NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2015

The NHMRC Clinical Trials Centre at the University of Sydney conducts investigator-initiated clinical trials with national and international collaborators, and contributes expertise to trials run by others. It also:

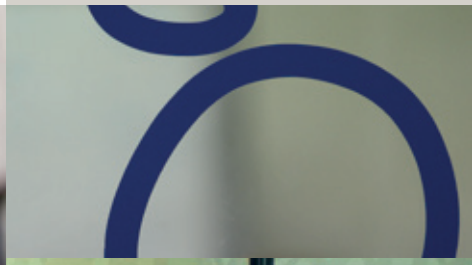
- takes a lead in proposing new directions for clinical research in Australia, particularly research aligned with national policy and clinical practice
- participates in translational research, from bench to bedside
- conducts methodological research in relation to clinical trials
- reviews and synthesises 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.
- undertakes health technology and diagnostic test assessments, economic analyses, biostatistical design and analysis, and automated central randomisation services.

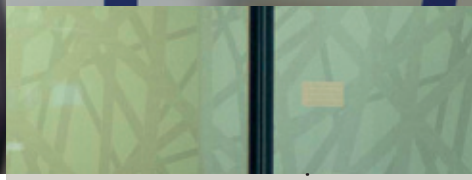
Core funding is provided by the NHMRC, and specific projects are funded by government, public and private institutions and the pharmaceutical industry.

The CTC is at two sites in Camperdown in inner Sydney — the Medical Foundation Building on Parramatta Road and Chris O'Brien Lifehouse on Missenden Road.

This report describes highlights of the CTC's achievements for 2015.

Since 1998, the CTC has been initiating, leading, conducting, analysing and publishing collaborative trials and related research, with the aim of improving health outcomes in Australia and internationally.





DIRECTORS' REPORT

The CTC, over the past 28 years, has been helping improve health in Australia and elsewhere by advancing clinical trial research. We do this, with our collaborators, through designing and conducting trials for public good, interpreting and combining results from other trials and studies worldwide, and conducting associated research that maximises the scientific value of these efforts.

Major achievements in 2015 have included significant findings in several areas of health care, especially in oncology, diabetes, cardiovascular disease and neonatology; biomarker discovery; advances in trial methodology; integrating evidence from trials; leadership of the international symposium; and strong growth in grants and publications.

Over this decade we have seen a transformational change in clinical trials. In some settings, trials have become smaller, with defined subpopulations for targeted therapies, and the increasing use of adaptive methods, molecular profiling and surrogate endpoints. These developments are continuing, but large-scale trials are also still needed in areas where moderate treatment effects in broader populations can lead to substantial public health benefit. CTC, with its strength in clinical research methodology, is well placed to develop ways of meeting the associated challenges and provide reliable, valid and relevant results.

A key tenet of our research direction is the need to make clinical research a more integral part of health care, for the benefit of practice, research, and health care expenditure. This means a paradigm shift that captures effort and goodwill across the whole health system, including clinical trial networks and centres developing trials in areas of need, with generic infrastructure and intellectual underpinning for conducting them.

CTC has been very supportive in the formation, development and activities of the Australian Clinical Trials Alliance. ACTA is a means for triallists across all disciplines and across the full range of disease areas to work together, and with governments, to generate scientific evidence for new and existing health care treatments most efficiently and at the lowest cost. The highly successful ACTA symposium in October brought together new ideas and challenges and opened them to debate and development. These include global trends towards embedding clinical trials in clinical care, challenges in trial design and conduct, maximising the value of clinical registries, and improving public awareness and consumer involvement in clinical research. The symposium attracted over 500 people attending from all over Australia and elsewhere, including a faculty of 45 international and national speakers.

Working with individuals and groups with diverse perspectives allows us to achieve better and more relevant results. Patients, carers and supporters have long been part of the clinical trials program—through consumer advisory panels and associated groups. This is an area that we see as important and that has been growing. In our neonatal studies, for example, parent groups are closely involved as full partners in the collaborative research process.

Increasingly, Australian trials are registered on the Australian New Zealand Clinical Trials Registry. The registry supports research transparency by making current trials public. We recently used data from the registry to quantify current research in relation to government-established health priority areas, which are based on the burden of the disease. This showed that some disease areas, such as obesity and dementia, may be under-researched, and also that larger trials or planned meta-analyses of smaller ones are needed if Australian health care is to be based on the most robust available evidence.

Our oncology trials continue to generate new evidence for practice. A La CaRT, an AGITG-RACS-CSSANZ-CTC study, which was one of the largest trials of complex surgery ever conducted, reported on the current value of laparoscopic surgery, compared with open surgery, for rectal cancer. The international Symptom Benefit study explored how we measure the benefit of chemotherapy, and led to worldwide reflection on use of palliative chemotherapy for marginal benefits.

Especially in its close ties with Sydney Catalyst, CTC's oncology researchers are embracing the full research pathway, in which clinical trials in their various phases are the link between laboratory discoveries and treatment protocols. Trials more often include thorough genetic and molecular typing as a condition of enrolment. In this way, treatment is tailored to the individual patient, with greater chance that the treatment will be successful.

In the area of cardiovascular disease, the CTC's early landmark trial, LIPID, is still a source of active research: in the laboratory exploration of potential biomarkers of cardiovascular risk; and in international meta-analysis of data on statins, which is guiding treatment of cardiovascular diseases. Similarly, the FIELD trial, with nearly 10,000 patients with adult diabetes, was completed many years ago, but opened a door to new insights into vascular disease in diabetes, where several exciting laboratory investigations are continuing.

In other initiatives, our diabetes group have approached the worldwide scourge of diabetes from several different directions: including type 1 diabetes trials and novel trials in remote areas; advocacy initiatives; and extensive laboratory studies on mechanisms of treatment and risk. For example, the 12-year study showing that undernutrition over generations caused epigenetic changes in rats was an illustrated cover story in Cell Metabolism.

Major new trials in perinatal and neonatal medicine were launched in 2015. These trials require large numbers of infants, the goodwill and trust of parents and a high degree of organisation and motivation from the investigators and staff. CTC's neonatal group focuses on improving the prospects of newborn infants at risk, while also seeking better ways of conducting trials in this area.

Two senior academics joined CTC in 2015. Professor Philip Hogg became Chair Translational Cancer Research at CTC and head and Professor of Translational Cancer Research for Sydney Catalyst. We also appointed a new health economics director, Associate Professor Rachael Morton. Her group adds value to the conduct of CTC trials by within-trial and modelled economic evaluation, and also pursues independent research.

Our increasing income from public grants, which owes to our strong research record, indicates our competitiveness, with our collaborators, in a time of very tight funding. Together, we published 170 journal articles and presented 100 research studies at national and international conferences during 2015.

Success in any endeavour depends on diverse skills and expertise. We appreciate the joint efforts of many people. Collaborating investigator groups and other research organisations have come together to complete projects that will ultimately benefit many people worldwide. The CTC itself now numbers almost 200 people, most actively involved in research. The directors acknowledge the quality and energy of all their undertakings.

In this report we highlight some examples in which our staff and our collaborators have contributed to the future of medical research and patient care in 2015.

CTC executive:
John Simes, director;
Anthony Keech, deputy director;
Wendy Hague, clinical trials program director; and
Vera Terry, business director

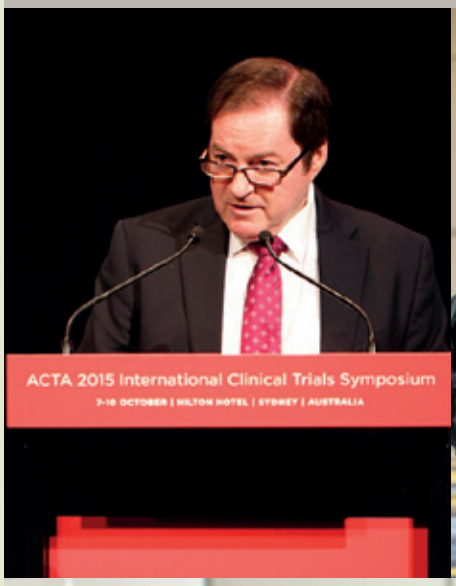
ACTA International Clinical Trials Symposium 2015

The Australian Clinical Trials Alliance staged the highly successful International Clinical Trials Symposium in October 2015, with the theme 'Better Evidence Better Health'. It was a platform to discuss global advances toward self-improving health care systems, including embedding clinical trials in clinical care, challenges in trial design and conduct, maximising the value of clinical registries improving public awareness and consumer involvement in clinical research, and other issues of the moment.

The symposium attracted over 500 people from all over Australia and elsewhere, including a faculty of 45 international and national speakers. It was a forum for everyone involved in funding, developing and undertaking clinical research. Attendees were clinicians, policy-makers, triallists and researchers, clinical trial coordinators and nurses, biostatisticians, allied healthcare professionals, public health specialists, health economists, regulators and industry.

The symposium was a step taken in furthering ACTA's aims to promote effective and cost-effective health care in Australia.

The CTC, with its past experience of three previous such symposia, had a key role in organising the 2015 symposium and contributed to its undoubted success.



Pictured at the rostrum, ACTA symposium chair and convener, Anthony Keech

ONCOLOGY PROGRAM

CTC collaborates with national and international investigator groups to develop and conduct trials and associated research in several areas of oncology— in gastrointestinal, gynaecological, urogenital, lung and brain cancer. The team of over 40 coordinate the trials from start-up to close-out, and are focused on development of new trials and other research initiatives, supported by infrastructure grants from the state and federal government.

The collaborative relationships with five of the national cancer cooperative groups (AGITG, ANZGOG, ANZUP, ALTG and COGNO) set the group apart from other research teams. Together, these collaborations are able to secure competitive funding to carry out investigator-initiated trials to improve the outcomes of cancer patients. As part of continuing efforts to better support colleagues at hospital sites, the group has established dedicated interactive trial pages on the CTC website for access by staff at hospital sites.

Strategic planning with cooperative group colleagues and through international links with similar research groups allows the CTC's modus operandi to move forward in step with a changing clinical trials climate. The solid team and practices ensure that the group is well equipped to move with the developing landscape of trends to wider collaboration, more personalised medicine and targeted treatments.

CTC oncology executive. Left: Wendy Hague, clinical trials program director with Burcu Vachan, oncology program manager. Right: Cancer trials co-director, Martin Stockler with Mustafa Khasraw, clinical lead for brain cancer trials and Sonia Yip, oncology translational senior research fellow (not present: John Simes, Val Gebski and Katrin Sjoquist)

Sarah Chinchen, CTC-ALTG trials manager, who worked on the NITRO trial

A novel idea to improve the effect of lung cancer chemotherapy

The NITRO trial was part of the search for better treatments for patients with lung cancer.[28]

The aim of NITRO was to test whether giving nitroglycerin via a skin patch would improve the effectiveness of chemotherapy. The patch had been beneficial for patients in a small trial in Japan. Also, there were good scientific reasons why nitroglycerin might improve the effect of chemotherapy, including possible enhancement of drug delivery, sensitising tumour cells to chemotherapy and reducing resistance to chemotherapy.

Half the patients were randomly allocated to having a nitroglycerin patch applied for five days around each chemotherapy infusion. The other half had chemotherapy but no patch. Most patients had carboplatin with gemcitabine as their chemotherapy treatment.

Although the trial was to have 500 patients, a planned interim analysis at only 372 participants recruited had definitive results. Nitroglycerin had no effect on progression-free survival, nor on the response of the tumour. Because nitroglycerin did slightly increase the frequency and severity of adverse events, the investigators recommended that further research on its use not be pursued.

Most of the participants were men, and about two-thirds had been smokers within the past 15 years.

ALTG

The CTC's lung cancer trials are collaborations with the Australasian Lung Cancer Trials Group. The group aims to reduce the incidence, morbidity and mortality of lung and other thoracic cancers and improve the quality of life of patients, carers and families in Australia and New Zealand.

The ALTG has been actively involved in developing high-quality trial concepts and supports the active engagement of its 421 members—clinicians, researchers, allied health professionals and consumers—in all aspects of the development and conduct of its trials.

Oncology staff, Emily Tu, Claudia Bishop, Di Winter, Annie Yeung, Nick Muljadi, Lesley Brassel and Anna Walsh

HIGHLIGHT: RENAL CANCER

Everolimus for renal cell cancer in the EVERSUN trial

The activity, feasibility and safety of a new drug regimen is customarily tested in a small group of patients in a phase 2 trial. Its results determine whether the regimen will go on to full evaluation in a randomised phase 3 trial.

Several drugs are available for treating advanced renal cell carcinoma, the most common type of kidney cancer. EVERSUN was a phase 2 trial testing a regimen of alternating two of these: sunitinib and a more recent drug, everolimus. The rationale for the treatment was that switching two drugs with different mechanisms of action would prevent or delay drug resistance.[29]

Fifty-five patients participated. After 6 months, 29 were free of progression of their disease. The investigators had set the level for success of the regimen at 84% of patients without disease progression at 6 months, so they concluded that the results of the trial did not support further investigation of this novel regimen. However, the alternating treatment was safe and well tolerated.

The evidence from the trial suggested that clinicians should maximise the value from the individual drugs, as there was no evidence of benefit (or harm) from alternating them.

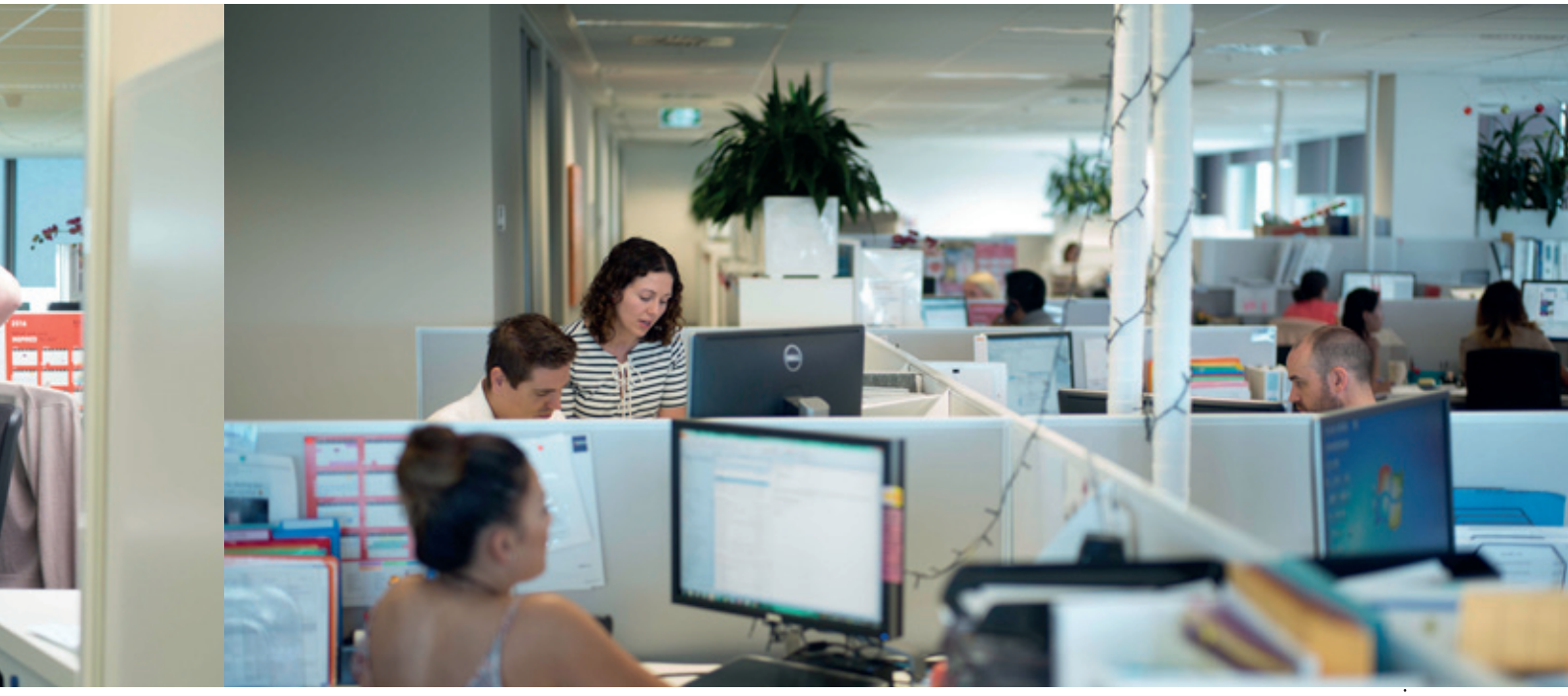
As part of the trial, potential tumour biomarkers in blood were also tested to see if any specific tumour characteristics were related to success or failure of the regimen, but the chosen biomarkers did not correlate with individual outcomes.

ANZUP

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group collaborates with CTC in clinical trial research to improve treatment of bladder, kidney, testicular and prostate cancers.

ANZUP brings together the professional disciplines and groups involved in researching and treating prostate and other urogenital cancers.

ANZUP also works closely with its consumer advisory panel to achieve better understanding of consumer and community perspective on issues related to their clinical trials and to ensure that results are communicated back to patients and the community.



Salma Fahridin, in CTC's oncology operations area

Mustafa Khasraw, oncologist, is the clinical lead for brain cancer trials at CTC

COGNO

Collaborative research by CTC and the Cooperative Trials Group for Neuro-Oncology has the purpose of better outcomes for those with brain tumours, and others affected by these diseases, such as their families. COGNO's main aim is to conduct investigator-initiated and collaborative group trials addressing important clinical questions.

COGNO now has members in New Zealand, Singapore, Canada, Ireland, India, Sweden and the USA. The group also has consumer and industry associate members. COGNO's annual scientific meetings have been hugely successful in bringing together professionals from all over the world.

HIGHLIGHT: BRAIN CANCER

Glioblastoma is an important target in the search for better cancer treatment

The CABARET trial of a potential treatment for glioblastoma is an example of a trial addressing an urgent clinical question. Glioblastoma is a serious brain malignancy provoking major research efforts. It is not common, but patients usually survive only a short time and there is no effective treatment if the disease recurs after chemotherapy. It is distressing for patients and their families and friends and has one of the highest average years of life lost for any cancer. It is treated with various chemotherapy agents, but there is no standard Australian treatment.

In CABARET, a large, multicentre phase 2 study, participants were randomised to a synthetic antibody, bevacizumab, along with chemotherapy, or to bevacizumab alone. In part 1 of CABARET, completed in 2015, bevacizumab alone did not benefit patients as much as expected, which may have been because some of them had had several recurrences.[46] Also, combination therapy did not improve this result. Even so, some patients did respond to the treatment. In ongoing laboratory research, the relevant individual markers of benefit may be identified from tumour samples.

When their disease recurred, patients graduated from Part 1 to Part 2 of the trial and were randomised again to continue or stop bevacizumab treatment. This second, exploratory, stage of the CABARET trial is continuing and when completed in 2016 will add value to the Part 1 results.

The trial has achieved international prominence and is likely to change international clinical practice.

Jenny Chow, executive officer of COGNO (right), with assistant Yi Feng

HIGHLIGHT: OVARIAN CANCER

Patient-reported outcomes validated

In ovarian cancer trials, the most common measure of the success of treatment is progression-free survival, that is, the time between starting treatment and when scans show that the disease becomes worse. But most women with ovarian cancer have advanced-stage disease and their priority is not progression-free survival but to maintain their quality of life and to reduce distressing symptoms.

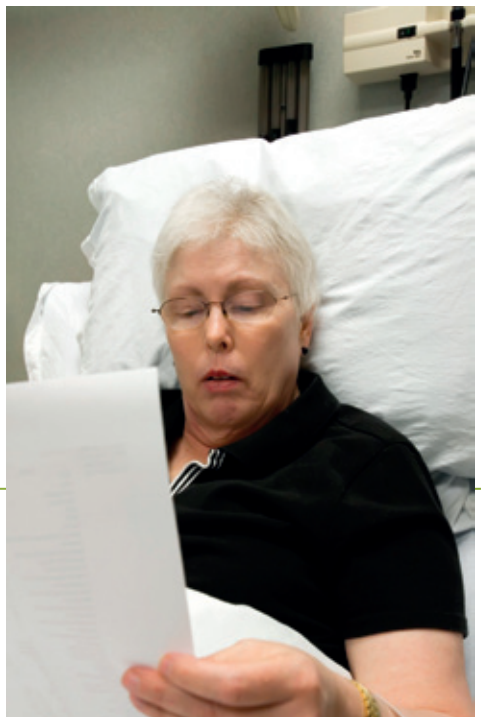
The Symptom Benefit trial of palliative chemotherapy for ovarian cancer is an international collaborative study of ANZGOG-CTC investigators with other members of the Gynecological Cancer Intergroup. Traditionally, the outcome measured would be the size of the tumour measured by scanning or the level of cancer markers in the blood. Symptom Benefit is unusual in that its main focus is the subjective effect of treatment on the patients and their quality of life.

Patient-reported outcomes can be more difficult to measure and analyse than objective outcomes. The investigators are acquiring insights into the symptom burden, patients' and clinician's expectations of treatment, and outcomes in a real world setting, with the aim of measuring the results of treatment in a way that is meaningful to patients.

From data from 852 trial patients, they developed a measure of ovarian symptoms and treatment concerns (MOST). This was recently validated in relation to trial outcomes and existing widely used ovarian cancer symptom scales.[214] The MOST index has good validity and similar or better statistical efficiency than other scales.

Including patient-reported outcomes in trials also acknowledges the centrality of trial participants in research, and is one of the recent steps in the policies of CTC and its collaborators to ensure that patients are involved and informed at each stage of all trials.

Chemotherapy may improve a patient's quality of life by reducing cancer symptoms and prolonging survival, or it may detract from quality of life because of the side-effects of drugs. Teasing out this balance through patient preference studies in various cancer types is a continuing research theme of the CTC.[10,176,177]



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ANZGOG

The Australia New Zealand Gynaecological Oncology Group conducts research into cancers of the ovaries, cervix, uterus, vulva and vagina at sites throughout Australia and New Zealand.

ANZGOG collaborates with over 20 study groups in other countries through membership of the international Gynecologic Cancer Intergroup. ANZGOG has members in all medical and health specialties, as well as patients and other nonprofessional members, some of whom form an advisory panel for consumer outreach and trial development.

ANZ BCTG

The Australian and New Zealand Breast Cancer Trials Group conducts a program of multicentre national and international clinical trials involving over 700 researchers. Its trials cover all aspects of breast cancer, including new treatments, prevention, quality of life, and treatment cost-effectiveness.

CTC is biostatistical centre for trials coordinated by the ANZ BCTG, and has a formal relationship with the group spanning nearly 30 years.

PERSONAL STORY

RESEARCH FELLOW CONTRIBUTES TO NEW INTERNATIONAL TRIALS

I joined the CTC as a research fellow for the Australia New Zealand Gynaecological Oncology Group early in 2015, and I support the trial coordinators in their management of ongoing ANZGOG trials. It was quite a change compared with my job as a gynae-oncologist in Oslo, Norway, but I immediately enjoyed the work in a multinational team.

The collaboration with other international trial groups have provided some very interesting insight into the design and implementation of clinical trials. I had the opportunity to contribute to the protocol development of a surgical trial in endometrial cancer, and that work helped me a lot in my understanding of the processes but also the challenges and compromises involved in clinical trial development.

We have just recently started a project to assess current perioperative care of ovarian cancer patients in Australia and New Zealand. I hope that this may turn into a continuing collaboration also with the NSGO (Nordic Society of Gynaecological Oncology), as I will return to Norway in 2016. It has been a privilege to work with this group of enthusiastic, skilled and supportive people.

Kristina Lindemann
Research fellow, clinical oncology, ANZGOG trials

Lucy Davies, biostatistician for the A La CaRT trial

A La CaRT trial shows that evidence for routine laparoscopic surgery for rectal cancer is still to be established

Laparoscopic (or keyhole surgery) for abdominal operations has many obvious benefits and has become common with advances in surgical technology over the past 10 to 15 years. Bowel tumours are often removed laparoscopically. For rectal cancer (the last 15 cm of the bowel), however, surgeons have been cautious because of uncertainty about removal of all parts of the tumour. Open surgery remains the standard treatment for many rectal cancers.

To this point, there has been little definitive evidence to guide surgeons about the safety and efficacy of laparoscopic versus open resection in rectal cancer. The multicentre Australasian Laparoscopic Cancer of the Rectum Trial (A La CaRT) is a collaboration of AGITG and CTC with colorectal surgeons in Australia and New Zealand. 472 participants were enrolled, 237 randomised to open surgery and 238 to laparoscopic surgery. Its aim is to find out whether laparoscopic surgery is as good as, or

no worse than, open surgery as an approach to rectal cancer.

In 2015, the investigators reported the first results of the trial, the comparison of laparascopic surgery and open surgery in terms of removal of all the tumour, in *JAMA*.[132] The results were unexpected, confirming that experience and observation is no substitute for planned clinical trial evidence. The trial showed that non-inferiority was not ruled out. That is, open surgery might be better, but was not statistically different from laparoscopic surgery. The pathology results showed that the tumour was completely or almost completely removed in 97% of the laparoscopic surgery group and 99% of the open-surgery group. There were low rates of complications and no differences between the two surgery groups in complications, pain or the time in hospital. On the basis of this evidence, surgeons will be cautious when considering a laparoscopic approach, which might be less successful for some patients, including those who are obese.

The trial was designed and conducted to ensure not only the best evidence but the best outcomes for patients. Surgeons could only take part after specific accreditation, which included video evidence of their expertise.

The trial participants will be followed up for 5 years for evaluation of other outcomes, such as disease-free survival, recurrence of the cancer and quality of life. Ultimately the case for recommending the routine use of laparoscopic surgery for these patients will be based on the long-term outcomes of each procedure.

AGITG

The Australasian Gastro-Intestinal Trials Group has been conducting trials in gastrointestinal cancer with CTC for over 25 years.

The group's purpose is to achieve better health outcomes for patients with gastrointestinal cancers by conducting and promoting clinical and related biological research in Australasia and internationally.

The AGITG is strongly focused on encouraging members of the medical and scientific community to participate in AGITG-sponsored trials. Members are actively engaged in identifying and developing novel clinical questions to answer in trials addressing common or rare gastrointestinal cancers. Several of these trials have led to improvements in clinical management internationally.

Eric Tsobanis, CTC manager of the INTEGRATE trials

Promising treatment for oesophagogastric cancer

In Australia, there are around 3400 new cases a year of cancers at the junction between the oesophagus and the stomach. Around 2400 people a year die from these cancers. New treatment options are urgently needed, because when surgery and chemotherapy fail, no other proven effective treatments have been available.

The phase 2 INTEGRATE trial tested the potential of regorafenib as a treatment for these cancers.[233,234] Regorafenib is a relatively new biological treatment that had been in use for colon tumours and gastrointestinal stromal tumours.

An Australasia-led trial, INTEGRATE involved investigators and patients from Korea and Canada as well as Australia and New Zealand. The study recruited 152 patients across 54 centres in the four countries. The response of the tumours to the treatment was assessed relative to a prespecified benchmark, a median progression-free survival of 8 weeks. The study also had a placebo arm as a calibration group to assess this reference. Patients receiving regorafenib had a significantly lower rate of disease progression at 8 weeks, 18%, compared with 46%in the placebo group. The Korean patients were more likely to benefit from treatment, a finding not explained by the trial, but it could be due to genetic or molecular differences affecting response to treatment or the way the drug is metabolised.

INTEGRATE was the first study to show activity of regorafenib in oesophagogastric cancer following failure of chemotherapy. A follow-up multinational phase 3 trial, INTEGRATE II, will start in 2016.

Translational oncology research—from bench to bedside

Translational research covers the full research pathway from laboratory science through clinical research and evidence-based clinical practice. From one point of view, it is a way to make the research process more efficient. It is also the foundation of personalised cancer treatment.

Typically, biological samples are collected from patients—for example blood or tumour tissue—then analysed for a range of biomarkers that are correlated with clinical outcomes to obtain indicators of risk. Biomarkers may predict the response of a patient to a particular treatment or forecast survival, an important part of personalising medicine.

In over half of the trials that the CTC designs and coordinates, patients may choose to consent to their biological samples being used in research. As new technologies develop and scientific knowledge advances, these biospecimens might be analysed at a later time. For some trials, genetic or molecular testing of tissue is part of the process of screening potential patients for recruitment. The CTC and its collaborative groups now embed their trials in a translational pathway where possible, with the aim of future applications at the bedside. CTC's oncology translational research collaborations across Australia include the Kolling Institute, Queensland Institute of Medical Research, the Centre for Translational Pathology, Peter MacCallum Cancer Centre, Monash University, NCIC Clinical Trials Group in Canada, and the MRC in the UK.

The CTC is a member of the virtual consortium, Sydney Catalyst, the Translational Cancer Research Centre of Central Sydney and Regional NSW. Sydney Catalyst is one of several translational cancer research centres funded by the Cancer Institute NSW. Sydney Catalyst brings together outstanding teams of researchers and clinicians from over 20 leading NSW institutions with the ability to undertake oncology translational research across the full continuum through basic biosciences, molecular biomarker discoveries, descriptive research, clinical trials, and implementation of best evidence-based care into practice.

In 2015, Professor Philip Hogg became head and Professor of Translational Cancer Research for Sydney Catalyst, and also joined the CTC as Chair Translational Cancer Research

Pancreas cancer treatment personalised in an ambitious novel trial

Advances in genetic testing have made it possible to choose suitable treatments on the basis of the characteristics of individual tumours. However, such personalised treatments have practical challenges, meaning that before they are validated in clinical trials, investigators have had to re-think the way trials are conducted.

The Individualized Molecular Pancreatic Cancer Therapy (IMPaCT) is a trial that used genome sequencing to choose the best individual treatment for each patient. IMPaCT screened pancreas tumours for three molecular targets: HER2 amplification, which is treated with trastuzumab and gemcitabine; KRAS wild type, which is treated with erlotinib and gemcitabine; and mutations in DNA damage-repair pathways (BRCA1, BRCA2, PALB2, ATM), which are treated with platinum-based chemotherapy.

The trial investigators assessed the conduct of the trial early in 2015 when recruitment difficulties had become apparent. Of 93 patients who had the screening and 22 who were found to have one of the three molecular targets, only one went on to be randomised to specific treatment. This was because the disease could progress very quickly,

meaning patients needed to start treatment immediately, while the process of obtaining and testing tumour specimens, with its many steps, was often not at the desired speed. Also some screened patients did not want to be randomised to treatment or they did not fit the other requirements to go on the trial.

When people with advanced cancer are being considered for targeted therapy, clinicians and scientists from various disciplines have to be able to work very quickly and in a coordinated way. Evaluating the treatment in a clinical trial is made even more complex and challenging by adding and standardising processes of obtaining consent, acquiring and analysing tumour samples, and discussing options of treatment. IMPaCT showed that we need rapid approaches when tumour samples need to be sequenced for clinical trials, and also to the way health care is delivered.

The investigators published their experience, and adapted the trial to meet the challenges.[18] The study used a central multidisciplinary team, working to produce faster and more focussed tissue analysis. Trial participants could receive standard treatment while they awaited molecular results. Nevertheless, the trial closed at the end of 2015.

The trial was a collaboration between Sydney Catalyst, the Australasian Gastro-Intestinal Trials Group and the CTC, in partnership with the Garvan Institute of Medical Research and the Australian Pancreatic Cancer Genome Initiative.

A search for individual targeted treatment for lung cancer

Chee Lee, oncologist and biostatistician, led the lung cancer meta-analysis

Some cancer therapies work for some patients but not others. Many CTC research studies aim to identify the characteristics of patients or their tumours that will predict success of a particular treatment.

One of these studies has looked at treatment for non-small-cell lung cancer, the most common type of lung cancer. It resulted in new evidence that a drug that targets a genetic abnormality is better than chemotherapy, in terms of progression of cancer.[83]

The study, the largest so far in this area, was a collaborative project, led from the CTC and involving researchers from Australia, Taiwan, China, Japan, Spain and the USA. They analysed data from seven trials carried out in various countries evaluating treatment with an EGFR tyrosine kinase inhibitor.

The study aimed to answer the important question: do patients with specific clinical characteristics or whose tumours have mutations benefit more from an EGFR tyrosine kinase inhibitor than chemotherapy? Most patients had one of the common EGFR mutations: exon 19 deletion or exon 21 L858R substitutions. About two-thirds had never smoked and about two-thirds were women.

The group of patients on the EGFR tyrosine kinase inhibitor, overall, benefited substantially from the drug, as compared with chemotherapy. The group whose tumours had a specific mutation (exon 19 deletions) did better on the drug than the group with the other mutation (exon 21 L858R substitution). Patients who had never smoked were more likely to benefit from the drug than smokers or ex-smokers, and women had slightly more benefit than men.

The study is a step in the endeavour to treat individual patients with the right drugs and to save others from suffering treatment regimens that may not help

CARDIOVASCULAR RESEARCH

CTC's cardiovascular studies rely on a workforce with complementary skills in basic science, clinical medicine and biostatistics from several groups within the CTC.

New molecular and genetic markers in patients from CTC's cardiovascular trials are being identified and validated, as a precursor to future work on finding new targets for prevention of heart and blood vessel disorders.

Extending trial results through international prospective meta-analysis

The CTC's large-scale clinical trials in cardiovascular disorders are integrated in translational research. That is, the program combines trial results with other evidence to influence clinical care and policy decisions.

For example, the CTC's large-scale cardiovascular trials, LIPID and FIELD, have both generated clinical evidence far beyond the outcomes of the trials themselves.

LIPID is part of the international Cholesterol Treatment Trialists' Collaboration, whose secretariat is at CTC and Clinical Trial Service Unit in Oxford. CTC, a pioneer of prospective meta-analyses, was one of the lead instigators of the CTTC's studies. The collaboration analyses data from, currently, 28 trials involving 175,000 patients, including the 9014 LIPID patients. One major analysis was published in 2015[24] and more are in progress.

The FIELD trial's study drug, fenofibrate, was expected to benefit people with diabetes, because it reduces the levels of triglycerides in the blood. However, FIELD results revealed that it substantially reduced patients' risks of amputation, kidney disease and eye disease, leading to ongoing further research in laboratory animals into the mechanisms of fenofibrate.[269]

Cardiovascular disease trials provide data for markers of risk

Knowing an individual's risk level for a heart attack or stroke can show when preventive treatment, such as statin drugs or lifestyle changes, will make a difference. The wealth of data from large cardiovascular trials allows researchers to continue to improve and refine models of risk. This is the aim of some of the cardiovascular research by the LIPID trial investigators (as our example shows),[143] the FIELD trial investigators,[108,109,158,159] and others.

HIGHLIGHT: LIPID

Diagnosis of cardiovascular risk in the LIPID study

People who have had a heart attack are at risk of another, as are those who have unstable angina. The LIPID trial showed many years ago how this risk could be reduced with statin therapy. The LIPID data has continued to provide new insights into cardiovascular risk. Most of the over 9000 patients provided samples of blood before and during the trial. Using these samples, the investigators recently analysed eight potential blood biomarkers of cardiovascular risk.[143] These biomarkers were known to be associated with distinct physiological characteristics.

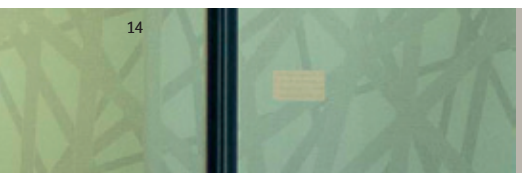
Of the markers in blood taken at the start of the trial, the best predictors were brain natriuretic peptide (BNP), a reflecting heart failure, and sensitive troponin 1, which is a marker of ischaemic heart damage.

They were stronger predictors than the conventional risk factors, including age. The only stronger predictor was if their heart disease had led to a heart attack in the past.

Blood biomarkers may be changed over time by underlying physiological

PHYSIOLOGICAL FACTORS ASSOCIATED WITH HEART DISEASE RISK

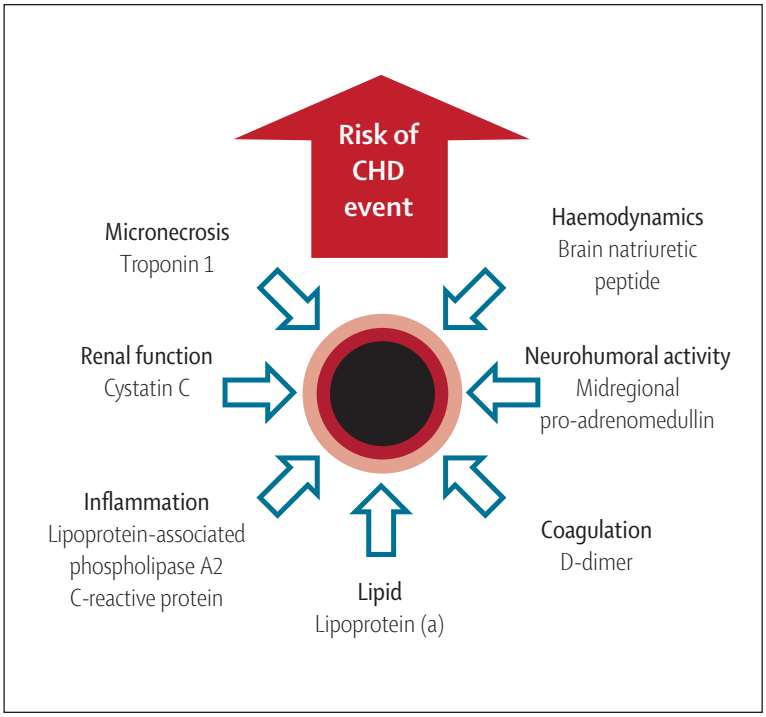
- lipid levels
- inflammation
- blood flow and pressure
- hormones
- heart muscle damage
- kidney function
- blood clotting



conditions and the effects of medical treatment. In LIPID, half the patients were taking pravastatin to help prevent further cardiovascular events.

The levels of potential blood biomarkers were measured after one year of treatment. Changes in the levels of some of the biomarkers over that year correlated with later cardiovascular events. Two, BNP and sensitive troponin 1, were familiar as predictors at baseline, and another was lipoprotein-associated phospholipase, which reflects inflammation.

As these biomarkers become more routinely measured, they are likely to be included with conventional risk factors in models for clinical decision making.



PERSONAL STORY

PHD RESEARCH WITH RELEVANCE TO CARDIOLOGY PRACTICE AND GUIDELINES

Jordan Fulcher, PhD student in cardiovascular disease

Since completing specialty training in cardiology I've been completing a PhD on statins and cardiovascular disease as well as a Master of Clinical Trials Research at the CTC, which have been highly complementary in improving my research skills.

Much of my work,, with statisticians at the CTC and the Clinical Trial Service Unit in Oxford, has involved analysis of data from the huge dataset of the Cholesterol Treatment Trialists' Collaboration. In 2015, the CTC group analysed data from nearly 80,000 cardiovascular disease patients in 8 large trials. We found that statin therapy continued to have a benefit 5 years after the trials ended.[197]

We have also examined the accuracy of popular risk calculators used in practice by cardiologists: the Framingham, the QRisk2 and Pooled Cohort Equations.[198] We compared these with the risk data of over 30,000 patients in 22 trials who did not have heart disease and were not taking statins. Our study found that risk is usually overestimated by these metrics.

In 2015 I was able to present some of this work at the American Heart Association meeting and Australian conferences.I've also been mentoring medical students and collaborating on various studies with other CTC researchers. Overall it has been a diverse and enriching experience.

NEONATAL TRIALS

‘Are there any randomised trials my baby can join?’[155]

Trials of interventions that might lead to the best outcomes for extremely premature or other babies at high risk can be challenging. Trials must aim for the best long-term physical and psychological health of the child as well as successful discharge of the infant from intensive care. Neonatal clinicians and triallists make special efforts to acquire the trust of the parents at trial entry and maintain it during long follow-up periods. Neonatal trials often need to be large, because participation of hundreds or thousands of babies is needed for clear evidence of benefit of treatment.

The CTC neonatal team work with clinicians through global partnerships in areas of need, such neonatal infection, oxygen therapy and simple cost-effective measures to reduce neonatal problems.

The CTC’s neonatal group continues to grow, with more trials and more collaborations and more staff. The BOOSTII trials, which examined the optimum level of oxygen saturation for premature infants, were completed in 2015, for publication in 2016. Data from 1135 Australian and 973 British patients are being analysed together with results from four other trials in an international prospective meta-analysis, the NeoPROM collaboration.

The Australian Placental Transfusion Study of deferred cord clamping for premature infants is now the largest trial of placental transfusion and is recruiting steadily. The LEAP1 and LIFT trials are using lactoferrin to treat, respectively, iron deficiency anaemia in pregnant women, and infection in preterm infants.

JOHN COLE/SCIENCE PHOTO LIBRARY

William Tarnow-Mordi, professor of neonatology

Lucille Sebastian, manager of PAEAN and APTS trials

The group is also establishing two new trials: TORPIDO2 is investigating the developmental effects of targeted oxygenation in the respiratory care of premature infants; PAEAN is using erythropoieten plus cooling to treat infants who have suffered from low blood or oxygen supply to the brain at birth, and will assess them at two years of age.

Improvement of specific methods for and approaches to neonatal trials is a central concern of CTC investigators.[138]

One of the aims of the neonatal group is to promote moves toward a health system in which every premature infant has the opportunity to participate in a clinical trial.[155] An important aspect of this is including parents and others with the experience of having a premature or fragile infant when neonatal trials are being designed and conducted. These valued parent contributors also have roles in recruitment of patients and in publication of the results.[106]

PERSONAL STORY

MANAGING TRIALS TO IMPROVE SURVIVAL OF NEWBORNS

I work with leading Australian and International neonatal researchers developing new studies and implementing funded studies.

We have a number of large neonatal trials ongoing, and no two projects, and no two days in the office, are alike. The size and the motivation of the neonatal team is at the highest that has ever been at CTC as we coordinate and manage several studies for better outcomes for premature babies.

Because of the size and duration of baby trials, seeing a project through from its conception to completion is rare for a project manager. For me it has been extremely rewarding to be part of the team to submit a paper of the results of one such trial in the *New England Journal of Medicine* under the leadership of our charismatic leader William Tarnow-Mordi, professor of neonatal medicine at the CTC. He is a champion of trials to improve the treatment and prospects of newborn babies. He says 'Randomised trials are the best way to determine which treatments provide the best outcomes. More trials of other treatments for premature babies are urgently needed to improve their quality of survival. With innovative investment in clinical trial networks and point of care data capture, trials like these could finish much faster, at a fraction of the cost'.

Alpana Ghadge, Project manager, neonatal trials

DIABETES RESEARCH

CTC's diabetes group undertakes research into type 1 and type 2 diabetes. The team consists of clinicians and laboratory scientists who work with colleagues in other countries, particularly India, the United States, Qatar, the United Kingdom, Israel and Ireland, and in remote parts of Australia. These varied projects are funded by government and non-profit agencies and charities that aim to reduce the burden of diabetes nationally and internationally.

The team's research focus includes:

- biomarkers related to diabetes outcomes in type 1 and type 2 diabetes
- prediction and prevention of diabetes and diabetes complications in children and adults
- use of technology in type 1 diabetes care, including insulin pumps
- use of telehealth to improve outcomes for Indigenous Australians with diabetes in remote regions of Australia
- Clinical trials: T4DM (testosterone for men with pre-diabetes), REMOVAL (metformin for prevention of cardiovascular complications), FAME-1 Eye (fenofibrate for prevention of retinopathy in type 1 diabetes), FIELD (biomarkers as indicators of diabetes complication risk) and closed loop insulin pumps in the home.

The group also collaborates with Insulin For Life and the International Diabetes Federation Life for a Child in research that supports some of the world's most vulnerable people with diabetes. The research includes simple health economics analyses showing the impossibly high costs of essential medicines for a poor child with type 1 diabetes in many disadvantaged countries and assessment of how families without refrigerators can keep insulin cool.

Students are a valuable part of their research team, with all receiving scholarships, publishing in peer-reviewed journals, and most presenting their research at national and international conferences.

From back row left: Andrzej Januszewski, Ryan Farr, Daniel Calandro, Alicia Jenkins, Anandwardhan Hardikar, Sarang Satoor, Wilson Wong, Mugdha Joglekar, Sven-Erik Bursell, and visiting researcher Dvaki Kher

HIGHLIGHT: DIABETES AND ISLET BIOLOGY

Thin rats and fat rats: ancestral diets determine vulnerability to type 2 diabetes

The middle classes from developing countries are more susceptible than western Caucasians to obesity, type 2 diabetes and cardiovascular disease in today's changing environment. This may be a result of the nutrition endured by their ancestors.

Unsurprisingly, increasing prosperity in developing countries has been accompanied by a sudden increase in caloric intake across the population, but their epigenetic make-up (whereby changing environmental factors alter how people's genes are expressed) has not compensated for these dietary changes. This means their bodies are still designed to cope with undernourishment; so they store fat in a manner that makes them more prone to obesity and its resulting diseases than populations accustomed to several generations of a 'normal' diet.

The latest research from the Diabetes and Islet Biology group, published as a cover story in *Cell Metabolism,*[57] demonstrates from an experimental model using rats that eating a 'normal' diet can make animals obese if their ancestors have been undernourished for several generations.

This scenario was created in a 12-year study of two groups of rats. The first group was undernourished for 50 generations and then put on a normal diet for two generations. The second (control) group maintained a normal diet for 52 generations. At the end of the study, the descendants of the first group were exposed

to a normal diet, but the epigenetic modifications of their undernourished forebears persisted. These rats were eight times more likely to develop diabetes and multiple metabolic defects than the control group. Lower vitamin B12 levels in the undernourished rats could also be an indicator of this trend.

With increasing migration of populations from developing to affluent countries, there is a need to identify factors that minimise their risk of diabetes and obesity—one of Australia's national health priorities. Laboratory studies like this one start the process by enlightening us on the circumstances of metabolic disorders.

PERSONAL STORY

ISLET BIOLOGY AND DIABETES

Anandwardhan Hardikar, who leads the Islet Biology and Diabetes research team

My major research interest is early prediction of diabetes and its complications. Research in our state-of-art, purpose-built laboratory is focused on understanding islet biology and development of insulin-producing cells. We work with cadaveric human pancreatic islets as well as biliary duct- and gallbladder-derived cells to gather information that would help us understand development of insulin-producing cells.

Other projects in the lab are focused on understanding the epigenetic modifications in insulin-producing cells in a unique model of multigeneration undernutrition. These studies involve understanding the influence of diet, micronutrients, intrauterine programming and gut microbiota in development of central adiposity, insulin resistance and type 2 diabetes. As part of this research, we are interested in analysing baby poo to understand how gut microbiota are established in the immediate postnatal period. We aim to identify the mechanisms that link gut microbes to development of diabetes and metabolic disease.

PERSONAL STORY

LAB RESEARCH MOTIVATED BY CURIOSITY ABOUT SCIENCE

Mugdha Joglekar, senior research fellow in diabetes

I have always loved to explore biology and discover new areas of science. I think this curiosity to understand, identify and investigate newer areas of research got me interested in pursuing science as a career. I work with Professor Alicia Jenkins and Associate Professor Anand Hardikar in the Jenkins-Hardikar lab as a JDRF international postdoctoral fellow, pursuing my interests in microRNAs and epigenetics. I was recently awarded the ADS Skip Martin Fellowship, followed by the JDRF (USA) advanced postdoctoral fellowship for work aimed at understanding the molecular mechanisms involved in immunomodulation and diabetes.

I am involved in multiple projects that will identify molecular cues during pancreas development and diabetes, so as to apply this knowledge towards development of therapies aiming to retard the death of insulin-producing cells and complications of diabetes.

These form foundation steps toward improving the treatment of diabetes.

SYSTEMATIC REVIEWS AND ASSESSMENT OF TESTS AND TECHNOLOGY

The CTC's systematic reviews and health technology assessment group integrates trial results and other findings of health research to obtain the best unbiased evidence to support effective and efficient health policy and practice.

A systematic review of high-quality trial data, with reanalysis of the data at an individual-patient level is the optimal way to arrive at valid evidence to underpin clinical and policy decision making. Such a meta-analysis enlarges the participant pool from the limitations of a single trial and therefore can increase the statistical power of the results.

Where a local population is too small to support a large trial, a meta-analysis of several far-flung trials can be a substitute, especially where the investigators cooperate to plan their coordinated trials in advance in a prospective meta-analysis. Examples can be found in neonatology, where extremely high numbers of participants are required to reach the statistical power to prove a result, and cardiovascular disease, where common serious disease means there are high numbers of patients and large trials. CTC has provided leadership in the rationale and implementation of many of these.

Systematic reviews of available evidence are recommended as the starting point for any new research study, even before funding is applied for. A review will show whether the new trial is actually needed and where the gaps in evidence are. CTC undertakes such reviews as part of the process of beginning a new study.[15,101,184,185] Such reviews also inform the methods of CTC trials[17] and extend and generalise results obtained from CTC trials.[219]

CTC contributes internationally to advances in the methodology of systematic reviews, through leadership in the Cochrane Prospective Meta-Analysis Methods Group. In 2015 the group published a review of on how meta-analyses influence the progress of subsequent medical research.[142] CTC is also the editorial base of Cochrane Breast Cancer, which oversees Cochrane's systematic reviews of evidence in all aspects of breast cancer.They recently published two new reviews on lymphoedema and also produced a final update of their review of the value of taxane chemotherapy for metastatic breast cancer.[54]

CTC's Lisa Askie, director of the CTC's systematic review group, is a convener of the Cochrane Prospective Meta-Analysis Methods Group

PERSONAL STORY

STUDIES OF CLINICAL TESTS AND DISEASE RISKS INVOLVE DIVERSE SKILLS AND A MULTIDISCIPLINARY TEAMWORK

My research area is studies of medical tests, biomarkers and clinical risk prediction models. My goal is to help develop and evaluate the use of these 'tools' to improve the understanding and classification of disease to guide treatment decisions. The skills and expertise needed for these traverse epidemiology, clinical medicine and research methodology.

I work with clinicians, biostatisticians, laboratory scientists and health economists. My role is to contribute to study design, analysis, interpretation and reports. Recent studies range from biomarker discovery[83] to a pragmatic randomised controlled trial of implementing a new model of risk.[81] We used the model to predict how likely it would be that a patient presenting to the emergency department with chest pain and a non-diagnostic ECG was having a serious coronary event.

Other studies take advantage of existing treatment trial data to evaluate biomarkers and develop models to improve treatment selection.[105] I also collaborate with international groups to improve the methods for evaluating diagnostic and other clinical tests.

I feel very fortunate to be working with such a multidisciplinary group at CTC. I enjoy the collegial spirit and the lively open discussion of research questions and problems.

Sally Lord, senior research fellow, is an epidemiologist and clinical researcher, whose work is at the forefront of new ideas in decision analyses and evaluation of health technologies and tests

HIGHLIGHTS: SYSTEMATIC REVIEWS

How do doctors know that using a new clinical test will be worthwhile?

Evaluation of diagnostic tests has been an area of interest for CTC researchers for many years. It is a complex process involving many steps. Evaluation takes in methods for arriving at the best evidence of the benefits of treatment, such as clinical trial evidence.

A new test may detect a disorder accurately, but that is only the start. If detection of a disorder does not lead to more and better treatment, the test may be useless in practical terms. If it detects a harmless disorder, the test may lead to overtreatment. Therefore, evaluating a new test must take account of the consequences of diagnosis and the effects of the subsequent treatment for a patient. The final outcome in the treatment pathway is what matters most. Ideally, the benefits of a new diagnostic test are evaluated by a randomised trial, but CTC researchers are looking for simpler and faster ways of determining whether a new test should be adopted in place of an old one.

The Test Evaluation Working Group of the European Federation of Clinical Chemistry and Laboratory Medicine, with Sally Lord, have applied these principles to examining the relative advantages of different ways of specifying the performance of laboratory tests.[64] These tests can be used for many purposes, such as screening, diagnosis, prognosis, risk assessment, selection of treatment, and monitoring the effects of

treatment. A laboratory test can be evaluated on the basis of randomised evidence of its direct outcomes for the patient (using a controlled clinical trial that measures the endpoint). Alternatively, it may be evaluated on linked evidence from simulation models of real-life clinical decision making, which use data from a variety of existing studies. The latter is faster but the model may be diluted by the diversity of clinical practice, leading to evidence that may be less strong than that generated by a clinical trial.

An analysis of Australian clinical trial activity in relation to national health priorities

Clinical trials provide high-quality evidence of the effectiveness, or not, of treatments and other health interventions in health care. But the results of trials are only important if there is a need for treatment in that area.

In the first overview of clinical trial activity in Australia, a recent CTC study assessed whether clinical research being done reflects national priorities, defined by the burden of disease (box).[80]

The researchers had access to detailed data from the Australian New Zealand Clinical Trials Registry, a national resource sited at the CTC. They measured the number of trials (as a proxy for the number of current research questions) and the planned recruitment to those trials (to show the number of patients actively participating in research) in the nine national health priority areas.

From an analysis of 5143 registered trials recruiting participants in Australia, the main finding was that obesity, dementia and asthma are under-researched. These areas have few trials with few participants in relation to their disease burden. Cancer and cardiovascular disease, on the other hand, have high trial activity, with mental disorders not far behind.

The registry collects data on the design of trials, health conditions treated, treatments or interventions, planned recruitment, outcomes of treatment, funding and sponsorship. It is one of several national registries recognised by the World Health Organisation. To date, 11,460 trials have been registered. The team at the CTC continues to improve the functioning and utility of the registry and monitor the characteristics of Australasian trials research. They keep up to date with international guidelines for accountability and transparency in clinical research.

One of the original purposes of the registry was to allow investigators from anywhere in the world to get information on current research endeavours before they embarked on a trial. Registries like the Australian one are important for preventing duplication of research effort. Now, the findings of this new study are showing researchers and policy makers where to direct their attention to reduce the burden of disease in Australia.

CTC's ANZCTR project officers Ava Tan-Koay, Slavica Berber, Kylie Hunter and Ailsa Langford

NATIONAL HEALTH PRIORITY AREAS

- Cancer control
- Cardiovascular health
- Mental health
- Injury prevention and control
- Diabetes mellitus
- Obesity
- Arthritis and musculoskeletal conditions
- Dementia
- Asthma

HEALTH ECONOMICS

Proven new health-care treatments must be shown to be value for money before they can be put into practice, whether they are publicly or privately funded. Affordability must be justified in a national climate of increasing competition for funding. Economic evaluations have long been integral to CTC's trials and systematic reviews of evidence. This is the responsibility of the health economics group.

The group also pursues collaborations with other trial groups, such as in melanoma and kidney disease.

Economic evaluation is prioritised and incorporated into trials when:

1. Evidence of cost-effectiveness is needed or is likely to help decision making (that is, whether the intervention is cost-effective or not cost-effective);
2. When the intervention is known to be expensive; or
3. When the intervention has a substantial impact on quality of life.

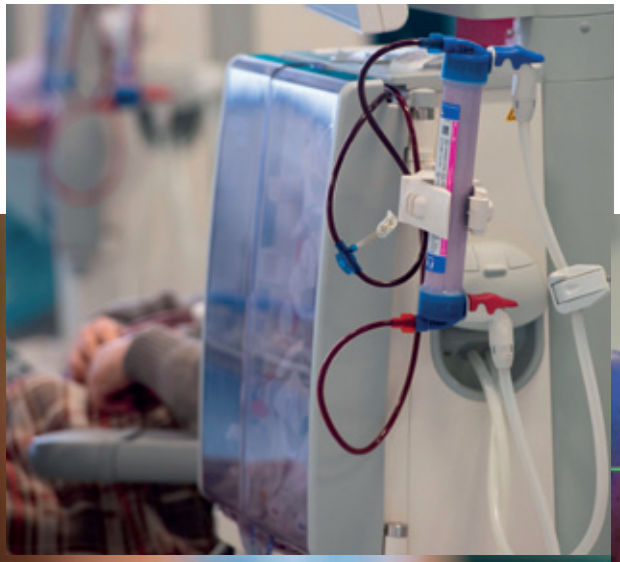
Typically, this is conducted alongside phase 3 clinical trials, but economic evaluations often require additional modelling to make use of all the available evidence.

Economic evaluation also includes studies of preference elicitation, which answer questions about patient, clinician or community preferences for particular aspects of screening or treatment using discrete choice experiment methods. These studies can inform the design of new interventions used in trials and advise on incentives or reimbursement in health policy.

The health economics group is involved in policy-relevant implementation science, in particular budget impact analyses, to determine the financial impact of 'rolling out' new cancer treatments and programs nationwide, for example, the impact of specialised surveillance clinics for people at high risk of melanoma skin cancer.[95]

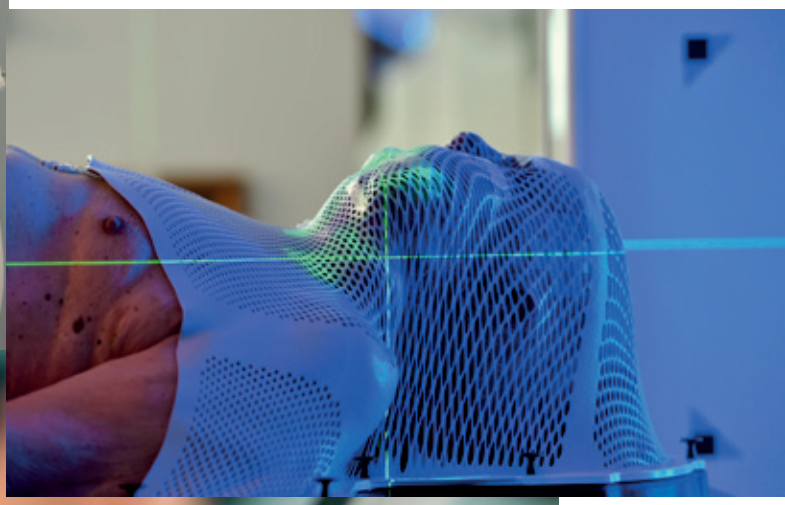
Finally, the health economics group leads research in the area of health equity, with a focus on the financial impact of cancer and chronic kidney disease on individuals and households.[228–230] Several projects have been undertaken with the Cochrane Equity Methods group to incorporate health equity considerations into systematic reviews and guidelines.

Kidney dialysis



ALAMAY

Cancer radiotherapy



DR. P. MARAZZI/SCIENCE PHOTO LIBRARY

HIGHLIGHT: SHARP STUDY

Associate Professor Rachael Morton, director of health economics and SHARP study investigator

'The SHARP study highlights the large proportion of patients with CKD who are in financial hardship, which is not restricted to people living in low- or middle-income countries, but includes those living in relative poverty in high income countries such as Australia. Successful kidney transplantation may benefit not only the individual in terms of their health and quality of life, but also the economic stability of their household.'

—Rachael Morton

Does health affect wealth?

Advanced stages of chronic kidney disease may cause considerable financial strain for patients and their families.

To find out whether the severity of chronic kidney disease and side-effects associated with the disease and its treatment were associated with a fall into poverty, Rachael Morton and her colleagues studied people participating in the international Study of Heart and Renal Protection (SHARP), who were followed up for a median of 5 years.[229]

Of the 2914 people with moderate to severe kidney disease, 933 were in poverty at the time of screening and a further 436 had moved into poverty by the end of the study. The severity of the disease was a significant predictor of a fall into poverty, as were low education and low income. People who received kidney transplants were much less likely to fall into poverty.

The authors concluded that kidney transplantation may have a role in reducing the risks of household poverty due to chronic kidney disease.

Does education level make a difference to health?

In another study, with data from over 9000 people with chronic kidney disease, the SHARP investigators examined the relationship between education level and progression of kidney disease, cardiovascular events and death.[98] Cardiovascular risk and mortality were both associated with low education, but most of this risk was attributed to lifestyle factors and poor health literacy. Surprisingly, education level generally was not related to progression of kidney disease.

BIOSTATISTICIANS ARE CENTRAL TO INNOVATION IN CLINICAL TRIALS

The CTC's biostatistics group are innovators and practitioners in all areas of clinical trial methodology. They lead the design and analysis of trials of the CTC and its collaborative groups. They take part in the trials of national and international groups. CTC has a long-standing role as a biostatistical centre for the Australian and New Zealand Breast Cancer Trials Group.[167, 270]

All the biostatisticians also collaborate in research in hospitals and universities in Sydney, visiting these sites and helping clinicians and others conduct their research to rigorous standards. They therefore find themselves involved in many varied areas of medicine, such as radiation oncology,[37, 38, 102, 113, 140] emergency medicine,[67] childbirth,[41, 42, 75, 145] immunology,[11,65, 181] urology,[55,103] neurology,[115] ophthalmology,[118,162] and medical education.[126,148]

Back at the CTC, they also undertake studies in statistical methodology to improve approaches to clinical trials. An example is the recent exploration of heterogeneity in global clinical trials, which showed that the apparently large variation in a country-specific treatment effect could be due to chance.[124]

Professor Val Gebski and Valérie Garès, research fellow in biostatistics

Rachel O'Connell, senior biostatistician

HIGHLIGHT: ONTRAC

Vitamin B3 derivative cuts risk of new skin cancers: ONTRAC (Oral Nicotinamide to Reduce Actinic Cancer)

Andrew Martin, senior biostatistician and ONTRAC investigator

Positive results from ONTRAC, an important study on prevention of skin cancer by University of Sydney researchers, were published in the *New England Journal of Medicine* in October.[19] The investigators found that a year of treatment with nicotinamide, a form of vitamin B3, significantly lowered the risk of common, non-melanoma skin cancer in people who were at high risk because they had already had such skin cancers.

CTC's senior biostatistician, Andrew Martin, is an ONTRAC chief investigator, and presented the results at the meeting of the American Society of Clinical Oncology.[225]

In Australia, non-melanoma skin cancer affects more than half of the population. It is four times as common as all other cancers combined, and costs the nation more than $500 million annually.

The most common types are squamous cell carcinoma and basal cell carcinoma. Squamous cell carcinomas can spread to lymph nodes and internal organs. Basal cell carcinomas rarely spread but can cause huge cosmetic problems, as they often occur on the face. Nicotinamide was equally effective in preventing both types.

The study was not designed to test whether nicotinamide would benefit people in the general population who have not had skin cancer, or whether it would affect melanoma.

This study built on a decade of evidence from preclinical and early clinical studies, which suggests nicotinamide enhances the repair of DNA in skin cells damaged by sunlight. Nicotinamide also appears to protect the skin's immune system from ultraviolet radiation by providing skin cells an extra energy boost when they are in repair mode after sun exposure.

The ONTRAC study was funded by the National Health and Medical Research Council and conducted at Royal Prince Alfred and Westmead Hospitals in Sydney.

PERSONAL STORY

VARIETY IN INTERNATIONAL COLLABORATION FOR CTC BIOSTATISTICIAN

Working in collaboration with other international organisations has provided a useful and challenging insight into how other institutions are run. The biostatistics team at the CTC are currently in collaboration with AstraZeneca, based in the UK, and Gineco, based in France, on the SOLO2 trial, which is a multicentre phase 3 study of olaparib in patients with BRCA-mutated advanced ovarian cancer.

My role in the project is, as part of a team, to replicate primary trial results calculated by the AstraZeneca team. It has been very useful to work on new techniques that are incredibly useful in helping to develop my own statistical knowledge further.

So far, the project has been an experience that I am very much enjoying, despite a few challenges along the way. It has also been a privilege to represent the CTC at an international level and something I am very much looking forward to continuing in the future.

Emma Gibbs, biostatistican

HIGHLIGHT: HIRT

Trial of on-the-spot emergency medical treatment for severe head injuries

If a person is unconscious after being hit in a motor vehicle accident or falling from a building, does it help to send a specialist physician as well as the paramedic team? The Head Injury Retrieval Trial (HIRT) was an attempt to obtain definitive evidence on whether physician treatment in addition to standard paramedic treatment results in better outcomes for people with severe blunt traumatic brain injury.[51]

Physician-staffed prehospital services can provide a wider range of stabilising and rescue procedures than paramedics. Observational studies and reviews had suggested that the long-term outcomes for patients may be better, although the cost per life year saved, especially if the physician is sent by helicopter, is very high.

The HIRT trial, by Careflight, Westmead Hospital and CTC, was conducted in the Sydney area.

It was complex, incorporating protocols of the Royal Australasian College of Surgeons and the NSW Ambulance Service, resulting in practical challenges that may need to be addressed in future studies. Helicopter flights were limited by the hours of daylight, reducing recruitment to the trial in winter. Recruitment could not be expanded to new jurisdictions, but had to be restricted to areas where ambulance protocols and policies allowed random allocation of patients. The trial design had to allow for unexpected sudden changes to the planned treatment or allocation of patients if the situation required it. Of the patients randomised to the trial, many were then excluded because their injuries did not fit the eligibility criteria, or they were not transported to a trauma centre, or they died before the emergency team arrived. The comparison of the randomised groups did not show a difference, but this could well have been because so many patients did not receive their allocated treatment. In an analysis of the groups as actually treated, the death rate was significantly lower in the medically treated group.

PERSONAL STORY

CTC BIOSTATISTICIANS BENEFIT FROM BEING PART OF A VITAL GROUP

Every CTC trial is unique, and our trials often present new methodological problems that challenge us to find a solution that ensures trial results and conclusions are valid for general practice.

One problem that I have worked on involves a cardiovascular study in which participants could experience multiple events of different types (such as angina and a stroke) over time. We aimed to establish how these events are interconnected, and how we can use this information to estimate the risk of a future event, and see if we are able to summarise the complex effects of a trial treatment in a simple way.[35]

I'm fortunate to be part of a strong team of biostatisticians at the CTC, who have a wide range of experience that we can draw upon. We have a regular 'discussion forum', when members of the team present their recent problems to the group. We bounce ideas off each other and suggest potential angles of attack in searching for a solution. These have proven to be invaluable learning experiences for me, and will no doubt continue to improve the way that clinical trials are conducted at the CTC.

Mark Donoghoe, biostatistician

EDUCATION

Masters degree in clinical trials research

The University of Sydney's Clinical Trials Research postgraduate course leads to formal qualifications in the design, conduct and interpretation of clinical trials.

It was developed by the CTC in response to a need for understanding of clinical trials and their regulations by health care professionals, who increasingly find that research is a customary part of a clinical role. Students complete the course with a solid understanding of research methodologies, clinical trials literature and the clinical trials process, including design, regulations, and statistical and ethical considerations. The program is delivered 100% online, including lectures, discussion forums and supplementary notes.

The course is taught online by clinicians and researchers who have designed, conducted and published more than 150 clinical trials over the past 28 years, as well as teaching short courses, masterclasses and seminars over that time. It is coordinated by Adrienne Kirby, Val Gebski and Anthony Keech.

Adrienne Kirby (right), senior CTC statistician, is co-coordinator of the postgraduate clinical trials course, here with Rebecca Asher, biostatistician

CTC honorary associate researcher in cardiovascular disease, Boris Waldman, with his supervisors, Val Gebski, Tony Keech and Alicia Jenkins, at his graduation. Boris received the University of Sydney Medal and other prizes in the university's graduate medical program

Biostatistics Collaboration of Australia

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 and administered from the CTC. Over 300 students are enrolled, 164 of them new in 2015, and on graduation will contribute to solving the shortage of well qualified biostatisticians in Australia and elsewhere.

BIO STATISTICS COLLABORATION OF AUSTRALIA
www.bca.edu.au

CURRENT CTC TRIALS

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
NEONATAL DISORDERS			
Trials in start-up			
TORPIDO2: Targeted oxygenation in the respiratory care of premature infants at delivery: effects on developmental outcome *CTC-led study*	Neonates born before 29 weeks' gestation	1200	—
PAEAN: Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy *CTC -led study*	Newborn infants with signs of brain damage	300	—
Current trials			
APTS: Australian placental transfusion study *CTC-led study*	Neonates born before 30 weeks' gestation	1600	1288
LEAP: Lactoferrin evaluation in anaemia in pregnancy *CTC-led study*	Pregnant women with anaemia	900	143
LIFT: Lactoferrin infant feeding trial *CTC-led study*	Infants born weighing under 1500 g	1100	143
Trials in follow-up			
APTS Echo: Australian placental transfusion study (Echo substudy) *CTC-led study*	Neonates born before 30 weeks' gestation	242	266
CARDIOVASCULAR DISORDERS			
Trials in start-up			
CARSK: Canadian-Australian trial screening for coronary artery disease *RPA, Westmead, St Paul's, Auckland City hospitals, University of Sydney, CTC study*	Kidney transplant candidates	3306	–
Trials in follow-up			
FIELD: Fenofibrate intervention and event lowering in diabetes *CTC-led study*	Patients with type 2 diabetes	8000	9795
LIPID: Long-term intervention with pravastatin in ischaemic disease *CTC-led study*	Patients with a history of coronary heart disease	9000	9014
DIABETES			
Trials in start-up			
e-PREDICE: Early prevention of diabetes complications in people with hyperglycaemia in Europe and Australia *International study, BIONE and CTC*	Adults with hyperglycaemia	100 (Australia); 3000 (int.)	—
FAME1-Eye: Fenofibrate and microvascular events in type 1 diabetes *CTC-led study*	Adults with type 1 diabetes and nonproliferative retinopathy	450	—
Current trials			
Performance of closed-loop artificial pancreas at home compared with best available technology *St Vincent's Hospital, Melbourne, JDRF, Medtronic, CTC study*	People with type 1 diabetes	24	—
REMOVAL: Effects of metformin added to insulin on atheroma progression *University of Glasgow and NHS-led, and CTC study*	Adults with type 1 diabetes at risk of cardiovascular disease	105 (ANZ); 450 (int.)	106(ANZ); 450 (int.)
T4DM: efficacy of adding testosterone to a lifestyle program to prevent progression to type 2 diabetes *University of Adelaide and CTC study*	Men with prediabetes and low testosterone	1500	591

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Trials in follow-up			
TEAMSnet: using internet and mobile technologies for coordinated diabetes and heart *University of Melbourne, Fred Hollows Foundation, AMSANT, CERA, CTC study*	Indigenous people from remote and rural Australian communities	600	600

ONCOLOGY

Current trial			
iTool: Evaluating a web-based tool for estimating and explaining prognosis *CTC study*	Patients with incurable cancer who attend clinics of participating oncologists and who want information about life expectancy	70 patients; 70 oncologists	219 patients; 28 oncologists

BREAST CANCER (COLLABORATING WITH RACS)

Current trials			
SNAC 2: Sentinel node biopsy versus axillary clearance *RACS and CTC study*	Women with operable breast cancer, stratified by factors including age and tumour size	1012	326
Trials in follow-up			
SNAC 1: Sentinel node biopsy versus axillary clearance *RACS and CTC study*	Women with a single operable breast tumour <3 cm, stratified by factors including age and tumour size	1000	1088

GASTROINTESTINAL CANCER (COLLABORATING WITH AGITG)

Trials in start-up			
ACTICCA-1: Phase III trial of adjuvant gemcitabine and cisplatin chemotherapy compared with observation *AIO (Germany)-led, AGITG, and CTC study*	Patients with biliary tract cancer after resection	440 (int.)	—
CONTROL NETS: phase II open-label trial of lutetium-177 octreotate added to capecitabine and temozolomide for neuroendocrine tumours *AGITG and CTC study*	Patients with pancreatic or midgut neuroendocine tumours	165	—
NABNEC: Phase II study of nab-paclitaxel and carboplatin as first-line treatment *AGITG and CTC*	Patients with advanced gastrointestinal neuroendocrine carcinoma	80	—
Current trials			
ALT GIST: Imatinib alternating with regorafenib compared to imatinib alone for GIST *AGITG, CTC, SSG, EORTC study*	Adults with previously untreated metastatic gastrointestinal stromal tumours	240	10 (ANZ); 14 (int.)
ASCOLT: Aspirin for Dukes C and high-risk Dukes B colorectal cancers *National Cancer Institute (Singapore)-led, AGITG and CTC study*	Patients with colorectal cancer who have completed surgery and other treatment	200 (ANZ); 2660 (int.)	121 (ANZ); 790 (int.)
DOCTOR: Phase II trial of preoperative cisplatin, 5-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer *AGITG and CTC*	Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy	150 registered; 60 randomised	126 registered; 66 randomised
ICECREAM: Irinotecan cetuximab evaluation and cetuximab response evaluation among mutants *AGITG- and CTC-led international study*	Patients with Kras-WT metastatic colorectal carcinoma or a G13D mutation	100	99
IMPACT: Phase II trial using genomic sequencing and protein expression to direct first-line treatment *Garvan, AGITG, CTC and Sydney Catalyst*	Patients with metastatic pancreatic cancer	20	2
InterAACT: phase II open-label trial comparing cisplatin plus 5-fluorouracil versus carboplatin plus paclitaxel for anal cancer *Cancer Research UK, AGITG and CTC study*	Patients with locally recurrent or metastatic anal cancer	80 (int.)	0 (ANZ); 36 (int.)
TOPGEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer *AGITG- and CTC-led international study*	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	120 (stage 1); 118 (stage 2)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Trials in follow-up			
A La CART: Australian phase III randomised trial of laparoscopy-assisted resection compared with open resection *AGITG and CTC study*	Patients with primary rectal cancer	470	475
ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases *AGITG and CTC study*	Patients with confirmed resectable liver metastases and no other disease	200	8
CO.23: BBI608 and supportive care compared with placebo and supportive care for colorectal carcinoma *NCIC-CTG-led AGITG and CTC study*	Patients with advanced colorectal carcinoma	275 (ANZ); 650 (int.)	78 (ANZ); 282 (int.)
GAP: Phase 2 study of gemcitabine and nab-paclitaxel for pancreas cancer *AGITG and CTC*	Patients with resectable pancreas cancer	50	42
PETACC 6: Addition of capecitabine to preoperative oxaliplatin chemoradiotherapy and postoperative oxaliplatin chemotherapy for rectal cancer (AG0707R) *EORTC (PETACC)-led, AGITG and CTC*	Patients with locally advanced rectal cancer	135 (ANZ); 1090 (int.)	127 (ANZ); 1094 (int.)
Quasar 2: Phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer (AG0107CR) *OCTO-led, AGITG and CTC*	Patients with colon cancer treated by surgery	120 (ANZ); 1892 (int.)	219 (ANZ); 1952 (int.)
REGISTER: Multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response *AGITG- and CTC-led international study*	Patients with gastrointestinal stromal tumour not suitable for curative surgery	80	47
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer *MRC-led, AGITG and CTC*	Patients with fully resected stage III colorectal cancer	225 (ANZ): 9500 (int.)	213 (ANZ); 6144 (int.)

GYNAECOLOGICAL CANCER (COLLABORATING WITH ANZGOG)

Current trials			
ECHO: Exercise during chemotherapy for ovarian cancer (ANZGOG 1304) *ANZGOG and CTC study*	Women with newly diagnosed ovarian cancer starting treatment	500	11
Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer (ANZGOG 0902) *ANZGOG- and CTC-led international study*	Women with locally advanced cervical cancer	780 (int.)	136 (ANZ); 682 (int.)
OVAR2.21: Noninferiority phase III trial of bevacizumab + gemcitabine and carboplatin compared with bevacizumab + doxorubicin and carboplatin *GCIG-led, ANZGOG and CTC study*	Women with recurrent cancer sensitive to platinum-based treatment	120 (ANZ); 654 (int.)	76 (ANZ); 682 (int.)
PARAGON: Phase II study of anastrozole in gynaecological cancers (ANZGOG 0903) *ANZGOG- and CTC-led international study*	Women with potentially hormone-responsive gynaecological cancers	350 (int.)	208 (ANZ); 315 (int.)
REZOLVE: Phase II study to evaluate the safety and potential palliative benefit of intraperitoneal bevacizumab (ANZGOG 1101) *DGOG-led, ANZGOG and CTC*	Women with symptomatic ascites due to advanced chemotherapy-resistant ovarian cancer	24	13
Trials in follow-up			
BNC105P Phase I–II combination study (ANZGOG 1103) *ANZGOG- and CTC-led international study*	Women with partly platinum-sensitive ovarian cancer in first or second relapse	Phase 1: up to 24 (int.)	12 (ANZ); 15 (int.)
GOG182 *GOG-led, ANZGOG and CTC*	Women with advanced stage (FIGO III-IV) epithelial ovarian or primary peritoneal carcinoma.	4200 (int.)	184 (ANZ), 4312 (int.)
ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy *MRC-led, ANZGOG and CTC*	Women with platinum-sensitive relapsed ovarian cancer	400 (int.)	17 (ANZ); 486 (int.)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy	Women with epithelial ovarian cancer who have not received systemic antitumour therapy	1444 (int.)	76 (ANZ); 1450 (int.)
ICON 8: Dose-fractionated chemotherapy compared with 3-weekly chemotherapy for ovarian cancer *MRC-led, ANZGOG and CTC*	Women with ovarian, fallopian tube or primary peritoneal cancer.	145 (ANZ); 1485 (int.)	70 (ANZ); 1566 (int.)
OVAR 16: Pazopanib versus placebo for ovarian cancer *AGO-led, ANZGOG and CTC*	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	900 (int.)	65 (ANZ); 940 (int.)
PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with pelvic radiation alone in high-risk endometrial carcinoma *ANZGOG- and CTC-led international study*	Women with advanced endometrial carcinoma	120 (ANZ); 670 (int.)	122 (ANZ); 688 (int.)
Symptom benefit: Does palliative chemotherapy improve symptoms in women with recurrent ovarian cancer? (ANZGOG 0701) *ANZGOG- and CTC-led international study*	Women with platinum-resistant or platinum-refractory ovarian cancer	200 (ANZ); 800 (int.)	143 (ANZ); 948 (int.)

GENITOURINARY CANCER (COLLABORATING WITH ANZUP)

Current trials			
BL 12: Phase II trial comparing nab-paclitaxel with paclitaxel *ANZUP and CTC study*	Patients with metastatic urinary tract cancer and previous platinum therapy	199 (ANZ)	9 (ANZ); 101 (int.)
Pain Free TRUS B: Phase III trial of methoxyflurane with periprostatic local anaesthesia to reduce discomfort of transrectal ultrasound-guided prostate biopsy *ANZUP and CTC study*	Men scheduled to undergo first TRUS biopsy of the prostate	420 (ANZ)	0
BCG+MMC: Phase III trial of adding mitomycin C to BCG as adjuvant intravesical therapy for bladder cancer *ANZUP and CTC study*	Patients with high-risk, non-muscle-invasive bladder cancer	500	62
ENZAMET: phase III trial of enzalutamide in androgen-deprivation therapy for metastatic prostate cancer *ANZUP and CTC study*	Men with metastatic prostate cancer	1100	322 (ANZ): 431 (int.)
ENZARAD: phase III trial of enzalutamide in androgen-deprivation therapy for localised prostate cancer *ANZUP and CTC study*	Men with high-risk localised prostate cancer	800	143 (ANZ); 155 (int.)
P3BEP: Phase III trial of accelerated versus standard BEP (ANZUP 1302) *ANZUP, ANZGOG and CTC study*	Patients with intermediate and poor-risk metastatic germ-cell tumours	Stage 1: 90 (ANZ); 150 (int.) Stage 2: 350	20 (int.)
Trials in follow-up			
Accelerated BEP: Feasibility study of accelerated BEP for advanced germ cell tumours *ANZUP and CTC study*	Patients with advanced germ cell tumours	Up to 50	45
Chemo & cognition: Cognitive function and treatment for testicular cancer (ANZGCTG 0106) *ANZUP and CTC*	Patients being treated and followed up for testicular cancer	154	151
Eversun: Phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901) *ANZUP and CTC*	Patients starting first-line systemic therapy for advanced renal cell carcinoma	55	56
SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05) *MRC-led, ANZUP and CTC*	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ); 1656 (int.)	168 (ANZ); 1711 (int.)

LUNG CANCER (COLLABORATING WITH ALTG)

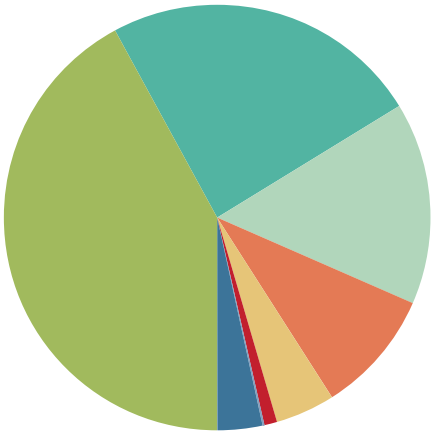
Trial in start-up			
NIVORAD: Nivolumab and stereotactic radiotherapy versus nivolumab alone *ALTG and CTC*	Patients with advanced non-small- cell lung cancer progressing after chemotherapy	120	—

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Current trial			
BR.31: Phase III study of adjuvant MEDI4736 *NCIC-led, ALTG and CTC*	Patients with resected primary stage IB, IB (>4 cm), II or IIIA non-small-cell lung cancer	200 (ANZ); 1100 (int.)	1 (ANZ); 25 (int.)
BRAIN CANCER (COLLABORATING WITH COGNO)			
Trial in start-up			
ACED: Phase II study of acetazolamide + dexamethasone v dexamethasone alone for cerebral oedema *COGNO and CTC*	Adults with recurrent or progressive high-grade glioma, who require dexamethasone or dose increase for cerebral oedema	84	—
Current trials			
VERTU: Veliparib, radiotherapy and temozolomide in unmethylated MGMT glioblastoma *COGNO and CTC*	Patients with newly diagnosed resected glioblastoma with unmethylated MGMT promoter gene	120	4
Trials in follow-up			
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC 26053-22054) *EORTC-led, COGNO and CTC*	Patients with non-1p/19q-deleted anaplastic glioma	100 (ANZ); 748 (int.)	82 (ANZ); 751 (int.)

FUNDING

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

- Public grants for trials
- Pharmaceutical industry grants for trials
- Other public grants
- University infrastructure and grants
- Consulting
- Interest and donations
- Other



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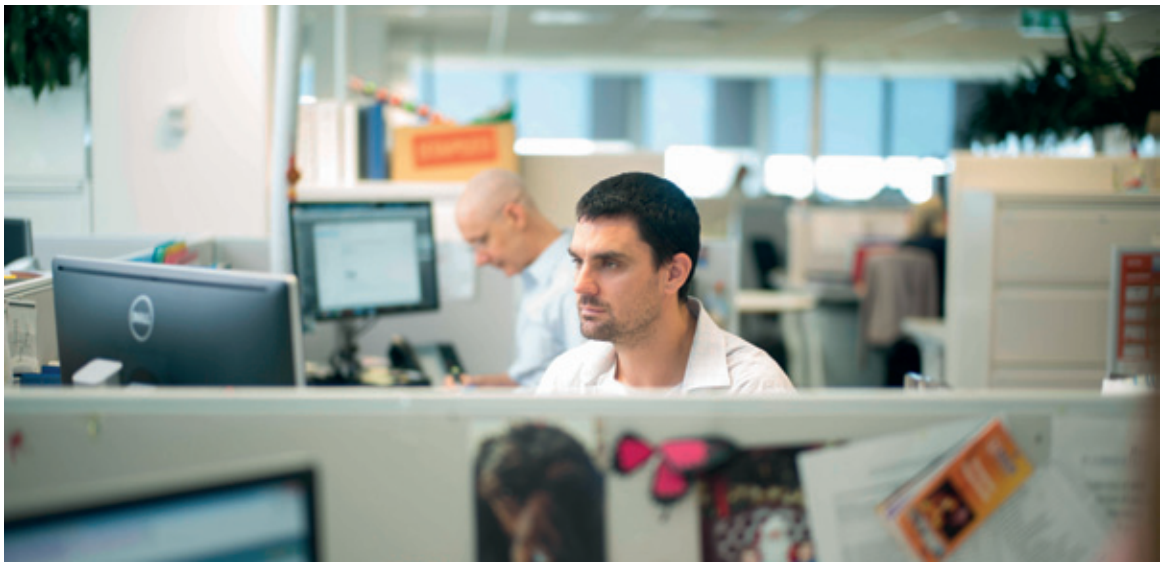

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Dr Hany Abed, cardiovascular group
Associate Professor Meera R Agar, COGNO scientific advisory and management committees
Dr Andrew Barbour, PI, DOCTOR and GAP trials (AGITG)
Dr Sally Baron-Hay, ANZGOG executive
Dr Andrew Berry, BOOST II safety and data monitoring committee chair
Dr Andrew Biankin, PI, LAP07 trial (AGITG)
Dr Alex Boussioutas, Gastric trial (AGITG)
Dr Ian Campbell, PI, SNAC 2 trial
Dr Matthew Chan, Oncology
Professor Christopher Christophi, AGITG management committee
Dr Yu Jo Chua, PI, PAN1 trial (AGITG)
Professor Alan Coates, Biostatistics, ANZBCTG and AGITG
Ms Melinda Cruz, LIFT study
Dr Andrew Davidson, PI, NITRO trial (ALTG)
Associate Professor Ian D Davis, PI, SORCE trial and chair, ANZUP
Professor Paul de Souza, Oncology
Dr Andrew Dean, PI, ICON8 trial
Dr Jayesh Desai, PI, REGISTER trial (AGITG)
Professor Catherine D'Este, BOOST II trial Safety and Data Monitoring Committee
Dr Pei Ni Ding, Oncology
Associate Professor Katherine Drummond, COGNO scientific advisory and management committees
Dr John Eikelboom, ASPIRE
Dr Jonathan Fawcett, co-PI, ATTACHE trial (AGITG)
Dr Kathryn Field, PI, CABARET trial (COGNO)
Ms Marcia Fleet, COGNO management committee
Dr Matthew Foote, COGNO scientific advisory and management committees
Dr Michael Friedlander, ANZGOG executive and PI, GOG182, TRIPOD, OVAR16, Symptom Benefit and PARAGON trials
Professor Sanjeev Galande, Diabetes, Molecular Medicine and Telehealth
Professor P Grantley Gill, PI, SNAC trials
Professor David Goldstein, PI, LAP07 trial, co-PI, ATTACHE trial, AGITG board
Dr Andrew Haydon, Oncology
Dr Sandra Hayes, ECHO ovarian cancer study
Professor Dickon Hayne, BCG+MMC trial, ANZUP
Professor Gillian Heller, Biostatistics
Dr Elizabeth Hovey, COGNO operations executive and management committee and chair, scientific advisory committee
Dr H Malcolm Hudson, Biostatistics
Dr Michael Jefford, SCOT trial (AGITG)
Dr Lindy Jeffree, COGNO scientific advisory committee
Dr Terrance Johns, COGNO scientific advisory and management committees
Dr David Joseph, ENZAMET study
Ms Marina Kastelan, COGNO scientific advisory committee
Dr Eng-Siew Koh, COGNO executive and management committee, deputy chair, scientific advisory committee
Dr Dusan Kotasek, ENZARAD and ENZAMET studies
Dr Danette Langbecker, COGNO scientific advisory committee
Ms Robyn Leonard, COGNO scientific advisory and management committees
Dr Trevor Leong, PI, TOP GEAR, Gastric trial (AGITG)
Dr Helen Liley, PAEAN study
Professor Ronald Ma, FIELD trial
Dr Kerrie McDonald, COGNO scientific advisory committee
Dr Sue-Anne McLachlan, PACT in SCLC (ALTG)
Associate Professor Peter Meikle, LIPID and FIELD studies
Dr Linda Mileshkin, ANZGOG executive, PI,PORTEC-3 and OUTBACK trials
Professor Michael J Millward, ALTG operations executive, scientific advisory and management committees; PI, BR26 trial
Associate Professor Paul Mitchell, ALTG scientific advisory and management committees, chair, operations executive
Dr Paul Nguyen, ANZUP
Dr Louise Nott, AGITG, ANZUP and COGNO trials
Professor Anna Nowak, COGNO scientific advisory committee, PI, CATNON trial
Associate Professor Ju-Lee Oei, BOOSTII and TORPIDO2 trials
Dr Robert Padbury, AGITG
Dr Nicholas J Petrelli, AGITG
Associate Professor Timothy J Price, PI, PETACC6 trial (AGITG)
Dr Kushwin Rajamani, FIELD trial
Dr David T Ransom, PI, SCOT and ARCTIC trials (AGITG)
Associate Professor Danny Rischin, PARAGON, 1105, ICON8 (ANZGOG)
Professor Mark Rosenthal, COGNO chair; COGNO operations executive, scientific advisory and management committees
Dr Amitesh Roy, ANZUP trials
Dr Gail Ryan, COGNO scientific advisory committee
Associate Professor Eva Segelov, PI, ICECREAM, TACTIC and SCOT trials (AGITG)
Dr Shomik Sengupta, ANZUP
Dr Catherine Shannon, ANZGOG trials
Dr Jennifer A Shannon, PI, TACTIC trial (AGITG)
Professor Karen Simmer, neonatal trials
Associate Professor Mark Smithers, TOPGEAR, DOCTOR trials (AGITG)
Dr Allan Spigelman, Sydney Catalyst
Dr Nigel A Spry, PI, LAP07 trial (AGITG)
Dr Andrew R Stevenson, PI, A La CART (AGITG)
Associate Professor David Sullivan, LIPID and FIELD trial management committees
Dr Christopher Sweeney, ANZUP
Associate Professor Niall Tebbutt, PI, ATTAX, ATTAX2, ATTAX3 and MAX trials (AGITG)
Professor David Thomas, TOPGEAR, C0.23 (AGITG)
Associate Professor Damien Thomson, co-PI, Aprepitant trial (ANZUP) and ANZUP germ-cell subcommittee
Dr Ru-Dee Ting, FIELD trial
Dr Andrew Tonkin, BiomarCare, LIPID study chair
Dr Ben Tran, BL12 study (ANZUP)
Dr Boris Waldman, cardiovascular studies
Dr Euan Walpole, AGITG
Dr Neil Wetzig, co-PI, SNAC trial
Dr Helen Wheeler, COGNO scientific advisory committee
Dr Louise Wigston (Nott), C0.23 trial (AGITG)
Associate Professor Nicholas Wilcken, Cochrane Breast Cancer Group and oncology trials
Dr Scott Williams, ENZARAD trial (ANZUP)
Professor Gary Wittert, PI, T4SDM trial
Associate Professor Desmond Yip, Oncology
Professor John Zalcberg, AGITG chair

STAFF ACTIVITIES

Supervision of research in 2015

John Simes

Jordan Fulcher, Nicola Lawrence, Manjula Schou, Katrin Sjoquist

Anthony Keech

Daniel Calandro, Jordan Fulcher, Surya Sutanto, Caroline Traill, Boris Waldman, Kathryn Williams

Lisa Askie

Ziad Al-Rubiae, Jake Chia, Jacquelyne Lam, Eveline Staub

Val Gebski

Alan Garner, Farnoush Noushi

Anandwardhan Hardikar

Erin Bell, Luke Carroll, Ryan Farr, Emma Scott, Malati Umrani, Wilson Wong

Andrzej Januszewski

Daniel Calandro, Ben Ma

Alicia Jenkins

Erin Bell, Claudia Boubeta, Daniel Calandro, Yoon Hi Cho, Ben Inja, Faizy Kakkat, Hannah Kim, Joanne Lee, Ben Ma, Ming Pan, Harris Schlen, Karin Schwartz, Emma Scott, Caroline Traill

Chee Lee

Amira Elmadahm, Felicia Roncolato

Sally Lord

Amira Elmadahm, Jacquelyne Lam

Andrew Martin

Deme Karikios, Erin Moth

Rachael Morton

Caroline Watts, Mbathio Dieng, Rachael Walker, Melanie Wyld

Martin Stockler

Lesley Chim, Deme Karikios, Nicola Lawrence, Kate Mahon, Rebecca Mercier-Bebber, Felicia Roncolato, Katrin Sjoquist, Michaela Smith, Puma Sundaresan, Anuradha Vasista

External committees

John Simes

Advancing the evidence base program grant research committee

ASPIRE and INSPIRE steering committees (chair)

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

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

Australian Clinical Trials Alliance (ACTA) founding member and chair, governance working group

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

BOOST II, APTS and LIFT trial management committees (neonatal)

Cholesterol Treatment Trialists Collaboration (CTTC) (joint coordinator)

Cochrane Breast Cancer Group editor

Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee (deputy chair), management committee, operations executive

ENCHANTED safety and data monitoring committee (chair)

FIELD management committee, executive, and cost-effectiveness subcommittee

IMPACT trial management committee (co-chair)

LIPID management committee, executive, and biomarker subcommittee

SNAC trial management committee

Sydney Catalyst governing council and scientific advisory committee (director)

Trials associate editor

Anthony Keech

Advancing the evidence base program grant research committee

Australian Clinical Trials Alliance (ACTA) founding member

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

Clinical Trials Centre research committee (chair)

FAME-1 diabetes trial steering committee (chair)

FIELD management committee (principal investigator and study chairman), and quality-of-life and cost-effectiveness, ophthalmology, and scientific substudies committees

Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk (FOURIER) executive committee

Heart Protection Study steering committee

International Clinical Trials Symposium joint coordinator and convener

International Journal of Cardiology editorial board

LIPID study management committee and executive

NHMRC training fellowships primary health care/ ATIS review (chair)

New South Wales Department of Health shared assessment committee

PLoS Medicine editorial board

REMOVAL trial steering committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

University of Sydney Department of Public Health research committee

Lisa Askie

AMICABLE, MAPPiNO, PARIS, PRECISE, and PreVILIG collaboration steering committees

Australian Clinical Trials Alliance network profiling expert working group

Australian New Zealand Clinical Trials Registry operational executive committee

Clinical Trials Centre research committee and neonatal executive committee

Clinical Trials Sub-Committee, Royal Prince Alfred Hospital Human Research Ethics Committee

Cochrane Collaboration prospective meta-analysis methods group (convener), neonatal collaborative review group, handbook advisory group and individual participant data methodology group

CCPT collaboration, co-chairperson

EPOCH and NeOProM collaborations, chair

German Clinical Trials Registry and Pan African Clinical Trials Registry scientific advisory committees

International Forum for Standards for Research in Children sample size and data safety monitoring subcommittee

IPPIC Steering Committee

NHMRC assigners academy, Australian Clinical Trials Website Portal advisory group, national ethics application form advisory group, National Trials Core Competencies advisory group, National Statement Chapter 3 Revision Working Group, research translation faculty.

PRISMA-IPD reporting standard working group

PROMPT, PRISMA-C, and STARD Trial Registration advisory Groups

Systematic Reviews editorial board

World Health Organization International Clinical Trials Registry Platform advisory committee and best practice group

Elizabeth Barnes

Biostatistics Collaboration of Australia teaching committee

Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee and VERTU and ACED trial management committees

DOCTOR trial management committee (AGITG)

Outback and ECHO trial management committees (ANZGOG)

Karen Bracken

T4DM study steering committee

Jenny Chow

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

Xanthi Coskinas

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

Val Gebski

Advancing the evidence base program grant research committee

AURELIA (Bevacizumab use in platinum-resistant epithelial ovarian cancer), GAS (Effect of Spinal versus General Anaesthesia in Neonates undergoing Hernia Repair), TO2RPIDO (Targeted Oxygenation in the Resuscitation of Premature Infants and their Developmental Outcome), and PAN-2 safety and data monitoring committees

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

Australasian Kidney Trials Network advisory board

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

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

Australian New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and group statistician, and SOLO2 trial management committee, PARAGON and OUTBACK trial management committees

Biostatistics Collaboration of Australia steering committee

COMPASS (cervical screening) and REINVEST (Reducing impulsivity in repeat violent offenders) trial steering committees

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

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

NSW Health Central Sydney Area ethics committee clinical trials subcommittee

SNAC and T4DM trial management committees

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

Alpana Ghadge

BOOST II, LIFT, LEAP, Torpido2 trial management committees

Westmead international update management committee

Wendy Hague

ASPIRE, INSPIRE, and LIPID management committees (cardiovascular)

Australasian Gastro-Intestinal Trials Group (AGITG) trials operations committee and A La CaRT trial management committee

Australia New Zealand Gynaecological Oncology Group (ANZGOG) trials operations committee

APTS, BOOST II, LEAP and PAEAN management committees (neonatal)

SNAC 1 and SNAC 2 trial management committees

T4DM trial management committee

Anandwardhan Hardikar

1000 QatarOmics Study, co-principal investigator and Australian co-lead investigator

2015 Islet Society and Australian Islet Study Group Annual meeting convenor

Islet Society (vice-president)

Lifestyle Interactions in Fenofibrate and the Epigenome (FIELD-LIFE) study (co-investigator)

Nature Scientific Reports and *Islets* editorial boards

NHMRC grant review panel for diabetes, obesity, stem cell panels, project grant assigners academy member, translational research faculty member

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

RAPID study principal investigator

Springer series 'Regenerative medicine', pancreatic islet biology editor

Alicia Jenkins

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

International Diabetes Federation Life For a Child program board member

REMOVAL metformin study, co-principal investigator and Australian lead

TEAMSNET telehealth initiative principal investigator

T4DM steering committee

International Diabetes Federation Western Pacific executive council

Australian Diabetes Society committees: disaster response; lipid guidelines, and type 1 diabetes consulting skills book

Diabetes Management Journal and *Diabetes Reviews* editorial boards

Diabetes Control and Complications trial and Epidemiology of Diabetes Interventions and Complications study cardiovascular disease biomarker writing committees

Adrienne Kirby

APTS, BOOST II and TORPIDO2 management committees (neonatal)

ASPIRE and INSPIRE steering committees

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

Faculty of Medicine, University of Sydney postgraduate coursework committee

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

LIPID management committee

Master of Clinical Trials (Research) committee

Randomised Trial on Surgical Treatment for Otitis Media in children Living in Remote Australian Communities trial management committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Chee Lee

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

Genomic Cancer Clinical Trials Initiative (GCCTI)

Study of Olaparib Clinical Effect (SOLACE) trial management committee

Ann Livingstone

Australasian Lung Cancer Trials Group (ALTG) operations executive and scientific advisory committees

Cancer Institute NSW Neuro-oncology Group (NSWOG)

Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees

Sally Lord

European Federation of Clinical Chemistry and Laboratory Medicine test evaluation working group

Patient-centered research for standards of outcomes in diagnostic tests group

Protocol advisory subcommittee (PASC) for Medical Services Advisory Committee

Ian Marschner

Australasian Gastro-Intestinal Trials Group (AGITG) independent data and safety monitoring committee

APTS trial independent data and safety monitoring committee
Biostatistics Collaboration of Australia steering committee
Advancing the evidence base program grant research committee

Andrew Martin

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

Julie Martyn

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

Danielle Miller

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

Rebecca Mister

ASPIRE and INSPIRE management committees

Rachael Morton

Australia and New Zealand Melanoma Trials Group (ANZMTG) executive board
Cancer Australia grant review panel
Cochrane economics methods and equity methods groups
Joanna Briggs Institute expert reference group
Home Dialysis Advisory Committee to Kidney Health Australia
Nephrology, Dialysis, Transplantation editorial board
Whole brain radiotherapy for metastatic melanoma (WBRT), Evaluation of Groin Lymphadenectomy Extent for Metastatic Melanoma (EAGLE-FM), and Mel-D trial management committees (ANZMTG)
CARSK trial management committee (AKTN)
Effectiveness of social dancing as a strategy to prevent falls in older people (DANCE) trial committee

Rachel O'Connell

D-Health (a study of vitamin D and health) trial management committee
PARAGON and Symptom Benefit trial management committees (ANZGOG)
TACTIC and TOPGEAR trial management committees (AGITG)
LEAP1 and PAEAN trial management committee (neonatal)

Kristy Robledo (Mann)

T4DM trial management committee
APTS management committee

Lucille Sebastian

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

Katrin Sjoquist

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

Martin Stockler

Advancing the evidence base program grant research committee
Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee and operations executive, BR31, DREAM, NITRO, NIVORAD, and PEARL trial management committees
Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee (convenor and chair)
Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee, ECHO, OUTBACK, PHAEDRA trial management committees
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee (deputy chair), operations executive and Accelerated BEP, Aprepitant, Chemo & Cognition, and EVERSUN, RAMPART, and SORCE trial management committees
Cancer Council Australia national oncology education committee
National Health and Medical Research Council grant review panels for oncology
University of Sydney Faculty of Medicine oncology block committee (chair), EBM in GMP3/4 (chair), evidence-based medicine resource group, integrated clinical attachment committee and University of Sydney Medical Program cancer planning committee

William Tarnow-Mordi

APTS, BOOST II, LEAP 1, LIFT, and Torpido2 trial management committees
IMPACT trial management committee
NHMRC grant review panel for clinical trials
Westmead international update management committee

Burcu Vachan

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

Melina Willson

Cochrane Managing Editors' Executive
Guidelines International Network (GIN) Implementation working group

Kate Wilson

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

Nicole Wong

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations and scientific advisory committees, and BL.12, TrusB, BCG+MMC, EVERSUN, SORCE, Chemo & Cognition and Accelerated BEP trial management committees

Sonia Yip

Australasian Gastro-Intestinal Trials Group (AGITG) operations executive, scientific advisory committee and biological subcommittee, AGITG-NCIC-CTG correlative research committee, and ALT-GIST,

ASCOLT, GAP, IMPACT, INTEGRATE trial management committees

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee

Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and cervix working group, REZOLVE trial management committee.

Australian and New Zealand Urogenital and Prostate Group (ANZUP) scientific advisory committee, renal cell subcommittee, germ cell subcommittee, translational subcommittee, and EVERSUN, SORCE, ENZAMET, ENZARAD, P3BEP trial management committees, ENZAMET and ENZARAD international translational research steering committee

Cooperative Trials Group for Neuro-Oncology (COGNO) VERTU trial management committee

Sydney Catalyst scientific advisory committee, operations executive committee, T1/T2 working group; Post-Graduate and Early Career Researcher Symposium 2015 organising committee

Cancer Institute NSW Biobanking Stakeholder Network Working Group

Genomic Cancer Clinical Trials Initiative (GCCTI) project team

Regular academic teaching

John Simes

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

Anthony Keech

Royal Prince Alfred Hospital cardiology training, and clinical tutor

Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

Master of Clinical Trials, University of Sydney (co-coordinator)

Lisa Askie

Advanced systematic reviews, Master of Clinical Epidemiology, University of Sydney (co-coordinator)

Controlled clinical trials, Master of Public Health And Master of Clinical Epidemiology, University of Sydney

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

Elizabeth Barnes

ACORD faculty

Basic sciences in oncology, Health Education and Training Institute

Principles of statistical inference, Biostatistics Collaboration of Australia (coordinator)

Statistical principles and clinical trials, Master of Clinical Trials Research, University of Sydney (coordinator)

Controlled clinical trials, School of Public Health, University of Sydney (co-coordinator)

Mark Donoghoe

Basic sciences in oncology, Health Education and Training Institute

David Espinoza

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

Val Gebski

Basic sciences in oncology, NSW Cancer Council

Controlled clinical trials, Master of Public Health and Master of Medicine, University of Sydney

Radiation oncology training, RACR trainees, Westmead Hospital, NSW Cancer Council

Wendy Hague

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

Deme Karikios

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

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

Adrienne Kirby

Master of Clinical Trials, University of Sydney (course coordinator)

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

Henry Ko

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

Chee Lee

ACORD faculty

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

Controlled clinical trials, School of Public Health, University of Sydney

Basic Sciences in Oncology, NSW Health Health Education and Training Institute

Sally Lord

Biomarker studies, Master of Clinical Trials, University of Sydney

Decision analysis, Master of Public Health, University of Sydney

Andrew Martin

ACORD faculty

Decision analysis (coordinator) and Controlled clinical trials (coordinator), School of Public Health, University of Sydney

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

Rebecca Mister

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

Rachael Morton

Making decisions in public health, Health economic evaluation, and Decision analysis, Master of Public Health and Master of Medicine, University of Sydney

Applied methods for cost-effectiveness analysis, University of Oxford

Rachel O'Connell

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

Kristy Robledo (Mann)

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

Katrin Sjoquist

ACORD faculty

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

Martin Stockler

Australia & Asia-Pacific Clinical Oncology Research Development (ACORD) convenor, and international steering committee workshop (chair)

Making sense of cancer clinical trials for NSW medical oncology trainees (convenor)

Clinical epidemiology for physician trainees, Royal Prince Alfred Hospital

Evidence-based medicine in the clinical years, (chair and coordinator), and Oncology and palliative care (block chair), University of Sydney Medical Program

Medical oncology clinical training, Royal Prince Alfred Hospital

Oncology block chair and coordinator, University of Sydney Medicine Program

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

Melina Willson

Basic Sciences in Oncology, NSW Health Health Education and Training Institute

Sonia Yip

Biomarker studies, Master of Clinical Trials, University of Sydney (coordinator)

PUBLICATIONS

Book chapters

1. **Farr RJ**, **Joglekar MV**, **Hardikar AA**. Circulating microRNAs in diabetes progression: Discovery, validation, and research translation. In: Igaz P, editor. *Circulating microRNAs in Disease Diagnostics and their Potential Biological Relevance.* 27 Nov 2015 ed: Springer; 2015. p. 215–244.
2. **Jenkins AJ**, O'Neal D, **Keech AC**. Fenofibrate and diabetic retinopathy [internet]. *Diapedia: the Living Textbook of Diabetes.* Rev. 13. 2 Feb 2015. dx.doi.org/10.14496/dia.7105268810.13.

Report

3. **Lewis S, Stoklosa A, Irving A, Jack B**. *Assessment of breast magnetic resonance imaging (MRI). MSAC application no. 1333, assessment report.* Canberra: Department of Health; 2015. www.msac.gov.au/internet/msac/publishing.nsf/Content/1333-public

Journal articles

4. Agar M, Koh ES, **Gibbs E, Barnes EH**, Hovey E, **Livingstone A**, **Sawkins K**, Chye R, Lovell MR, Clark K, Vardy J, King M. Validating self-report and proxy reports of the Dexamethasone Symptom Questionnaire-Chronic for the evaluation of longer-term corticosteroid toxicity. *Supportive Care in Cancer* 2015: 1–10.
5. **Askie L**, Offringa M. Systematic reviews and meta-analysis. *Seminars in Fetal and Neonatal Medicine* 2015; 20(6): 403–409.
6. Baker J, Janda M, **Gebski V**, Forder P, Hogg R, Manolitsas T, Obermair A. Lower preoperative quality of life increases postoperative risk of adverse events in women with endometrial cancer: results from the LACE trial. *Gynecologic Oncology* 2015; 137(1): 102-105.
7. Basu A, **Jenkins AJ**, Zhang Y, Stoner JA, Klein RL, Lopes-Virella MF, Garvey WT, Lyons TJ. Nuclear magnetic resonance-determined lipoprotein subclasses and carotid intima-media thickness in type 1 diabetes. *Atherosclerosis* 2015; 244: 93–100.
8. Basu A, Yu JY, **Jenkins AJ**, Nankervis AJ, Hanssen KF, Henriksen T, Lorentzen B, Garg SK, Menard MK, Hammad SM, Scardo JA, Aston CE, Lyons TJ. Trace elements as predictors of preeclampsia in type 1 diabetic pregnancy. *Nutrition Research* 2015; 35(5): 421-430.
9. Benitez-Aguirre PZ, Craig ME, Cass HG, Sugden CJ, **Jenkins A**, Wang JJ, Cusumano J, Hodgson LA, Lee K, Wong TY, Donaghue KC. Gender differences in retinal microvasculature through puberty in type 1 diabetes: are girls at greater risk of diabetic microvascular complications? *Investigative Ophthalmology and Visual Science* 2015; 56(1): 571.–577.
10. Blinman P, Hughes B, Crombie C, Christmas T, Hudson M, **Veillard AS, Muljadi N**, Millward M, Wright G, Flynn P, Windsor M, **Stockler M,** McLachlan SA. Patients' and doctors' preferences for adjuvant chemotherapy in resected non-small-cell lung cancer: What makes it worthwhile? *European Journal of Cancer* 2015; 51(12): 1529–1537.
11. Bradstock KF, Bilmon I, Kwan J, Micklethwaite K, Blyth E, Deren S, Bayley A, **Gebski V**, Gottlieb D. Single agent high dose cyclophosphamide for graft-versus-host disease prophylaxis in HLA-matched reduced intensity peripheral blood stem cell transplantation results in an unacceptably high rate of severe acute GVHD. *Biology of Blood and Marrow Transplantation* 2015; 21(5): 941-944.
12. Brennan DJ, Hackethall A, **Mann KP,** Mutz-Dehbalaie I, Fiegl H, Marth C, Obermair A. Serum HE4 detects recurrent endometrial cancer in patients undergoing routine clinical surveillance. *BMC Cancer* 2015; 15: 33.
13. Burgess NG, Pellise M, Nanda KS, Hourigan LF, Zanati SA, Brown GJ, Singh R, Williams SJ, Raftopoulos SC, Ormonde D, Moss A, **Byth K,** P'Ng H, McLeod D, Bourke MJ. Clinical and endoscopic predictors of cytological dysplasia or cancer in a prospective multicentre study of large sessile serrated adenomas/polyps. *Gut* 4 Mar 2015.
14. **Callander E, Schofield DJ**. Multidimensional poverty and health status as a predictor of chronic income poverty. *Health Economics* 2015; 24(12): 1638–1643.
15. **Chan MM, Sjoquist KM,** Zalcberg JR. Clinical utility of ramucirumab in advanced gastric cancer. *Biologics* 2015; 9: 93–105.
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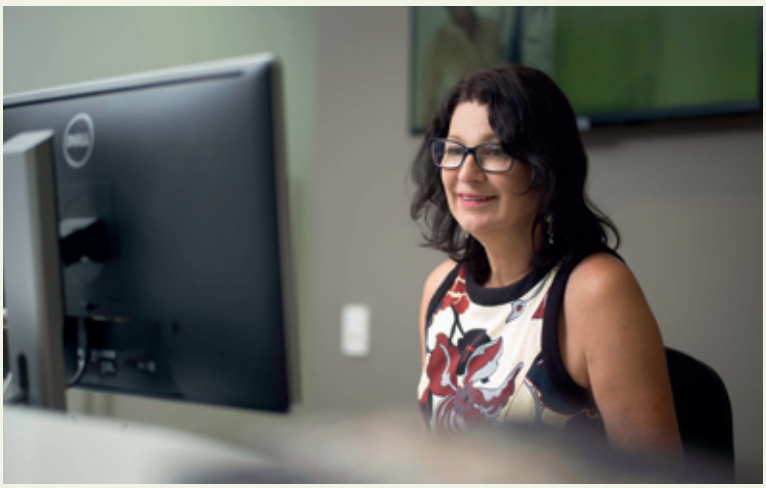

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