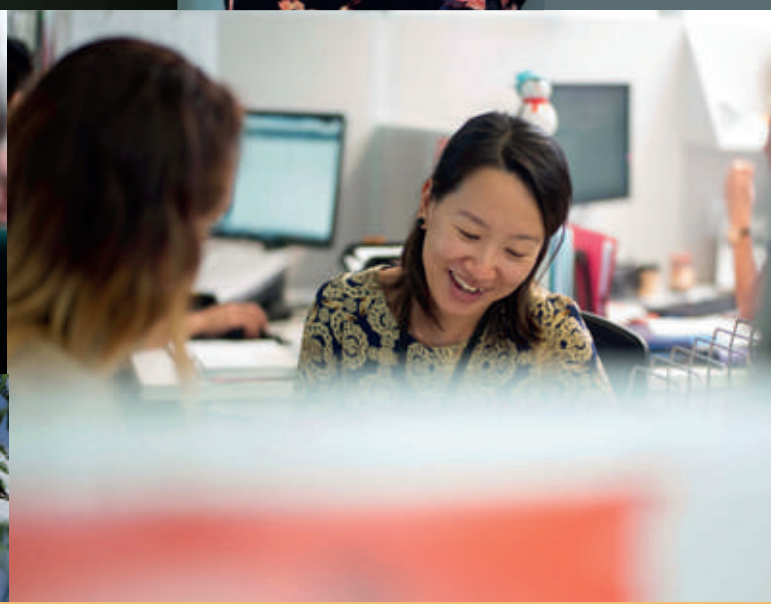
NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2016


NHMRC Clinical Trials Centre
The University of Sydney
NHMRC



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 in all aspects of clinical trials 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 2016.

DIRECTORS' REPORT

2016 was another year of continuing strong research achievement. Our aim has been to lead high-quality clinical research, develop new trial methods, and to integrate trial evidence in new analysis. We initiated, led or collaborated in a growing number of studies started or completed, and had the satisfaction of seeing reports of completed research at a new high.

This report highlights examples from the past year of trials in our established clinical areas: oncology, cardiovascular disease, diabetes and perinatal medicine, which together account for a substantial part of Australia's disease burden. Our trials program has covered the full spectrum of clinical trials research, from small trials aimed at evaluating targeted therapies for individual patients through to large-scale trials in areas where moderate treatment effects lead to substantial public health benefit. Our work in methodology, translational studies, and integrational studies, such as meta-analysis and economic evaluation, provide a firm footing and context to our trials.

We have a strong commitment to keep training the next generation of biomedical researchers. As well as personal supervision of PhD and other research students, CTC's academics all play a part in postgraduate courses, masterclasses and workshops designed to improve the quality of scientific and clinical research in Australia.

This report includes some inspiring stories of past postgraduate students who have been trained and postdoctoral trainees who have been mentored at CTC. They have gone on into the wider world to rewarding and fruitful careers shaped by the experience. They have carried the experience and knowledge gained at CTC into various academic, government and health care settings. Most continue to work with CTC as valued collaborators. There are also some personal stories of CTC collaborators and current CTC staff who are undertaking excellent work in clinical trials research.

Our contributions to national and international investigator-initiated clinical trials and associated research in oncology have led to improvements in quality of life, survival and cancer control, and to new research questions. Some of the trials leading to new findings and completed in 2016 (in breast, gastrointestinal, gynaecological, lung, brain and urogenital cancers), conducted as collaborations with national investigator groups, are highlighted in this report.

These examples also reflect the shift in cancer treatment research toward immunotherapy and personalized medicine: many of the trials, such as TACTIC and ICECREAM, now select patients on the basis of individual genetic characteristics and most include analysis of tumour tissue and blood for indicators for future research. We also highlight some studies in which meta-analysis of biological data linked with clinical outcomes from several trials has led to definitive evidence to inform clinical guidance.

In cardiovascular disease, we were pleased to report the extended follow-up over 16 years of the LIPID study, which showed that patients treated with pravastatin had sustained survival benefits with no adverse effects on non-cardiovascular deaths or cancer. The evidence that cholesterol lowering with statin drugs prevents cardiovascular events and deaths continues to grow even for those at low risk of such events and for a wide range of groups—including women—based on the the international meta-analyses prospectively planned by CTC jointly

with the Clinical Trials Service Unit in Oxford.

CTC's other historic large cardiovascular trial, FIELD, which enrolled nearly 10,000 patients with type 2 diabetes, has been a springboard for investigations of new indications for fenofibrate, including FAME1-Eye, which is investigating retinopathy in type 1 diabetes. Our diabetes research extends to type 1 diabetes trials in remote areas, new indications for a simple drug (metformin), improving availability of insulin treatment internationally, use of advanced insulin pump and glucose sensors in type 1 diabetes, and, especially, the search for better ways of producing insulin when the pancreas fails. Our diabetes group has a strong commitment to teaching, including each year offering summer scholarships to medical students and training graduates in the fundamentals of biomarkers.

We are currently conducting six large international trials in perinatal or neonatal medicine. In neonatal trials, in common with many prevention trials, treatment benefits may be moderate, so they may require thousands of patients to arrive at reliable results. They require special efforts to make them simpler, more inexpensive and efficient, and reflect the urgency of making trials a routine part of clinical practice. CTC's neonatal group is focusing on staff development, point-of care data collection, close liaison and partnership with parents, and clarifying benefits and harms for parents. In 2016, we reported the results of the BOOST II neonatal oxygen trials, whose data are now contributing to the international NeOProM meta-analysis we are leading.

In 2016, CTC's methodological experts made substantial contributions to our own trials and many other international trials, and a wide variety of clinical areas in Australia. Biostatistics is the core of most clinical research projects, and our biostatisticians are committed to sharing their expertise in consulting, postgraduate courses and regular workshops, as well as training biostatisticians for Australian research in the Biostatistics Collaboration of Australia.

A long-standing aim of CTC is to help bridge the gap between research evidence and clinical practice through integration of trial results with other evidence and through economic analyses. In 2017, the Cochrane Breast Cancer Group, whose editorial base is at CTC, reached 20 years of facilitating and coordinating reviews and updates of breast cancer evidence for the world. We also completed a major review of the evidence on the value of fluoride in water supplies in Australia and reviews of new technology for government.

In Australia, rapid growth in health technologies contributes to the continuously increasing rise in health care costs, now over $150 billion a year. In this environment, new and existing recommendations and policy will be based on sound evidence of cost-effectiveness and strategies that are smarter and better targeted. Trial programs have been shown by us and others to be much more cost-effective use of the health care dollar than many of the treatments accepted into routine care.

None of our achievements could happen without the efforts of many people. We are fortunate to work with exceptional individuals in our collaborating investigator groups and other research organisations in Australia and internationally. We appreciate the efforts of CTC staff; the quality and extent of their work is reflected in the achievements reported here.

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

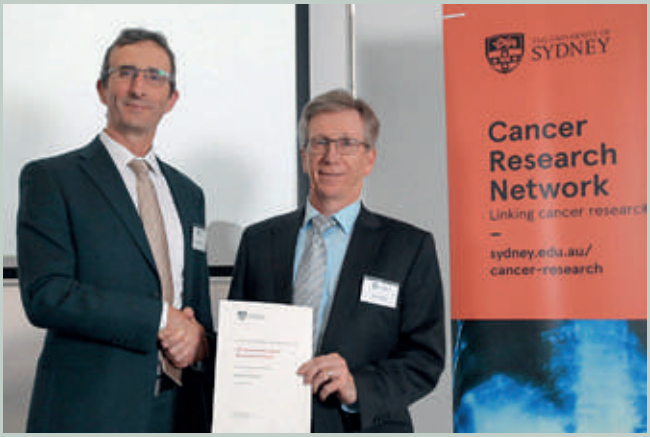
JOHN SIMES' LEADERSHIP RECOGNISED

John Simes received three major awards in 2016, which reflect the many achievements of the Clinical Trials Centre and its collaborators over nearly 30 years.

The NSW Premier's Outstanding Cancer Researcher of the Year award was for leadership in clinical trials and translational research. The Alan Coates Award for Excellence in Clinical Trials Research recognised a research career over four decades, including contributions to the Australian and New Zealand Breast Cancer Trials Group. And colleagues in cancer research honoured him with the Cancer Research Network's 10th Anniversary Career Achievement Award for broad areas of leadership, advocacy, research, and teaching.

John Simes has helped establish or develop national cancer research groups, which run high-quality clinical trials in areas of need, often in collaboration with CTC. He is a founding director of the Australian Clinical Trials Alliance (the peak body for advancing trials research in Australia's health system) and of the Australian New Zealand Clinical Trials Registry, and founding director of Sydney Catalyst.

John Simes has been a tireless champion of the value of clinical trials and was an early advocate of making trials research a routine part of clinical practice. The monetary value of these awards will be used to help provide endowments for postgraduate research students.



Top: Outstanding Cancer Researcher of the Year, with Morris Iemma, Cancer Institute chair

Middle: John Simes, Alan Coates (right), a founder of the Australian and New Zealand Breast Cancer Trials Group (ANZBCTG), and Stephen Ackland, ANZBCTG chair (left)

Above: Graham Mann of the Cancer Research Network with John Simes

ONCOLOGY TRIALS

The CTC has long-standing relationships with national cancer cooperative groups and is well represented in clinical trials initiatives in cancer. It has collaborated in over 170 cancer trials recruiting many thousands of patients in breast, oesophageal, gastric, colorectal, lung, gynaecological, neurological, and urogenital cancers and melanoma.

The CTC is the coordinating centre for the:

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

In the conduct of trials, the CTC covers the full range of responsibilities — from assisting in establishing new groups by creating a research governance structure and terms of reference, identifying important questions related to public health — through to large-scale trial operations in collaboration with the groups, for example, in concept and protocol development, randomisation, data collection, ethics and regulatory compliance, on-site monitoring and audit, and analyses and manuscript preparation.

Burcu Vachan, oncology program manager, operations

Felicia Roncolato and Nicola Lawrence, clinical research fellows for ANZUP urogenital trials, with colleague Deme Karikios

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.

Katrin Sjoquist, CTC's clinical lead for trials in gastrointestinal and gynaecological cancers

Cheryl Friend, associate oncology program manager, AGITG trials

AGITG

The Australasian Gastro-Intestinal Trials Group has been conducting trials in gastrointestinal cancer with CTC since the early 1990s.

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.

Completion of INTEGRATE trial leads to INTEGRATE II

The AGITG-CTC INTEGRATE trial was completed and its results published in the *Journal of Clinical Oncology* in 2016.[141] It was one of the journal's most accessed and important articles for the year and was promoted to oncologists worldwide in a special journal collection.

The INTEGRATE trial was the first study to show that regorafenib (a treatment that inhibits the growth of abnormal cells and blood vessels) was active against oesophagogastric cancer after chemotherapy had failed to arrest the disease.

As a phase 2 trial, INTEGRATE was designed to show the response the tumour to regorafenib and that it was safe, but it also had a placebo arm as a calibration group. There was a significantly lower rate of disease progression or death among patients receiving regorafenib, 18%, compared with placebo, 46%. This was more marked in the South Korean patients, possibly because of genetic differences or differences in the way the drug is metabolised in different populations. This finding raises important questions for future research. The first of several planned molecular biomarker studies was presented at an international meeting in January 2016. The study found several strong molecular correlations with responses to treatment and inter-country differences,

but so far no clear basis for predicting prognosis or the likely effect of treatment in individuals.

On the basis of the success of INTEGRATE, the investigators have started a phase 3 trial, INTEGRATE II, to investigate whether regorafenib prolongs survival in patients overall and in an Asian subpopulation. Biological samples from patients will again be used to identify biomarkers that predict study endpoints relating to survival, response, and safety and to further investigate the questions about biology and regional differences. The study will recruit patients from Australia, New Zealand, Korea, Japan, Taiwan, Canada and the United States over the next 2 years.

Patients with bile duct cancers selected for treatment by gene testing

The AGITG-CTC biliary tract cancer trial, TACTIC, was completed and published in 2016. The results showed that a monoclonal antibody, panitumumab, is likely to be a suitable targeted treatment for selected patients with biliary tract (bile duct) cancers.[53] TACTIC also showed that the new drug can be combined safely with standard cisplatin and gemcitabine chemotherapy.

TACTIC was a phase 2 trial investigating the feasibility of selecting patients for treatment with panitumumab on the basis of gene testing. This approach had been successful in trials of other cancer types. This experience, supported by evidence that some biliary tract cancers responded to panitumumab, provided the rationale for TACTIC. Patients with advanced or inoperable tumours were eligible for the trial if tumour testing before enrolment showed no mutations in the *KRAS* gene.

Biliary tract cancers are rare, which can be a challenge for trials research. TACTIC surpassed its target and recruited 45 eligible patients. Of these, 80% had a clinical benefit from the treatment when tested after 3 months, an improvement over the rate with chemotherapy alone.

The investigators consider that this rate of benefit might be even better with finer selection of patients. Tumour genes can be tested further for other mutations that might predict how well this antibody treatment works for an individual. This is a promising area for further research to improve the prospects of patients with biliary tract cancers.

ICECREAM colorectal cancer trial answers questions and opens up new hypotheses

Bowel cancer is relatively common, and accounts for about 10% of all cancers. When it has metastasised, it is not curable, but new treatment regimens have been improving survival, so that now many patients survive for years.

In particular, molecular biomarkers can indicate whether specific biological treatments are likely to be successful. Patients are increasingly being offered treatments tailored to their individual cancers. Patients with bowel cancers with specific genetic mutations are known not to benefit from some antibody treatments. However, before the ICECREAM trial, a question remained about one mutation variant. Some small retrospective studies had suggested an antibody treatment, cetuximab, might be effective for tumours with the relatively rare G13D mutation. ICECREAM addressed this question

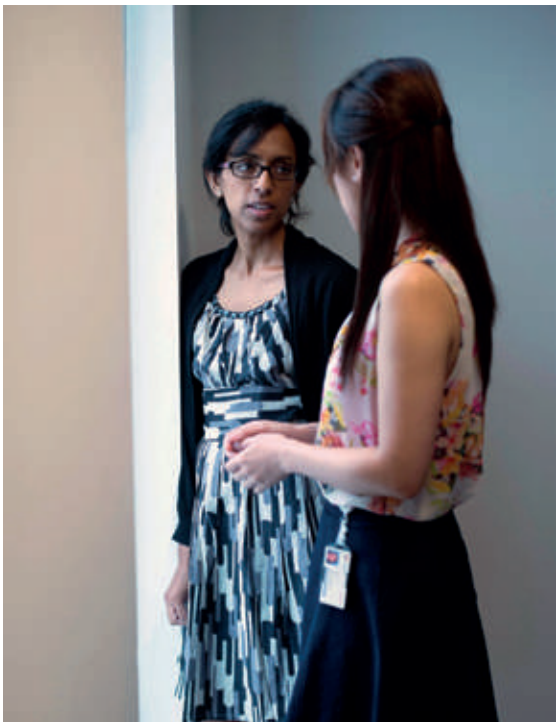
Eric Tsobanis, manager of the INTEGRATE trials

and also aimed to evaluate whether adding standard chemotherapy would improve outcomes.

The cetuximab treatment alone was not effective, although some patients who received chemotherapy as well appeared to benefit, an unexpected result.

ICECREAM can claim several achievements. It showed that tumours with the G13D mutation did not respond to cetuximab treatment. Its results suggested that there could be a synergistic effect of cetuximab with chemotherapy, or that repeat chemotherapy could be effective after an interval without treatment.[159] These are new questions for further research. ICECREAM also reinforced the value of a prospective trial to test findings from retrospective analyses and demonstrated that treatments for rare molecular subtypes of cancer could be evaluated in clinical trials.

ICECREAM is continuing with a larger patient group, with the aim of answering the second question: does cetuximab make chemotherapy more effective? Only patients with non-mutated tumours are being selected for part 2.



Subotheni Thavaneswaran, clinical research fellow for ICECREAM and other gastrointestinal cancer trials

Peey Sei Kok, clinical research fellow, ALTG and ANZGOG trials

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. Current trials of the ANZGOG-CTC collaboration are investigating chemotherapy, immunotherapy, hormone blockers and exercise for a range of gynaecological cancers.

ANZGOG has members in all medical and health specialties, as well as patients and other non-professional members, some of whom form an advisory panel for consumer outreach and trial development.

GYNAECOLOGICAL CANCER: HIGHLIGHT

Measuring the effects of treatment from patients' reports

Quality of life and other patient-reported outcomes are important criteria for evaluating treatments for ovarian cancer—at least as important as objective measures such as the response of a tumour to treatment or survival time. Most women with ovarian cancer have advanced-stage disease and their priority is not survival but to maintain their quality of life and to reduce distressing symptoms.

Due to concern that this issue may be neglected in clinical trials, a recent systematic review of phase 3 trials evaluated the content of trial protocols in relation to patient reported outcomes.[120] Although most of the trials reviewed used a patient-reported primary or secondary endpoint, less a third had an explicit patient-reported objective. The researchers concluded that clear guidance is needed for ensuring that patient-reported outcomes are properly included in protocols for new ovarian cancer trials.

Including patient-reported outcomes in trials also acknowledges that patients make a major contribution to research, often without expectation of personal benefit, when they consent to participate. Policies of CTC and its collaborators aim to ensure that patients are involved and informed at each stage of all trials.

PERSONAL STORY

JOHN STARK: COORDINATING TRIALS MAKING A DIFFERENCE IN GYNAECOLOGICAL CANCER

One of the most motivating aspects of working as a trial coordinator at the CTC is having a hand in multiple studies. Operating across different patient populations—in terms of disease of origin and disease staging—has allowed me to broaden my knowledge set and ensure that no two days are ever the same.

2016 gave me an opportunity to coordinate three ANZGOG studies, all of which were at different stages of their life cycle. PARAGON was an open phase 2 trial of an oral hormone treatment for women with gynaecological cancers, with patients in Europe and Australia. It closed to recruitment and there was extensive data cleaning to ensure we were prepared for subsequent statistical analysis and manuscript writing. ECHO is evaluating the effect of 18 weeks of aerobic and resistance exercise during chemotherapy and for up to 18 weeks for women with ovarian cancer. The trial has been recruiting steadily and achieved the milestone of 50% of its overall target. The PHAEDRA trial has been preparing to open to recruitment. PHAEDRA is investigating the effect of a targeted antibody treatment in two groups of women with different gene types. Setting firm groundwork in 2016 will ultimately ensure that 2017 is a productive and conducive year for these studies.

It is rewarding to be aware that my work will play a part in improving the lives of women with gynaecological cancers.

John Stark, trial coordinator for ANZGOG, with colleague Anna Walsh

Should glioma patients have chemotherapy, and when?

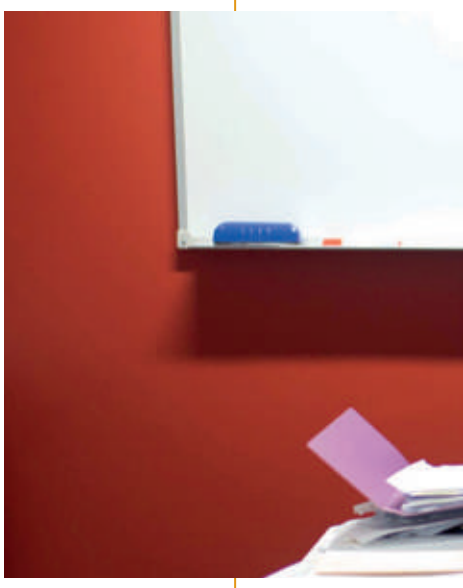
High-grade glioma is a relatively rare aggressive brain tumour that most commonly affects people in middle adulthood. It is treated by surgery to remove the tumour as far as possible, followed by radiotherapy with or without chemotherapy.

A potentially practice-changing trial, CATNON, which may improve the survival of people with these tumours has started showing promising results. CATNON is an international phase 3 trial led by the European Organisation for Research and Treatment in Cancer and is a COGNO-CTC collaboration in Australia. The trial is taking advantage of modern methods of genetic selection to advance targeted individual treatment.

It has been known that temozolomide chemotherapy can delay the growth or spread of a high-grade glioma in patients who have a specific genetic flag: that is, in their tumour cells the 1p and 19q chromosome arms are missing. For others, who do not have this genetic type, it has so far not been clear whether chemotherapy performs similarly. To answer this question, CATNON has enrolled 748 patients worldwide without the deletion of 1p and 19q, with 82 patients coming from the sites from within the COGNO group. They have been allocated to one of four treatment regimens: 33 daily doses of radiation alone; the same radiation with concurrent daily oral temozolomide chemotherapy; 12 weeks of chemotherapy after the end of the radiotherapy; or all these treatments.

The patients are still being followed up, but promising and important interim results were presented at a plenary session of the 2016 meeting of the American Society of Clinical Oncology. The patients in the two groups who received chemotherapy after radiotherapy had twice as long before their tumour began to grow again. At 5 years, 56% were alive, compared with 44% of those in the other two groups.

The investigators are also conducting detailed genetic studies of tumour samples to further identify the characteristics of individual patients who are most likely to benefit from temozolomide chemotherapy.



Merryn Hall, associate oncology program manager, operations, for the Cooperative Trials Group for Neuro-Oncology, who oversees project management of the CATNON trial

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 that matter to patients.

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.

Jenny Chow, executive officer for the Cooperative Trials Group for Neuro-Oncology (COGNO)

CTC ALUM

ANNA NOWAK: LEADING RESEARCH TRANSLATION TO FIGHT DEADLY CANCERS

What do you do now?

I'm professor in medical oncology at the University of Western Australia and a medical oncologist at Sir Charles Gairdner Hospital in Perth. I mainly treat patients with mesothelioma—the lung cancer caused by asbestos exposure—and glioblastoma brain tumours. Caring for patients with these cancers is immensely rewarding. This motivates my research, aimed at improving the treatment and prospects of patients with these diseases, where there are few options. As a clinician and researcher, I am able to make a difference to national and international research progress and to teach and mentor young oncologists.

In Australia, and especially Western Australia, the rate of mesothelioma is high by world standards, because of our extensive mining and use of asbestos. Because of the lag between exposure and illness, the rates have not gone down and may be increasing. It is a deadly disease, like many lung cancers, and is desperately in need of new treatments. My PhD was a study of combined chemotherapy and immunotherapy for mesothelioma in mice. Immunotherapy has progressed remarkably since then and become mainstream, although mesothelioma is a difficult area. We are trying to translate successful treatment regimens in mice to treatment that works for patients.

When were you at CTC?

In 2003–2004 I was the inaugural postdoctoral fellow in clinical trials and quality of life at CTC, working with Martin Stockler and John Simes. It complemented my PhD experimental research, revealing the full translational research pathway.

How did your CTC experience influence your career?

While I was at the CTC I was able to make invaluable contacts with people who are still at the centre of academic trials research in Australia and to understand how the cooperative trials groups worked. I collaborate with the CTC still, through ALTG and COGNO. Currently, I'm principal investigator on DREAM, which is using combined chemotherapy and durvalumab, an immune checkpoint inhibitor, for mesothelioma. As well as looking at the effect of treatment, we are collecting biological samples for analysing individual predictors of treatment benefit. DREAM has really drawn together my PhD and subsequent laboratory work with the skills I gained at CTC. I am also leading the Australian part of CATNON and contributing to other brain and lung cancer trials.

CTC ALUM

PETER GRIMISON, SYDNEY CANCER CLINICIAN AND LEADER OF CLINICAL TRIALS

What do you do now?

I am a medical oncologist at the Chris O'Brien Lifehouse cancer hospital in Sydney and see patients with testicular cancer, other genitourinary cancers, and upper gastrointestinal cancers. An important aspect of my work is coordinating and teaching in the Royal Australasian College of Physicians program for advanced trainees in medical oncology. I also teach students in the University of Sydney Medical Program, and serve on the Australian Government Pharmaceutical Benefits Advisory Committee.

The Australian cancer cooperative groups of investigators initiate and conduct trials where clinicians and patients have identified a need for them. I am involved as a leader and study investigator in trials for two of these groups: the Australian and New Zealand Urogenital and Prostate group and the Australasian Gastro-Intestinal Trials Group. I chair ANZUP's phase 3 Accelerated BEP trial, which is following a successful phase 2 trial, and currently recruiting. It has attracted strong international interest, with participation from groups in the UK and USA.

Nausea and vomiting in patients undergoing chemotherapy is a major problem affecting quality of life. In 2016, a group that I am chairing began the largest and most definitive randomised trial of medical cannabinoids to prevent chemotherapy-induced nausea, Cannabis CINV, which is being coordinated at CTC.

When were you at CTC?

In 2009, as a newly certified medical oncologist, I completed a PhD in quality-of-life assessment in clinical trials, and developed a utility measure that has informed analyses of quality of life and quality-adjusted survival in recent trials.

How did your CTC experience influence your career?

CTC is a fertile training ground for all aspects of clinical trials, with incredible opportunities for mentoring by Australia's leading clinical researchers. This has enabled me to lead and contribute to trials in my areas of interest. I learned research methodology, including concept and protocol design, how to incorporate patient-reported outcomes and health economic evaluations, trial operations, and the skills for writing conference abstracts, manuscripts and grant applications.

UROGENITAL CANCER: HIGHLIGHT

Promising efficacy of testicular cancer regimen

Germ-cell tumours, such as testicular cancer, typically affect adolescent and young adult males. Over 80% are considered cured after three or four cycles of chemotherapy, given at 3-weekly intervals. This has been the standard treatment for a long time, but a third of patients with worst risk features still relapse and die.

The ANZUP-CTC phase 2 trial, Accelerated BEP, showed that administering the same chemotherapy every 2 weeks instead of every 3 weeks was a safe, feasible and active treatment. In 2016, the investigators published the results

BREAST CANCER: SNAC

Sentinel node biopsy compared with axillary clearance: 5-year outcomes

The SNAC (Sentinel Node Biopsy versus Axillary Clearance) trial was the first multicentre trial of surgical treatment of breast cancer in Australasia—a collaboration of the CTC and the Royal Australasian College of Surgeons.

Thorough biopsy, or full clearance, of the axillary lymph nodes can lead to arm swelling, pain, numbness and restricted movement. In SNAC, with the notion that these side-effects might be avoidable with a less invasive procedure, women with single tumours smaller

of the analysis of survival five years after treatment.[94] The 5-year survival rate was over 90%for all risk groups.

The results of this trial, and other evidence, supported the case for a phase 3 trial. The ANZUP-CTC phase 3 randomised trial, P3BEP, is comparing the new accelerated regimen with the standard 3-weekly regimen in 500 men, women and children with intermediate or poor risk germ-cell tumours in Australia, New Zealand, the UK and the USA. This trial will eventually compare the two treatment groups for survival. The investigators will compare the two treatment arms for changes in the size of tumours, changes in serum tumour markers, the results of surgery after chemotherapy, quality of life, and patients' preferences about treatment. The investigators are collecting tumour tissue and blood for future molecular and genetic studies.

ANZUP

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group conducts trial research to improve treatment of bladder, kidney, testicular and prostate cancer. It brings together the professional disciplines and groups researching and treating prostate and other urogenital cancers and also seeks guidance from its consumer advisory panel, representing those with personal experience of these cancers.

ANZUP collaborates with CTC to conduct independent, investigator-initiated clinical trials.

than 3 cm were randomised to either full clearance or biopsy of sentinel nodes only.

It was found that clinical management based on sentinel-lymph-node biopsy was as accurate for diagnosis. Both treatment groups had moderate limitations in arm movement over the first 6 months, which then recovered to near normal levels. Swelling and symptoms increased over 2 years and then levelled off.

Data from patients in SNAC were assessed after 5 years, though objective measurements of arm volume and also subjectively by questionnaire. The subjective scores only moderately correlated with a change in arm volume. The 5-year results showed that the women who had only the sentinel-node procedure on average still had less swelling and reported better quality of life on the questionnaires. The 5-year results were published in 2016.[198] Ten-year follow-up is now complete, and analyses are assessing the relative survival of the randomised groups.

The SNAC 2 trial is currently in progress. The investigators are recruiting women with large or multiple tumours in a more extensive trial asking similar clinical questions.

Rebecca Mister, SNAC and SNAC 2 trials manager, and CTC's head of site management

Ann Livingstone, associate oncology program manager for ALTG trials

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 collaboration is currently conducting trials of immunotherapy with new antibodies for non-small-cell lung cancer (BR.31) and mesothelioma (DREAM), and a trial of radiotherapy with an antibody for advanced non-small-cell lung cancer (NIVORAD).

LUNG CANCER: HIGHLIGHT

How much involvement does an individual patient prefer?

The CTC has a tradition of research to draw out the individual preferences of patients in decision making about treatment—whether to undergo a treatment and how much involvement in the decision. This is especially important for patients with poor prognosis. For example, people with advanced lung cancer need to consider chemotherapy that will affect their quality of life but is not likely to cure their disease. Patients with non-small-cell lung cancer vary more than their doctors in how they judge the worth of treatment.

A recent study recruiting 98 patients from 16 sites and Australia and New Zealand has explored the preferences of lung cancer patients for participating in the decision making about their treatment.[129] Does an individual patient prefer an active, collaborative or passive role? Understanding these individual preferences is important for their doctors to meet their expectations, to guide discussions about treatment recommendations, and to increase patient satisfaction.

Most patients preferred a collaborative role. Those who preferred an active role demanded more of their chemotherapy treatment than the others; that is, they thought that chemotherapy would have to result in longer survival to be worthwhile. A patient's preferred decision making role can change over time, some wanting more control and others less, as their illness progresses. The implications for oncologists are that they should consider each patient's decision making preferences every time a treatment decision is made.

This study was first brought as a concept by author Dr Prunella Blinman to an Australia & Asia Pacific Clinical Oncology Research Development (ACORD) workshop, where it was developed into a clinical study proposal for implementing by the Australasian Lung Cancer Trials Group and CTC. ACORD workshops are run by the Medical Oncology Group of Australia, and currently chaired by Martin Stockler, to educate health professionals in clinical trial design.

Patient-preference studies such as this have used and extended methods originally pioneered by CTC's John Simes and Alan Coates in the 1980s, which asked patients who had undergone a particular cancer treatment to judge its value to them.

ONCOLOGY STUDIES LEAD TO PERSONALISED TREATMENT FOR PATIENTS

Mustafa Khasraw, clinical lead for neuro-oncology trials

Personalised cancer treatment—that is, treatment based on an individual's specific molecular biomarker landscape—depends on a spectrum of research that includes clinical trials and laboratory testing. Biological markers and genetic variants and mutations may predict the response of a patient to a particular treatment or forecast survival and thus represent an important part of choosing the right treatment for the individual patient.

The CTC and its collaborative groups now embed their cancer trials in a translational research spectrum that extends over laboratory analyses, clinical trials, and meta-analyses of combined data. In most of the trials that the CTC designs and coordinates, patients may choose to consent to their biological samples being used in research that benefits other patients and helps the design of future trials.

When predictive biomarkers in these samples have been identified and verified, this information can be used for genetic or molecular testing as part of screening patients before they are enrolled in a new trial. Recent examples highlighted here are TACTIC (page 9)[53] and ICECREAM (page 9).[159]

CTC investigators apply statistical techniques to pooled data from completed trials to explore new targeted treatments[97] and evaluate predictors of disease progression.[105] In some collaborative studies, the researchers have assayed samples collected in several similar high-quality completed trials and have linked results with pooled trial data to arrive at new insights and clinical applications; for example, the HER2 breast cancer study (page 18).[96]

The CTC is a member of, and works closely with, the virtual research consortium, Sydney Catalyst, the Translational Cancer Research Centre of Central Sydney and Regional NSW. Sydney Catalyst brings together outstanding teams of researchers and clinicians from over 20 leading NSW institutions with the ability to undertake oncology 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 2016, CTC researchers and their colleagues attended major international meetings and presented results and progress of various studies identifying prognostic markers or markers predicting individual responses to particular treatments. These included INTEGRATE, the CO.17 and CO.20 gastrointestinal cancer trials, the NEONAB breast cancer trial, and the CATNON and VERTU brain cancer trials.

PERSONAL STORY

PHILIP HOGG: NEW CANCER TREATMENT TARGETS IDENTIFIED IN LABORATORY STUDIES

Professor Philip Hogg, Chair of Translational Cancer Research at CTC and Sydney Catalyst, has discovered a new type of chemical modification in proteins that appears to be important for all life forms. He has shown that the modification of allosteric disulphide bonds in proteins is related to cancer.

Allosteric disulphide bonds are being identified in many other biological systems such as blood coagulation, immunity and inflammation. Phil is using his novel findings to develop innovative drugs targeting several of these bonds for new cancer therapies.

In 2016, he chaired the first international scientific meeting dedicated to this chemical modification in Colorado, sponsored by the Federation of American Societies for Experimental Biology (FASEB), which represents over 125,000 researchers in 30 scientific societies in the USA and around the world. The meeting is a significant milestone for Phil and his research field.

A potential predictive test for targeted breast cancer treatment

A recent study CTC study involving oncologists, statisticians and other clinical triallists has uncovered the value of a blood test to predict whether a specific targeted treatment for advanced breast cancer will be effective.[96]

Some breast cancers are HER2-positive. HER2 (human epidermal growth factor receptor 2) is a protein on the surface of breast cells. High levels of these receptors can cause breast cancers to grow and spread. Patients with invasive or advanced breast cancer routinely have biopsies that test their tumours for HER2, and their treatment is chosen accordingly. If the tumour is considered HER2-positive, the patient may benefit from a drug that blocks HER2, such as trastuzumab or lapatinib. If results are negative, this class of drugs might not benefit the patient.

A blood test is generally more convenient than a tumour biopsy. The new study examined whether HER2 protein shed by the breast tumour into the blood (serum HER2) might be useful for an alternative test. The research team exhaustively analysed data and blood results from nearly 2000 women in three trials of lapatinib treatment (versus chemotherapy alone or a placebo) for advanced breast cancer.

They found that patients with higher values of serum HER2 did better on lapatinib than those with lower values, but had worse outcomes than those with lower HER2 if they did not get lapatinib, reflecting the fact that untreated HER2-positive tumours may progress more quickly.

These results are exploratory, and investigations of other drugs in this class have so far been inconsistent. However, the prospect of testing blood to predict the benefit of anti-HER2 treatment holds promise.

Chee Lee, clinical lead for oncology studies, with Sally Lord, epidemiologist and research fellow with an interest in clinical testing

PERSONAL STORY

MYTHILY SACHCHITHANANTHAN: COORDINATOR OF THE VIRTUAL BIOBANK FOR BRAIN TUMOURS

I work at CTC as the senior project coordinator for Brain Cancer Biobanking Australia, a consortium of brain cancer clinicians, researchers and biobankers who have joined forces to overcome the fragmentation and variable quality of brain cancer biobanking operations in Australia.

We aim to provide researchers with the amount, quality and type of tissue and associated data they need to accelerate brain cancer research. It is a virtual biobank, networking independent biobanking operations Australia-wide, leveraging existing systems to arrive at standardised procedures and protocols and a searchable online register to expedite access to samples.

Brain Cancer Banking Australia was founded by a consumer advocate, Robyn Leonard, in 2015, with the goal of ensuring that all donated biospecimens are used for maximum health and scientific benefit.

It has been rewarding to bring my background and experience in research and biobanking to help set up the network. I interact with various stakeholders and I am learning new things constantly. Being part of COGNO and the CTC allows us to be connected to clinical trials research and potentially help facilitate translation of any promising preclinical research into clinical trials that can eventually lead to new treatments.

Libby Cregan, in the CTC Oncology offices at Chris O'Brien Lifehouse

CARDIOVASCULAR RESEARCH

Focus on preventing heart attack and stroke

Cardiovascular disease is still the leading cause of early death in Australia. Developing countries have been catching up, with increases in the prevalence of cardiovascular risk factors led by demographic changes. In Australia and elsewhere, better treatments mean that more people are living longer with heart disease. The burden of chronic heart disease is a national health priority and a target of CTC research into prevention and treatment.

Cardiovascular risk is known to be related to LDL cholesterol levels. Over the past decade, the international Cholesterol Treatment Trialists' Collaboration (coordinated by CTC and the Clinical Trial Service Unit at Oxford) has published results of several major studies on cholesterol lowering with statin therapy and the subsequent reduction in heart attacks, strokes and other cardiovascular events. The collaboration has analysed data from 28 trials internationally, including 9014 LIPID patients. Current evidence for the benefit of using statin therapy for prevention was reviewed in a *Lancet* article by the collaboration in 2016.[39] In another study, statin therapy was shown to be less effective for patients with severe chronic kidney disease.[36]

Recently, public debate has arisen about whether there might be potential harms of statin treatment as well as benefits, such as respiratory conditions, fractures and Parkinson's disease. In response, in 2016, the collaboration published its formal plans for meta-analyses seeking definitive evidence of adverse events in 30 statin-therapy trials with about 200,000 participants.[37]

Another question now is whether even lower LDL cholesterol levels (less than 1.0 mmol/L), attainable only with newer drugs, the PCSK9 inhibitors, can further reduce risk. This is being tested in several international mega-trials, including FOURIER, with 27,500 participants.[155]

Anthony Keech, CTC deputy director and head of cardiovascular research

HIGHLIGHT: LIPID

Long-term follow-up of heart patients shows statin therapy is safe

After a total of 16 years of follow-up, CTC's Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) trial has shown clearly that the higher survival rate due to 6 years of statin treatment is sustained over a long period, mainly because of prevention of death from cardiovascular disease.[63] Long-term follow-up also has the reassuring finding that treatment with statins is not related to any increase in any new cancer, or deaths from cancer or from other causes.

The LIPID trial was a major early achievement of the CTC. In the early 1990s, the trial recruited over 9000 patients who had recently had a coronary event but who had normal cholesterol levels. These patients, from 87 hospitals in Australia and New Zealand, were randomised to commence pravastatin or placebo and then followed up for 6 years. The treatment significantly and cost-effectively reduced mortality and major cardiovascular events. Overall mortality was reduced by 23% and death from coronary heart disease by 24%. Clinical evidence from LIPID enabled subsidy for pravastatin treatment through the Pharmaceutical Benefits Scheme and changed the Australian treatment guidelines.

After the 6 years of the trial finished, participants were all offered treatment with pravastatin, and most continued with it. During the years of extended follow-up, almost the same proportion of each group received statin therapy (about 85%).

The longer-term effects of statins on net clinical benefit had been questioned in public forums over the years, particularly in relation to cancer and other serious disorders. As part of the follow-up study, the LIPID investigators particularly focused on cancers and, for further reassurance, also conducted a meta-analysis of the cancer data available from other similar statin trials. This meta-analysis resulted in conclusions that allocation to pravastatin rather than placebo had no significant link with cancer mortality or cancer incidence, during the trials or the long period afterward.

CTC ALUM

TOM BRIFFA: RESEARCH LEADER AND ADVOCATE FOR CARDIAC EVIDENCE TRANSLATION AND SERVICES

What do you do now?

I am director of the health services and cardiovascular research in the School of Population and Global Health at the University of Western Australia, with adjunct appointments at the George Institute and the South Australian Health and Medical Research Institute and other national health agencies.

I am a senior health researcher with specific expertise in clinical cardiovascular epidemiology, clinical trials, evidence translation and health services. Coronary heart disease has a high disease burden in Australia, second only to cancer. The cost of repeat heart attacks in Australia runs into billions. People with coronary heart disease can reduce their risk of a heart attack or stroke with preventive lifestyle and drug therapies as part of a systematic program. This must be evidence based, tailored to the individual patient and sustainable over a lifetime. Hospitals and their rehabilitation teams, GPs, patients and health systems are all involved.

My work is built on data linkage. Western Australia is unique in Australia in having had health data linkage since the 1970s, with the WA Data Linkage System formally established in 1995 and able to use de-identified health data for research.

I have spent 25 years examining trends and models of care in cardiovascular disease treatment and management. I am able to follow my interest in the prevention and treatment of cardiovascular disease and its translation into practice.

When were you at CTC?

My PhD thesis, through the CTC, was completed in 1999. It was a randomised controlled trial of cardiac rehabilitation with an associated cost-effectiveness analysis. The cost-effectiveness analysis strengthened the case for rehabilitation to be routinely offered to all acute coronary syndrome survivors.

How did your CTC experience influence your career?

CTC developed my ability to conduct a methodological rigorous randomised controlled trial in an area that is still very relevant to my work today. I stay in regular touch with the CTC researchers.

Alicia Jenkins, head of CTC's diabetes group

INTERNATIONAL MULTIFACETED RESEARCH IN DIABETES

Diabetes mellitus, which is associated with elevated glucose levels, and also widespread disturbances in carbohydrate, fat and protein metabolism, is a major health problem in Australia and the rest of the world. Diabetes causes a death somewhere in the world every 6 seconds and a leg amputation every 20 seconds. It is the commonest cause of working-age adult-onset blindness in the Western world and a common cause of kidney failure, and at least doubles the risk of heart disease.

Diabetes, including the common type 1 and type 2 forms, is an important area of clinical practice and also of CTC's research, in the laboratory, with people with diabetes, and in advocacy and training the next generation of medical researchers.

The CTC's diabetes group, with its national and international collaborators and trainees approach this devastating disorder from multiple directions: laboratory research to advance the understanding of the molecular and genetic processes of insulin production;[73,74,86] preventing the onset and progression of diabetes complications;[101,143,169,183,208] clinical projects to advance insulin delivery for people with type 1 and type 2 diabetes,[112,114,115,161,162] including the artificial or bionic pancreas;[114,161] and in advocacy of access to insulin and its storage in disadvantaged regions.[138,139.]

Clinical study highlights in 2016 have included, first, closing of the REMOVAL trial, which has tested the type 2 diabetes oral drug, metformin, added to insulin to protect people with type 1 diabetes against atherosclerosis and, second, commencing recruitment for FAME-1 Eye, to determine whether oral fenofibrate acts against the progression of eye disease in adults with type 1 diabetes. A Centre for Research Excellence in Diabetic Retinopathy grant allowed progress in studies related to improving eye care in Indigenous Australians. Studies in type 1 and type 2 diabetes explored new molecular and biochemical markers that may predict diabetes complications.[72,200,201]

Laboratory research in understanding the epigenetic regulation of insulin gene expression is being led by Anand Hardikar, who leads the Islet Biology and Diabetes group. Other areas of research include identifying the molecular processes of insulin production, validating molecular biomarkers of diabetes progression and leading research in understanding the role of gut microbes in obesity and type 2 diabetes using cell culture and animal models.

These projects involve national and international teams of clinicians and scientists and trainees, from short-term summer students to postdoctoral fellows, and are funded by various non-profit agencies, including government, the Fred Hollows Foundation and the Juvenile Diabetes Research Foundation (International and Australia).

HIGHLIGHTS

Adults with type 1 diabetes have shorter telomeres, thought to reflect accelerated ageing

Genetic material (such as DNA) is contained in specialised structures—chromosomes— inside the nuclei of many body cells. Telomeres are highly specialised regions at each end of a chromosome that protect them when cells divide. They are sometimes likened to the caps that prevent the ends of shoelaces from fraying. Telomeres shorten each time a cell divides, until eventually, at a critical telomere length, the cell dies. Telomere length is a marker of ageing. It has been shown that high blood sugar and blood pressure, smoking and body fat are associated with shorter telomeres. In diabetes, telomere length and accelerated ageing are closely related, and in some small studies shorter telomeres have predicted long-term outcomes such as death and kidney failure. Telomere length can be measured in research laboratories and potentially in hospital laboratories in white blood cells, which are included in commonly taken blood samples.

A study by the CTC diabetes group and their colleagues comparing a group of people with type 1 diabetes and a control group without diabetes has shown that telomeres are relatively shorter in type 1 diabetes patients and, as expected, they are shorter in in older people with and without diabetes.[72] However, in this study telomere length did not differ significantly between diabetes patients with long-term diabetes complications such as eye or kidney damage and those without complications. A relatively shorter telomere length was shown to be associated with some traditional risk factors for long-term diabetes complications, like age, male sex and diabetes duration, but not with body build, blood sugar control, blood pressure, smoking, kidney disease, inflammation or oxidative stress.

This study had over 300 participants who had a particularly wide variety of carefully validated measurements of characteristics related to diabetes, such as blood pressure, blood vessel elasticity, blood sugar control, cholesterol levels, kidney function and novel markers of risk factors such as inflammation and oxidative stress.

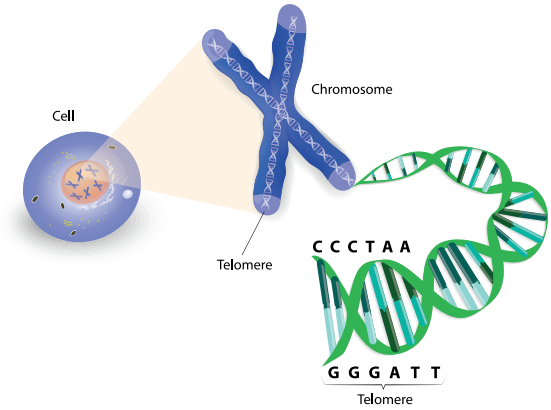
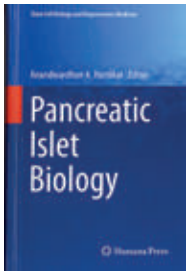


Diagram showing telomeres the ends of chromosome

Studies over time, where the measurements are repeated, is the next step to extend the results. If found to be clinically helpful, this telomere length assay could be established in clinical laboratories and used to predict outcomes for individual diabetes patients. Other research is exploring lifestyles and drugs that may protect people against telomere shortening.

Pancreatic Islet Biology



In 2016, the leader of the CTC's Diabetes and Islet Biology group, Anand Hardikar, published a comprehensive textbook reflecting his international standing in the mechanics of insulin production.[1] The book covers genetic mechanisms of insulin production, development of embryonic stem cells, insulin regulation, and pancreas transplantation.

The book aims to educate young researchers who are starting a career in islet biology, senior researchers who want to understand fundamental aspects in different areas, and cross-disciplinary scientists interested in islet cell development; lineage commitment; cell differentiation, regeneration and function; the pathobiology of diabetes; and clinical replacement of pancreatic islet cells in people with diabetes.

Contributors to the book's 12 chapters come from leading basic science and clinical research groups around the world, and include CTC's Alicia Jenkins, Andrzej Januszewski, Wilson Wong and Mugdha Joglekar.[2,3]

William Tarnow-Mordi, director of neonatal and perinatal trials

MAJOR PROGRAM OF CLINICAL TRIALS IN NEONATOLOGY AND PERINATAL MEDICINE

The CTC neonatal team work with clinicians through global partnerships in areas of need, to improve the lifelong consequences of neonatal and perinatal disorders.

Important in these partnerships are parents, family members and others with the experience of having a premature infant. They are welcome at the annual Sydney International Update on Advances in Perinatal Care, run by CTC and the WINNER Centre, and other interdisciplinary conferences and as partners and contributors in all aspects of clinical trials. They contribute their experience and views in the choice of research questions and the design and interpretation of neonatal trials.

Neonatal trials have special challenges. They must often be surprisingly large to detect moderate benefits, and thousands of children may be needed to show a definite result. Some disorders are rare, so accrual is drawn out. The effects of preterm birth may not unfold for some years, so long-term follow-up is needed to capture effects on physical, mental and social development.

The CTC neonatal group and WINNER Centre for Newborn and Perinatal Research advocate systemic and methodological improvements in the way clinical trials are conducted to keep them manageable and affordable. These strategies include embedding clinical trials in routine care, closer partnerships between clinicians and parents, use of high-quality point-of-care data, exploration of opt-out consent in low-risk comparative effectiveness research and the newly conceived ALPHA Collaboration, which aims to advance large efficient perinatal trials of health outcomes assessment of 5000 to 50,000 or more participants, through international collaboration.

The PROTECT trial began in 2016. This new trial brings the number of current neonatal trials to six, all large complex international studies, which will eventually recruit about 7000 patients, with total funding of over $15 million.

The health and future prospects of infants born before 29 weeks' gestation are steadily improving, largely thanks to well organised clinical trials.

Even so, many preterm or severely ill infants die or develop disabilities.

CTC's neonatal and perinatal trials are at the forefront in addressing the causes and promoting healthy survival through international collaboration.

Sarah Finlayson, Elisabeth Coates and Rebecca Brown, with neonatal program manager, Alpana Ghadge

Higher oxygen saturation levels improve survival of very preterm infants, without increasing disability or blindness

In 2016, the combined results of the Australian and UK BOOST II trials in 1135 infants born before 28 weeks gestation were published in the *New England Journal of Medicine*.[174]

Infants born before 28 weeks have immature lungs and often require supplemental oxygen. Before this evidence, neonatal specialists targeted oxygen between 85% and 95%. It was known that higher levels could cause death and disability but also carried a risk of eye damage. It was thought that the lower range might reduce the risk of eye damage from retinopathy while being effective against the risk of other disabilities.

Data from BOOST II in Australia with 1135 infants and BOOST II in the UK with 973 infants were combined. In the combined analysis, 48.1% of the infants in the lower-target group and 43.1% in the higher-target group had died or had a disability by the age of 2 years. This was a statistically significant difference. Of every 28 infants allocated to the higher rather than the lower oxygen target, there was one extra survivor.

NeOProM combines BOOST II data in a fresh analysis of more data from five trials

Data from patients in these trials is being combined with data from similar Canadian and US trials in the prospective NeOProM meta-analysis. This study is producing evidence from newly analysed data from 4965 patients.

Preliminary results were presented by Lisa Askie at the Congress of the European Academy of Paediatric Societies, Geneva, in October, and at Hot Topics in Neonatology in Washington in December. For every 1000 infants aged 18 to 24 months, a higher oxygen saturation target of 91–95% compared with a lower oxygen target of 85–90% made no difference to the rate of death or major disability, but resulted in 28 more survivors, 22 fewer babies with necrotizing enterocolitis (a severe gastrointestinal emergency) and 40 more babies having treatment for retinopathy of prematurity, with no increase in blindness.

PERSONAL STORY

KAREN SIMMER AO: RESEARCH LEADER IN NEONATOLOGY COLLABORATING WITH CTC

I am the inaugural Professor of Newborn Medicine at the University of Western Australia and co-director of the NHMRC Centre of Research Excellence for preterm infants and the director of the busiest neonatal intensive care unit in Australia. We have a successful record of recruitment to neonatal trials. I lead a large multidisciplinary team and have developed extensive clinical and research networks in this area.

One of my main areas of research interest is neonatal infection and prevention of the serious consequences of infection and inflammation. These include white matter injury and neurodevelopmental impairment. I am leading the PROTECT trial, a major new collaborative project coordinated by CTC, starting in 2016 with funding from a NHMRC project grant of 2.9 million.

PROTECT is investigating whether pentoxifylline can improve long-term outcomes (measured at 2 to 3 years of age) of very preterm infants with late-onset sepsis or necrotizing enterocolitis. We are recruiting 1800 infants born before 29 weeks' gestation in Australia, NZ, Taiwan, Singapore and Canada. They will be allocated to intravenous pentoxifylline,an anti-inflammatory drug, or placebo, as adjunct to antibiotics.

My other main research interest is the effect of early nutrition, especially human milk, on the health and development of infants.

APTS SUBSTUDY

Placental transfusion for preterm infants: first short-term results

Advances in the treatment of premature infants have already reduced the incidence of death and disability.

An unanswered question in neonatology is the best time to clamp the umbilical cord. Very premature infants are at risk of later disabilities, particularly neurological problems and infections. The standard procedure in Australia is to clamp the cord immediately to allow the infant and mother to be cared for efficiently, but delay in cord clamping might increase the volume and flow of blood in the infant, reducing the need for blood transfusions, and might have other benefits. Another approach to increasing the infant's blood volume is milking the cord of placental blood. The optimum procedure has not been guided by trial evidence, particularly for infants born by caesarean section.

The Australian Placental Transfusion Study is comparing immediate and delayed cord clamping. The trial has recently completed recruitment of over 1600 infants born before 30 weeks' gestation. The trial was designed to establish whether obstetricians and midwives could reduce the risk of death and disabilities in children born early by delaying clamping the umbilical cord for a minute, thus allowing more placental blood to flow into the infant. These trial participants will be followed up over 3 years.

In a substudy of the trial using data now available, the investigators determined whether delayed cord clamping resulted in better blood flow in the first day of life.[149] The main measure, blood flow into the heart, was found to be similar in both groups of infants, overall and in subgroups. There was no difference between the groups according to whether it was a vaginal or caesarean birth. The study raised some concerns about the feasibility of delayed cord clamping for very premature infants, as in some cases, the attending clinician had to abandon this practice to resuscitate the infant. The final outcomes of APTS and similar trials are awaited before any changes to obstetrical guidelines can be considered.

The substudy has attracted attention, and the results were highlighted by an editorial when published in 2016 in the *Journal of Pediatrics*.[149]

PERSONAL STORY

HELEN LILEY: RESEARCH LEADER IN NEONATOLOGY COLLABORATING WITH CTC

I am a practising neonatal paediatrician and a research physician collaborating with CTC on clinical trials. I undertook paediatric training in Auckland and the Children's Hospital in Boston, and first became involved in research at the University of California, San Francisco.

While my early scientific interest was in the cell biology of lung and blood vessel development, my current clinical research, including multicentre trials, is to improve the outcomes of infants who need resuscitation at birth and subsequent neonatal intensive care.

In my current collaboration with the CTC, I am chief investigator of PAEAN, a trial recruiting 300 infants with high risk of brain damage due to low oxygen or blood supply to the brain at birth. We are randomly allocating infants already on whole-body cooling treatment to either placebo or erythropoietin. Erythropoietin is best known for stimulating production of red blood cells, but it also has protective effects on the brain. The children in the study will be assessed at two years of age.

Aside from the clinical trials, I also undertake research into aspects of training clinical teams in neonatal resuscitation and monitoring with Professor Penelope Sanderson, an expert in safety-critical workplaces. Our projects have the general aim of optimising the performance of doctors, midwives and nurses working together to give frail infants a better start.

INTEGRATING TRIAL EVIDENCE FOR POLICY AND PRACTICE

The Systematic Reviews and Health Technology Assessment group at CTC undertake work to integrate trial and other evidence into a foundation for effective decision making in health policy and clinical practice.

Their projects include reviews for the international Cochrane Collaboration, mainly in breast cancer, and reviews of new technology where effectiveness or suitability for funding has to be established.[228–233] The group also has a reputation for its individual participant data meta-analyses answering important clinical questions across a range of areas such as maternal and child health, including the NeOProM (Neonatal Oxygenation Prospective Meta-analysis) and PARIS (Perinatal Antiplatelet Review of International Studies) projects, which are completed but still raising new research questions.[8]

CTC is represented on the Test Evaluation Working Group of the European Federation of Clinical Chemistry and Laboratory Medicine, which recently developed a strategy and checklist for appropriately using tests for new molecular and genetic biomarkers in clinical practice.[124]

Lisa Askie, head of CTC's Systematic Reviews and Health Technology Assessment group and leader of international meta-analyses in neonatology

Systematic reviews and economics evaluations assist in government decision making and policy

The CTC undertakes systematic reviews and economics evaluations under contracts with the Commonwealth Department of Health and the National Health and Medical Research Council.

The group develops review protocols, critiques submitted evidence and conducts independent reviews to assist the Medical Services Advisory Committee make decisions on new listings for the Medical Benefits Schedule. In 2016, this work spanned health areas that included cardiology, oncology,[228,229] gastroenterology, dermatology and prenatal screening.[232,233]

This group also reviews evidence and provides methodological expertise to the NHMRC, which develops health guidelines for Australia. This work often addresses broad public health questions.[231]

The best unbiased evidence on a particular aspect of clinical care is generally found by a systematic review of available research results.

Mark Ayson, Samara Lewis, Saskia Cheyne and Blaise Agresta, who evaluate evidence on new technologies and treatments for government

CTC ALUM

LUKAS STAUB: SENIOR RESEARCH FELLOW GENERATING EVIDENCE FOR USING NEW MEDICAL TESTS

What do you do now?

Starting in 2017, I will be returning to CTC to work with Sally Lord in the Epidemiology and Test Evaluation group, where we develop research methods for the evaluation of new medical tests. We do this because a new diagnostic test, even if it is accurate, must be evaluated for its ability to change clinical management and ultimately improve outcomes before it can be introduced into practice. The pathway from a new test to better health for patients can be complex, and clinical trials of the process are not always feasible.

I am also part of a health economics project with Rachael Morton on the cost-effectiveness of screening migrants to Europe for infectious diseases, and other test-related studies.

When were you at CTC?

I am a medical doctor primarily interested in research. I came from Switzerland and was a CTC PhD research student from 2008 to 2011. My thesis was entitled *Medical test evaluation—evidence beyond diagnostic accuracy*. Its aim was to advance the evidence base of medical test evaluation by improving the selection, design and interpretation of studies that investigate different test results along the causal pathway linking testing with patient health outcomes.

How did your CTC experience influence your career?

I remember many inspiring discussions with John Simes during which I learned to understand the complexities around the evaluation of medical tests. His clinical expertise ensured that my work was always based on real-world examples and applicable to daily practice.

My PhD studies fitted well with my continuing interest in diagnosis of causes of low back pain, because symptoms and radiological findings can be contradictory. I was part of a collaboration that identified a new sign to detect lumbar spinal stenosis. This work has been continuing in recent years through my tenure as a research fellow at the Institute of Social and Preventive Medicine, University of Bern.

HTA: HIGHLIGHT

Fluoride in public health

Over the past two years, the CTC has undertaken an evaluation of evidence on the health and dental effects of water fluoridation for the National Health and Medical Research Council. The review updated a previous review of the evidence on the health effects of water fluoridation.[230,231]

Programs of fluoridation of the water supply were first introduced in Australia half a century ago to reduce tooth decay, especially among children. The NHMRC last reviewed the evidence on risks and benefits of the practice in 2006, and decided to update the evidence in 2012 following ongoing community concerns regarding potential effects on health, and in line with its policy on maintaining currency of the NHMRC's evidence base.

CTC reviewers worked with a reference group comprising experts in the fields of public health, oral health, epidemiology, child health, toxicology, cancer, bone biology, neurodevelopment, Aboriginal and Torres Strait Islander health, water management and health ethics. The work was multifaceted, and included undertaking several evidence reviews, collating evidence submitted in a public consultation process and assisting in production of a public summary document.

The evidence evaluation concluded that fluoridating water helps to reduce tooth decay, by protecting against damage and helping with the repair of teeth. The review found no evidence that water fluoridation at current Australian levels causes health problems.

COCHRANE BREAST CANCER GROUP

Commitment to trusted evidence for informed decisions on breast cancer

For reputable evidence on questions of health care, the leading information source is the international Cochrane Library. The National Health and Medical Research Council in Canberra supports the Cochrane Library so that all Australians can access unbiased, high-quality, evidence-based health care information at no cost to themselves.

The Cochrane Breast Cancer Group, which coordinates and leads the review and publication of evidence from breast cancer research, has been based at CTC since 1996. On its 20-year anniversary the group acknowledged its founders, Iain Chalmers, Mike Clarke, Kay Dickersin, Davina Ghersi, Alessandro Liberati, Chris Silagy and John Simes, its early funders, and Martin Stockler and Nicholas Wilcken, who developed major practice-guiding Cochrane reviews on metastatic breast cancer. The efforts of all these people and their successors have led to better treatment and internationally used treatment guidelines for people with breast cancer.

The group now includes over 800 volunteers from diverse backgrounds: consumers, methods experts, statisticians, surgeons, radiation and medical oncologists, and guideline developers. The Cochrane Breast Cancer Group pioneered patient involvement across the board, inviting consumers to be authors, editors and peer reviewers since 1996.

The Cochrane Breast Cancer Group, like Cochrane generally, does not seek or accept any commercial funding. They have been funded by the National Breast Cancer Centre (NBCC), the Department of Health and Ageing, the National Breast Cancer Foundation, the US Department of Defense and the NHMRC.

An important review of evidence in 2016 examined research on radiotherapy regimens, and found that higher doses of radiotherapy in fewer treatment sessions was as effective as and less toxic than the conventional 25 to 30 treatments. This new evidence will be incorporated into clinical guidelines and will be particularly beneficial for patients living in remote and regional areas.

ANZCTR

Australian New Zealand Clinical Trials Registry: for better health and better research

The Australian New Zealand Clinical Trials Registry (ANZCTR) continues to provide a valuable service for registration of national and international clinical studies. In 2016, registry staff at CTC focused on spreading the word about the importance of trial registration and, improving the website to make it simpler for users to register their trials accurately and keep their records up to date. Enhancements in website functionality include automated checks and reminders and improving the search function.

The CTC's ANZCTR group have been actively engaging with the research community on the value of trial registration and sharing clinical data via presentations by Ailsa Langford and Kylie Hunter to various Australian groups and at the annual Cochrane Colloquium in Seoul. These presentations have also explained the processes of how to register studies. →

Between 2005 and the end of 2016, 13192 trials were registered on the Australian New Zealand Clinical Trials Registry

Melina Willson, managing editor for the Cochrane Breast Cancer Group

CTC ALUM

DAVINA GHERSI: SENIOR PRINCIPAL RESEARCH SCIENTIST AND SENIOR ADVISOR

What do you do now?

At the National Health and Medical Research Council (NHMRC) in Canberra I provide advice and support across the agency on matters associated with creating and translating research evidence. NHMRC is the leading expert body for developing and maintaining individual and public health standards.

I believe that those engaged in health and medical research have a moral responsibility to conduct their investigations in accordance with sound scientific principles, and to report their results completely, honestly and transparently.

My role is an opportunity to make a real difference and improve the health of Australians through doing what I can to facilitate functioning working relationships between researchers and decision makers.

Australia is fortunate to have strong research governance and regulatory systems to ensure the integrity of research. NHMRC is uniquely positioned to bridge gaps between research, policy and practice and has great potential to accelerate translation of research evidence into better clinical decision making.

I am also an adjunct professor with CTC.

When were you at CTC?

I worked at CTC from 1992, initially as a cancer trial coordinator. Later, when I was head of Systematic Reviews and Health Care Assessment, I started a PhD, completed in 2007 while I was at the World Health Organisation in Geneva, where I established the International Clinical Trials Registry Platform and fostered the relationship between the WHO and the Cochrane Collaboration.

My thesis was on issues in the design, conduct and reporting of clinical trials that influence the quality of decision making. Research transparency, clinical evidence and the ethical translation of research into practice have been long-standing interests.

How did your CTC experience influence your career?

My supervisor, John Simes, who was a leader in advocating research transparency, had published on publication bias as early as the 1980s.

We worked together on evidence reviews and editorial responsibilities for the Cochrane Breast Cancer Group and setting up the Australian and New Zealand Clinical Trials Registry, projects that were an ideal basis for my later achievements at the WHO and in government.

The registry improves the efficiency and value of Australian clinical trials research by helping to increase trial participation and showing the current status of clinical research. It allows policy makers to identify potential gaps between current trials research activity and health priorities.

For the public, registration of all clinical trials is important to health, as it is a way of disclosing all current research involving humans. It enables everyone to know what research is being done and whether any results might be missing from published science.

In 2016, the ANZCTR registered over 1400 Australian or New Zealand studies and almost 300 internationally run studies, 144 each month on average. This was a significant increase in activity on previous years. The registry has continued its partnership with Australian Clinical Trials and Australian Cancer Trials, providing a direct feed of trials for their websites.

Slavica Berber and Kylie Hunter, staff of the Australian New Zealand Clinical Trials Registry

Rachael Morton, director of health economics

HIGHLIGHT: MELANOMA MONITORING

Regular monitoring of people at high risk of melanoma saves lives and reduces costs.

About 10,000 people in Australia are at very high risk of developing melanoma because of genetic predisposition or because they or their family have a history of previous melanoma.

According to the clinical guidelines, they should be monitored regularly, so that any new melanomas will be picked up at an early, curable stage. On the other hand, monitoring skin lesions can lead to overtreatment and is time consuming for patients and clinics and requires highly trained staff.

A study by CTC's head of health economics, Rachael Morton, with the School of Public Health and the Melanoma Institute Australia, has analysed this balance. They found that surveillance in a specialised clinic is both less expensive and more effective than standard care.[194] Melanomas were detected earlier, so less extensive surgery was needed. Also, close expert monitoring allowed the clinicians to better judge which lesions could be left alone, resulting in less excision biopsies. The average saving compared with standard care was about $7000 per patient.

The high-risk melanoma clinic was started up by the Sydney Melanoma Diagnostic Centre and Melanoma Institute Australia with funding from the Cancer Institute NSW. Its methods of 6-monthly systematic surveillance with expert clinicians using digital dermatoscopy and total body photography were known from previous studies to be effective in detecting melanoma early. The investigators of this study wanted to find out if they were also cost-effective. They obtained evidence of the costs and benefits for 500 clinic patients and compared these with data on the standard care received by other Australian patients, who were identified from population health data and matched for melanoma risk.

Economic evaluation for better decision making

Economic evaluation is incorporated into clinical trials when 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); when the intervention is known to be expensive; or when the intervention affects quality of life.

Economic evaluation also includes preference studies, which answer questions about patient, clinician or community preferences.[189–191] These studies can inform the design of new interventions, prevention strategies or diagnostic tests used in trials and advise on incentives or reimbursement in health policy.

The health economics group leads methodological and applied research in the area of health equity, with a focus on the financial impact of cancer,[44] especially melanoma,[42,43,111,165,194] and chronic kidney disease[125–128,131,177,192,197,204] on individuals and households. In addition, the group is currently investigating the ways in which value of information (VOI) analysis can inform trial design and health policy decision making.

Proven new health-care treatments must be shown to be value for money before they are put into practice, whether they are publicly or privately funded.

Economic evaluations have long been integral to CTC's trials and systematic reviews of evidence.

BIOSTATISTICIANS HELP TURN IDEAS INTO WORKING TRIALS

Val Gebski, head of biostatistics

New concepts for trials are usually proposed by clinicians or groups of clinical investigators. Through clinical experience and contact with patients they know where new treatments need solid evidence arising from testing in trials. CTC has the range of sophisticated skills and fully formed processes for turning ideas into functioning trials. When new concepts are proposed by trial groups, biostatisticians develop the optimal trial designs most likely to result in the study delivering the best evidence as to the benefit of the proposed therapy. The biostatisticians are the methodological engines, translating trial concepts into workable projects that answer clinical questions in a scientific way.

CTC statisticians most often work on the CTC's flagship trials, which test new therapies in many types of cancer, cardiovascular disease, diabetes and neonatal disorders.

Biostatisticans also apply their expertise to clinical research in a wide range of medical specialties involving external collaboration. They join with national and international groups to play a part in designing, analysing and reporting trials which are efficient and methodologically rigorous. Examples are recent achievements in oncology,[52,57,185] radiation oncology,[51,144,182] medical specialist training,[184] Indigenous health,[151] infection,[41] and osteoporotic spinal fractures .[38]

An article on a new way of delivering radiation to secondary liver cancers was considered one of the important papers in that specialty for 2016. This was the subject of the phase 3 SIRFLOX trial, conducted as a partnership of international oncologists and the company that manufactures the treatment, with the analysis of results guided by CTC.[57] The treatment, called selective internal radiation therapy, uses tiny radioactive spheres, injected via an artery to flow to the small blood vessels in the liver. The radiation did not affect or reduce any cancers elsewhere in the body, but in the liver it enhanced the effect of standard chemotherapy.

Below: Adrienne Kirby, senior CTC biostatistician, with Professor Ian Marschner
At right: Rachel O'Connell, senior biostatistician

In other projects, CTC biostatisticians take time to meet with researchers at hospitals and universities in Sydney at regular intervals to see projects through to completion. Their recent projects have included a wide variety of clinical areas, including cancers,[67–69,102,133] especially skin[32,33] and gastrointestinal cancer,[11,24,25,142] neurology,[92,147] allergy,[70,98,130,173] obstetrics,[19,80,81,203] emergency medicine,[89,123,163] diabetes,[91,100] psychiatry,[20,21] and infection.[12,27,90,148]

Keeping abreast of the latest approaches to trial design has the biostatisticians reaching in many directions. They teach postgraduate students in university degrees and other health professionals in short courses and masterclasses. Innovative methodology is developed, especially by CTC PhD students and their supervisors,[49,157] to eventually be applied to trials and other clinical research at the CTC and elsewhere.

Elizabeth Barnes, biostatistics research fellow with administrative officer, Vanessa Cochrane

CTC ALUM

ANDREW MARTIN: FROM ACADEMIA TO INDUSTRY AND BACK

What do you do now?

After several years of postdoctoral work in pharmaceutical organisations I returned to academia to my current appointment at CTC.

Here, I provide direction on study design and conduct, data analysis, and the interpretation and dissemination of results across national and international projects, mainly in oncology and perinatal medicine. I also develop course material for, coordinate, and teach trial methods and decision analysis, and supervise and mentor university staff and students. Recent postgraduate students have explored questions about the treatment of latent tuberculosis, the cost of anticancer therapies, the clinical significance of treatment effects, the role of geriatric assessment in treatment decisions in oncology, and the effect of nicotinamide on skin cancer biology.

In the pharmaceutical industry I directed statistical aspects of international programs in which candidate drugs or devices in the company's pipeline were taken from discovery through to regulatory approval and mainstream use. Companies have resources to fund specialised teams and bespoke systems to drive this process. Academic research has a much broader focus as to the types of interventions that receive attention, research objectives, and ways of getting the work done.

When were you at CTC?

My PhD was awarded when I was at CTC in 2000. It addressed the problem of how to measure aspects of quality of life and distil these into a valid overall index that can be formally combined with survival and financial cost to evaluate trade-offs and facilitate decision making.

How did your early CTC experience influence your career?

I learned to think strategically about research design and its implementation, and about how to present research to make it readily accessible to others. I routinely apply these ideas when specifying study designs and statistical methods and explaining the meaning of results. Communicating this information to non-statisticians can be challenging because of its technical nature. I apply the knowledge I've gained to deal with this challenge when teaching, collaborating with clinical investigators, preparing grant applications, and preparing publications.

PERSONAL STORY

KRISTY ROBLEDO: BIOSTATISTICIAN

Engaging people with statistics is a difficult task. Our statistics department is involved in a wide range of statistics teaching.

We teach postgraduate students in public health, biostatistics and clinical trials programs and other health professionals in our workshops and masterclasses.

One that I have been part of in the past five years is a statistical workshop for trainee radiation oncologists. Each year, we run an interactive one-day workshop, alternating workshop A and workshop B. Attending these workshops gives the trainees 'SMART points'. It's part of their program that gives them the skills to appraise evidence and understand and participate in oncology-related research.

Different trial methods are addressed in each of the workshops with short didactic talks, followed by small group sessions that are led by facilitators (radiation oncologists with trials experience). As one of two statisticians at the workshop, my role is to give several talks over the day, and then to rove around the groups to assist with any questions.

The day always has many questions raised, equally from the trainees and the facilitators! This has become one of my favourite teaching activities, and I think I learn just as much as some the trainees in how to articulate concepts in multiple different ways.

EDUCATION

Comprehensive education in clinical trials through postgraduate degrees and short courses

CTC offers training for people with a broad range of needs related to clinical trials. For those requiring a recognised postgraduate qualification for working in clinical trials, the Master of Clinical Trials Research delivers solid understanding and the necessary skills to design and lead trials. The Master of Biostatistics is a multi-university program to train professional biostatisticians. For those wanting an introduction to trials, without formal accreditation, the masterclasses in trial methodology and conduct give an overview, provided by CTC experts, over a week. Other intensive short courses are offered by CTC faculty on specialised areas of scientific and clinical research.

Postgraduate study

Master of Clinical Trials

As health care and health research become more closely intertwined, many health professionals need skills and knowledge to plan and conduct clinical trials in their area of expertise.

The CTC developed its postgraduate course at the University of Sydney in response to this need. It covers research methods, clinical trials literature and the clinical trials process, including design, regulations, and statistical and ethical considerations. The program is delivered online, including lectures, discussion forums and supplementary notes.

Students not wishing to immerse themselves in the full master's course have the opportunity to qualify for a graduate diploma or graduate certificate. The postgraduate program is coordinated by Adrienne Kirby, Val Gebski and Anthony Keech.

Currently, about 25 students join the course each year.

Short courses

Concept development workshops

Ideas for new clinical trials come from patients, practising clinicians, scientists, and others who identify gaps in research evidence. Promising trial questions can be workshopped into structured research plans at CTC's popular one-day concept development workshops, held several times a year.

Methodological experts from the CTC provide information, advice and guidance on how to develop a concept outline from an initial idea or scientific question. The day covers specifying a suitable aim, objectives, sample size, population, interventions, randomisation, study design, outcome measures, analysis plan and funding strategy, as well as further tips and hints on developing the proposal into a funding application or full protocol.

CTC faculty have long experience in the full lifecycle of a clinical research project: clarifying the idea; protocol development, ethics issues, obtaining finance, budgeting, research design, operations, results analysis, and reporting.

These workshops are provided at low cost, not for profit, as a contribution to building skills and knowledge to advance public-good clinical trials in Australia.

Masterclasses in clinical trials

Masterclasses in how to plan, develop and manage clinical trials feature the core skills of CTC faculty developed over 28 years of experience and over 180 clinical trials conducted. In 2016, CTC held masterclasses for professionals in various clinical areas who came to learn about trials operations, design, methods, conduct and interpretation.

Introduction to economic evaluation in health

Health economics is an increasingly important feature of health systems and research. Economic studies focus on the equity, efficiency, costs and benefits of new and existing health care. CTC conducted a course in the fundamentals of economic evaluation in April 2016. It covered measuring and valuing resource use and costs, as well as outcomes, such as survival and utility-based quality of life. It placed economic analysis in the framework of health technology assessment and policies for national funding.

Corresponding with the broad application and increasing importance of health economics to research, it attracted a diverse student group: clinicians, marketers, managers, advisers and financiers, from academia, government, hospitals and the pharmaceutical and insurance industries. The course will be offered annually.

Rachael Morton, director of health economics

Short courses

Diabetes and vascular disease masterclass

The CTC's popular annual diabetes and vascular disease masterclass for clinicians was again held in 2016 in Melbourne. The program, convened by Anthony Keech and Alicia Jenkins, included case studies attracting lively debate and input from the panel and audience, especially discussions on depression in diabetes, palliative care in end-stage renal disease and gestational diabetes. This year's lectures included a focus on recent molecular discoveries.

'It is the best and most interactive meeting of the year.'

'...valuable opportunity to see other perspectives in diabetes care and vascular disease'

'As a rural physician, opportunities to interact with colleagues from across the specialities are few. This was a fantastic meeting with a very nice balance of science and clinical medicine'

Alicia Jenkins, head of CTC's diabetes group and co-convener of the diabetes and vascular disease masterclass

The diabetes and vascular disease masterclass

Mugdha Joglekar, Anandwardhan Hardikar, Wilson Wong and Andrzej Januszewski

Intensive personal training in molecular biology

In 2016, CTC's Diabetes and Islet Biology Group conducted a 6-week structured intensive personal training program for six overseas students in molecular markers of disease, from cell and tissue culture ('Life in a dish') to next-generation sequencing modules ('Discovering the unknown'). This course was conceived, designed and directed by Anand Hardikar and co-directed by Dr Ammira Akil from Sidra Research Centre and Cornell University in Doha. It has become an annual activity.

The course consists of comprehensive practical lab-based training and seminars, with weekly exams and a certificate of training and performance at the end. Past participants have mainly been students of research collaborators in the Middle East, Europe or Asia, although anyone is welcome to apply. Students benefit from the renowned expertise of Professor Hardikar and the Diabetes and Islet Biology group generally.

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 350 students are enrolled, 170 of them new in 2016, and on graduation will contribute to solving the shortage of well qualified biostatisticians in Australia and elsewhere.

Erica Jobling, Biostatistics Collaboration of Australia (BCA) executive officer

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

CURRENT CTC TRIALS

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Neonatal disorders			
Current trials			
LEAP: Lactoferrin evaluation in anaemia in pregnancy *CTC-led study*	Pregnant women with anaemia	900	19
LIFT: Lactoferrin infant feeding trial *CTC-led study*	Infants born weighing under 1500 g	1100	1073
PAEAN: Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy *CTC-led study*	Newborn infants with signs of brain damage	300	21
PROTECT: Can pentoxifylline improve long-term outcomes in preterm infants with late-onset sepsis or necrotizing enterocolitis? *CTC-led study*	Neonates born before 29 weeks' gestation	1800	7
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	9
Trials in follow-up			
APTS: Australian placental transfusion study *CTC-led study*	Neonates born before 30 weeks' gestation	1600	1633
Cardiovascular disorders			
Trials in follow-up			
FIELD: Fenofibrate intervention and event lowering in diabetes *CTC-led study*	Patients with type 2 diabetes	8000	9795
Diabetes			
Trials in start-up			
Hybrid closed-loop study: adult *St Vincent's Hospital Melbourne, JDRF Australia, Medtronic, CTC*	Adults aged 25–70 with type 1 diabetes	120	
Hybrid closed-loop study: paediatric *Princess Margaret Hospital Perth, JDRF Australia, Medtronic, CTC*	Young people aged 12–24 with type 1 diabetes	160	
Current trials			
6-month closed loop insulin pump *CTC, St Vincent's Hospital, Melbourne, and Telethon Institute study*	Adults and youth with type 1 diabetes	120 adults; 150 youth	
e-PREDICE: Early prevention of diabetes complications in people with hyperglycaemia in Europe and Australia *International study, BIONE and CTC*	Adults with hyperglycaemia	3000	404
FAME1-Eye: Fenofibrate and microvascular events in type 1 diabetes *CTC-led study*	Adults with type 1 diabetes and nonproliferative retinopathy	450	
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	946
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.)	105 (ANZ); 450 (int.)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Trials in follow-up			
2-week closed-loop insulin pump in home study *CTC, St Vincent's Hospital, Melbourne, and Telethon Institute study*	Adults and youth with type 1 diabetes	60	
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

Trials in start-up			
MOST: Cancer Molecular Screening and Therapeutics	Patients with advanced solid cancers and available tumour tissue	1000	43
Addendum 1: palbociclib	Patients with mutations in Rb pathway	16	1
Addendum 2: durvalumab plus tremelimumab	Enrolled patients with no actionable mutations	64	2
CTC and Kinghorn Centre study			
Current trial			
Cannabis CINV: Pilot and definitive trials of cannabis extract for prevention of secondary nausea and vomiting *CTC-led study*	Adults with cancer with significant nausea or vomiting during cycle 1 of intravenous chemotherapy	330	1

BREAST CANCER (COLLABORATING WITH RACS)

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
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

GASTROINTESTINAL CANCER (COLLABORATING WITH AGITG)

Current trials			
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.)	1 (ANZ); 160 (int.)
ALT GIST: Imatinib alternating with regorafenib compared to imatinib alone for GIST *AGITG, EORTC , SSG and CTC study*	Adults with previously untreated metastatic gastrointestinal stromal tumours	60	16 (ANZ); 41 (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); 1200 (int.)	189 (ANZ); 976 (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 tumous	72	37
INTEGRATE II: Phase 3 trial comparing regorafenib and placebo for oesophagogastric cancer *AGITG- and CTC-led international study*	Patients with refractory advanced oesophageal or gastric cancer	90 (ANZ); 260 (int.)	2 (ANZ); 0 (int.)
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.)	1 (ANZ); 63 (int.)
NABNEC: Phase II study Of nab-paclitaxel and carboplatin as first-line treatment *AGITG and CTC*	Patients with advanced gastrointestinal neuroendocrine carcinoma	70	1
TOPGEAR: Randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer *AGITG- and CTC-led international study*	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	120 (stage 1); 205 (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
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
GAP: Phase 2 study of gemcitabine and nab-paclitaxel for pancreas cancer *AGITG and CTC*	Patients with resectable pancreas cancer	50	42
ICECREAM: Irinotecan-cetuximab evaluation and cetuximab response evaluation among mutants *AGITG- and CTC-led international study*	Patients with ***Kras*** wild-type metastatic colorectal carcinoma	100	101
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.)
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	46
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	900 (int.)	157 (ANZ); 701 (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); 680 (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	333 (int.)	219 (ANZ); 114 (UK, Belgium)
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	19
Trials in follow-up			
GOG182 (ICON 5) *GOG-led, ANZGOG and CTC*	Women with advanced stage (FIGO III-IV) epithelial ovarian or primary peritoneal carcinoma.	4200 (int.)	184 (ANZ), 4312 (int.)
GOG199 *GOG-led, ANZGOG and CTC*	Women at high risk of ovarian cancer	800 (int.)	83 (ANZ), 800 (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.)
ICON 7: Randomised trial of adding bevacizumab to standard chemotherapy *MRC-led, ANZGOG and CTC*	Women with epithelial ovarian cancer who have not received systemic antitumour therapy	1444 (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.)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
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 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.)	144 (ANZ); 948 (int.)
GENITOURINARY CANCER (COLLABORATING WITH ANZUP)			
Current trials			
BL 12: Phase 2 trial comparing nab-paclitaxel with paclitaxel (ANZUP 1401) *NCIC-led, ANZUP and CTC study*	Patients with metastatic urinary tract cancer and previous platinum therapy	100 (ANZ)	35 (ANZ); 83 (int.)
Pain Free TRUS B: Phase 3 trial of methoxyflurane with local anaesthesia to reduce discomfort of transrectal ultrasound-guided prostate biopsy (ANZUP 1501) *ANZUP and CTC study*	Men scheduled to undergo first TRUS biopsy of the prostate	420 (ANZ)	31
BCG+MM: Phase 3 trial of adding mitomycin to BCG as adjuvant intravesical therapy (ANZ 1301) *ANZUP and CTC study*	Patients with high-risk, non-muscle-invasive bladder cancer	500	92
ENZAMET: phase 3 trial of enzalutamide in androgen-deprivation therapy for prostate cancer (ANZUP 1304) *ANZUP and CTC study*	Men with metastatic prostate cancer	1100	615 (ANZ): 373 (int.)
ENZARAD: phase 3 trial of enzalutamide in androgen-deprivation therapy for localised prostate cancer (ANZUP 1303) *ANZUP and CTC study*	Men with high-risk localised prostate cancer	800	306 (ANZ); 73 (int.)
P3BEP: phase 3 trial of accelerated versus standard BEP chemotherapy (ANZUP 1302) *ANZUP and CTC study*	Patients with intermediate and poor-risk metastatic germ-cell tumours	Stage 1: 90 (ANZ) Stage 2: 350	32 (ANZ)
Trials in follow-up			
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: nivoumab and stereotactic radiotherapy versus nivolumab alone *ALTG and CTC*	Patients with advanced non-smal- cell lung cancer progressing after chemotherapy	120	
PEARL: Phase 3 trial of palliative care early in advanced lung cancers *ALTG and CTC*	Adults with advanced lung cancer newly diagnosed within the last 60 days	200	
Current trial			
BR.31: Phase III study of adjuvant MEDI4736 *NCIC-led, ALTG and CTC*	Patients with resected primary stage IB (>4 cm), II or IIIA non-small-cell lung cancer	200 (ANZ); 1100 (int.)	18 (ANZ); 280 (int.)
DREAM: Phase 2 study of durvalumab with first-line chemotherapy *ALTG and CTC*	Patients with malignant pleural mesothelioma not amenable to surgery	51	1

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
BRAIN CANCER (COLLABORATING WITH COGNO)			
Current trials			
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	1
VERTU: Veliparib, radiotherapy and temozolomide in glioblastoma *COGNO and CTC*	Patients with newly diagnosed resected glioblastoma with unmethylated MGMT promoter gene	120	124 registered; 40 randomised
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.)

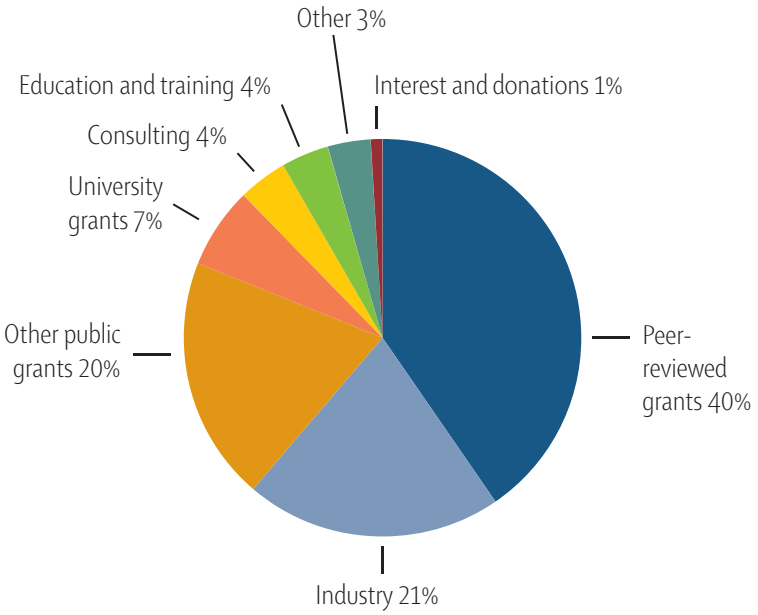
FUNDING

CTC has continued to receive highly sought-after peer reviewed funding from Australia, United Kingdom and the United States.

The NSW government and national funding bodies also continue to provide crucial support.

Pharmaceutical industry support reflects the strength of CTC's collaborative relationships, research quality and innovative edge in academic clinical trials.

Total income for 2016: $34,496,180



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Kate Wilson, BA, MPH, AGITG

Nicole Wong, RN, BN, BSc(hons), ANZUP

Oncology trials staff

Christine Aiken, BSocSc, MHlthSc

Lisa Bailey, BAppSc

Claudia Bishop, BSc

Lesley Brassel, BMgmt, DipEvents

Hannah Cahill, BAppSc, BA

David Cannan, BSc(hons)

Tara Flores, BAppSc

Kate Ford, MHSc, GradDipClinEpi

Brad Green, BSc(hons), PhD

Oncology research fellow, Nicola Lawrence

Lara Hall, DipNutr, DipBotMed, DipCom

Hannora Jurkovic, BMedSc, BA

Marzena Kucharska-Kelly, BSc(hons)

Joseph Levitt, RN

Jenna Mitchell, BHSc(hons)

Karen Miranda, BBiomedSc

Catherine O'Connor, RN, BN

Martijn Oostendorp, MSc

Raynelle Penaflor, GradCertClinTPrac

Mariya Pysarenko, BSc, GradDipInfImm

Beau Salwin, BSc, GradDipAppSc, MMedSc

John Stark, BSc

Janette Stevens, BSocSc

Thida Thien, BPsych(hon), PhD

Emily Tu, BSc(hons), PhD

Tina Van Tonder, BHlthSc, MOrth

Jaclyn Verghis, BA, MIntS

Kate Walker, BSc(hons)

Diana Winter, BMedSc

Anna Walsh, BSc

Annie Yeung, BSc

Oncology research fellows

Mustafa Khasraw, MBChB, MD, MRCP, FRACP, clinical lead, COGNO

Chee K Lee, MB BS(hons), MMedSc, MBiostat, PhD, FRACP, clinical lead

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

Howard Chan, MB BS, clinical research fellow, AGITG and ANZUP trials

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

Peey Sei Kok, MB ChB, BSc, BAO, FRACP clinical research fellow, ALTG and ANZGOG trials

Nicola Lawrence, BHB, MB ChB, FRACP, clinical research fellow, ANZUP trials

Kristina Lindemann, MD, PhD, clinical research fellow, ANZGOG trials

Felicia Roncolato, MBChB, FRACP, MMed(Clin Epi), clinical research fellow, ANZGOG and ANZUP trials

Subotheni Thavaneswaran, MB BS, clinical research fellow, AGITG trials

Annette Tognela, LLB/BSc, MB BS, clinical research fellow, ALTG trials

Oncology translational research

Philip J Hogg, BSc, PhD, chair, translational cancer research

Garry Chang, BMedSc(hons), PhD, translational research assistant and ethics coordinator

Michelle Parry, BSc, PhD, translational research officer

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

Cooperative Trials Group for Neuro-Oncology

Jenny Chow, AssocDip, executive officer

Mythily Sachchithananthan, PhD, project coordinator, Brain Cancer Biobanking Australia

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

Neonatal trials

William O Tarnow-Mordi, MRCP(UK), FRCPCH, professor and director of neonatal trials

Alpana Ghadge, BSc, MSc, PhD, GradCert TradeMarksLawPract, neonatal program manager

Rebecca Brown, BMedSc(hons), trial coordinator

Sarah Finlayson, BSc(Adv)(hons), GradCertPharmMed, trial coordinator

Elisabeth Coates, BS, trial coordinator

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

Cardiovascular trials

FIELD follow-up

Li Ping Li, BMed, GradCertDM, project manager

San Yip Chan, administrative assistant

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

LIPID follow-up

Helen Pater, BAppSc, project manager

Diabetes trials

REMOVAL

Helen Pater, BAppSc, project manager

T4DM

Karen Bracken, BEc, MPH, project manager

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

Sandra Healey, BA(hons), GradDipFA, RN, clinical trial assistant

FAME1 Eye

Andrzej S Januszewski, MD, PhD, MClinTRes senior research fellow, project manager

Li Ping Li, BMed, GradCertDM, project manager

Quality assurance

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

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

Clinical data management

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

Salma Fahridin, BAppSc(HIM), MHlthSc(CDM), clinical data project manager

Yuvi Ghodke, BSc, clinical data coordinator

Ilka Kolodziej, BAppSc(hons), MPH

Nicole McKay, BAppSc (HIM), clinical data coordinator

Liam Murphy, BSc, clinical data project manager

Sandhya Waghulde, DCEngg, GradDipCS, BusMgtCert, PM

Site management

Rebecca Mister, BSc, MSc, head

Diabetes molecular medicine and telehealth

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

Sven-Erik Bursell, PhD, professor of telehealth

Anandwardhan A Hardikar, BSc,MSc, PhD, associate professor, Juvenile Diabetes Research Foundation Australia type 1 diabetes clinical research network fellow

Andrzej S Januszewski, MD, PhD, MClinTRes senior research fellow

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

Chris Ryan, BSc, BIS, telehealth program manager

Sarang Satoor, BSc, MSc, research fellow

Wilson Wong, BSc(hons), clinical trials assistant

Systematic reviews and health technology assessment

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

Jenny Chow, AssocDip, executive officer

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

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

Health technology assessment

Blaise Agresta, BSc, MPH, GradDip HealthEcon, project manager

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

Mark Ayson, MB ChB, GradDipPH, project officer

Saskia Cheyne, MSc, project officer

Cochrane breast cancer group

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

Slavica Berber, BSc (Hons), PhD, trial search coordinator

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

Australian New Zealand Clinical Trials Registry

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

Slavica Berber, BSc (Hons), PhD, project officer

Ailsa Langford BSc(hons), project officer

Ryan Sausa, BE, computer systems officer

Thuyen Vu, BSc, computer systems officer

Ava Grace Tan-Koay, BSc(hons), MAIT, MPH, project officer

Health economics

Rachael Morton, MScMed (ClinEpi)(hons), PhD, director and associate professor

Ann Livingstone, RN, MHlthServMgt, GradDipHE, economics evaluator

Edward Peyton, BEng, research assistant

Nick Rowbotham, BEc, research assistant

Hang Yue Adrian Siu, research assistant

Anh Tran, MHEc,PhD, research fellow

Systematic reviews training session

Biostatistics and consulting

Val J Gebski, BA, MStat, professor and principal research fellow
Vanessa Cochrane, administrative officer
H Malcolm Hudson, BSc(hons), PhD, honorary professor
Ian C Marschner, BSc(hons), PhD, professor

Senior biostatisticians

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

Research fellows

Elizabeth H Barnes, BAppSc, MStat
Christopher SB Brown, BSc, MBiostat

Biostatisticians

Rebecca Asher, BSc, MSc
Luke Buizen, BSc
Lucy Davies, BSc, MSc
Mark W Donoghoe, BSc(Adv)(hons), PhD
David Espinoza, BArch(hons), BSc(hons)
Emma Gibbs, BSc, MSc
Kristy P Robledo (Mann), BScAgr (hons), MBiostat
Simone Marschner, BSc(hons), MSc

Biostatistics Collaboration of Australia (BCA)

Erica Jobling, executive officer
Emily Higginson, BA/BSc, senior administration officer

Information systems

Infrastructure

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

Database administration

Anh Tai Nguyen, BMath, database administrator

Software development

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

Business administration

Vera Terry, BSc, PhD, LLB, GradDipLP, MIP, MBA, general manager
Libby Cregan, administration assistant
Lena Germinarios, administration assistant (from July)
Rodd Hills, administration assistant (to July)
Lia Sherwood, BBiomedSc, MSc, grants and contracts coordinator

Finance

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

Human resources

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

In March, Karen Bracken received a Faculty of Medicine award for exceptional performance

Publications

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

Research students

Daniel Calandro, BSc
Ryan Farr, BSc, MPhil
Jordan Fulcher, BSc(Med), MB BS, FRACP
Deme Karikios, BSc, MB BS, FRACP
Nicola Lawrence, BHB, MB ChB, FRACP
Anna Martin
Emma Scott, MB BS
Hang Yue Adrian Sui
Boris Waldman, BSc, MB BS
Wilson Wong, BSc(hons)

Academic staff

Hany Abed, BPharm, MBBS, PhD, research fellow
Lisa M Askie, BN, MPH, PhD, associate professor and principal research fellow
Elizabeth H Barnes, BAppSc, MStat, research fellow
Christopher SB Brown, BSc, MBioStat, research fellow

Lia Sherwood, grants coordinator

Karen Byth, BSc(hons), MSc, PhD, DIC, CStat RSS, senior lecturer

Val J Gebski, BA, MStat, professor and principal research fellow

Wendy Hague, MB BS, MBA, PhD, senior research fellow

Anandwardhan A Hardikar, BSc, MSc, PhD, associate professor and Juvenile Diabetes Research Foundation Australia type 1 diabetes clinical research network fellow

Philip J Hogg, BSc, PhD, senior principal research fellow and professor

Mugdha Joglekar, BSc, MSC, PhD, research fellow

Andrzej S Januszewski, MD, PhD, senior research fellow

Alicia J Jenkins, MB BS, MD, MRCP, FRACP, FRCP, professor

Anthony C Keech, MB BS, MSc, FRACP, FCSANZ, FAHMS, principal research fellow and professor

Adrienne C Kirby, BSc(hons), MSc, senior lecturer

Mustafa Khasraw, MBChB, MD, MRCP, FRACP, senior research fellow

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

Peey Sei Kok, MB ChB, research fellow

Nicola Lawrence, BHB, MB ChB, FRACP, research fellow

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

Kristina Lindemann, MD, PhD, clinical research fellow, ANZGOG trials

Sally (Sarah) J Lord, MB BS, DipPaed, MSc, FRACGP, senior research fellow

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

Andrew J Martin, BA, MA, GradDip, PhD, AStat, senior lecturer

Rachael Morton, MScMed (ClinEpi)(hons), PhD, associate professor

Rachel L O'Connell, BMath, MMedStat, PhD, senior research fellow

Felicia Roncolato, MBChB, clinical research fellow, ANZGOG and ANZUP trials

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

Katrin M Sjoquist, BSc(Med), MB BS, MClinTRes, FRACP, senior research fellow

Martin R Stockler, MB BS(hons), MSc, FRACP, professor

William O Tarnow-Mordi, MRCP(UK), FRCPCH, professor

Subotheni Thavaneswaran, MB BS, research fellow

Annette Tognela, LLB/BSc, MB BS, research fellow

Sonia Yip, BSc(hons), PhD, senior research fellow

CTC research associates

Associate Professor Meera R Agar

Dr Yoland Antill

Professor Andrew Barbour

Dr Andrew Berry

Professor Andrew Biankin

Associate Professor Alex Boussioutas

Associate Professor Alison Brand

Dr Tim Brighton

Associate Professor Ian Campbell

Dr Yu Jo Chua

Professor Alan Coates

Ms Melinda Cruz

Dr Andrew Davidson

Professor Ian Davis

Professor Paul de Souza

Dr Andrew Dean

Professor Catherine D'Este

Dr John Eikelboom

Dr Kathryn Field

Ms Marcia Fleet

Dr Matthew Foote

Dr Michael Friedlander

Adjunct Professor Davina Ghersi

Professor P Grantley Gill

Professor David Goldstein

Associate Professor Peter Grimison

Dr Andrew Haydon

Associate Professor Sandra Hayes

Professor Dickon Hayne

Professor Gillian Heller

Dr Elizabeth Hovey

Associate Professor Michael Jefford

Dr Lindy Jeffree

Associate Professor Terrance Johns

Associate Professor Anthony Joshua

Dr Eng-Siew Koh

Dr Dusan Kotasek

Dr Danette Langbecker

Ms Robyn Leonard

Dr Trevor Leong

Associate Professor Helen Liley

Professor Ronald Ma

Dr Kerrie McDonald

Dr Sue-Anne McLachlan

Associate Professor Peter Meikle

Associate Professor Linda Mileshkin

Professor Michael J Millward

Associate Professor Paul Mitchell

Associate Professor Martin Ng

Dr Louise Nott

Professor Anna Nowak

Associate Professor Paul Nguyen

Dr Graham Ogle

Associate Professor Ju-Lee Oei

Associate Professor David O'Neal

Dr Robert Padbury

Dr Nicholas J Petrelli

Professor Timothy J Price

Dr David T Ransom

Professor Danny Rischin

Professor Mark Rosenthal

Dr Amitesh Roy

Dr Gail Ryan

Associate Professor Eva Segelov

Associate Professor Shomik Sengupta

Dr Catherine Shannon

Dr Jennifer A Shannon

Professor Karen Simmer

Professor Mark Smithers

Dr Allan Spigelman

Dr Andrew R Stevenson

Associate Professor Tobias Strunk

Associate Professor David Sullivan

Professor Christopher Sweeney

Associate Professor Niall Tebbutt

Professor David Thomas

Associate Professor Damien Thomson

Professor Andrew Tonkin

Dr Ben Tran

Associate Professor Euan Walpole

Dr Neil Wetzig

Associate Professor Nicholas Wilcken

Associate Professor Scott Williams

Professor Gary Wittert

Professor Desmond Yip

Professor John Zalcberg

STAFF ACTIVITIES

Supervision of postgraduate research in 2016

John Simes

Jordan Fulcher, Doah Cho, Nicola Lawrence, Katrin Sjoquist

Anthony Keech

Karen Bracken, Daniel Calandro, Jordan Fulcher, Surya Sutanto, Caroline Traill, Boris Waldman, Ceren Guler, Grace McKenzie, Georgia Shimmin, Amanda Ifejika, Patrick Rundle

Lisa Askie

Ziad Al-Rubiae

Val Gebski

Alan Garner

Wendy Hague

Karen Bracken

Anandwardhan Hardikar

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

Andrzej Januszewski

Daniel Calandro, Ben Ma, Aycel Al-Alosi

Alicia Jenkins

Emma Scott, Erin Bell, Yoon Hi Cho, Ben Ma, Harris Schlen, Daniel Calandro, Caroline Traill, Ryan Farr,Christine Larsson, Joanne Lee, Gabriel Gregory, Denira Govendir, Yifan Zang, William Yuen, Feng Chunzhi Cao, Eugene Hao Jun Ng, Jessica Ng, Laura Nichols, Benjamin Zhu

Mugdha Joglekar

Emma Somerville Glover, Wilson Wong

Chee Lee

Amira Elmadahm, Felicia Roncolato, Doah Cho

Sally Lord

Amira Elmadahm, Doah Cho

Andrew Martin

Deme Karikios, Nicola Lawrence, Erin Moth, Rashi Minocha

Rachael Morton

Caroline Watts, Mbathio Dieng, Rachael Walker, Melanie Wyld, Marcus Sellars, Laverne Lok, Anna Martin

Martin Stockler

Deme Karikios, Nicola Lawrence, Rebecca Mercieca-Bebber, Felicia Roncolato, Katrin Sjoquist, Puma Sundaresan, Anuradha Vasista

Degrees awarded in 2016

Mark Donoghoe, PhD

Manjula Schou, PhD

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, management committee (deputy chair), operations executive

ENCHANTED safety and data monitoring committee (chair)

FIELD management committee and executive

LIPID management committee and executive

Molecular Screening and Therapeutics program (MoST) steering committee

SNAC trial management committee

Sydney Catalyst governing council and scientific advisory committee (director)

VERTU and ACED trial management committees (COGNO)

Anthony Keech

Advancing the evidence base program grant research committee

Australian Academy of Health and Medical Sciences fellowship review committee

Australian Clinical Trials Alliance (ACTA) founding member

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

Clinical Trials Centre research committee (chair)

Department of Health Post Market Review Committee

FAME-1 diabetes trial steering committee (co-chair)

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

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

International Journal of Cardiology editorial board

LIPID study management committee and executive

New South Wales Department of Health shared assessment committee

PLoS Medicine editorial board

Rebecca Cooper grant review committee

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 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.

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

Systematic Reviews editorial board

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

Chris Brown

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

Basic sciences in oncology, Health Education and Training Institute

Sarah Chinchen

Australasian Lung Cancer Trials Group (ALTG) operations executive committee BR.31 trial management committee

Jenny Chow

Cancer Institute NSW Neuro-Oncology Group (NSWOG)

Cooperative 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

Brain Cancer Biobanking Australia (BCBA) operations group

Xanthi Coskinas

ENZARAD executive, international steering and trial management committees

ENZAMET executive, international steering and trial management committees

Val Gebski

Advancing the evidence base program grant research committee

CHIVA, COMPASS, EWOC-1; OVAR2.21, PREVANZ and PREVENT safety and data monitoring committees

Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and group statistician, and A La Cart, ALT-GIST, TOPGEAR, DOCTOR and ICECREAM 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 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 trial management committee

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, PAEAN and PROTECT trial management committees

Sydney international update management committee

Wendy Hague

ASPIRE, and LIPID management committees (cardiovascular)

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

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

Molecular Screening and Therapeutics program (MoST) steering committee

T4DM trial management committee

Merryn Hall

Cooperative Trials Group for Neuro-Oncology (COGNO) operations executive committee

VERTU, ACED and CATNON trial management committees (COGNO)

Anandwardhan Hardikar

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

Australian Research Council and Juvenile Diabetes Research Foundation Australia RAPID study and PREDICT type 1 diabetes clinical research network principal investigator

Center of Excellence in Epigenetics, Indian Institute for Science Education and Research visiting professor

Danish Diabetes Academy, visiting professor

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 review committee, translational research faculty member and assigners academy member

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

Philip Hogg

FASEB Science Research Conference on Functional Disulfide Bonds in Health and Disease, convener and chair

Andrzej Januszewski

e-PREDICE trial steering committee

FAME-1 diabetes trial steering committee

Alicia Jenkins

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

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

Diabetes Management Journal and *Diabetes Reviews* editorial boards

FAME-1 diabetes trial steering committee (co-chair)

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

International Diabetes Federation Life for a Child program board member

International Diabetes Federation Western Pacific executive council

Juvenile Diabetes Research Foundation clinical research network advisory board, and lead, research node at CTC

REMOVAL metformin study, co-principal investigator and Australian lead

T4DM trial steering committee

TEAMSNET telehealth initiative principal investigator

Mustafa Khasraw

Asian Society of Neuro-oncology meeting scientific chair

Australian Medicare Benefit Scheme oncology clinical committee

Cancer Australia Breast Cancer Best Practice advisory group
NABNEC trial lead (AGITG)
NEONAB trial lead and Local HER-O trial committee (breast cancer)
NHMRC grant review panel
NUTMEG, VERTU, and ExCentric trial lead, GBM AGILE executive committee and ACED trial committee (brain cancer)
TULIP trial lead (lung cancer)

Hannora Jurkovic

Australasian Lung Cancer Trials Group (ALTG) operations executive committee, BR.31 trial management committee

Adrienne Kirby

APTS, BOOST II and TORPIDO2 trial management committees (neonatal)
Faculty of Medicine, University of Sydney postgraduate coursework committee
Improving Delivery of Secondary Prophylaxis for Rheumatic Heart Disease trial management committee
INSPIRE steering committee
LIPID management committee
Master of Clinical Trials (Research) coursework teaching 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

Australasian Lung Cancer Trials Group small-cell lung cancer co-chair
ANZ Breast Cancer Trials Group scientific advisory committee
Genomic Cancer Clinical Trials Initiative (GCCTI)
Molecular Screening and Therapeutics program (MoST) steering committee
Study of Olaparib Clinical Effect (SOLACE) trial management committee

Liping Li

e-PREDICE trial steering committee
FAME-1 diabetes trial steering committee

Ann Livingstone

Australasian Lung Cancer Trials Group (ALTG) 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

Advancing the evidence base program grant research committee
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

Andrew Martin

Australia & Asia Pacific Clinical Oncology Research Development (ACORD) workshop statistical working group
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee
INTEGRATE II, P3BEP, BCG+MM, LIFT, ONTRANS, EPOCH, SCORE, CHEST and LEAD trial management committees
Royal Prince Alfred Hospital clinical trials subcommittee of the ethics review committee

Danielle Miller

Australasian Gastro-Intestinal Trials Group (AGITG) TOPGEAR trial management committee.
Sydney Catalyst operations group, executive, scientific advisory committees, and themed working groups.
Primary Care Collaborative Cancer Clinical Trials Group (PC4) advisory group.

Rebecca Mister

INSPIRE management committee
SNAC1 and SNAC2 trial management committees

Meeting of the advisory committee of the Australian New Zealand Clinical Trials Registry

Rachael Morton

Australia and New Zealand Society of Nephrology, Dialysis Advisory Committee

Cochrane economics methods and equity methods groups

Joanna Briggs Institute expert reference group

Health Economics Collaboration (HEC), steering group

Health Services Research Association Australian and New Zealand, Treasurer

Melanoma genomics for prevention, trial management committee

Australian and New Zealand dialysis and Transplant Association) registry patient reported outcomes working group member

Nephrology, Dialysis, Transplantation editorial board

Whole brain radiotherapy for metastatic melanoma, Evaluation of Groin Lymphadenectomy Extent for Metastatic Melanoma, and Mel-D trial management committees (Australia and New Zealand Melanoma Trials Group)

CARSK trial management committee (Australian Kidney Trials Network)

Effectiveness of social dancing as a strategy to prevent falls in older people (DANCE) trial committee

Rachel O'Connell

D-Health trial management committee

PARAGON and Symptom Benefit trial management committees (ANZGOG)

TACTIC and TOPGEAR trial management committees (AGITG)

LEAP1 and PAEAN trial management committees (neonatal)

Kristy Robledo

T4DM trial management committee

APTS management committee

Kate Sawkins

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

Australia New Zealand Gynaecological Oncology Group (ANZGOG) operations executive

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

Lucille Sebastian

APTS and APTS echo substudy trial management committees

Interdisciplinary Maternal Perinatal Australasian Collaborative Trials (IMPACT) network steering committee

Molecular Screening and Therapeutics Program (MoST) operations and steering committee and molecular tumour board

MoST substudy management committees: palbociclib, durvalumab plus tremelimumab, olaparib plus durvalumab

Pharmacodynamic effects of the heat shock protein 90 (Hsp90) inhibitor AUY922 in high-risk, localised prostate cancer (HSP 90 inhibitor study) trial management committee

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, PARAGON, OVAR2.21 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, ACTICCA trial management committees

INTEGRATE 1 & 2 trial management committees (CTC clinical lead) and international trial management group,

Genomic Cancer Clinical Trials Initiative (GCCTI)

NHMRC grant review panel

Molecular Screening and Therapeutics program (MoST) clinical lead, substudy module chair, steering committee

Martin Stockler

Advancing the evidence base program grant research committee

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee and operations executive, BR31, DREAM, NIVORAD, and PEARL trial management committees

Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee (convener 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 Chemo & Cognition, and EVERSUN 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

Sydney International Update on Advances in Perinatal Care organizing committee chair

Eric Tsobanis

CONTROL NETS trial management committee

INTEGRATE executive and trial management committees and international trial management group

INTEGRATE II executive and trial management committees and international trial management group

Burcu Vachan

Australia New Zealand Gynaecological

Oncology Group (ANZGOG) and Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations executive committees

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, CONTROL-NETS, 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, Trus B, BCG+MMC, EVERSUN, SORCE, P3BEP, Chemo & Cognition, TIGER and Accelerated BEP trial management committees

CannabisCINV trial executive and 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 ACTICCA, ALT-GIST, ASCOLT, GAP, IMPACT, INTEGRATE I, INTEGRATE II and NABNEC trial management committees

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee

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

Australian and New Zealand Urogenital and Prostate Group (ANZUP) scientific advisory committee, renal cell subcommittee, germ cell subcommittee, translational research 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; LC-PLAT management committee, Post-Graduate and Early Career Researcher Symposium 2015 convener

Cancer Institute NSW Biobanking Stakeholder Network Working Group

Genomic Cancer Clinical Trials Initiative (GCCTI) project team

Regular academic teaching

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

Australia & Asia Pacific Clinical Oncology Research Development (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)

Chris Brown

Australia & Asia Pacific Clinical Oncology Research Development (ACORD) faculty

Basic sciences in oncology, Health Education and Training Institute

Controlled clinical trials, Master of Public Health and Master of Medicine, University of SydneyCapstone project, Master of Clinical Trials, University of Sydney (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

Royal Australian and New Zealand College of Radiologists radiation oncology training (SMART)

Emma Gibbs

Master of Clinical Trials Research, University of Sydney

Basic sciences in oncology, Health Education and Training Institute

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

Anthony Keech, CTC deputy director, and Rachael Morton, director of health economics

Adrienne Kirby

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

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

Chee Lee

Australia & Asia Pacific Clinical Oncology Research Development (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

Basic sciences in oncology, Health Education and Training Institute

Andrew Martin

Australia & Asia Pacific Clinical Oncology Research Development (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

Health economic evaluation, Master of Public Health and Master of Medicine, University of Sydney

Rachel O'Connell

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

Kristy Robledo (Mann)

Australia & Asia Pacific Clinical Oncology Research Development (ACORD) faculty

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

Royal Australian and New Zealand College of Radiologists radiation oncology training (SMART)

Katrin Sjoquist

Australia & Asia-Pacific Clinical Oncology Research Development (ACORD) steering committee & faculty member

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

Medical oncology clinical training, St George Hospital

Martin Stockler

Australia & Asia-Pacific Clinical Oncology Research Development (ACORD) faculty

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

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)

Wendy Hague, CTC clinical trials program director

PUBLICATIONS

Book

1. *Pancreatic Islet Biology.* **Hardikar A,** editor. Cham, Switzerland: Springer; 2016. 324 pp.

Chapters

2. **Jenkins AJ,** O'Neal DN, Nolan CJ, **Januszewski AS.** The pathobiology of diabetes mellitus. In: Hardikar A, editor. *Pancreatic Islet Biology.* Cham: Springer; 2016. p. 1–48.
3. **Wong W, Hardikar AA, Joglekar MV.** Generation of human islet progenitor cells via epithelial-to-mesenchymal transition. In: **Hardikar A,** editor. *Pancreatic Islet Biology.* Cham: Springer; 2016. p. 217–240.

Journal articles

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