a thorough understanding of clinical trials and their regulations when conducting research and collaborating in Australia or internationally.

The online clinical trials research course offers formal qualifications in the design, conduct and interpretation of clinical trials. It was developed and is taught by the CTC and provides a qualification from Sydney Medical School at the University of Sydney.

Students—doctors, health care professionals, academics, and others working in clinical research— learn about research methods, clinical trials literature and the clinical trials process, including design, protocol development, doses of treatment, statistics and ethics.

Adrienne Kirby (left), senior lecturer, coordinates the postgraduate course in clinical trials research

'I am an ophthalmic clinician-scientist and did the BCA course one subject per semester over 6 years. Each one added to a powerful statistical toolkit that has given me confidence to handle the design and analysis aspects of all my research endeavors.

'Becoming a trained statistician has improved the quality of my research and provided an unfair advantage when writing manuscripts and grant proposals.'

— Robert Casson

'Through this course I have developed an understanding of clinical research that has enabled me to work more effectively alongside our researchers, engage the institute's operations in the research process and therefore contribute far more effectively to our research effort.'

— Kellie Ridges, operations manager at a medical research institute, is a student in the Master of Clinical Trials (Research) course

BIOSTATISTICS COLLABORATION OF AUSTRALIA— ADMINISTERED FROM THE CTC

The Biostatistics Collaboration of Australia (BCA) is a consortium of biostatistical experts from around Australia with representatives from universities, government and the pharmaceutical industry who have combined to offer a national (and international) program of postgraduate courses via an alliance of universities. The BCA program is delivered entirely by distance by consortium universities. Since the first graduating year, 2003, the BCA has had 278 graduations. In 2012, 275 students were enrolled in BCA courses.

COLLABORATIONS

The CTC works with organisations around the world in collaborations that lead to better health outcomes in Australia and internationally. New collaborations are continually sought and then consolidated in research projects benefiting the health of Australians and others.

GROUP	NATURE OF GROUP	CTC ACTIVITY
Australasian Gastro-Intestinal Trials Group (AGITG)	Collaborative group for gastrointestinal cancer trials: Australia, New Zealand International collaborations: Cancer Clinical Trials Unit Scotland (CACTUS), Eastern Cooperative Oncology Group (ECOG), European Organisation for Research and Treatment of Cancer (EORTC) , European Study Group for Pancreatic Cancer (ESPAC) , Groupe Coopérateur Multidisciplinarie en Oncologie (GERCOR), National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) , National Surgical Adjuvant Breast and Bowel Project (NSABP), Medical Research Council (MRC), Oxford Clinical Trials Office, Oxford University (OCTO) , Pan-European Trials in Alimentary Tract Cancer (PETACC)	Coordinating centre 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
Australasian Society of Thrombosis and Haemostasis	Professional group undertaking thrombosis trials: Australia, New Zealand	Coordinating centre and collaborator
Australia New Zealand Gynaecological Oncology Group (ANZGOG)	Collaborative group for gynaecological cancer trials: Australia, New Zealand 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
Australian New Zealand Clinical Trials Registry (ANZCTR)	National register of clinical trials: Australia, New Zealand and international	Coordinating centre
Biostatistics Collaboration of Australia	Universities undertaking postgraduate education in biostatistics: Australia	Coordinating centre
Cholesterol Treatment Trialists' Collaboration (CTTC)	Investigators of cholesterol treatment trials: Australia, New Zealand, United Kingdom, United States, Italy	Coordination of meta-analyses in heart disease
Clinical Trial Development Unit (CTDU)	Partnership with the Centre for Biostatistics and Clinical Trials, Peter MacCallum Cancer Institute: Australia	Trial operation and statistical support for cancer trials
Cochrane Collaboration Breast Cancer Group	Collaborative group undertaking systematic reviews of trial evidence: international	Editoral base
Cochrane Prospective Meta-Analysis Methods Group	Collaborative group undertaking systematic reviews of trial evidence: international	Coordinating centre
Cooperative Trials Group for Neuro-Oncology (COGNO)	Collaborative group for brain cancer trials: Australia International collaboration: European Organisation for Research and Treatment of Cancer (EORTC)	Coordinating centre and collaborator
Early Prevention of Obesity in Children (EPOCH) collaboration	Prospective meta-analysis collaboration: international	Data coordination centre
Fenofibrate and Event-Lowering in Diabetes (FIELD) Study Investigators	Collaborative group for FIELD diabetes trial genetic, molecular and follow-up substudies: Australia, New Zealand, Finland, Germany	Coordinating centre
INSPIRE	Meta-analysis: ASPIRE and WARFASA (Italy)	Member

GROUP	NATURE OF GROUP	CTC ACTIVITY
International Neonatal Immunotherapy Study (INIS) Study Group	Collaborative group for INIS trial: Australia, New Zealand, Europe, Argentina	Regional coordinating centre
Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group	Collaborative group for LIPID cholesterol-lowering trial genetic, molecular and follow-up substudies: Australia, New Zealand, Germany	Coordinating centre
Medical Services Advisory Committee (MSAC) and Department of Health and Ageing	Government: Australia	Assessments of new technologies and other research services
Menzies Research Institute and Charles Darwin University	Research institution: Australia	Collaborator
Meta-analysis collaboration (AMICABLE)	Meta-analysis collaboration: international	Collaborator
Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPiNO) collaboration	Meta-analysis collaboration: international	Data coordination centre
Heart Foundation	Nongovernment organisation: Australia	Cardiovascular research
National Perinatal Epidemiology Unit (NPEU), University of Oxford	Research institution: UK	Collaborator on the INIS neonatal trial
Neonatal Oxygenation Prospective Meta-analysis (NeOProM) collaboration	Prospective meta-analysis collaboration; international	Coordinating centre
NSW Cancer Council	Cancer Epidemiology Research Unit	Collaborator
Perinatal Antiplatelet Review of International Studies (PARIS) collaboration	Meta-analysis collaboration:international	Co-coordinating centre
Prenatal repeat corticosteroid international individual-patient-data study group: assessing the effects using the best level of evidence (PRECISE) collaboration	Meta-analysis collaboration: international	Collaborator
Prevention of Ventilator Induced Lung Injury collaborative study group (PreVILIG)	Meta-analysis collaboration: international	Data coordination centre
Primary Care Cancer Trials Group (PC4)	Collaborative group: Australia	Collaborator
Primary Coronary Angioplasty versus Thrombolysis (PCAT)	Meta-analysis collaboration: international	Co-coordinating centre
Prospective Pravastatin Pooling (PPP) project	Collaborative group: international	Coordinating centre
RNA-based Analysis for Prediction of Islet Death (RAPID)	Collaborative group: Australia	Collaborator
REMOVAL	Collaborative group for type 1 diabetes trial: international	Co-coordinating centre and collaborator
Royal Australasian College of Surgeons (RACS)	Professional society undertaking trials of surgery: Australia and New Zealand	Coordinating the SNAC trials in breast cancer with the RACS
Sydney Catalyst	Consortium for translational research in cancer	Collaborator
T4DM	Collaborative group for diabetes prevention trial: Australia	Co-coordinating centre and collaborator
Star Child Health	Meta-analysis collaboration: international	Member
VIGOUR group	Collaborative group for trials of heart disease: 40 countries	VIGOUR leader

CURRENT CTC TRIALS

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
NEONATAL DISORDERS			
Current trials			
APTS: Australian placental transfusion study CTC trial	Neonates born before 30 weeks' gestation	1600	300
Trials in follow-up			
BOOST II: Benefits of oxygen saturation targeting CTC trial	Neonates born before 28 weeks' gestation	1200	1135
CARDIOVASCULAR DISORDERS			
Trials in start-up			
REMOVAL: Effects of metformin added to insulin on atheroma progression University of Glasgow and NHS-led, and CTC trial	Adults with type 1 diabetes at risk of cardiovascular disease	90 (ANZ): 500 (international)	
T4DM: efficacy of adding testosterone to a lifestyle program to prevent progression to type 2 diabetes CTC study	Men with prediabetes and low testosterone	1500	
Trials in follow-up			
FIELD: Fenofibrate intervention and event lowering in diabetes	Patients with type 2 diabetes	8000	9795
LIPID: Long-term intervention with pravastatin in ischaemic disease	Patients with a history of coronary heart disease	9000	9014
BREAST CANCER (COLLABORATING WITH RACS)			
Current trials			
SNAC 2: Sentinel node biopsy versus axillary clearance *RACS and CTC study*	Women with operable breast cancer, stratified by factors including age and tumour size	1012	266
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 WITH AGITG)			
Trials in start-up			
ICECREAM: Irinotecan Cetuximab Evaluation and Cetuximab Response Evaluation Among Mutants AGITG and CTC study	Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation	100	
IMPACT: Phase 2 trial using genomic sequencing and protein expression to direct first-line treatment Garvan, AGITG and CTC study	Patients with metastatic pancreatic cancer	90	
Current trials			
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	163
ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases AGITG and CTC study	Patients with confirmed resectable liver metastases and no other disease	200	5
DOCTOR: Phase 2 trial of preoperative cisplatin, 5-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer AGITG and CTC study	Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy	150	48
GAP: Phase 2 study of gemcitabine and NAB-paclitaxel AGITG and CTC study	Patients with resectable pancreas cancer	50	3

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
INTEGRATE: Phase 2 trial comparing regorafenib and placebo **AGITG and CTC-led international study**	Patients with advanced oesophagogastric cancer	150	22
PAN1: Phase II study evaluating potential predictive biomarkers in treatment of locally advanced and metastatic pancreatic cancer **AGITG and CTC study**	Patients with confirmed metastatic pancreatic adenocarcinoma	80	8
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer **MRC-led, AGITG and CTC study**	Patients with fully resected stage III colorectal cancer	225 (ANZ): 9500 (international)	163 (ANZ): 4680 (international)
TACTIC: Phase 2 trial of panitumumab, cisplatin and gemcitabine **AGITG and CTC study**	Patients with biliary tract cancer	45	7
TOP GEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer **AGITG and CTC study**	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	64
Trials in follow-up			
Adjuvant GIST: adjuvant imatinib mesylate versus no further therapy after complete surgery (AG0403, EORTC 62024) **EORTC-led, AGITG and CTC study**	Patients with resected gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ)	81 (ANZ)
Advanced GIST: Relation between dose and clinical activity of imatinib mesylate (AG0102, EORTC 62005) EORTC-led, AGITG and CTC study	Patients with unresectable or metastatic malignant gastrointestinal stromal tumours (GIST) expressing KIT receptor	80 (ANZ): 600 (international)	116 (ANZ); 946 (international)
ATTAX 3: Phase 2 trial of docetaxel, cisplatin and fluoropyrimidine with or without panitumumab for oesophagogastric cancer (AG06070G) **AGITG and CTC study**	Patients with metastatic or locally recurrent oesophagogastric cancer	100	77
CO.20: Phase III study of BMS-582664 with cetuximab versus placebo with cetuximab **NCIC CTG-led, AGITG and CTC study**	Patients with metastatic colorectal carcinoma previously treated with combination chemotherapy	370 (ANZ); 750 (international)	416 (ANZ); 686 (international)
EORTC liver metastases: Oxaliplatin, 5-fluorouracil and leucovorin versus surgery for resectable colorectal cancer liver metastases (EORTC 40983) **EORTC-led, AGITG and CTC study**	Patients with colorectal cancer with resectable liver metastases	330 (international)	35 (ANZ); 364 (international)
LAP07: Randomised multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib **GERCOR-led, AGITG and CTC study**	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 study**	Patients with locally advanced rectal cancer	135 (ANZ); 1090 (international)	127 (ANZ); 1094 (international)
Quasar 2: Phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer (AG0107CR) **OCTO-led, AGITG and CTC study**	Patients with colon cancer treated by surgery	120 (ANZ); 1892 (international)	219 (ANZ); 1952 (international)
REGISTER: Multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response **AGITG and CTC study**	Patients with gastrointestinal stromal tumour not suitable for curative surgery	80	47

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
GYNAECOLOGICAL CANCER (COLLABORATING WITH ANZGOG)			
Current trials			
ANZGOG 1103: Phase I–II BNC105P combination study **ANZGOG study**	Women with partly platinum-sensitive ovarian cancer in first or second relapse	up to 24 Phase I (international)	5 (ANZ); 6 international
Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer **ANZGOG and CTC-led international study**	Women with locally advanced cervical cancer	780 (international)	46 (ANZ); 113 international
PARAGON: Phase II study of anastrozole in gynaecological cancers **MRC, ANZGOG and CTC-led international study**	Women with potentially hormone-responsive gynaecological cancers	350 (international)	92 (ANZ); 110 (international)
PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with with pelvic radiation alone in high-risk endometrial carcinoma **GCIG-led, ANZGOG and CTC study**	Women with advanced endometrial carcinoma	120 (ANZ); 670 (international)	89 (ANZ); 499 (international)
Symptom benefit: does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG 1103) **ANZGOG and PoCoG study**	Women with platinum-resistant or refractory ovarian cancer	800 (international)	x185 (ANZ); 317 (international)
Trials in follow-up			
ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy **MRC-led, ANZGOG and CTC study**	Women with with platinum-sensitive relapsed ovarian cancer	400 (international)	17 (ANZ); 486 (international)
ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy *MRC-led, ANZGOG and CTC*	Women with epithelial ovarian cancer who had not received systemic antitumour therapy	1444 (international)	76 (ANZ); 1450 (international)
OVAR 16: Pazopanib versus placebo for ovarian cancer **GCIG-led, ANZGOG and CTC study**	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	900 (international)	65 (ANZ); 940 (international)
SCOTROC 4: Multicentre trial of carboplatin flat dosing vs 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)
CALYPSO : phase III study 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)
Tarceva : phase III study of erlotinib versus observation (EORTC 55041) **EORTC-led, ANZGOG and CTC**	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	830 (international)	41 (ANZ), 830 (international)
Phase III randomised trial of paclitaxel + carboplatin versus triplet or sequential doublet combinations (GOG 182) **GOG-led, ANZGOG and CTC**	Women with advanced stage (FIGO III-IV) epithelial ovarian or primary peritoneal carcinoma	4200 (international)	184 (ANZ) 4312 (international)
Prospective study of risk-reducing salpingo-oophorectomy and longitudinal CA-125 screening (GOG 199) **GOG-led, ANZGOG and CTC**	Women at high risk of ovarian cancer	800 (international)	83 (ANZ); 800 (international)
TRIPOD: phase II trial of intraperitoneal chemotherapy (ANGOG-0601) **ANGOG- and CTC-led**	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			
Mitomycin C added to BCG as adjuvant intravesical therapy for bladder cancer **ANZUP and CTC study**	Patients with non-muscle-invasive bladder cancer	500	
Phase 3 trial of accelerated versus standard BEP chemotherapy of germ cell tumours **ANZUP and CTC study**	Patients with metastatic germ-cell tumours with intermediate or poor prognosis	500	

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Current trials			
SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05) MRC-led, ANZUP and CTC study	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ); 1656 (international)	2250 (ANZ); 159 (international)
Trials in follow-up			
Accelerated BEP: feasibility study of accelerated BEP as first-line chemotherapy for advanced germ cell tumours (ANZGCTG 0206, ANZGOG 0603) ANZUP, ANZGOG and CTC study	Patients with intermediate and poor-risk advanced germ-cell tumours (and selected good-risk tumours)	25	45
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
LUNG CANCER (COLLABORATING WITH ALTG)			
Current trials			
BR.26: Phase III trial of PF-804 in patients with incurable, non-small-cell lung cancer (ALTG 09/002) NCIC-led, ALTG and CTC study	Patients with stage IIIB or IV non-small-cell lung cancer	180	78
NITRO: phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for advanced non-small-cell lung cancer (ALTG 06/003) ALTG and CTC study	Patients with advanced non-small-cell lung cancer	500	250
PACT in NSCLC: Preferences for adjuvant chemotherapy in non-small-cell lung cancer ALTG and CTC observational study	Patients, surgeons and oncologists	200	122
Trials in follow-up			
B2P2M2: phase II trial of BNC105P as second-line chemotherapy for pleural mesothelioma (ALTG 09/004) ALTG and CTC study	Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy	30	30
BRAIN TUMOURS (COLLABORATING WITH COGNO)			
Trials in start-up			
Phase II study of acetazolamide plus dexamethasone versus dexamethasone for cerebral oedema in high-grade glioma COGNO and CTC study	Patients with high-grade glioma requiring new dexamethasone or dose increase due to progressive or recurrent disease	86	
Phase II study of psycho-educational intervention in patients with primary brain tumour PoCoG-led and COGNO study	Patients with confirmed primary brain tumours	60	
Current trials			
CABARET: Phase II study of carboplatin and bevacizumab in recurrent glioblastoma multiforme COGNO and CTC study	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); 47 (part 2)
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC 26053-22054) EORTC-led COGNO and CTC study	Patients with non-1p/19q- deleted anaplastic glioma	100 (ANZ); 748 (international)	43 (ANZ); 419 (international)
SEED: Self-reported evaluation of the adverse effects of dexamethasone COGNO and CTC study	Patients with brain tumours or brain metastases or advanced cancer using steroids	50 patients, 50 caregivers	12
Trials in follow-up			
LGG: Phase III study of primary chemotherapy with temozolomide versus radiotherapy (TROG 06.01, EORTC 22033-26033) EORTC, COGNO, TROG and CTC study	Patients with low-grade glioma, stratified for genetic 1p loss	100 (ANZ); 560 (international)	79 (ANZ); 419 (international)

Staff

CTC EXECUTIVE

R John Simes, BSc(Med)(hons), MB BS(hons), MD, SM, FRACP, director and senior principal research fellow

Anthony C Keech, MB BS, MSc, FRACP, deputy director and principal research fellow

Wendy Hague, MB BS, MBA, PhD, director, clinical trials program, and senior research fellow

Kim Russell-Cooper, BA(hons), MBA, general manager

Executive support

Thalia Hambides, executive assistant to the director

Katie Doyle, executive assistant to the deputy director

ONCOLOGY TRIALS

Martin R Stockler, MB BS(hons), MSc, FRACP, cancer trials co-director and associate professor

Venu G Chalasani, MB BS, FRACP, clinical research fellow, ANZUP

Rasha Cosman, BSc(Med), MBBS, FRACP, clinical research fellow, ALTG and COGNO

Danielle Ferraro, MB BS (hons), FRACP, clinical research fellow, ALTG and AGITG

Belinda Kiely, BSc(Med), MB BS, FRACP, senior clinical research fellow, ANZUP

Chee K Lee, MB BS(hons), MB BS(hons), MMedSc, MBiostat, PhD, FRACP, senior clinical research fellow

Katrin M Sjoquist, BSc(Med), MB BS, FRACP, clinical lead , AGITG and ANZGOG trials

Dirkje Sommejier, MD, PhD, clinical research fellow, AGITG and ANZGOG

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

Oncology trials managers

Burcu Vachan, BSocSc(hons), MPH, DipMan, oncology program manager

Amy L Boland, BPsych(hons), GradCertHlthSc, senior associate program manager, AGITG

Xanthi Coskinas, BHlthSc, GradDipHIM, MSc(ClinEpi), associate program manager, ALTG

Trevor France, BSc, BTeach, senior associate program manager, ANZUP

Ann Livingstone, RN, MHlthServMgt, associate program manager, COGNO

Julie Martyn, BSc, GradDip HortSc, PhD, associate program manager, ANZGOG

Danielle Miller, BSc(hons), MPH, associate program manager, PC4, Sydney Catalyst research manager

Kate Wilson, BA, MPH, associate program manager, AGITG

Nicole Wong, RN, BN, BSc(hons), associate program manager, AGITG

Oncology trials staff

Hani Adhami, BAppSc, MHlthSc

Christine Aiken, BSocSc, MHlthSc

Lisa Bailey, BAppSc

Lesley Brassel, BMgmt

Hannah Cahill, BAppSc, BA

David Cannan, BSc(hons)

Kerrie Carlton, BAppSc, MSc, GradDipBioethics

Sarah Chinchen, BSc(hons), MPH

Rachel Cole, BA

Michelle M Parry, BSc, PhD

Fabyolla El-Tahche, BSc

Kim Gillies BA(hons), MHlthSc

Merryn Hall, BSc

Ilka Kolodziej, BAppSc(hons), MPH

Alan Lucas, BAppSc

Oliver Martyn, BExPhys

Angus McDonald, BEc(SocSc)

Jenna Mitchell, BHSc(hons)

Karen Miranda, BBiomedSc

Nick Muljadi, BSc(hons)

Daniel Obanda, BSc, PhD

Sophie Quiene, BSc, MSc

Kate Roff, BSc(hons)

Kate Sawkins, BAppSc(Phty)(hons)

Bhagwant Sekhon, BSc, MHerbMed

Shona Silvester, BSc, MMedSc

Helen Taylor, BSc, PhD

Jennifer Thompson, Cert IV BusAdmin

Bernadette Tomes, BClinSc

Eric Tsobanis, BScN(hons), MBA

Diana Winter, BMedSc

COOPERATIVE TRIALS GROUP FOR NEURO-ONCOLOGY

Jenny Chow, executive officer

Yi Feng, administrative assistant, BE(aeronautical)

NEONATAL TRIALS

William O Tarnow-Mordi, MRCP(UK), FRCPCH, coordinator of neonatal trials

INIS and APTS trials

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

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

BOOST II trial

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

Nick Muljadi, BSc(hons), clinical trial assistant

CARDIOVASCULAR TRIALS

ASPIRE

Rebecca Mister, BSc, MSc, project manager

Alan Lucas, BAppSc

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

FIELD follow-up

Li Ping Li, BMed, GradCertDM, project manager

San Yip Chan, administrative assistant

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

LIPID follow-up

Helen Pater, BAppSc, project manager

DIABETES

REMOVAL

Helen Pater, BAppSc, project manager

T4DM

Karen Bracken, BEc, MPH, project manager

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

QUALITY ASSURANCE

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

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

CLINICAL DATA MANAGEMENT

Mark Maclean, BA, DCR(T), CM, head

Salma Fahridin, BAppSc(HIM), MHlthSc, clinical data coordinator

Liam Murphy, BSc, clinical data coordinator

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

Lindsay Stevens, BSc, clinical data coordinator

SITE MANAGEMENT

Rebecca Mister, BSc, MSc, head

DIABETES MOLECULAR MEDICINE AND TELEHEALTH

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

Sven-Erik Bursell, PhD, professor of telehealth

David Calandro, BSc, research assistant

Veronica Dy, PhD, clinical trials assistant

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

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

Andrzej S Januszewski, MD, PhD, senior research fellow

Thomas McCorquodale, BSc, clinical trials assistant

Sarang Satoor, BSc, MSc, research fellow
Wilson Wong, BSc(hons), research assistant

SYSTEMATIC REVIEWS AND HEALTH TECHNOLOGY ASSESSMENT

Lisa M Askie, BN, MPH, PhD, director, and senior research fellow
Jenny Chow, AssocDip, executive officer
Sally J Lord, MB BS, DipPaed, MS, FRACGP, epidemiologist and research fellow
Lukas Staub, Dr med, DAS, project officer
Nicholas RC Wilcken, MB BS, FRACP, PhD, consultant

Health technology assessment

Martin Flattery, BSc, MSc project manager
Samara Lewis, BA/BSc(hons), PhD, project manager (maternity leave)
Toby Gould, BA, BSc, MPH, project officer
Anna Stoklosa, BA, MA, PhD, project officer
Sally Wortley, BHlthSc(hons), MPH, Grad Cert Hlth Econ, project officer

Cochrane breast cancer review group

Melina Willson, BSc (hons)/BA, PhD, project manager
Fergus Tai, BAppSc, DipIT, MPH, trials search coordinator

Australian New Zealand Clinical Trials Registry

Kylie E Hunter, BA, BA(hons), project officer
Henry CH Ko, BEng(Med)(hons), PhD, project officer
William YT Ooi, MHlthSc, BAppSc, project officer

HEALTH ECONOMICS

Deborah J Schofield, BSpPath, GradDipComp, PhD, professor
Emily J Callander, BA, research officer
Rupendra N Shrestha, MSc, PhD, research fellow
Hannah Carter (Verry), BEc, health economist
Jean Yarbrough, MMath, research officer

BIOSTATISTICS AND CONSULTING

Val J Gebski, BA, MStat, professor and principal research fellow
Alan S Coates, AM, AStat, MD, FRACP, clinical professor
Kew Flood, administrative officer
H Malcolm Hudson, BSc(hons), PhD, honorary professor
Ian C Marschner, BSc(hons), PhD, professor

Senior biostatisticians

Karen Byth (Wilson), BSc(hons), MSc, PhD, DIC, CStat RSS, senior lecturer
Adrienne C Kirby, BSc(hons), MSc, senior lecturer
Andrew J Martin, BA, MA, GradDip, PhD, AStat, senior lecturer

Research fellows

Elizabeth E Barnes, BAppSc, MStat
Christopher SB Brown, BSc
Diana Zannino, BSc(hons), MSc

Biostatisticians

Mark D Chatfield, BA, MSc
Mark W Donoghoe, BSc(hons)
David Espinoza, BSc(hons)
Marion Fournier, MSc
Kristy P Mann, BScAgr(hons)
Rachel L O'Connell, BMath, MMedStat, PhD
Anne-Sophie Veillard, BSc, MSc

BIOSTATISTICS COLLABORATION OF AUSTRALIA (BCA)

Erica Jobling, executive officer
Helen Johnson, BA, MMuseumStud

INFORMATION SYSTEMS

Infrastructure

Dinh Tran, BMath, MCompSc, infrastructure manager
Asanka Perera, BSc, 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
Mira Mikulic, receptionist
Lia Sherwood, BBiomedSc, MSc, grants and contracts coordinator

Finance

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

Human resources

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

PUBLICATIONS

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

RESEARCH STUDENTS

Prunella Blinman, BMed, FRACP
Jordan Fulcher, BSc(Med), MB BS,
Deme Karikios, BSc, MB BS, FRACP
Annette Kifley, MB BS, MAppStat
Zhixin Liu, PhD
Kushwin Rajamani, MB BCh
Michaella Smith, BSc, MB BS(hons), MMSc
Ru-Dee Ting, MB BS, FRACP

ACADEMIC STAFF

Lisa M Askie, BN, MPH, PhD, senior research fellow
Elizabeth E Barnes, BAppSc, MStat, research fellow
Christopher SB Brown, BSc, research fellow
Karen Byth, BSc(hons), MSc, PhD, DIC, CStat RSS, senior lecturer
Emily J Callander, BA, research officer
Hannah Carter (Verry), BEc, research associate
Val J Gebski, BA, MStat, principal research fellow and professor
Toby Gould, BA, BSc, MPH, associate lecturer
Wendy Hague, MB BS, MBA, PhD, senior research fellow
Anandwardhan A Hardikar, BSc, MSc, PhD, associate professor
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, principal research fellow and professor
Adrienne C Kirby, BSc(hons), MSc, senior lecturer
Chee K Lee, MB BS(hons), MMedSc, MBiostat, PhD, FRACP, research fellow
Sally (Sarah) J Lord, MB BS, DipPaed, MS, FRACGP, research fellow
Andrew J Martin, BA, MA, GradDip, PhD, AStat, senior lecturer
Rachel L O'Connell, BMath, MMedStat, PhD, 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, FRACP, clinical research fellow
Martin R Stockler, MB BS(hons), MSc, FRACP, associate professor
Sonia Yip, BSc(hons), PhD, senior research fellow

Honorary associates of the CTC

Associate Professor Meera R Agar, COGNO scientific advisory committee
Dr Andrew Barbour, PI, DOCTOR and GAP trials (AGITG)
Dr Sally Baron-Hay, ANZGOG executive
Dr David Bernshaw, 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 Alison Brand, ANZGOG executive
Dr Timothy Brighton, PI, ASPIRE trial
Dr Ian Campbell, PI, SNAC 2 trial
Professor Christopher Christophi, AGITG management committee
Dr Yu Jo Chua, PI, PAN1 trial (AGITG)
Professor Forrester Cockburn, BOOST II trial Safety and Data Monitoring Committee
Professor Alan Coates, Biostatistics
Ms Melinda Cruz, LIFT study
Dr Andrew Davidson, PI NITRO trial (ALTG)
Associate Professor Ian D Davis, PI, SORCE trial and chair, ANZUP
Dr Jayesh Desai, PI, REGISTER trial (AGITG)
Dr Katherine Drummond, COGNO management committee
Dr John Eikelboom, co-PI, ASPIRE and PREDICT trials
Dr Jonathan Fawcett, co-PI, ATTACHE trial (AGITG)
Dr Kathryn Field, PI, CABARET trial (COGNO)
Ms Marcia Fleet, COGNO management committee
Dr Matthew Foote, COGNO management committee
Dr Michael Friedlander, ANZGOG executive and PI, GOG182, TRIPOD, OVAR16, Symptom Benefit and PARAGON trials
Professor Alexander Gallus, ASPIRE trial management committee
Dr Davina Ghersi, Australian New Zealand Clinical Trial Registry advisory committee and CTC adjunct professor
Professor P Grantley Gill, PI, SNAC trial
Dr David Goldstein, PI, LAP07 trial, co-PI, ATTACHE trial, AGITG board
Dr Andrew M Haydon, PI, SCOT trial (AGITG)
Professor Dickon Hayne, PC4 trial, ANZUP
Dr Elizabeth Hovey, COGNO executive
Dr H Malcolm Hudson, Biostatistics
Dr Monika Janda, COGNO scientific advisory committee
Dr Michael Jefford, SCOT trial (AGITG)
Professor Alicia Jenkins, FIELD trial management committee
Dr Terrance Johns, COGNO management committee
Dr David J Joseph, COGNO scientific advisory committee
Dr Andrew Kneebone, AGITG
Dr Eng-Siew Koh, COGNO management committee
Ms Robyn Leonard, COGNO management committee
Dr Trevor Leong, PI, TOP GEAR, Gastric trial (AGITG)
Professor G Bruce Mann, PI, EORTC 62063 trial (AGITG)
Dr Kerrie McDonald, COGNO scientific advisory committee
Dr Sue-Anne McLachlan, PACT in SCLC (ALTG)
Associate Professor Peter Meikle, LIPID and FIELD studies
Dr Michael Michael, PI, TOPGEAR trial (AGITG)
Dr Linda Mileshkin, ANZGOG executive, PI,PORTEC-3 and OUTBACK trials
Dr Jeremy Millar, PI, START trial(ANZUP)
Professor Michael J Millward, PI, BR26 trial (ALTG)
Professor Anna Nowak, PI, CATNON trial (COGNO)
Professor Andreas Obermair, ANZGOG executive
Dr Robert Padbury, AGITG
Professor Lyle J Palmer, Dr Nicholas J Petrelli, AGITG
Associate Professor Timothy J Price, PI, PETACC6 trial (AGITG)
Professor Michael Quinn, ANZGOG chair
Dr Kushwin Rajamani, FIELD study
Dr David T Ransom, PI, SCOT and ARCTIC trials (AGITG)
Dr Danny Rischin, ANZGOG executive
Dr Mark Rosenthal, COGNO chair
Associate Professor Eva Segelov, PI, ICECREAM, QUASAR2 and SCOT trials (AGITG)
Dr Shomik Sengupta, ANZUP
Dr Jennifer A Shannon, PI, TACTIC trial (AGITG)
Dr Bernard M Smithers, TOPGEAR trial (AGITG)
Dr Benjamin Solomon, PI, BR24 trial (ALTG)
Dr Nigel A Spry, AGITG
Dr Christopher Steer, ANZGOG executive, PI ,TARCEVA trial
Dr Andrew R Stevenson, PI, A La CART(AGITG)
Mr John Stubbs, patient advocate, oncology
Associate Professor David Sullivan, LIPID and FIELD trial management committees
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
Associate Professor Guy Toner, ANZUP executive
Dr Andrew Tonkin, BiomarCare, LIPID study chair
Dr Paul Vasey, PI, SCOTROC4 trial (ANZGOG)
Dr Michelle Vaughan, ANZGOG executive, PI ICON6
Dr David G Walker, COGNO scientific advisory committee
Dr Euan Walpole, PI, SCOT trial (AGITG)
Dr Neil Wetzig, co-PI, SNAC trial
Professor Gary Wittert, PI, T4DM trial
Dr Desmond Yip, SCOT (AGITG)
Professor John Zalcberg, AGITG chair

Staff activities

SUPERVISION OF RESEARCH DEGREES

John Simes
- Claudia Dobler, PhD
- Manjula Schou: PhD

Anthony Keech
- Dijana Bosnjak: MPhil
- Jordan Fulcher: PhD
- Jason Harmer: PhD
- Kushwin Rajamani: PhD
- Suraya Sutanto: PhD
- Ru-Dee Ting: PhD

Lisa Askie
- Angela Carberry: PhD

Val Gebski
- Mithilesh Dronavalli: MMedSc
- Annette Kifley: PhD
- Zhixin Liu: PhD
- Farnoush Noushi: PhD
- Manjula Schou: PhD

Anandwardhan Hardikar
- Ryan Farr: PhD
- Wilson Wong: MPhil/PhD
- Michael Williams: PhD
- Malcolm Hudson
- Prunella Blinman: PhD
- Zhixin Liu: PhD

Alicia Jenkins
- Paul Benitez Aguirre: PhD
- Yoon Hi Cho: PhD
- Andrzej Januszewski: MCT
- Ben Ma: PhD
- Jon Noonan: PhD
- Kushwin Rajamani: PhD
- Harris Schlen: PhD
- Ru-Dee Ting: PhD

Sally Lord
- Jillian Patterson: MBiostat

Andrew Martin
- Claudia Dobler, PhD

Deborah Schofield
- Emily Callander: PhD
- Hannah Carter (Verry): PhD
- Deme Karikios: PhD

Rupendra Shrestha
- Emily Callander: PhD
- Hannah Carter (Verry): PhD

Martin Stockler
- Prunella Blinman: PhD
- Lesley Shan Wu Chim: PhD
- Deme Karikios: PhD
- Belinda E Kiely: PhD
- Michaella Smith: PhD

DEGREES COMPLETED IN 2012

Chee K Lee: PhD

Kristy Mann: MBiostat

Lukas Staub: PhD

Anna Stoklosa: PhD

EXTERNAL COMMITTEES

John Simes
- Australia & New Zealand Breast Cancer Trials Group (ANZBCTG) scientific advisory committee
- Aspirin to Prevent Recurrent Venous Thrombo-embolism (ASPIRE) trial management committee (chair)
- Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee, operations executive committee, MAX trial management committee
- Australian New Zealand Clinical Trials Registry (ANZCTR) policy advisory committee
- Cholesterol Treatment Trialists Collaboration (CTTC) (joint coordinator)
- Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee (deputy chair), management committee, operations executive
- Benefits of Oxygen Saturation Targeting (BOOST) II trial management committee
- Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee, executive, and cost-effectiveness subcommittee
- Intensive Blood Pressure Reduction for Acute Cerebral Haemorrhage Trial (INTERACT) safety and data monitoring committee (chair)
- International Breast Cancer Intervention Study (IBIS-II) international steering committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-embolism (INSPIRE) steering committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee (chair)
- Kanyini GAP Polypill Study safety and data monitoring committee (chair)
- Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee, executive, and biomarker subcommittee
- National Health and Medical Research Council Academy
- NHMRC Clinical Trials Centre management review committee and scientific advisory committee
- Sentinel Biopsy versus Axillary Clearance (SNAC) trial management committee
- Sydney Catalyst governing council and scientific advisory committee
- *Trials* associate editor
- Virtual Coordinating Centre for International Collaborative Cardiovascular Research (VIGOUR) statistical group (chair) and a VIGOUR leader

Anthony Keech
- Cholesterol Treatment Trialists' Collaboration (CTTC) (joint coordinator and convenor)
- FAME-1 diabetes trial steering committee (chair)
- Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee (principal investigator and study chairman), and quality-of-life and cost-effectiveness, ophthalmology, and scientific substudies committees
- Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) study management committee and executive
- NHMRC Clinical Trials Centre management review committee and scientific advisory committee
- National Health and Medical Research Council grant review panel
- *PLoS Medicine* editorial board
- REMOVAL trial steering committee
- Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Lisa Askie
- Antenatal Magnesium IPD International Collaboration (AMICABLE) individual patient data collaboration steering committee
- Cochrane Collaboration prospective meta-analysis methods working group (co-convenor) and methods editorial board
- Early Prevention of Childhood Obesity (EPOCH) prospective meta-analysis collaboration steering committee (chair)
- International Clinical Trials Registry Platform, World Health Organization, best practice group
- International Forum for Standards for Research in Children sample size and data safety monitoring committee subcommittee
- Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPINO) Collaboration steering group
- Neonatal Oxygen Prospective Meta-analysis (NeOProM) collaboration steering committee (chair)
- NHMRC Project Grant Review Panel for Clinical Trials
- Perinatal Antiplatelet Review of International Studies (PARIS) collaboration steering committee (chair)
- *PLoS ONE* academic editor
- Prenatal Repeat Corticosteroid International IPD Study Group: Assessing the Effects Using the Best Level of Evidence (PRECISE) steering committee
- Prevention of Ventilation Induced Lung Injury Collaborative Group (PREVILIG) steering committee
- Royal Prince Alfred Hospital clinical trials (ethics) subcommittee
- *Systematic Reviews* editorial board

Elizabeth Barnes
- Outback trial management committee (ANZGOG)
- DOCTOR trial management committee (AGITG)

Amy Boland
- Australasian Gastro-Intestinal Trials Group (AGITG) trials operations committee, upper and lower working parties
- INTEGRATE trial operations executive

Christopher Brown
- Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee, operational executive committee; NITRO trial management committee, B2P2M2 trial management committee
- Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee, operational executive committee; CABARET trial management committee; SEED trial study management committee

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

Xanthi Coskinas

- Australasian Lung cancer Trials Group (ALTG) scientific advisory committee, operational executive committee; NITRO trial management committee, B2P2M2 trial management committee, PACT in NSCLC trial management committee

Trevor France

- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations executive committee, scientific advisory committee, and Accelerated BEP, Aprepitant and EVERSUN trial management committees
- Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees, and CABARET and CATNON trial management committees

Val Gebski

- AGITG scientific advisory committee and MAX, TOPGEAR, IMPACT, PAN-1, ATTACHE, ATTAX3, TACTIC, DOCTOR, ICECREAM and REGISTER trial management committees
- ANZ BCTG scientific advisory committee
- ANZGOG Research Advisory Committee and PARAGON and OUTBACK trial management committees
- ANZUP scientific advisory committee and Accelerated BEP and EVERSUN trial management committees
- Australasian Kidney Trials Network advisory board
- Biostatistics Collaboration of Australia steering and teaching committees
- Crown Princess Mary Cancer Care Centre (Westmead) Radiation Oncology research committee
- GCIG/GINECO GCIG intergroup study comparing pegylated liposomal doxorubicin (Caelyx) and carboplatin versus paclitaxel and carboplatin in patients with epithelial ovarian cancer trial management committee
- Group statistician: Australia & New Zealand Breast Cancer Trials Group (ANZBCTG); Australasian Gastro-Instestinal Trials Group (AGITG); Australian New Zealand Gynaecological Oncology Group (ANZGOG); Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP); Trans-Tasman Radiation Oncology Group (TROG)
- Independent safety and data monitoring committees: Bevacizumab use in platinum-resistant epithelial ovarian cancer; CLASSIC (Adjuvant Chemotherapy versus Surgery in Gastric Adenocarcinoma); GAS (Effect of Spinal versus General Anaesthesia in Neonates undergoing Hernia Repair); TO2RPIDO (Targeted Oxygenation in the Resuscitation of Premature Infants and their Developmental Outcome)
- LACC (Laparoscopic Surgery versus Hysterectomy in Patients with Cervical Cancer) trial management committee
- LACE (Laparoscopic Surgery versus Hysterectomy in Patients with Endometrial Cancer) trial management committee
- LATER, NeoGem, GALA and SORBET trial management committees
- NSW Health Central Sydney Area ethics committee clinical trials subcommittee
- SNAC trial management committee
- T4DM trial management committee

Alpana Ghadge

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

Wendy Hague

- Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee
- Australasian Gastro-Intestinal Trials Group (AGITG) trials operations committee
- Australia New Zealand Gynaecological Oncology Group (ANZGOG) trials operations committee
- A La CaRT trial management committee
- Australian Placental Transfusion Study (APTS) management committee
- Benefits of Oxygen Saturation Targeting (BOOST II) management committee
- Cancer Australia Clinical Trials Development Unit (CTDU) program management committee and strategic advisory committee
- Cancer Institute NSW human research ethics committee
- Cancer Institute NSW infrastructure grant subcommittee
- International Neonatal Immunotherapy Study (INIS) Australian and New Zealand management committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee
- Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee
- Sentinel Biopsy versus Axillary Clearance (SNAC) 1 and SNAC 2 trial management committees

Anandwardhan Hardikar

- Islet Society, Stockholm, Sweden, vice-president
- *Islets* editorial board
- Lifestyle Interactions in Fenofibrate and the Epigenome (FIELD-LIFE), co-investigator
- *MicroRNAs in Diabetes and Obesity,* editor-in-chief
- NHMRC Grant Review Panel member for Diabetes/ Obesity/ Stem cell panels
- NHMRC Translational Research Faculty member
- *Review of Diabetic Studies,* editorial and review board
- RNA-based Analysis for Prediction of Islet Death (RAPID), principal investigator
- Special issue on non-coding RNAs, *Experimental Diabetes Research*, chief guest editor
- *Stem Cells and Discovery*, editor
- *World Journal of Diabetes,* editorial board

Alicia Jenkins

- Australian Diabetes Society council member and treasurer
- Insulin For Life Australia and Global and Insulin For Life USA board member
- International Diabeted Federation Life For a Child program board member
- REMOVAL study of metformin in type 1 diabetes, co-principal investigator and Australian lead
- TEAMSNET telehealth initiative principal investigator

Adrienne Kirby

- Combination Antibiotic Treatment for Methicillin Resistant Staphylococcus Aureus (CAMERA) trial management committee
- Faculty of Medicine, University of Sydney postgraduate coursework committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee
- Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee
- Randomised Trial on Surgical Treatment for Otitis Media in children Living in Remote Australian Communities trial management committee
- Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Ann Livingstone

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

Sally Lord

- Protocol Advisory Committee (PASC) for Medical Services Advisory Committee
- European Federation of Clinical Chemistry and Laboratory Medicine Test Evaluation Working Group
- McMaster University Evidence-based Practice Center assessment of the Use of Natriuretic Peptide Measurement in the Management of Heart Failure

Andrew Martin

- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee
- BLOCADE safety data monitoring committee
- ONTRAC, ProCare, INTEGRATE, EPOCH, NeuHorizons, LIFT and EVERSUN trial management committees

Julie Martyn

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

Danielle Miller

- Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee and TOPGEAR trial management committee
- Primary Care Collaborative Cancer Clinical Trials Group (PC4) operations team and scientific advisory committee
- Sydney Catalyst operations committee and executive committee

Rebecca Mister

- Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee
- Rachel O'Connell
- PARAGON and Symptom Benefit trial management committees (ANZGOG)
- PAN-1 and TOPGEAR trial management committees (AGITG)

Rhana Pike

- Australasian Medical Writers Association executive committee

Deborah Schofield

- Australian Government Department of Health and Ageing Professional Programs and Services Advisory Committee (PPSAC) research and development committee,
- Department of Health North Coast Area Health Service workforce development plan implementation steering committee
- Health Workforce Australia expert reference group
- University of Sydney School of Public Health research committee
- University of Sydney vice-chancellor's health strategy group for intergovernmental relations

Lucille Sebastian

- International Neonatal Immunotherapy Study (INIS) Australian and New Zealand management committee
- Australian Placental Transfusion Study (APTS) management committee
- Australian Placental Transfusion Study echocardiography substudy management committee

Katrin Sjoquist

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

Martin Stockler

- Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee and operations executive
- Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee (convenor)
- Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee, operations executive and Accelerated BEP, Aprepitant, Chemo & Cognition and EVERSUN trial management committees
- Cancer Council Australia national oncology education committee
- European Union Health & Innovation grant review board
- *Journal of Clinical Oncology* editorial board
- National Cancer Institute (NCI) Intergroup health related quality-of-life 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 USMP cancer planning committee

Burcu Vachan (to September)

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

Anne-Sophie Veillard

- ATTAX3 trial management committee

Kate Wilson

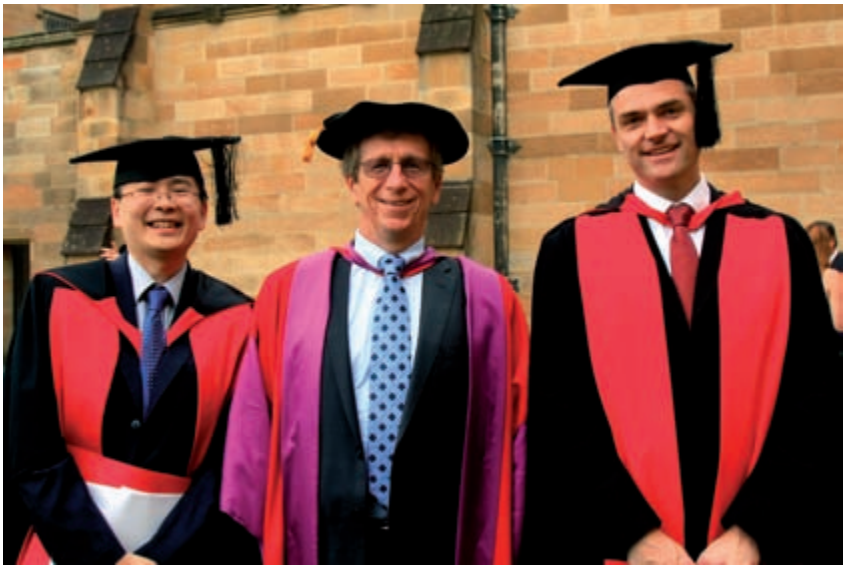
- Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee, scientific advisory committee, study coordinators subcommittee (chair), annual scientific meeting committee, and MAX, Quasar 2, PETACC6, A La CaRT and SUPER trial management committees
- Cancer Institute NSW infrastructure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

Nicole Wong

- Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee and ATTACHE, LAP07, SCOT, ATTAX 3, PAN1 and TACTIC trial management committees

Sonia Yip

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



Chee Lee and Lukas Staub, University of Sydney PhD graduates with supervisor, Professor John Simes

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

- Basic sciences in oncology, NSW Cancer Council
- Principles of statistical inference, and teaching committee, Biostatistics Collaboration of Australia
- Understanding trials methods, Master of Clinical Trials, University of Sydney

Christopher Brown

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

Mark Donoghoe

- Basic sciences in oncology, Health Education and Training Institute
- Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

Val Gebski

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

Wendy Hague

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

Adrienne Kirby

- Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney
- Trial design and methods, Master of Clinical Trials, University of Sydney (coordinator)
- Master of Clinical Trials, University of Sydney (course coordinator)

Chee Lee

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

Sally Lord

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

Kristy Mann

- Advanced systematic reviews, Master of Clinical Epidemiology, University of Sydney
- Basic sciences in oncology, NSW Cancer Council
- Critical appraisal of evidence and Understanding trial methods, Master of Clinical Trials, University of Sydney

Andrew Martin

- Decision analysis (coordinator) and Controlled clinical trials (coordinator), Master of Public Health and Master of Medicine, 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 fClinical Trials Research, University of Sydney

Rachel O'Connell

- Principles of statistical inference, Biostatistics Collaboration of Australia (coordinator)
- Advanced trial design, Master of Clinical Trials Research, University of Sydney

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

Katrin Sjoquist
- Evidence-based medicine, University of Sydney Medical Program
- Australia & Asia-Pacific Clinical Oncology Research Development (ACORD) faculty

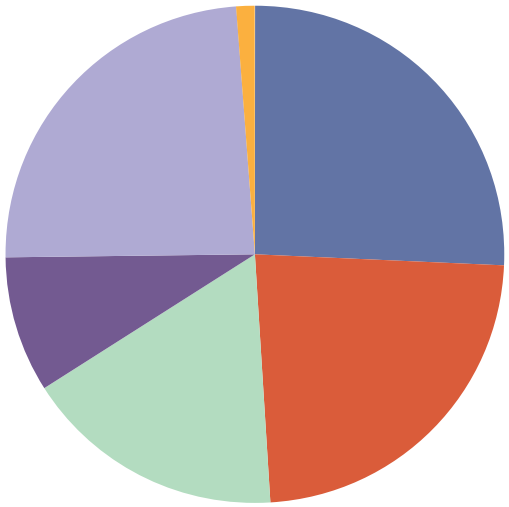
Martin Stockler
- Australia & Asia-Pacific Clinical Oncology Research Development (ACORD) convenor, and international steering committee workshop (chair)
- Making sense of cancer clinical trials for NSW medical oncology trainees (convenor)
- Clinical epidemiology for physician trainees, Royal Prince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

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

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

CTC's research funding



Publications

JOURNAL ARTICLES

1. Alexandre J, **Brown C,** Coeffic D, Raban N, Pfisterer J, Maenpaa J, Chalchal H, Fitzharris B, Volgger B, Vergote I, Pisano C, Ferrero A, Pujade-Lauraine E. CA-125 can be part of the tumour evaluation criteria in ovarian cancer trials: experience of the GCIG CALYPSO trial. *British Journal of Cancer* 2012; 106(4).
2. Baker J, Obermair A, **Gebski V,** Janda M. Efficacy of oral or intrauterine device-delivered progestin in patients with complex endometrial hyperplasia with atypia or early endometrial adenocarcinoma: A meta-analysis and systematic review of the literature. *Gynecologic Oncology* 2012; 125: 263–270.
3. Beith JM, Oh B, **Chatfield MD,** Davis E, Venkateswaran R. Electroacupuncture for nausea, vomiting, and myelosuppression in women receiving adjuvant chemotherapy for early breast cancer: a randomized controlled pilot trial. *Medical Acupuncture* 2012; 24(4): 241–248.
4. Best JD, Drury PL, Davis TME, Taskinen MR, Kesäniemi YA, Scott R, **Pardy C, Voysey M, Keech AC,** on behalf of the FIELD study investigators. Glycemic control over 5 years in 4900 people with type 2 diabetes: real-world diabetes therapy in a clinical trial cohort. *Diabetes Care* 2012; 35(5): 1165–1170.
5. Blinkhorn F, Brown N, Freeman R, Humphris G, **Martin A,** Blinkhorn A. A phase II clinical trial of a dental health education program delivered by Aboriginal health workers to prevent early childhood caries. *BMC Public Health* 2012; 12: 681.
6. **Blinman P,** King M, Norman R, Viney R, **Stockler MR.** Preferences for cancer treatments: an overview of methods and applications in oncology. *Annals of Oncology* 2012; 23(5): 1104–1110.
7. Blumenthal N, **Byth K,** Eastman CJ. Iodine intake and thyroid function in pregnant women in a private clinical practice in northwestern Sydney before mandatory fortification of bread with iodised salt. *Journal of Thyroid Research* 2012: 798963.
8. Boekholdt SM, Arsenault BJ, Mora S, Pedersen TR, LaRosa JC, Nestel PJ, **Simes RJ,** Durrington P, Hitman GA, Welch KM, DeMicco DA, Zwinderman AH, Clearfield MB, Downs JR, Tonkin AM, Colhoun HM, Gotto AM, Ridker PM, Kastelein JJ. Association of LDL cholesterol, non-HDL cholesterol, and apolipoprotein B levels with risk of cardiovascular events among patients treated with statins: a meta-analysis. *JAMA* 2012; 307(12): 1302–1309.
9. Brighton TA, Eikelboom JW, **Mann K, Mister R,** Gallus A, Ockelford P, Gibbs H, **Hague W,** Xavier D, Diaz R, **Kirby A, Simes J,** ASPIRE Investigators. Low-dose aspirin for preventing recurrent venous thromboembolism. *New England Journal of Medicine* 2012; 367(21): 1979–1987.
10. Brundage M, Gropp M, Mefti F, **Mann K,** Lund B, **Gebski V,** Wolfram G, Reed N, Pignata S, Ferrero A, **Brown C,** Eisenhauer E, Pujade-Lauraine E. Health-related quality of life in recurrent platinum-sensitive ovarian cancer—results from the CALYPSO trial. *Annals of Oncology* 2012; 23(8): 2020–2027.
11. **Callander EJ, Schofield DJ, Shrestha RN,** Kelly SJ. Sufficient education attainment for a decent standard of living in modern Australia. *Journal of Social Inclusion* 2012; 3(1): 7-20.
12. **Callander EJ, Schofield DJ, Shrestha RN.** Capacity for freedom: a new way of measuring poverty amongst Australian children. *Child Indicators Research* 2012; 5(1): 179-198.
13. **Callander EJ, Schofield DJ, Shrestha RN.** Capacity for freedom: using a new poverty measure to look at regional differences in living standards within Australia. *Geographical Research* 2012; 50(4): 411–420.
14. **Callander EJ, Schofield DJ, Shrestha RN.** Multiple disadvantages among older citizens: what a multidimensional measure of poverty can show. *Journal of Aging & Social Policy* 2012; 24(4): 368–383.
15. **Callander EJ, Schofield DJ, Shrestha RN.** Towards a holistic understanding of poverty: a new multidimensional measure of poverty for Australia. *Health Sociology Review* 2012; 21(2): 141-155.
16. **Chan KH, O'Connell RL,** Sullivan DR, Hoffmann LS, **Rajamani K,** Whiting M, **Donoghoe MW,** Vanhala M, Hamer A, Yu B, Stocker R, Ng MK, **Keech AC,** on behalf of the FIELD study investigators. Plasma total bilirubin levels predict amputation events in type 2 diabetes mellitus: the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study. *Diabetologia.* Published online 17 Jan 2013.
17. Chen Y, Hu Y, Lin M, **Jenkins AJ, Keech AC,** Mott R, Lyons TJ, Ma JX. Therapeutic effects of PPARα agonists on diabetic retinopathy in type 1 diabetes models. *Diabetes.* Published online 5 Oct 2012.
18. Cholesterol Treatment Trialists' (CTT) Collaboration; Emberson JR, Kearney PM, Blackwell L, Newman C, Reith C, Bhala N, Holland L, Peto R, **Keech A,** Collins R, **Simes J,** Baigent C. Lack of effect of lowering LDL cholesterol on cancer: meta-analysis of individual data from 175 000 people in 27 randomised trials of statin therapy. *PLoS One* 2012; 7(1): e29849.
19. Coburn N, Beldham-Collins R, Westling J, Trovato J, **Gebski V.** Evaluation of flexible and rigid (class solution) radiation therapy conformal prostate planning protocols. *Medical Dosimetry* 2012; 37(1): 5-8.
20. Crowther CA, Aghajafari F, **Askie LM,** Asztalos EV, Brocklehurst P, Bubner TK, Doyle LW, Dutta S, Garite TJ, Guinn DA, Hallman M, Hannah ME, Hardy P, Maurel K, Mazumder P, McEvoy C, Middleton PF, Murphy KE, Peltoniemi OM, Peters D, Sullivan L, Thom EA, **Voysey M,** Wapner RJ, Yelland L, Zhang S. Repeat prenatal corticosteroid prior to preterm birth: a systematic review and individual participant data meta-analysis for the PRECISE study group (Prenatal repeat corticosteroid international IPD study group: assessing the effects using the best level of evidence): study protocol. *Systematic Reviews* 2012; 1(1): 12.
21. Cruz MF, Edwards J, Dinh MM, **Barnes EH.** The effect of clinical history on accuracy of electrocardiograph interpretation among doctors working in emergency departments. *Medical Journal of Australia* 2012; 197(3): 161–165.
22. Dahlen HG, Tracy S, Tracy M, Bisits A, **Brown C,** Thornton C. Rates of obstetric intervention among low-risk women giving birth in private and public hospitals in NSW: A population-based descriptive study. *BMJ Open* 2012; (5): 001723.
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NHMRC CLINICAL TRIALS CENTRE
UNIVERSITY OF SYDNEY
Locked Bag 77
Camperdown NSW 1450 Australia

92–94 Parramatta Road, Camperdown NSW 2050
6–10 Mallett Street, Camperdown NSW 2050
T: +61 2 9562 5000
F: +61 2 9565 1863
E: enquiry@ctc.usyd.edu.au
W: www.ctc.usyd.edu.au