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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 Trials’ 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
Preventing cardiovascular disease

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)

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 Clinicos 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 2006.

‘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.’

—Professor John Simes
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.

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. 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.

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.
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, 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 cardiovascular research.

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. 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.

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 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

**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.
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. 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. 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.

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

Danielle Ferraro and Dirkje Sommejier, medical oncologists and CTC clinical research fellows for AGITG trials
Improving quality of life and survival for people with cancer

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. 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. 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 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.

Symptom Benefit is another highly successful international collaboration led by ANZGOG.
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.1,12,37,123

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 cancer 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
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)

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 cancer121

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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 Australian report 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. 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. 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. 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. 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. 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.

Can Australia afford new cancer treatments?

Dr Demé 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. 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.
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.
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. 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.

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

Sarang Satoor, Wilson Wong, Anandwardhan Hardikar, Mugdha Joglekar
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. 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.

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

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.
CoRHRANE 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

CoRHRANE 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 Cochrane 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

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

Global diversity
Evidence for clinical practice and policy

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 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.

No. of new authors

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<th>Allied health professional</th>
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<th>Methodologist or statistician</th>
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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, the International Journal of Cardiology, and Spine.
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 laparoscopic approach and standard open abdominal surgery for endometrial cancer. The CTC contributed to the trial through design and analysis of results, which showed that patients having laparoscopic 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.

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. 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.

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.

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. Health-related quality of life was also related to inflammation and survival.

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. In another study, they analysed the relationship between injury severity and resource utilisation and the relative effect of age on these costs. 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. They developed a novel step-wedge statistical model describing infection transmission.
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.

‘Through 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

‘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

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

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.
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.

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<td>Prenatal repeat corticosteroid international individual-patient data study group assessing the effects using the best level of evidence (PRECISE) collaboration</td>
<td>Meta-analysis collaboration: international</td>
<td>Collaborator</td>
</tr>
<tr>
<td>Prevention of Ventilator Induced Lung Injury collaborative study group (PrevILIG)</td>
<td>Meta-analysis collaboration: international</td>
<td>Data coordination centre</td>
</tr>
<tr>
<td>Primary Care Cancer Trials Group (PC4)</td>
<td>Collaborative group: Australia</td>
<td>Collaborator</td>
</tr>
<tr>
<td>Primary Coronary Angioplasty versus Thrombolysis (PCAT)</td>
<td>Meta-analysis collaboration: international</td>
<td>Co-coordinating centre</td>
</tr>
<tr>
<td>Prospective Pravastatin POoling (PPP) project</td>
<td>Collaborative group: international</td>
<td>Coordinating centre</td>
</tr>
<tr>
<td>RNA-based Analysis for Prediction of Islet Death (RAPID)</td>
<td>Collaborative group: Australia</td>
<td>Collaborator</td>
</tr>
<tr>
<td>REMOVAL</td>
<td>Collaborative group for type 1 diabetes trial: international</td>
<td>Co-coordinating centre and collaborator</td>
</tr>
<tr>
<td>Royal Australasian College of Surgeons (RACS)</td>
<td>Professional society undertaking trials of surgery: Australia and New Zealand</td>
<td>Coordinating the SNAC trials in breast cancer with the RACS</td>
</tr>
<tr>
<td>Sydney Catalyst</td>
<td>Consortium for translational research in cancer</td>
<td>Collaborator</td>
</tr>
<tr>
<td>T4DM</td>
<td>Collaborative group for diabetes prevention trial: Australia</td>
<td>Co-coordinating centre and collaborator</td>
</tr>
<tr>
<td>Star Child Health</td>
<td>Meta-analysis collaboration: international</td>
<td>Member</td>
</tr>
<tr>
<td>VIGOUR group</td>
<td>Collaborative group for trials of heart disease: 40 countries</td>
<td>VIGOUR leader</td>
</tr>
</tbody>
</table>
## CURRENT CTC TRIALS

### NEONATAL DISORDERS

<table>
<thead>
<tr>
<th>Trial Description</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APTS: Australian placental transfusion study</td>
<td>Neonates born before 30 weeks’ gestation</td>
<td>1600</td>
<td>300</td>
</tr>
<tr>
<td>Trials in follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BOOST II: Benefits of oxygen saturation targeting</td>
<td>Neonates born before 28 weeks’ gestation</td>
<td>1200</td>
<td>1335</td>
</tr>
</tbody>
</table>

### CARDIOVASCULAR DISORDERS

<table>
<thead>
<tr>
<th>Trial Description</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trials in start-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>REMOVAL: Effects of metformin added to insulin on atheroma progression</td>
<td>Adults with type 1 diabetes at risk of cardiovascular disease</td>
<td>90 (ANZ); 500 (international)</td>
<td></td>
</tr>
<tr>
<td>University of Glasgow and NHs-led, and CTC trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T4DAM: efficacy of adding testosterone to a lifestyle program to prevent progression to type 2 diabetes</td>
<td>Men with prediabetes and low testosterone</td>
<td>1500</td>
<td></td>
</tr>
<tr>
<td>Trials in follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIELD: Fenofibrate intervention and event lowering in diabetes</td>
<td>Patients with type 2 diabetes</td>
<td>8000</td>
<td>9795</td>
</tr>
<tr>
<td>LIPID: Long-term intervention with pravastatin in ischemic disease</td>
<td>Patients with a history of coronary heart disease</td>
<td>9000</td>
<td>9014</td>
</tr>
</tbody>
</table>

### BREAST CANCER (COLLABORATING WITH RACS)

<table>
<thead>
<tr>
<th>Trial Description</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNAC 2: Sentinel node biopsy versus axillary clearance</td>
<td>Women with operable breast cancer, stratified by factors including age and tumour size</td>
<td>1012</td>
<td>266</td>
</tr>
<tr>
<td>RACS and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNAC 1: Sentinel node biopsy versus axillary clearance</td>
<td>Women with a single operable breast tumour &lt;3 cm, stratified by factors including age and tumour size</td>
<td>1000</td>
<td>1088</td>
</tr>
<tr>
<td>RACS and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### GASTROINTESTINAL CANCER (COLLABORATING WITH AGITG)

<table>
<thead>
<tr>
<th>Trial Description</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trials in start-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICECREAM: Irinotecan Cetuximab Evaluation and Cetuximab Response Evaluation Among Mutants</td>
<td>Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>AGITG and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMPACT: Phase 2 trial using genomic sequencing and protein expression to direct first-line treatment</td>
<td>Patients with metastatic pancreatic cancer</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Garvan, AGITG and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A La CART: Australian phase III randomised trial of laparoscopy-assisted resection compared with open resection</td>
<td>Patients with primary rectal cancer</td>
<td>470</td>
<td>153</td>
</tr>
<tr>
<td>AGITG and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases</td>
<td>Patients with confirmed resectable liver metastases and no other disease</td>
<td>200</td>
<td>5</td>
</tr>
<tr>
<td>AGITG and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOCTOR: Phase 2 trial of preoperative capcitabine, S-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer</td>
<td>Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy</td>
<td>150</td>
<td>48</td>
</tr>
<tr>
<td>AGITG and CTC study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GAP: Phase 2 study of gemcitabine and NAB-paclitaxel</td>
<td>Patients with resectable pancreas cancer</td>
<td>50</td>
<td>3</td>
</tr>
<tr>
<td>AGITG and CTC study</td>
<td></td>
<td></td>
<td></td>
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</table>
### Current Clinical Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTEGRATE: Phase 2 trial comparing regorafenib and placebo</td>
<td>Patients with advanced oesophagogastric cancer</td>
<td>150</td>
<td>22</td>
</tr>
<tr>
<td>PANI: Phase II study evaluating potential predictive biomarkers in treatment of locally advanced and metastatic pancreatic cancer</td>
<td>Patients with confirmed metastatic pancreatic adenocarcinoma</td>
<td>80</td>
<td>8</td>
</tr>
<tr>
<td>SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer</td>
<td>Patients with fully resected stage III colorectal cancer</td>
<td>225 (ANZ); 9500 (international)</td>
<td>163 (ANZ); 4680 (international)</td>
</tr>
<tr>
<td>TACTIC: Phase 2 trial of panitumumab, cisplatin and gemcitabine</td>
<td>Patients with biliary tract cancer</td>
<td>45</td>
<td>7</td>
</tr>
<tr>
<td>TOP GEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer</td>
<td>Patients with resectable gastric cancer suitable for these treatments</td>
<td>120 (stage 1); 632 (stage 2)</td>
<td>64</td>
</tr>
<tr>
<td>Adjuvant GIST: adjuvant imatinib mesylate versus no further therapy after complete surgery</td>
<td>Patients with resected gastrointestinal stromal tumours (GIST) expressing KIT receptor</td>
<td>80 (ANZ); 81 (ANZ)</td>
<td></td>
</tr>
<tr>
<td>Advanced GIST: Relation between dose and clinical activity of imatinib mesylate</td>
<td>Patients with unresectable or metastatic malignant gastrointestinal stromal tumours (GIST) expressing KIT receptor</td>
<td>80 (ANZ); 600 (international)</td>
<td>116 (ANZ); 946 (international)</td>
</tr>
<tr>
<td>ATTAX 3: Phase 2 trial of docetaxel, cisplatin and fluoropyrimidine with or without panitumumab for oesophagogastric cancer</td>
<td>Patients with metastatic or locally recurrent oesophagogastric cancer</td>
<td>100</td>
<td>77</td>
</tr>
<tr>
<td>CO20: Phase III study of S MS-582664 with cetuximab versus placebo with cetuximab</td>
<td>Patients with metastatic colorectal carcinoma previously treated with combination chemotherapy</td>
<td>370 (ANZ); 750 (international)</td>
<td>416 (ANZ); 686 (international)</td>
</tr>
<tr>
<td>EORTC liver metastases: Oxaliplatin, 5-fluorouracil and leucovorin versus surgery for resectable colorectal cancer liver metastases</td>
<td>Patients with colorectal cancer with resectable liver metastases</td>
<td>330 (international)</td>
<td>35 (ANZ); 364 (international)</td>
</tr>
<tr>
<td>LAP07: Randomised multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib</td>
<td>Patients with locally advanced adenocarcinoma of the pancreas</td>
<td>60 (ANZ); 900 (international)</td>
<td>32 (ANZ); 442 (international)</td>
</tr>
<tr>
<td>PETACC 6: Addition of capecitabine to preoperative oxaliplatin chemotherapy and postoperative oxaliplatin chemotherapy for rectal cancer</td>
<td>Patients with locally advanced rectal cancer</td>
<td>135 (ANZ); 1090 (international)</td>
<td>127 (ANZ); 1094 (international)</td>
</tr>
<tr>
<td>Quan2: Phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer</td>
<td>Patients with colon cancer treated by surgery</td>
<td>120 (ANZ); 1892 (international)</td>
<td>219 (ANZ); 1952 (international)</td>
</tr>
<tr>
<td>REGISTER: Multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response</td>
<td>Patients with gastrointestinal stromal tumour not suitable for curative surgery</td>
<td>80</td>
<td>47</td>
</tr>
</tbody>
</table>
# Gynaecological Cancer (Collaborating with ANZGOG)

## Current Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANZGOG 1103: Phase I-II BNC105P combination study</td>
<td>Women with partly platinum-sensitive ovarian cancer in first or second relapse</td>
<td>up to 24 Phase I (international)</td>
<td>5 (ANZ); 6 (international)</td>
</tr>
<tr>
<td>Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer</td>
<td>Women with locally advanced cervical cancer</td>
<td>780 (international)</td>
<td>46 (ANZ); 113 (international)</td>
</tr>
<tr>
<td>PARAGON Phase II study of anastrozole in gynaecological cancers</td>
<td>Women with potentially hormone-responsive gynaecological cancers</td>
<td>320 (international)</td>
<td>92 (ANZ); 110 (international)</td>
</tr>
<tr>
<td>PORTIC-3: Chemoradiation and adjuvant chemotherapy compared with pelvic radiation alone in high-risk endometrial carcinoma</td>
<td>Women with advanced endometrial carcinoma</td>
<td>120 (ANZ); 650 (international)</td>
<td>80 (ANZ); 499 (international)</td>
</tr>
<tr>
<td>Symptom benefit: does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG 1103) ANZGOG and PoCoG study</td>
<td>Women with platinum-resistant or refractory ovarian cancer</td>
<td>800 (international)</td>
<td>x185 (ANZ); 317 (international)</td>
</tr>
</tbody>
</table>

## Trials in Follow-up

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy</td>
<td>Women with with platinum-sensitive relapsed ovarian cancer</td>
<td>400 (international)</td>
<td>17 (ANZ); 486 (international)</td>
</tr>
<tr>
<td>ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy</td>
<td>Women with epithelial ovarian cancer who had not received systemic antitumour therapy</td>
<td>144 (ANZ); 1450 (international)</td>
<td>76 (ANZ); 499 (international)</td>
</tr>
<tr>
<td>OHAR 36: Paclitaxel versus placebo for ovarian cancer</td>
<td>Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer</td>
<td>900 (international)</td>
<td>65 (ANZ); 940 (international)</td>
</tr>
<tr>
<td>SCOTROC 4: Multicentre trial of carboplatin flat dosing vs intrapatient dose escalation in first-line chemotherapy</td>
<td>Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum–taxane therapy</td>
<td>1300 (international)</td>
<td>64 (ANZ); 937 (international)</td>
</tr>
<tr>
<td>CALYPSO: phase III study comparing pegylated liposomal doxorubicin and carboplatin vs paclitaxel and carboplatin</td>
<td>Women with platinum sensitive relapsed ovarian cancer</td>
<td>974 (international)</td>
<td>71 (ANZ); 976 (international)</td>
</tr>
<tr>
<td>TARCEVA: phase III study of erlotinib versus observation</td>
<td>Women with advanced epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer</td>
<td>830 (international)</td>
<td>41 (ANZ); 830 (international)</td>
</tr>
<tr>
<td>Phase III randomised trial of paclitaxel + carboplatin versus triplet or sequential doublet combinations (GOG 182)</td>
<td>Women with advanced stage (FIGO III-IV) epithelial ovarian or primary peritoneal carcinoma</td>
<td>4200 (international)</td>
<td>184 (ANZ); 4312 (international)</td>
</tr>
</tbody>
</table>

## Genitourinary Cancer (Collaborating with ANZUp)

### Trials in Start-up

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitomycin C added to BCG as adjuvant intravesical therapy</td>
<td>Patients with non-muscle-invasive bladder cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I trial of accelerated versus standard BEP chemotherapy for germ cell tumours</td>
<td>Patients with metastatic germ-cell tumours with intermediate or poor prognosis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Current CTC trials

**Current trials**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
<th>Accrual</th>
</tr>
</thead>
<tbody>
<tr>
<td>SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05)</td>
<td>Patients with resected renal cell carcinoma at intermediate or high risk of relapse</td>
<td>250 (ANZ); 1656 (international)</td>
<td>2250 (ANZ); 155 (international)</td>
</tr>
</tbody>
</table>

**Trials in follow-up**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerated BEP: feasibility study of accelerated BEP as first-line chemotherapy for advanced germ cell tumours (ANZGCTG 0606; ANZGOG 0603)</td>
<td>Patients with intermediate and poor-risk advanced germ-cell tumours (and selected good-risk tumours)</td>
<td>25; 45</td>
</tr>
<tr>
<td>ChemO &amp; cognition: Cognitive function and treatment for testicular cancer (ANZGCTG 0006)</td>
<td>Patients being treated and followed up for testicular cancer</td>
<td>154; 151</td>
</tr>
<tr>
<td>Eversun: Phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901)</td>
<td>Patients starting first-line systemic therapy for advanced renal cell carcinoma</td>
<td>55; 56</td>
</tr>
</tbody>
</table>

**LUNG CANCER (COLLABORATING WITH ALTG)**

**Current trials**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>BR.26: Phase III trial of PF-804 in patients with incurable, non-small-cell lung cancer (ALTG 09/002)</td>
<td>Patients with stage III or IV non-small-cell lung cancer</td>
<td>180; 78</td>
</tr>
<tr>
<td>NITRO: Phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for advanced non-small-cell lung cancer (ALTG 06/083)</td>
<td>Patients with advanced non-small-cell lung cancer</td>
<td>500; 250</td>
</tr>
</tbody>
</table>

**Trials in follow-up**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACI in NSCLC. Preferences for adjuvant chemotherapy in non-small-cell lung cancer (ALTG and CTC observational study)</td>
<td>Patients, surgeons and oncologists</td>
<td>200; 122</td>
</tr>
</tbody>
</table>

**BRAIN TUMOURS (COLLABORATING WITH COGNO)**

**Trials in start-up**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II study of acetazolamide plus desmamethasone versus desmamethasone for cerebral oedema in high-grade glioma</td>
<td>Patients with high-grade glioma requiring new desmamethasone or dose increase due to progressive or recurrent disease</td>
<td>86</td>
</tr>
<tr>
<td>Phase II study of psycho-educational intervention in patients with primary brain tumour</td>
<td>Patients with confirmed primary brain tumours</td>
<td>60</td>
</tr>
</tbody>
</table>

**Current trials**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARARET: Phase II study of carboplatin and bevacizumab in recurrent glioblastoma multiforme</td>
<td>Patients aged 18 years and over with recurrent grade IV glioma after radiotherapy and temocloride chemotherapy</td>
<td>122 (part 1); 60 (part 2); 47 (part 2)</td>
</tr>
<tr>
<td>CATNON: Phase II trial of concurrent and adjuvant temocloride chemotherapy for anaplastic glioma (EORTC 26012-22054-2)</td>
<td>Patients with non-1p/19q-deleted anaplastic glioma</td>
<td>100 (ANZ); 748 (international)</td>
</tr>
<tr>
<td>SEED: Self-reported evaluation of the adverse effects of desmamethasone</td>
<td>Patients with brain tumours or brain metastases or advanced cancer using steroids</td>
<td>50 patients, 50 caregivers</td>
</tr>
</tbody>
</table>

**Trials in follow-up**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Participants</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>LGG: Phase III study of primary chemotherapy with temocloride versus radiotherapy (TROG 06.01, EORTC 22033-24033)</td>
<td>Patients with low-grade glioma, stratified for genetic 1p loss</td>
<td>100 (ANZ); 560 (international)</td>
</tr>
</tbody>
</table>

**TRIAL**

**PARTICIPANTS**

**TARGET**

**ACCRUAL**

---

NHMRC CLINICAL TRIALS CENTRE: 2012 RESEARCH REPORT
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Oliver Marty, BEdPhys
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Jenny Chow, executive officer
Yi Feng, administrative assistant, BE(aeronautical)

NEONATAL TRIALS

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

INS and APTS trials
Lorraine Sebastian, BSc(hons), PhD, project manager
Caitlin van Holst Pellekaan, BMEdSc(hons), data manager

BOOST II trial
Alpaha Ghande, BSc, MSc, PhD, GradCert TradeMarksLawPract, project manager
Nick Muljadi, BSc(hons), clinical trial assistant

CARDIOVASCULAR TRIALS

ASPIRE
Rebecca Minter, 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 Fater, BAppSc, project manager

DIABETES

REMOVAL
Helen Fater, BAppSc, project manager

T4DM
Karen Bracken, BSc, 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), CIA, head
Salma Fahdin, 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 Minter, 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 Oy, PhD, clinical trials assistant
Anandwardhan A Hardikar, BSc, MSc, PhD, associate professor, Aus tarrian Future Fellow (ARC)

Mugdha Joslekar, BSc, MSc, PhD, Juvenile Diabetes Research Foundation research fellow
Andrzej S Januszewski, MD, PhD, senior research fellow
Thomas McCorquodale, BSc, clinical trials assistant
Sarang Satoo, BSc, MsC, research fellow
Wilson Wong, BSc(hons), research assistant

SYSTEMATIC REVIEWS AND HEALTH TECHNOLOGY ASSESSMENT
Lisa M Aske, BN, MPH, PhD, director, and senior research fellow
Jenny Choe, AssocDip, executive officer
Sally J Lord, MB BS, DipPaed, MS, FRACGP, epidemiologist and research fellow
Lukas Staub, Dr med, DAS, project officer
Nicholas RC Wicke, MB BS, FRACGP, 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 Worleiy, DHRHSc(hons), MHP, Grad Cert Hlth Econ, project officer

Cochrane breast cancer review group
Melissa Wilson, BSc, BA(hons)/BA, PhD, project manager
Fergus Tai, BAAppSc, DipIT, MPH, trials search coordinator

Australian New Zealand Clinical Trials Registry
Kylie E Hunter, BA, BA(hons), project officer
Henny CH Ko, BEng(Med)(hons), PhD, project officer
William YT Ooo, MHlthSc, BAppSc, project officer

HEALTH ECONOMICS
Deborah J Schofield, BScAppSc, GradDipComp, PhD, professor
Emily J Callander, BA, research officer
Rupeenda N Shrestha, MSc, PhD, research fellow
Hannah Carter (Verry), BSc, health economist
Jean Vobrough, MMath, research officer

BIOSTATISTICS AND CONSULTING
Val J Gebki, 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
Elisabeth E Barnes, BAppSc, MStat
Christopher SB Brown, BSc
Diana Zamirno, BSc(hons), MSc

Biosstatisticians
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Mark W Donoghoe, BSc(hons)
David Espinoza, BSc(hons)
Marion Fournier, MSc
Kirsty P Mann, BSc(hons)
Rachel L O’Connell, BMath, MMedStat, PhD
Anne-Sophie Veillard, BSc, MSc

BIOSTATISTICS COLLABORATION OF AUSTRALIA (BCA)
Erica Jobling, executive officer
Helena Johnson, BA, MMuseumSud

INFORMATION SYSTEMS
Infrastructure
Dinh Tran, BMath, MCompSc, infrastructure manager
Asanka Pereira, BSc, computer systems officer
Thuyen Vu, BSc, computer systems officer

Database administrator
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 Mikolic, receptionist
Lisa Sherwood, BCom, MSc, MBIostat, finance and contracts coordinator

Finance
Paul Smyth, BCCom, CPA, finance manager
Agnes Ho, MPraAcc, CPA, finance officer
Maki Joseph, DipIrd, finance officer
Carlos Sterling, BEng, MBA, finance officer

Human resources
Cynthia Carr, BEd(HRD), human resources and administration manager

Suzanne Everette, BSW, human resources and administration coordinator

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

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Kushwin Rajamani, MB BS
Michaela Smith, BSc, MB BS(hons), MMSc
Ru-Dee Ting, MB BS, FRACP

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Christopher SB Brown, BSc, research fellow
Karen Byth, BSc(hons), MSc, PhD, DIC, CStat

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Ru-Dee Ting, MB BS, FRACP
Anandwardhan A Hardikar, BSc, MSc, PhD, associate professor
Andrzej S Januszewski, MD, PhD, principal research fellow and professor
Toby Gould, BA, BSc, MPH, associate lecturer
Wendy Haque, MB BS, MBA, PhD, senior research fellow
Anandwarthan A Hardikar, BSc, MSc, PhD, associate professor
Adrienne C Kirby, BSc(hons), MSc, senior lecturer

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Jordan Fulcher, BSc(Med), MB BS, Demie Karkkis, BSc, MB BS, FRACP
Annette Kiley, MB BS, MAppStat
Zhian Liu, PhD
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STAFF and staff activities
Ru-Dee Ting, MB BS, FRACP
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Alissa J Jenkins, MB BS, MD, MRCP, FRACP, FRCP, professor
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Adrienne C Kirby, BSc(hons), MSc, senior lecturer
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Andrew J Martin, BA, MA, GradDip, PhD, AStat, senior lecturer
Rachel L O’Connell, BMath, MMedStat, PhD, FRACP, research fellow
Deborah J Schofield, BScAppSc, GradDipComp, PhD, professor
Rupeenda N Shrestha, MSc, PhD, research fellow
R John Simex, BSc(Med)(hons), MB BS(hons), MD, SM, FRACP, senior principal research fellow and professor
Katerin M Spajuz, 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 Mirena R Agar, COGNO scientific advisory committee
Dr Andrew Harbour, PI, DOCTOR and GAP trials (AGITG)
Dr Sally Baron-Hay, ANZOGOG executive
Dr David Bernshaw, ANZOGOG executive
Dr Andrew Berry, BOOST II safety and data monitoring committee chair
Dr Andrew Birkner, PI, LAP07 trial (AGITG)
Dr Alex Bourouisoutas, Gastric trial (AGITG)
Dr Alison Brand, ANZOGOG 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 and chair, ANZUP
Dr Andrew R Stevenson, PI, A La
Dr Christopher Steer, ANZGOG executive, PI
Dr Nigel A Spry, AGITG
Dr Benjamin Solomon, PI, BR24 trial (ALTG)
Dr Bernard M Smithers, TOPGEAR trial
Dr Jennifer A Shannon, PI, TACTIC trial
Dr Shomik Sengupta, ANZUP
Associate Professor Eva Segelov, PI
Dr Mark Rosenthal, COGNO chair
Dr Danny Rischin, ANZOGOG executive
Dr Mark Rosenfield, COGNO chair
Associate Professor Eva Segelov, PI
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, FORTC 6.2063 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, TOPG2E trial (AGITG)
Dr Linda Mileskhiran, ANZOGOG executive, PI
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, ANZOGOG executive
Dr Robert Padbury, AGITG
Professor Lyle J Palmer, Dr Nicholas J Petrelli, AGITG
Associate Professor Timothy J Price, PI
Professor Michael Quinn, ANZOGOG chair
Dr Kushwin Rajamani, FIELD studies
Dr Shornik Sengupta, ANZUP
Dr Jennifer A Shannon, PI, TACTIC trial (AGITG)
Dr Bernard M Smithers, TOPGEAR trial
Dr Kenneth C. Tang, PI, SNAC trial
Dr Andrew Tonkin, BiomarCare, LIPID study
Dr Andrew Kneebone, AGITG
Dr Michelle Vaughan, ANZOGOG executive, PI
Dr David G Walker, COGNO scientific advisory committee
Dr Euan Walpole, PI, SCOT trial (AGITG)
Dr Neil Wetting, co-PI, SNAC trial
Professor Gary Wittert, PI, TAD trial
Dr Desmond Yip, SCOT (AGITG)
Professor John Zalcberg, AGITG chair

Staff activities
SUPERVISION OF RESEARCH DEGREES

John Simes
Claudia Dobler, PhD
Manjula Schoo, PhD

Anthony Keek
Djana Bozicak, PhD
Jordan Fulcher, PhD
Jason Harmer, PhD
Kushwin Rajamani, PhD
Suraya Sustanto, PhD
Ru-Dee Ting, PhD
Lisa Askie
Angela Carberry, PhD

Val Gebski
Mithilesh Dronavalli, MMedSc
Annette Kifley, PhD
Zhion Liu, PhD
Farnoush Noushi, PhD
Manjula Schoo, PhD
Anandwarthan Hardikar
Ryan Farr, PhD
Wilson Wong, MPhil/PhD
Michael Williams, PhD
Malcolm Hudson
Prunella Blinman, PhD
Zhion Liu, PhD

Alicia Jenkins
Paul Benitez Aguire, PhD
Yoon Hi Cho, PhD
Andraz Januzewski, MCT
Ben Ma, PhD
Jon Neonan, PhD
Kushwin Rajamani, PhD
Harris Schlen, PhD
Ru-Dee Ting, PhD
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)
Kanyins GAP PolyPhill 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 Trailists’ Collaboration (CTTC) (joint coordinator and convener)
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
Systematic Reviews editorial board

Elizabeth Barnes
Outback trial management committee (ANZCTR)
DOCTOR trial management committee

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

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, BIP2M trial management committee, FACT in NSCLC trial management committee
Trevor France
Australian and New Zealand Urological and Prostate Cancer Trials Group (ANZUP) operations executive committee, scientific advisory committee, and Accelerated BEP, Apepapint and EVERSUN trial management committees
Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees, and CABARET and CATHON trial management committees
Val Gebski
AGITG scientific advisory committee and MAX, TOPGEAR, IMPACT, PAN-1, ATTACCE, ATTAX3, TACTIC, DOCTOR, ICECREAM and REGISTER trial management committees
ANZ BCTG scientific advisory committee
ANZOG 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
Crowns 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-Intestinalal Trials Group (AGITG); Australian New Zealand Gynaecological Oncology Group (ANZOGOG); Australian and New Zealand Urological 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); T02RP10 (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-Intestinalal Trials Group (AGITG) trials operations committee
Australia New Zealand Gynaecological Oncology Group (ANZOGOG) 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-Embolicism (INSPIRE) steering committee
Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee
Randomised Trial on Surgical Treatment for Obese 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, CATHON and SEED trial management committees
Sally Lord
Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees, and CABARET, CATHON and SEED trial management committees
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

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29/08/2013 11:49:24 PM
Andrew Martin  
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee  
BLOCade safety data monitoring committee  
ONTAR, ProCare, INTEGRATE, EPOCH, NePHorzons, 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  
TRIPSOS, 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 (ASPITRE) management committee  
International Trials of Aspirin to Prevent Recurrent Venous Thromboembolism (INSPITRE) 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 ions 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  
Australasian 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), ERIM in GMP3/4 (chair), evidence-based medicine resource group, integrated clinical attachment committee and USMP cancer planning committee

Bucuc Vuchan (to September)  
Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee  
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, ATTAX3, 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  
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
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

Eliza 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

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Advanced clinical trials, Biostatistics Collaboration of Australia
Basic sciences in oncology, NSW Cancer Council

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Val Gebski
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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

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

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

Chee Lee
Global biomarker studies, Master of Clinical Trials, University of Sydney

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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

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

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Interpretation of trial analyses (coordinator), Master of Clinical Trials, University of Sydney

Rebecca Master
Project management in clinical trials: development, leadership and problem solving, Master of Clinical 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
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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 physicians, 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

- NHMRC
- Cancer Institute NSW and Cancer Australia
- Other public funding
- Overseas research grants
- Pharmaceutical industry
- Other
Publications

JOURNAL ARTICLES


NHHRC CLINICAL TRIALS CENTRE: 2012 RESEARCH REPORT


76. Nair-Shukler V, Fenech M, Forder PM, Clements MS, Armstrong BK. Sunlight and vitamin D affect DNA


100. Schofield DJ, Calleja E, Shrestha RN, Passey ME, Percival R, Kelly SJ. The association between labour force participation and being in income poverty amongst those with mental health problems. Aging & Mental Health. Published online 22 Oct 2012.


111 Taylor CJ, Satoor SN, Ranjan AK, Pereira E, Cotta MV, Joglekar MV. A protocol for measurement of noncoding RNA in human serum. Experimental Diabetes Research. Published online 1 Jul 2012.


COLLABORATIVE GROUPS


PRESENTATIONS


172. Hardikar AA. Epithelial-to-mesenchymal transition forms the basis for generation of lineage-committed pancreatic progenitor cells. 5th Diabetes Interest Group Meeting; 11–12 Dec 2012; Pune. [invited presentation]


COLLABORATIVE GROUPS


223. Hurwitz HI, Tebbutt NC, Kabbinavar F, Giantonio BJ, Guan Z, Mitchell L, Waterkamp D, Tabernero J. Efficacy and safety of bevacizumab in metastatic colorectal cancer: overall and subgroup analyses of pooled data from randomized controlled trials. ESMO 14th World Congress on Gastrointestinal Cancer; 27–30 Jun 2012, Barcelona. [AGITG]
