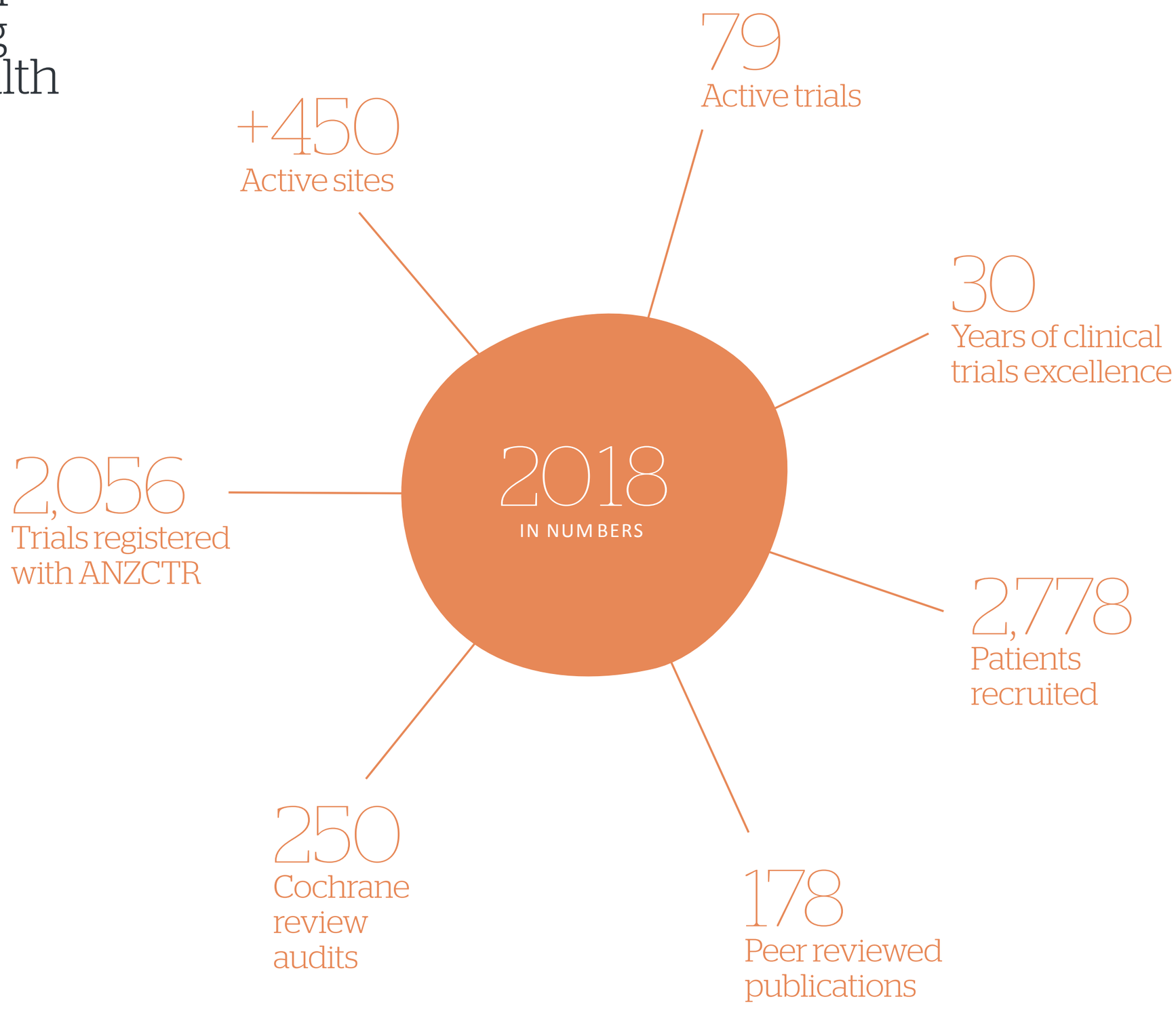
Research Report 2018

THE UNIVERSITY OF SYDNEY

NHMRC Clinical Trials Centre

Contents

30 years of improving global health outcomes



NHMRC Clinical Trials Centre (CTC)

30 years of improving global health outcomes through clinical trials and research

Oncology trials & other research

Cardiovascular trials & other research

Diabetes trials & other research

Neonatal & perinatal trials & research

Health economics

Integrating evidence

Biostatistics

Directors' report

‘Our mission is to achieve best practice and improve health outcomes in healthcare in Australia and internationally through the best use of clinical trials research.’

PROFESSOR JOHN SIMES, DIRECTOR

NHMRC Clinical Trials Centre (CTC)

This year the CTC celebrated 30 years since it was established in 1988 with a grant from the NHMRC. The trials we have undertaken with our collaborators and peers in the past 30 years have resulted in important new evidence and breakthroughs for those living with cancer, cardiovascular disease and diabetes, and for premature babies and their mothers. Our studies have helped to reduce mortality and illness, improve quality of life, and helped patients and hospitals to avoid unnecessary treatments and associated costs. With health conditions improving in society, trials need to target the most pressing health challenges, and trial evidence needs to be integrated into clinical practice efficiently and effectively. We are working hard on a number of related projects with the same mission we started with 30 years ago: to improve clinical practice and to improve health outcomes.

Some of the most satisfying outcomes of clinical trials are those that can be implemented by the medical community quickly and easily to save lives.

That was the case with the Australian Placental Transfusion (APTS) study, winner of the Trial of the Year award from the Australian Clinical Trials Alliance. APTS, led by Neonatal and Perinatal Head Professor William Tarnow-Mordi. The trial, together with a combined analysis of all other relevant randomised trials, showed that delaying clamping of the umbilical cord by just 60 seconds in pre-term babies might save many tens of thousands of lives worldwide ever year. The study involved more than 1,500 premature babies in seven countries, and was published in the New England Journal of Medicine. Results from the study are already being implemented by hospitals and reflected in professional guidelines.

Precision cancer medicine is one future-focussed project we are working on in partnership with the Garvan Institute. The MoST (Molecular Screening and Therapeutics) trials match therapies to patients with rare and uncommon cancers on the basis of genetic information, instead of the type of tumour they have. Rare and uncommon cancers when considered together still account for over 50% of cancer deaths in Australia every year. Since 2016, 1,000 patients with these cancers have been screened at the Garvan for the MoST trial program with the potential to receive targeted therapy related to cancer molecular profile or >

‘We are working hard on a number of related projects with the same mission we started with 30 years ago: to improve clinical practice and to improve health outcomes.’

< the latest immunotherapy. We were very pleased to see the Federal Government reward this work with a grant of $50 million over five years awarded in late 2018 to the Australian Genomic Cancer Medicine Program, with about half of this supporting the MoST program. This funding will help increase the number of patients who can participate in MoST trials around Australia.

Heart attacks and related cardiovascular disease are the number one cause of death globally. In response, the RESTORE-MI trial, led by Associate Professor Martin Ng and Professor Tony Keech, is targeting those patients who have already experienced a heart attack and had their arteries or veins widened (angioplasty). Around 50% of these patients are not benefiting from the angioplasty because their clots have moved further down into the microvessels of the heart. RESTORE-MI, which received further funding from the NHMRC in 2018, is identifying these patients and seeing whether a thrombolytic drug, tenecteplase, can reduce blood flow and pressure around the heart. If the drug is successful, patients will be at lower risk of suffering from another heart attack.

Another key topic for the future is better integration of patient-reported outcome measures (PROMs) in trials and their use to better direct patient care. Research in this field is being undertaken by our Health Economics team, led by Associate Professor Rachael Morton in collaboration with the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA). Their Symptom Monitoring With Feedback Trial (SWIFT) was awarded $1.7 million in funding from the NHRMC this year. SWIFT seeks to determine if symptom monitoring can improve quality of life and survival in patients with end-stage kidney disease on haemodialysis. Currently the patient’s voice is not accounted for. In a unique approach, SWIFT accesses patients through the ANZDATA registry. This registry, like many others, does not currently report on patient symptoms and quality of life. Adding these two measures will help drive future research efforts towards better patient outcomes for those with end-stage renal failure. This trial could set a benchmark for other registry-based trials.

In the middle of the year, John had the pleasure of undertaking several months’ work at the Julius Center, Utrecht University in the Netherlands, one of the top ranked academic medical centres in Europe. It was an exciting opportunity to further expand CTC’s network with leading researchers in related fields particularly related to improving methods in clinical trials and related prognostic studies. This has seen new partnerships in assessing evidence from patient data to better inform personalised decision making.

There are many other achievements in this report that demonstrate the CTC’s commitment to trials excellence, and to improving clinical practice and patients’ lives. Congratulations to our dedicated and talented staff throughout the entire organisation. These achievements would not be possible without our highly valued collaborators and partners. We are fortunate to work with exceptional people and organisations in Australia and internationally, and we look forward to strengthening these ties over the next 30 years to advance healthcare and the lives of patients.

John Simes & Tony Keech

Strategy

John Simes

Vera Terry

Burcu Vachan

Tony Keech

As part of the CTC's Strategic Plan 2017-21, we have identified six core strategic objectives to help us achieve our vision. Some examples of the progress we made in 2018 for each objective include:

1 Bring together world-class expertise in trial methods and conduct, clinical disciplines, biostatistics, health economics, biochemical and molecular sciences

We are taking up the challenge of finding solutions to rare and uncommon cancers in our MoST trials, in partnership with The Garvan Institute. These trials are made possible through partnerships with experts in rare and uncommon cancers, six hospitals across Australia, five pharmaceutical companies, two biotechnological companies, and the federal government.

2 Build international collaborations

The CTC works with impressive international collaborators across all of our areas of research, including new clinical trial sites in Japan and Taiwan for Oncology trials; new research ties with the UMC Utrecht led by our Director, Professor John Simes; our Diabetes team continued their fellowships and collaborations with India and Danish-based institutions; and our Health Economics team have been collaborating with the European Centre for Disease Control on migrant screening guidelines for the EU.

3 Embed translational studies into our research

In 2018, 52 of our Oncology trials had translational research activities embedded. This involved collecting over 12,000 samples from 615 sites. These samples can help predict a patient's response to a particular treatment or they can help better forecast survival.

4 Deliver quality education, training, teaching and development programs

Some examples of our leadership in education and training include our involvement in post-graduate education, with our staff helping teach over 70 students in the Master of Clinical Trials Research and Master of Biostatics degrees each year. We also hold short courses and masterclasses in key areas, like study design methods and the economics of trials, and our academics supervise PhD students in a range of trials research areas.

5 Extend our methodological work in adaptive trial designs, patient reported outcomes, prognostication, diagnostic test evaluation and cost-effectiveness analysis in practical application

Our Health Economics team working on the SWIFT trial that will see patient-reported experience outcomes and measures used for patients with kidney disease. This information, when factored into treatment guidelines, could help to improve the quality of life and survival rates of patients.

6 Combine findings from multiple trials in systematic reviews and to undertake health economic analyses to provide robust evidence for health care decisions for personalised care, guidelines and policy formulation

Our Integrating Evidence team helped audit 250 Cochrane reviews in the field of breast cancer, guiding future research and policy decisions. They also were awarded a grant to synthesise data from more than 100 trials in order to determine the best time to clamp the umbilical cord in preterm births compared to alternative policies, such as cord milking.

2018 CTC Executive Team

Director: John Simes, Deputy Director: Tony Keech, Business Director: Vera Terry, Director Clinical Trial Operations: Burcu Vachan

2018 awards

January

Dr Mugdha Joglekar was awarded the *Australia-India Early-Mid Career Research Fellowship* for travelling to Professor Ranjan Yajnik's (collaborator on PREDICT-T1D study) lab in India for research work in Type 1 diabetes.

March

Rebecca Mister received the *Sydney Medical School Award for Exceptional Performance by Professional Staff,* for her outstanding support of the activities in the CTC.

Dr Hao-Wen Sim was awarded the *Les Irwig General Epidemiology Award* by the University of Sydney for top student in Epidemiology Methods and Uses in 2017.

Dr Hao-Wen Sim was awarded *Top Student Prize* by the Australasian Epidemiology Association in recognition of exemplary performance in Epidemiology Methods and Uses unit, undertaken as part of the degree of Masters of Biostatistics at University of Sydney in 2017.

April

A/Prof Rachael Morton received the inaugural *Robinson Fellowship* from the University of Sydney. Only ten are awarded each year, with at least 50% going to women, for a term of four years, and the grant is worth up to $150,000 per annum.

May

Prof William Tarnow-Mordi and his team were awarded *ACTA Trial of the Year* for their ground-breaking insight into cord clamping of pre-term infants in the APTS study.

Mbathio Deng received the *University of Sydney Faculty of Medicine's Peter Bancroft prize* for her PhD research into managing stress and fear of cancer recurrence in early-stage melanoma patients at high risk of further melanoma.

Cody Lee Maynard received the *Best Poster Award* for presenting her research work at the NSW Stem Cell Network workshop.

June

Cody Lee Maynard received the *Postgraduate Travel Award* for presenting her research poster at the American Diabetes Association meeting in Orlando, USA.

A/Prof Anand Hardikar received the *JDRF–Macquarie Foundation Innovation Award* to initiate collaborative research on an innovative project idea related to Type 1 diabetes.

August

A/Prof Rachael Morton received a *Kidney Health Australia Award* for 'improving quality of life and duration of life for those living with chronic kidney disease'.

Dr Wilson Wong received the *Australian Diabetes Society Travel Grant Award* to attend and give an oral presentation at the annual Australasian Diabetes Congress (ADC) meeting held in Adelaide.

Mariam Chendeb received the *Professor Judyth Sachs PACE Prize* for a clinical trials internship with the Faculty of Medicine and Health at Macquarie University.

Dr Wilson Wong received the *Pincus-Taft Young Investigator Finalist Award* at the ADC meeting in Adelaide.

September

Dr Mugdha Joglekar was awarded *Best Image of the Conference at CUDOS* in Qatar for the best confocal image of human islets.

Dr Anh Tran received a *Young Investigator Award* at the ANZ Society of Nephrology Conference for her paper 'Annual screening versus no screening for asymptomatic coronary artery disease in wait-listed kidney transplant candidates: A modelled cost-effectiveness analysis'.

October

Kylie Hunter was awarded the *Best Poster Prize* at the Sydney Cancer Conference for her poster on breast cancer screening using tomosynthesis or mammography.

November

Dr Peey-Sei Kok was awarded *Best of the Best Orals* – clinical research featuring mesothelioma at the Clinical Oncology Society of Australia meeting.

Lene Seidler received a *Research Training Program scholarship* from the University of Sydney.

Prof John Simes received the *John Zalcberg OAM Award for Excellence in AGITG Research* at the 20th Annual AGITG Annual Scientific Meeting.

December

A/Prof Anand Hardikar was awarded the *Danish Diabetes Academy (DDA) Visiting Professorship* to continue collaborative research exchanges with researchers in and around Copenhagen.

Dr Wilson Wong received the *Australian Islet Study Group (AISG) Meeting Award* (JDRF Travel award (T1D)) to attend and present a poster at the 11th annual AISG meeting held in Canberra.

Dr Hao-Wen Sim received the *Judy Simpson Biostatistics Scholarship* from the University of Sydney, awarded annually to students receiving the highest marks in their units of study.

The following staff received the *CTC Staff Award* in recognition for their outstanding contribution to the CTC: Burcu Vachan, Ha Le, Sarah Finlayson, Andrew Martin, Katrin Sjoquist, Ilka Kolodziej.

Our 30 year journey 1988-2018

The CTC was born out of a need to provide evidence to help clinicians provide the best care and improve the lives of patients. Over the past 30 years we have lived up to this mission, in Australia and around the world.

1988 1995 1998 2000 2003 2005 2008 2012 2016 2018

$250k
INITIAL FUNDING
The CTC begins with two staff, John and his assistant.

A BIG YEAR
In the first year the CTC recruits 2,000 patients for trials.

+40,000
HEART ATTACKS
CTC and collaborators investigate the best life-saving treatments for patients experiencing a heart attack with over 40,000 trial participants.

ANZ
by 1991, the CTC is running 15 multicentre trials in australia and New Zealand involving 600 investigators.

9,000
LIPID
Completed in 1997, the LIPID trial is the biggest cholesterol-lowering study in the world, with over 9,000 patients.

IMPROVING DESIGN
The CTC adds expertise in research on the design, conduct, management and analysis of clinical trials.

10,000
FIELD STUDY
10,000 patients from Australia and New Zealand participate in a study that finds a drug can help diabetes sufferers reduce disability risks.

CANCER COVERED
CTC and its collaborators conduct 30 trials on some of the most common cancers.

664
INTERNATIONAL SYMPOSIUM
CTC hosts the first International Clinical Trials Symposium in Sydney, with 664 attending.

BREAST CANCER
An Australian first, the SNAC trial discovers women with breast cancer should choose Biopsy-based surgical management for better quality of life.

$1.5m
NATIONAL REGISTRY
CTC helps establish a national registry for trials with $1.5M in funding from the NHMRC.

MEDICARE
Members of CTC review existing literature around diagnostic tests for the government setting guidelines for Medicare funding.

COGNO
In 2007, the Cooperative Trials Group for Neuro-Oncology is set up and housed at the CTC.

75%
CANCER
Work with seven collaborator groups sees CTC research cover 75% of cancer disease in Australia.

SYDNEY CATALYST
The CTC helps establish a research centre involving researchers and clinicians from across NSW that aims to rapidly translate discoveries into practice.

27,000
CARDIOVASCULAR
To help ease the burden of cardiovascular disease, the CTC helps undertake nine trials involving 27,000 patients.

PREMATURE BABIES
High oxygenation levels are found to increase chances of survival in premature babies, according to a CTC-led study (boost II).

1,000
GENETICS
In partnership with the Garvan Institute, the CTC investigates assigning 1,000 patients to treatments based on their genes instead of their symptoms (MOST trial).

RECTAL CANCER
A CTC and AGITG study (A La CaRT) suggests open surgery may be better for patients with rectal cancer.

SKIN CANCER
In partnership with the Melanoma Institute, the CTC shows surveillance clinics would help cut costs and improve outcomes for at-risk skin cancer patients.

60 sec
UMBLICAL CORD
A CTC trial that shows clamping the umbilical cord 60 seconds later can improve survival rates among premature babies wins the ACTA trial of the year award.

CANNABIS
Can medical cannabis help chemo users with nausea? CTC completes the first stage of the Cannabiscinv trial.

To view videos and to access a book we produced to celebrate CTC's 30th birthday, head to our website https://ctc.usyd.edu.au/news-events/events/ctc-30th-symposium/.

Oncology trials

In the CTC oncology trials division our focus is to provide innovative clinical research to inform clinical practice, improve health outcomes and save lives in the expert areas of breast, oesophageal, gastric, colorectal, lung, gynaecological, neurological and urogenital cancers.

The CTC works collaboratively with five of the 13 national cancer cooperative groups in Australia to design and run clinical trials. We are a leader in developing and conducting novel trial designs, including adaptive designs and genomics-driven screening. We have collaborated in over 180 projects, which thousands of patients have joined.

Martijn Oostendorp, Associate Oncology Program Manager

Hannora Jurkovic, Associate Oncology Program Manager

'I am extremely proud to be part of CTC's oncology team. Our ground breaking, collaborative studies have helped improve the outcomes of so many people affected by cancer.'

PROFESSOR MARTIN STOCKLER, CO-DIRECTOR OF CANCER TRIALS

Brain cancer

Partner: Cooperative Trials Group for Neuro-Oncology

The Cooperative Trials Group for Neuro-Oncology (COGNO) is a network of clinicians, researchers, consumer representatives and allied health professionals who are dedicated to increasing awareness, improving treatment and end-of-life care for patients with brain tumours. The CTC coordinates the trials that are developed by the COGNO network. The group is located at the CTC.

Click here for more information.

COGNO team

2018 highlights

COGNO received a $2.5 million grant from the Australasian Brain Cancer Mission to improve treatments and outcomes for adults with brain cancer by increasing access to high quality international cancer clinical trials.

VERTU trial: reached target of 125 patients in glioblastoma (GBM). The trial investigates if the addition of a PARP inhibitor improves treatment for patients who have a common mutation in their cancer that makes currently available treatment less effective.

NUTMEG trial: opened for recruitment in February 2018 and is continuing to gain momentum, with more sites opening (see trial in focus).

Brain cancer in numbers

1,549
estimated number of deaths from brain cancer in 2019 (932 men + 617 women)

3.1%
estimated % of all deaths from cancer in 2019

22%
chance of surviving at least five years (2010–2014 data)

Source: Australian Government, Cancer Australia

Trial in focus: NUTMEG

Will the addition of an immune checkpoint inhibitor (nivolumab) to standard treatment of GBM have a survival benefit for patients over 65 years of age?

Challenge

We know that mutations increase as we age and brain cancer survival is worse in older patients. Using radiotherapy and chemotherapy (temozolomide) to treat GBM, a common and deadly form of brain cancer, is not as effective in elderly patients.

Trial

Nivolumab has revolutionised the treatment of other cancers such as melanoma and non-small cell lung cancer (NSCLC). The NUTMEG trial will examine the impact of adding this novel systematic therapy to TMZ chemotherapy to prolong survival in the elderly GBM population.

NUTMEG is a Phase II study investigating the use of nivolumab and temozolomide compared with only temozolomide in newly diagnosed elderly patients. NUTMEG will be the first randomised clinical trial to use immunotherapy and chemotherapy in elderly brain cancer patients with GBM.

The trial opened to recruitment in February 2018 and recruited 21 patients across 11 sites within Australia in 2018. Approximately 18–20 sites are expected to participate in the NUTMEG trial, and we hope to recruit a further 81 patients to reach our target of 102 patients.

Impact

The trial has the potential to impact GBM clinical management guidelines in Australia and globally, and improve elderly patients' responses to treatment for GBM.

The biospecimens collected from NUTMEG and the corresponding clinical data will be an invaluable resource for correlative studies and future research questions.

TRIAL SNAPSHOT

START DATE: 2018	21/102 PATIENTS RECRUITED	11 SITES OPEN (AUSTRALIA ONLY)

Gastro-Intestinal cancer

Partner: Australasian Gastro-Intestinal Trials Group

The CTC has collaborated with the Australasian Gastro-Intestinal Trials Group (AGITG) since 1991 to conduct clinical trials to improve treatments for gastro-intestinal cancers.

Together we have conducted over 57 trials involving more than 5,000 patients. Our research has changed treatment practices and improved patient life expectancy and quality of life.

Click here for more information.

GI cancer in numbers

28,880
Australians are diagnosed every year with GI cancer

38
Australians die every day of the year as a result of GI cancer; 1 person dies every 37 minutes

51%
chance of surviving five years

Source: Australian Government, Cancer Australia

AGITG team

2018 highlights

Three new studies opened to recruitment (SPAR, MONARCC, LIBERATE), investigating important research questions regarding the profiling and treatment of rectal and colorectal cancer.

MASTERPLAN trial: awarded a $2 million Medical Research Future Fund grant, recognising its importance in addressing the needs of patients with pancreatic cancer (see trial in focus).

INTEGRATE II trial: opened sites in Japan and Taiwan (an AGITG first). This Phase III multinational clinical trial investigates treatment options for patients with advanced gastro-oesophageal cancer. It is already open in Australia, New Zealand, Canada and Korea and is expected to open in the USA in 2019.

Trial in focus: MASTERPLAN

Is the addition of stereotactic radiotherapy to standard chemotherapy safe and beneficial for patients with pancreatic cancer?

Challenge

Pancreatic cancer has the fifth highest incidence of cancer-related mortality and accounts for the deaths of more than 2,900 Australians annually.

The five-year survival for patients with pancreatic cancer is only 8% and approximately half of all patients experience locoregional recurrence, a major contributor to the substantial morbidity and mortality of pancreatic cancer, within 12 months after initial treatment.

Trial

MASTERPLAN explores using stereotactic radiotherapy (SBRT), an innovative way of delivering targeted radiation therapy in addition to modern chemotherapy. It uses significant technological advances in radiation techniques to deliver a higher dose to targeted areas.

MASTERPLAN is the first published randomised trial that explores SBRT for pancreatic cancer. The trial includes ten sites in Australia and New Zealand.

Funding has been provided through a grant from the Medical Research Future Fund for Low Survival Cancers and Diseases. This highly competitive grant opportunity is awarded to innovative clinical trials of the highest quality design that address low survival cancers in Australians.

Impact

MASTERPLAN addresses some of the most significant morbidities experienced by patients with pancreatic cancer. A reduction in recurrence may translate into improved overall survival.

The trial is currently in start-up, with recruitment commencing in 2019. Recruitment is expected to remain open until 2023.

START DATE: 2018	10 SITES IN AUSTRALIA AND NEW ZEALAND	0/120 PATIENTS RECRUITED

Gynaecological cancer

Partner: Australia and New Zealand Gynaecological Oncology Group

The Australia and New Zealand Gynaecological Oncology Group (ANZGOG) is the peak national gynaecological cancer clinical trials organisation for Australia and New Zealand.

The CTC collaborates with ANZGOG to conduct clinical trials to test novel therapies that aim to improve treatments and patient outcomes for the prevention and mitigation of gynaecological cancer.

Click here for more information.

Gynaecological cancer in numbers

6,454
estimated new cases of gynaecological cancer diagnosed in 2019

2,040
estimated number of deaths from gynaecological cancer in 2019

70%
chance of surviving at least five years

Source: Australian Government, Cancer Australia

ANZGOG team

2018 highlights

Three new trial concepts were developed to investigate important research questions in gynaecological cancer, including advanced endometrial cancer (ATtEND); prevention of ovarian cancer in women with BRCA1/2 mutations (STICs and STONEs); and the optimisation of peri-operative care for women undergoing ovarian cancer surgery (TIPS).

ECHO trial: received an additional grant from Cancer Australia, enabling an additional 120 women to be recruited. The trial looks at the potential benefits of exercise for women with ovarian cancer (see trial in focus).

PHAEDRA trial: achieved its recruitment target of 71 patients in early September, four months ahead of expectations. This trial aims to determine whether immunotherapy (durvalumab) will benefit patients with advanced endometrial cancer. Early results will be available in 2019.

Trial in focus: ECHO

Does exercise positively impact physical wellbeing and overall health for patients with ovarian cancer undergoing chemotherapy?

Challenge

Ovarian cancer is the sixth most common cause of death from cancer in women. It is typically diagnosed at a late stage and has a five-year survival rate of less than 45%.

Trial

ECHO is a multicentre, randomised trial that will determine if an individually tailored exercise program for people with ovarian cancer under chemotherapy can improve wellbeing and overall health.

Does exercise assist with progression-free survival, overall survival, physical wellbeing, function and quality of life at six and 12 months post-randomisation? Does it improve chemotherapy adherence, lead to fewer and less severe adverse events during chemotherapy and lower healthcare costs for complications of ovarian cancer treatment?

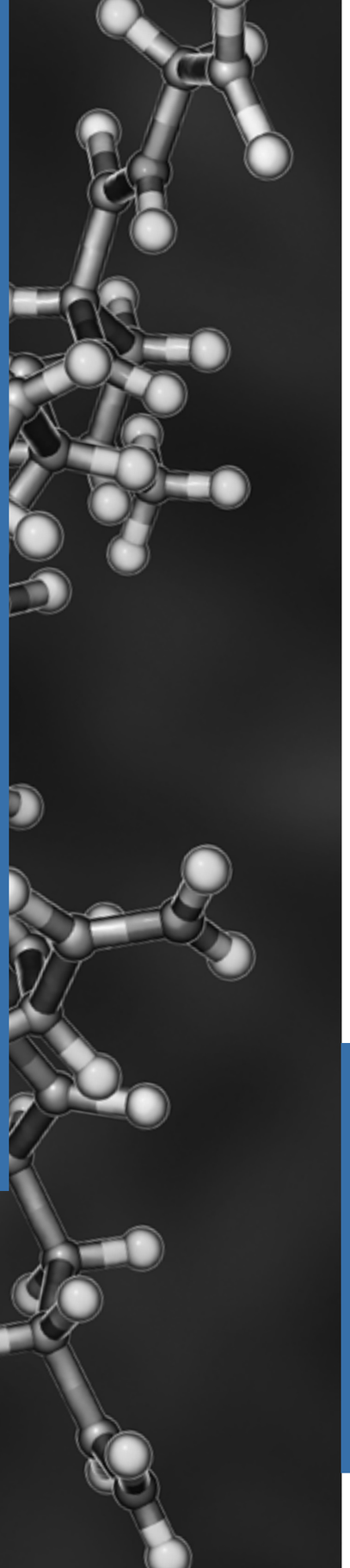
ECHO began recruiting in 2015. At the end of 2018, 185 patients had been randomised across eight Australian sites. CTC and ANZGOG are working with Queensland University of Technology on the trial. Cancer Australia provided funding for further support (2019–2021), allowing an additional 120 women to be recruited to the study.

Impact

ECHO will provide key evidence of the impact exercise has on women undertaking chemotherapy for ovarian cancer. The trial has the potential to influence guidelines around treatment, improve patient health and recovery, and provide a foundation for further studies to be undertaken around other cancers.

TRIAL SNAPSHOT

START DATE: 2015	185 PATIENTS RECRUITED	8 SITES IN AUSTRALIA



Lung cancer

Partner: Australasian Lung Cancer Trial Group

The Australasian Lung Cancer Trial Group (ALTG) is an initiative of Lung Foundation Australia's Lung Cancer National Program. The CTC collaborates with the ALTG to facilitate high quality clinical research in Australia and New Zealand.

Over the past five years, the partnership has continued to expand with new trials looking at immunotherapy and targeted therapies for lung cancers, as well as renewed interest in mesothelioma.

Click here for more information.

Lung cancer in numbers

9,198
estimated number of deaths from lung cancer in 2018 (5,229 men + 3,969 women)

18.9%
estimated % of all deaths from cancer in 2018

17%
chance of surviving at least five years (2010–2014 data)

Source: Australian Government, Cancer Australia

ALTG team

2018 highlights

The portfolio of lung trials grew significantly, as did the number of patients recruited, increasing by over 50% (from 117 in 2017 to 185 in 2018).

ILLUMINATE trial: secured funding and opened in Australia. This trial examines advanced EGFR mutant non-squamous NSCLC and is a unique partnership between the ALTG/CTC and the Taiwan Cooperative Oncology Group, the first of its kind.

Patient recruitment continued in trials of new therapies in all types of lung cancers, including: non-small cell (BR.31, BR.34, and OSCILLATE), mesothelioma (DREAM), radiotherapy and antibody therapy for advanced NSCLC (NIVORAD), small cell lung cancer (STIMULI), and early referral to palliative care in patients with a recent diagnosis of advanced thoracic cancer (PEARL).

Trial in focus: OSCILLATE

What is the impact of alternating medications (osimertinib and gefitinib) for patients with advanced lung cancer?

Challenge

Approximately 50% to 60% of patients with advanced NSCLC develop resistance to first-generation medications such as gefitinib and erlotinib due to the acquisition of a mutation (T790M). The inhibitor osimertinib is effective against the T790M mutation, however resistance to this medication is common among patients.

Trial

OSCILLATE is a Phase II trial testing the effect of alternating osimertinib with gefitinib in patients who have advanced NSCLC and have the T790 mutation that makes them resistant to inhibitor drugs.

This trial is investigating a novel strategy of alternating therapy to prevent or delay resistance to osimertinib, which in turn may enhance a patient's response to the drug and their overall condition. Recruitment began in 2017 across 14 sites in Australia. A total of 45 patients have been recruited.

Impact

OSCILLATE could provide evidence for a strategy to help patients with advanced lung cancer become less resistant to osimertinib, a drug that will improve their condition.

TRIAL SNAPSHOT

START DATE: 2017	45 PATIENTS RECRUITED	14 SITES IN AUSTRALIA

Urogenital and Prostate cancer

Partner: Australian and New Zealand Urogenital and Prostate Cancer Trials Group

The CTC collaborates with the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) to initiate and conduct high quality clinical trials research. This research aims to identify and promote better treatments to raise survival rates and enhance the quality of life of patients with urogenital and prostate cancer.

Click here for more information.

Urogenital and prostate cancer in numbers

1,209
estimated number of deaths from bladder cancer in 2019 (852 men + 357 women)

2.4%
estimated % of all deaths from cancer in 2019

54%
chance of surviving at least five years (2011-2015 data)

Source: Australian Government, Cancer Australia

ANZUP team

2018 highlights

ANZUP was awarded an NHMRC project grant to complete the BCG+MMC study in bladder cancer, and was also awarded a grant from Cancer Australia for the P3BEP study in germ cell cancer.

TheraP trial: exceeded recruitment expectations with over 50% completed by the end of 2018, ten months after the first patient's first visit (see trial in focus).

ENZARAD trial: reached its accrual target of 800 patients in June following three years of accrual in Australia, New Zealand, the USA, the UK, Ireland and Europe. This trial investigates the effectiveness of a hormone suppressing drug and radiotherapy treatment for prostate cancer.

Xanthi Coskinas – ANZUP Project Manager

Trial in focus: TheraP

How does lutetium compare to cabazitaxel chemotherapy in men with progressive prostate cancer?

Challenge
Prostate cancer is the most commonly diagnosed cancer in Australian men. Approximately 3,300 men will die from prostate cancer in Australia in 2019. Survival rates are high, with a 95% chance of surviving at least five years from the date of diagnosis.

Trial
The TheraP trial compares the use of lutetium versus chemotherapy with cabazitaxel for patients with castration-resistant prostate cancer.

Lutetium is a novel treatment that has demonstrated promising activity and tolerability in men who have undergone multiple lines of chemotherapy and endocrine therapy.

TheraP will determine the activity and safety of lutetium compared to cabazitaxel chemotherapy. The trial is an open-label, randomised, stratified, two-arm, multicentre, Phase II trial.

Recruitment for this study has continued to exceed initial expectations, with over 50% of recruitment completed at the end of 2018, after only ten months of recruitment.

Impact
TheraP has the potential to offer men with prostate cancer an alternative when chemotherapy, endocrine therapy and castration have failed as treatment options.

If the evidence suggests lutetium is successful and safe, this novel treatment could assist men with advanced prostate cancer to fight their cancer and improve their condition.

TRIAL SNAPSHOT

START DATE: 2015	103 PATIENTS RECRUITED	11 SITES (AUSTRALIA)

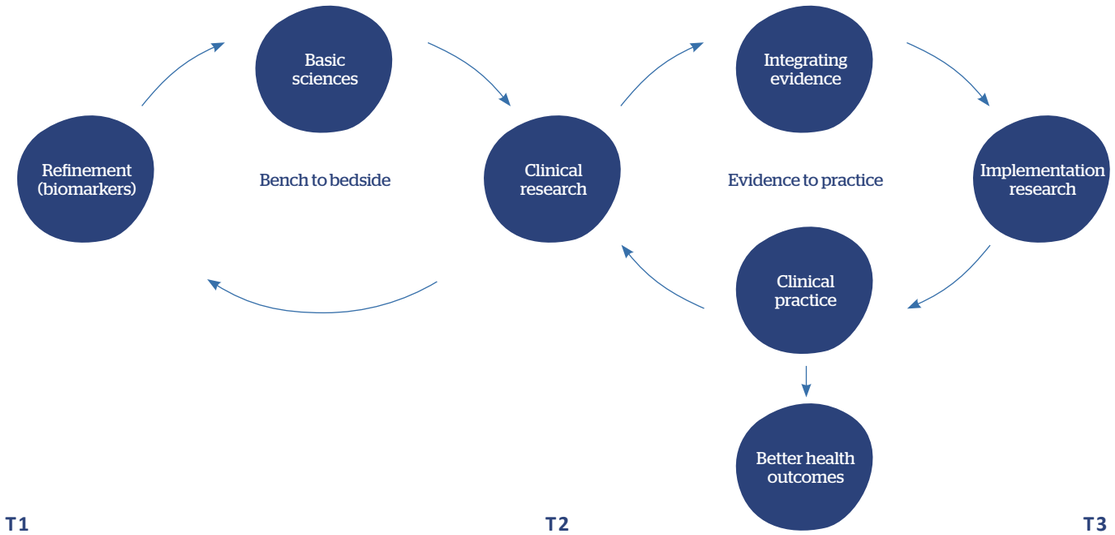
Translational research

Translational research studies involve examining patient samples from CTC trials for biological markers. These markers can help predict a patient's response to a particular treatment, or they can help better forecast survival. They can also be used as a tool to select the right treatment, delivered at the right time for the individual patient — the basis of precision medicine.

Patients may choose to donate tissue and blood samples for this research. Samples are studied collaboratively with partners around the world. Cutting-edge techniques known as 'omics' are used to study genes (genomics), proteins (proteomics) and mRNA (transcriptomics).

Click here for more information.

Translational Research Process



Translational research team

2018 highlights

EMBRACE trial: patients with breast or ovarian cancer selected based on their molecular profile, rather than their tumour type.

VERTU trial: screened patients for a specific biomarker to enter the trial. Only patients with an 'unmethylated' MGMT gene status are eligible for the trial.

Two translational research studies were awarded ANZGOG New Research Grants:

- molecular and genomic studies of the PHAEDRA trial (endometrial cancer)
- understanding resistance and sensitivity to PARP inhibitors studies of the EMBRACE trial (breast and ovarian cancers)

Trial in focus: AUTO-CHECK

What are the molecular determinants of autoimmunity and immune-related adverse events in advanced cancer patients treated with immune checkpoint inhibitors?

Challenge

Immune checkpoint inhibitors are remarkably active in a variety of cancers. Are patients with a genetic susceptibility to autoimmunity more likely to develop an immune-related adverse event after treatment with immune checkpoint inhibitors?

Study

AUTO-CHECK focusses on biomarkers of side-effects of immune checkpoint inhibitor drugs. This study aims to use the patient's biology; i.e., their genomic and cellular characteristics, to predict those likely to develop side-effects relating to the patient's immune system.

AUTO-CHECK is a first for the CTC Translational Research team. It uses data and biospecimens from six multi-site investigator-initiated trials across four cooperative trials groups (ALTG, ANZGOG, ANZUP and COGNO). These trials span five tumour types: mesothelioma (DREAM; NSCLC — NIVORAD and ILLUMINATE), endometrial (PHAEDRA), renal cell (KEYPAD) and GBM (NUTMEG). Each trial uses immune checkpoint inhibitors.

This study was developed through the Genomics Cancer Clinical Trials Initiative (GCCTI) funded by Cancer Australia.

Impact

The ability to predict, be vigilant for, and treat such side-effects in at-risk individuals would be an important advance in the care of patients across these five different cancers and help us personalise their anti-cancer treatment.

TRIAL SNAPSHOT

START DATE: 2017	177	63	244
	PATIENTS RECRUITED	SITES THROUGHOUT AUSTRALIA (50% ARE UNIQUE)	REAL-TIME SHIPMENTS OF SAMPLES

The molecular screening and therapeutics framework

The Molecular Screening and Therapeutics (MoST) program brings new targeted (or personalised) treatment options for rare or advanced cancers according to genes and proteins of the patient, instead of the type of cancer they have.

Partnerships have grown the program from a NSW pilot into a leading source of treatments for rare cancer patients in Australia, attracting $50m dollars in federal funding in 2018 to nationalise the program. Together with the Garvan Institute, we have founded a not-for-profit company called the Australian Genomic Cancer Medicine Centre (AGCMC), which MoST will continue to grow together with new national member centres.

Drug and funding partnerships are established with a growing list of pharmaceutical companies (including Pfizer, Astra Zeneca, Roche, LOXO/Bayer, Eisai) and two biotechnology companies (Roche Foundation Medicine and Illumina), with a total funding amount of $17.9 million.

Click here for more information.

Rare cancer in numbers

52,000
number of people diagnosed with a form of rare or less common cancer in Australia annually

25,000
estimated number of deaths from rare or less common cancer annually

1 in 5
cancers diagnosed is a rare cancer

Source: Australian Government, Cancer Australia

MoST team

Lucille Sebastian and Sarah Chinchen

2018 highlights

By November 2018, the molecular screening component of the MoST study had recruited 936 patients in total, exceeding the recruitment target by 171 patients. The target of 1,000 patients will be achieved by January 2019, 12 months ahead of schedule.

Of the patients enrolled to date, 806 have had molecular profiling completed and results returned. A promising 33% of patients (270) have been identified as having strong characteristics to benefit from therapy based on their genes and protein profiles.

Medical oncology referrals continue to be robust as a result of the MoST program (they increased by 40% in 2017).

Additional NSW sites at St George Hospital and Chris O'Brien Lifehouse opened MoST in Q4 2018. In December 2018, two non-NSW sites (ACT and Western Australia) opened MoST and commenced enrolment.

NSW MoST program has generated 15 research publications (from 2015–2018) and 35 oral presentations at national and international meetings.

Cardiovascular trials and other research

Cardiovascular disease is the leading cause of early death in Australia, while in developing countries the prevalence of cardiovascular risk factors has increased greatly, led by demographic and economic changes. In Australia, and indeed elsewhere, better treatments mean that more people are living longer with heart disease. The burden of chronic heart disease is a national health priority here in Australia, and a target of CTC research into prevention and treatment.

The CTC's cardiovascular team (CVD) evaluate medicines for prevention of cardiovascular diseases. Our research has influenced health outcomes globally, particularly in the treatment of acute myocardial infarction and the prevention of chronic heart disease.

Click here for more information.

Cardiovascular disease in numbers

1.2m
Australians had CVD in 2017-18

43,447
deaths in Australia from CVD in 2017

$5b
spent providing healthcare to admitted patients with CVD in 2012-13

119
Australians die from CVD each day, or one every 12 minutes

Source: heartfoundation.org

'Cardiovascular disease remains one of CTC's highest priorities, as the leading cause of death in Australians. Actively identifying and testing promising new treatments is essential to improve survival and health.'

PROFESSOR ANTHONY KEECH, CTC DEPUTY DIRECTOR AND DIRECTOR OF CARDIOVASCULAR (CVD)

Rebecca Mister
– CVD team lead

2018 highlights

Restore-MI trial: awarded an NHMRC project grant of $3.2M over five years (see trial in focus).

FOURIER LEGACY study: start-up agreement signed with Amgen. This study aims to evaluate the potential long-term effects of evolocumab treatment in patients who completed the FOURIER OUTCOMES trials. The CTC is the global coordinating centre, and will be coordinating the study in the Asia-Pacific region.

Rebecca Mister received the Sydney Medical School Award for Exceptional Performance by Professional Staff, for her outstanding support of the activities in the Cardiovascular division of the CTC.

Li Ping Li
– CVD team

Trial in focus: Restore-MI

Can the thrombolytic drug tenecteplase restore blood flow and save heart tissue in patients who have undergone angioplasty urgently for a heart attack but who have developed blockages in microvessels of the heart?

Challenge

In Australia, over 15,000 serious heart attacks occur annually. Despite angioplasty and stenting to widen arteries and veins, more than 50% of patients fail to regain complete blood flow due to blockages in micro circulation of the heart. These cases have a poor prognosis and account for over 70% of deaths and heart failure.

Trial

The Restore-MI study aims to determine the efficacy of the drug tenecteplase (TNK) in reducing mortality and rehospitalisation for heart failure in patients with significant microvascular obstruction who have undergone angioplasty and stenting but have blockages in the microvessels of their heart.

Impact

This study has the potential to significantly improve outcomes for a large proportion of patients who have experienced a serious heart attack. A key innovation is the use of an index measure, resistance to flow, to identify patients with microvascular obstruction after angioplasty and stenting, identifying the population most likely to benefit.

If low-dose TNK is effective at reducing mortality in high-risk patients, it could lead to a transformation in care of acute coronary syndrome patients worldwide. RESTORE-MI will cost a fraction of the annual cost of treating these patients, and would help to avoid their premature death.

TRIAL SNAPSHOT

START DATE: SEPT 2018	2 PARTICIPATING HOSPITALS	800 PATIENTS	$3.2m NHMRC PROJECT GRANT

LIPID study celebrates 20 years

On Friday 26 October 2018 the CTC hosted the LIPID 20th anniversary meeting. Over 50 guests attended to celebrate the global impact of the LIPID study and share many of the untold success stories of the study.

LIPID was the CTC's first large long-term multicentre trial. It was inspired by a study in Norway that showed that high cholesterol levels could be lowered with the drug statin, reducing the risk of a patient experiencing a cardiac event. The LIPID team wanted to see if this same approach could be used for people with normal cholesterol levels, as it is not unusual for those with normal levels to suffer a cardiac event. The statin-lowering approach vastly increased the chances of study participants having a longer and more fulfilling life, and changed clinical practice worldwide.

Fast facts

Pravastatin treatment for six years was found to reduce death from cardiovascular disease by 24%, and overall mortality by 23%

The results of the LIPID study have meant that statin treatment is now subsidised for Australian patients

Involved over 9,000 participants and 87 hospitals from across Australia and New Zealand

Long-term follow-up has shown that this improved survival rate continues for almost two decades, largely due to prevention of cardiovascular deaths

Long-term treatment with statins is not associated with an increase in the rates of new cancers or death

Blood samples collected over the initial phase of the trial are being used in new investigations to determine how various biological and genetic markers are related to the risk of cardiovascular disease and to the effects of pravastatin

Diabetes trials and other research

Type 1 and Type 2 diabetes are major causes of morbidity and premature death globally. The Diabetes team takes a multi-faceted approach, studying both types of diabetes in cell and animal models and in human observational studies and clinical trials.

CTC's Diabetes team aims to improve the prediction of diabetes onset and its complications, to explore underlying mechanisms of disease and treatment benefit, and to test drugs, devices and models of care, including telehealth, that improve outcomes for people with diabetes.

Click here for more information.

Diabetes in numbers

280
Australians develop diabetes every day. That's one person every five minutes

100,000
Australians developed diabetes in 2018

1.7m
estimated number of Australians with diabetes

$14.6b
estimated total annual cost impact of diabetes in Australia

Source: Diabetes Australia

'The personal and socioeconomic costs of diabetes are enormous, but there are many advances in diabetes prevention and treatment, including drugs, devices, and models of care to improve outcomes. The CTC is active in all these areas.'

PROFESSOR ALICIA JENKINS, PROFESSOR, DIABETES AND VASCULAR MEDICINE

Biomarker team

2018 highlights

Major improvements were made in measuring telomere length (which controls how long cells can live for) in human blood samples. This information can be used in major international studies.

Dr Mugdha Joglekar was awarded an Australia-India Fellowship to progress collaborative diabetes research.

Dr Anand Hardikar continued his JDRF Australia Fellowship and Danish Diabetes Program Visiting Scholar program.

Professor Alicia Jenkins continued her NHMRC Practitioner Fellowship.

Dr Andrzej Januszewski completed biostatistics and big data courses (University of Washington) and retinal grading software training (Singapore).

Dr Emma Scott received several major grants for her PhD funding. Both Dr Scott and Mr Luke Carroll completed the last full year of their PhD studies.

The team mentored 13 University of Sydney Medical Student MD research projects.

Trial in focus: The Adult Hybrid Closed-Loop Study

What is the impact of six months of hybrid closed-loop insulin delivery in adults with Type 1 diabetes?

Challenge

People with Type 1 diabetes need insulin to survive, however consistently administering the correct amount of insulin is often challenging and long-term vascular complications and reduced life expectancy are a reality.

Closed-loop systems can help. They are designed to maintain glucose levels at a predetermined target by linking continuous glucose monitoring (CGM) information with an insulin dosing algorithm for automated subcutaneous insulin delivery via a pump.

Trial

The Adult Hybrid Closed-Loop Study (HCL) aims to evaluate the efficacy and cost-effectiveness of long-term HCL insulin delivery versus standard therapy (MDI/CSII) to improve glycaemia, psychosocial wellbeing, sleep quality, cognition, and biochemical markers of vascular risk in people with Type 1 diabetes.

The trial is a collaborative study between the University of Melbourne, St Vincent's Hospital Melbourne, Deakin University and the University of Sydney. The CTC is responsible for data management and translational research.

Impact

The trial could provide evidence that the closed-loop device maintains glucose levels, thus reducing the risk of damage to the body from levels outside of a healthy range. If the device proves effective, this will improve the quality of life for people with Type 1 diabetes.

TRIAL SNAPSHOT

START DATE: 2017	7	120	6
	PARTICIPATING HOSPITALS	PARTICIPANTS	MONTH TREATMENT PERIOD

Diabetes and Islet Biology

The Diabetes and Islet Biology group focuses on three areas relevant to diabetes: discovering and validating molecular biomarkers predictive of future diabetes; addressing complications in diabetes; and identifying epigenetic regulators of insulin gene transcription.

Click here for more information.

Islet biology team

Islet biology team

2018 highlights

With support from the Helmsley Trust and JDRF Australia, the group continued to develop a highly innovative, five-minute detection chip costing $1, which can measure diabetes-associated microRNAs to risk-stratify diabetes progression.

Drug interventions that retard the death of insulin-producing cells in newly diagnosed Type 1 diabetes individuals were evaluated. The team lodged patents identifying microRNAs that are potential regulators of insulin transcription and/or biomarkers of progression to Type 1 diabetes.

PREDICT Type 1 diabetes study: assessed the majority of clinical samples planned for microRNA analysis in individuals with, without or at risk of Type 1 diabetes. The data was presented at the 78th Annual American Diabetes Association meeting in Orlando, USA.

DREAM-Nano study: presented at the 78th American Diabetes Association Scientific meeting in Orlando, USA.

A/Prof Anand Hardikar completed his two-year visiting professorship awarded by the DDA. The project led to the assessment of insulin cell-free DNA and microRNAs in obese teenage Caucasians and in adult women with polycystic ovarian syndrome, progressing to Type 2 diabetes.

Neonatal and perinatal trials and other research

The CTC's neonatal and perinatal trials are at the forefront in addressing the causes of mortality and morbidity in high-risk pregnancies and babies, and in developing interventions to promote healthy survival.

The CTC's neonatal and perinatal research program focuses on areas such as neonatal infection, oxygen therapy, maternal anaemia and pre-eclampsia and simple cost effective measures to improve outcomes for these high risk women and babies.

Through the ALPHA Collaboration for Advancing Large, collectively Prioritised trials of Health outcomes Assessment, we plan to prioritise core questions for a new generation of rapid and efficient large-scale international trials to improve disability-free survival, using digital technology to consult parents, patients, professionals, policymakers, funding agencies and the public.

Click here for more information.

Pre-term babies in numbers

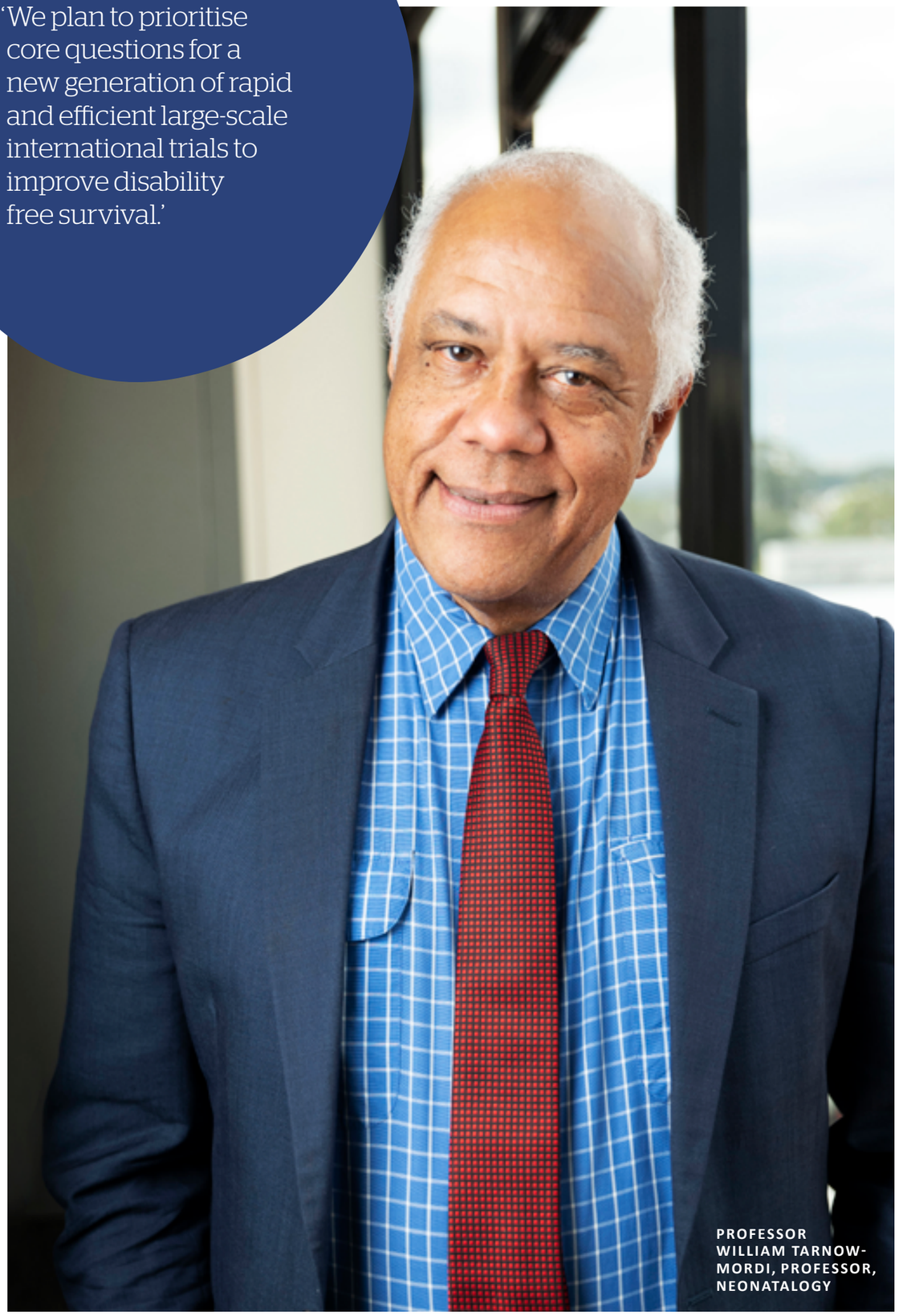
1 in 10
babies are born prematurely

42,422
babies are admitted to special care nurseries or neonatal intensive care units annually

1 in 5
babies require some form of resuscitation, receive suction or oxygen therapy

Source: Australian Institute of Health and Welfare 2016

'We plan to prioritise core questions for a new generation of rapid and efficient large-scale international trials to improve disability free survival.'



PROFESSOR WILLIAM TARNOW-MORDI, PROFESSOR, NEONATALOGY

Neonatal and
Perinatal team

2018 highlights

ESPRESSO trial: commenced looking at the impact of esomeprazole in women at risk of pre-eclampsia. A total of $1.6 million in funding was received from NHMRC.

TORPEDO 30/60 trial: waiver of initial parental consent approved and recruitment commenced.

APTS trial: awarded ACTA Trial of the Year. This is the largest ever randomised controlled trial of delayed placental cord clamping for premature infants, which has already lead to significant improvements in premature infant health simply by 'waiting a minute' during delivery.

Trial in focus: TORPEDO 30/60

How much oxygen is best for premature babies?

Challenge

Oxygen is necessary for life, but too much or too little can damage the eyes, lungs and brain of very premature babies. These babies often need additional oxygen after birth as their lungs are not fully developed; however, their ability to cope with too much oxygen (oxidative stress) is limited.

Trial

TOPRIDO 30/60 seeks to find out if an initial oxygen concentration of 30% or 60% given to pre-term babies when they are born helps to reduce avoidable deaths or long-term health problems.

The trial was abandoned in 2014 due to the challenges of gaining parents' permission before birth. In 2018, the TORPIDO team reached out to Miracle Babies Foundation co-founder Melinda Cruz to discuss ways to increase the number of babies benefiting from clinical trials in the delivery room.

This new researcher and consumer team worked with the Hunter New England Research Ethics Committee to allow waiver of initial consent for the TORPEDO 30/60 trial. Waiver of consent means that all babies can benefit by entering the study, including those born at night, on weekends, or in emergencies — a group that was often missing from previous trials.

Impact

The collaborative partnership between CTC and Miracle Babies Foundation received the inaugural consumer involvement award from the Australian Clinical Trials Alliance in May 2019 (see the CTC website for more details).

TORPIDO 30/60 could help resolve the long-running research debate around which level of oxygen is best for the survival and health of pre-term babies. This could ensure more pre-term babies survive and experience fewer health problems in the long term.

TRIAL SNAPSHOT

START DATE: 2015	2 PARTICIPATING HOSPITALS	28 PATIENTS RECRUITED

Health economics

The Health Economics team contributes to the development of healthcare programs in Australia and internationally by incorporating patient-centred, economic outcomes into clinical trials.

The team provides analysis on the efficiency, effectiveness and value of a healthcare program to facilitate policy decision-making across oncology, cardiometabolic disease and perinatal medicine. They also develop new methods of outcome assessment and resource measurement.

Click here for more information.

Health economics in numbers

1360
new clinical trials were started in 2015, contributing $1.1 billion to the Australian economy and supporting more than 6900 jobs (MTP Connect, 2017).

$5.80
The benefit-to-cost ratio for clinical trial networks is 5.8:1, or a return of $5.80 for every $1 invested (Clinical trials alliance, 2017)

'Research commissioned by the Australian Commission for Quality and Safety found clinical trials return on average, $5.80 for every $1 spent. The benefits from clinical trials knowledge represent excellent value for money'

A/PROF RACHAEL MORTON, PRINCIPAL RESEARCH FELLOW HEALTH ECONOMICS

Health
Economics team

2018 highlights

Seven guidelines were published for the European Centre for Disease Control on the effectiveness and cost-effectiveness of screening migrants to the EU for infectious diseases.

CARSK trial: awarded Young Investigator at the ANZ Society of Nephrology. This is a modelled economic evaluation of the Canadian-Australian screening transplant recipients for coronary artery disease.

Awarded Australian Cancer Research Foundation Centre of Research Excellence in Melanoma Imaging and Diagnosis (ACEMID) in collaboration with the University of Queensland and Monash University.

SWIFT study: pilot funding awarded from Kidney Health Australia and main trial funding from the NHMRC (see study in focus).

Study in focus: SWIFT

Is quality of life improved by three-monthly measurements of patient-reported symptoms, and is it cost-effective?

Challenge

PROMs and patient-reported experience measures (PREMs) are increasingly used in research to quantify how patients feel and function, and their experiences of care. However, knowledge of their use for patients with kidney disease is limited.

Trial

SWIFT is a novel registry-based cluster-randomised controlled trial being undertaken in kidney dialysis units in Australia and New Zealand. It aims to determine whether PROMs collected at regular intervals through the ANZDATA clinical quality registry can improve quality of life.

SWIFT is led by health economist Rachael Morton, and engages a truly multidisciplinary team of investigators including national and international nephrologists, nurses, consumers, a biostatistician, a health informatician, qualitative researchers, registry experts, and trialists. Ethics approval has been granted for the pilot study to be undertaken in four sites in South Australia and two sites in Queensland.

Impact

SWIFT is the first trial in kidney disease to assess the value of PROMS. If shown to be effective, SWIFT will facilitate the consideration of PROMS alongside traditional clinical and biochemical indicators (e.g. blood results) in doctors' and nurses' clinical consultations. This will ultimately reduce the burden of symptoms for adults on dialysis, and improve health-related quality of life. SWIFT also provides a framework for embedding PROMs into clinical quality registries.

TRIAL SNAPSHOT

START DATE: 2018	160 SITES IN TWO COUNTRIES	5 COLLABORATORS: KIDNEY HEALTH AUSTRALIA, UK RENAL REGISTRY, FRENCH RENAL REGISTRY, BEAT-CKD, ANZDATA

Integrating evidence

PROFESSOR LISA ASKIE, PRINCIPAL RESEARCH FELLOW HEALTH ECONOMICS

'We pushed new boundaries in 2018 using 'next gen' systematic review methods. This included the first ever neonatal prospective meta-analysis and other projects using network meta-analysis, individual participant data, and prediction modelling.'

Cochrane Breast Cancer Group

For trusted and reliable evidence on questions of healthcare, the leading information source is the international Cochrane Library. The CTC hosts the Cochrane Breast Cancer Group, which tackles a broad array of topics in breast cancer including prevention, treatment and survivorship care.

The group coordinates and leads the review and publication of evidence from breast cancer research undertaken around the world.

2018 highlights

Two new protocols of reviews were published:
- mammographic density, endocrine therapy and breast cancer risk: a prognostic and predictive biomarker review; risk prediction models for familial breast cancer.

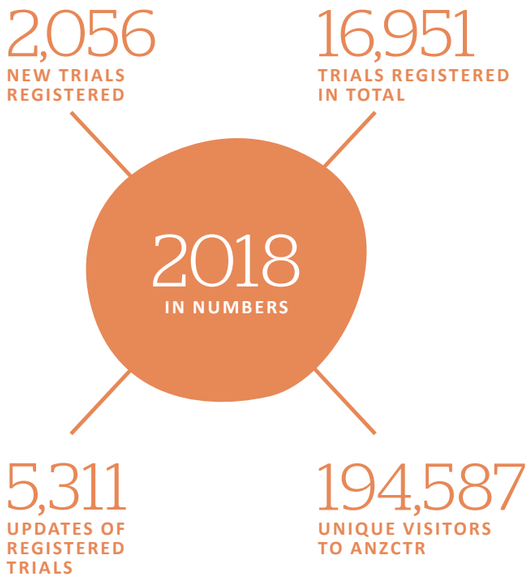
250 Cochrane reviews were audited to assess current practice in identifying and incorporating information from clinical trial registers.

The group contributed to the development of two key projects for Cancer Australia. One of these projects involved reviewing the evidence on risk factors for breast cancer with the findings published on Cancer Australia's website: canceraustralia.gov.au

Cochrane Breast Cancer team

Australian New Zealand Clinical Trials Registry

The Australian and New Zealand Clinical Trials Registry (ANZCTR) allows clinical trial researchers to register their studies and comply with ethical obligations. The registry serves as a national and international resource for clinical trials.



2018 highlights

Intention to share data and results summary options were added to ANZCTR forms, providing researchers and clinicians with information about the results from completed trials, even if they are not published. This is a major step forward in improving research quality, transparency and achieving better patient outcomes.

ANZCTR published 'The clinical trials landscape in New Zealand 2006–2015', a landmark report providing the most complete overview of clinical trial activity in New Zealand ever published.

The publication 'Prospective registration trends' was published. The first of its kind, the study showed a lack of awareness is the most common cause for failing to prospectively register a trial, indicating the need to continue to promote trial registration among researchers.

ANZCTR team

Evidence Evaluation team

Evidence evaluation

The Evidence Evaluation team undertakes systematic reviews, health technology assessments and economic evaluations under contracts with the Commonwealth Department of Health and the NHMRC. This work assists the Medical Services Advisory Committee to make decisions on new listings for the Medical Benefits Schedule.

The group also reviews evidence and provides methodological expertise to the NHMRC, which develops health guidelines for Australia.

2018 highlights

Reviews in cardiology, haematology, oncology, gastroenterology, and dermatology.

Methodological review of a clinical practice guideline for NHMRC on the health effects of alcohol consumption, and a review of the association between alcohol and certain health conditions.

Medical test research

The Medical Test Research (METRE) team is a group of clinical epidemiologists specialising in medical test research. They work closely with clinicians to design studies that identify tests and test strategies to improve clinical practice and patient outcomes.

The team works closely with international colleagues, such as the University of Bern, Switzerland, and the European Federation of Clinical Chemistry and Laboratory Medicine Test Evaluation Working Group (EFLM).

2018 highlights

Launched new website: www.medicaltestresearch.org to present an evaluation framework and examples of applied methods projects of the METRE team.

Received funding from Abbott Diagnostics for a research project on troponin testing for cardiovascular disease risk assessment in the general population.

Published seven papers in medical test and biomarker research, made three poster presentations at the Dutch MEMTAB conference, and co-supervised four PhD students.

METRE team

Individual participant data and prospective meta-analysis

IPD/PMA team

The Individual Participant Data and Prospective Meta-Analysis (IPD/PMA) team conduct systematic reviews using a wide range of innovative methods, such as prospective meta-analysis, network meta-analysis, individual participant data analysis, and rapid reviews.

They also provide methods support and advice to national and international external research teams and co-convene the Cochrane Prospective Meta-Analysis Methods Group.

2018 highlights

Neonatal Oxygenation Prospective Meta-Analysis (NeOProM), examining the association between oxygen saturation targeting and death or disability in extremely pre-term infants, was published in the Journal of the American Medical Association.

An NHMRC Project Grant was awarded for a project which will synthesise data from more than 100 trials in order to determine the best time to clamp the umbilical cord in pre-term births and the comparative effects of alternative policies for cord clamping, such as milking.

An NHMRC Project Grant commenced for a study aiming to develop accurate methods to predict pregnancies at risk of foetal growth restriction using individual participant data from a large collaboration of international researchers.

Biostatistics

Biostatisticians at the CTC work closely alongside investigators to evaluate and test new therapies in a number of important disease areas. They help design trials that are efficient and methodologically rigorous and they play a pivotal role in analysing and reporting on trials.

Outreach

CTC biostatisticians service a number of institutions and hospitals, advising on study designs and analyses in the areas of radiation and medical oncology, rheumatology, molecular studies, women's health and paediatric diseases.

Outreach services are provided to:

- Nepean Hospital
- Crown Princess Mary Cancer Care Centre (Radiation Oncology) and Women's Health, Westmead Hospital
- The Children's Hospital at Westmead
- Kolling Institute, Royal North Shore Hospital
- Departments of Radiation Oncology and Rheumatology Royal North Shore Hospital
- Department of Cancer Services
- Chris O'Brien LifeHouse

Teaching

CTC biostatisticians also play a key role in delivering:

- The postgraduate courses of Masters of Clinical Trials (Research) and the Controlled Trials Unit of the Master of Public Health and Masters of Clinical Epidemiology at the University of Sydney.
- The Principles of Statistical Inference unit through the Biostatistics Collaboration of Australia.
- Short courses in critical appraisal/ study design methods in the Basic Sciences in Oncology and the Statistical Methods, Evidence Appraisal and Research for Trainees (SMART) workshop, through the Royal Australian and New Zealand College of Radiologists.
- Supervision to postgraduate studies (PhD) and summer research students.

'Statistical involvement in studies is interesting; involvement in global studies is exciting; methodologically teaching studies which change clinical practice - an endorphin rush!'

PROFESSOR VAL GEBSKI, DIRECTOR, BIOSTATISTICS AND RESEARCH METHODOLOGY

Biostatistics team

2018 highlights

SOLO2 study: engagement of CTC statistical group for analysis of sub-studies from the international SOLO2 study (olaparib maintenance therapy for patients with relapsed ovarian cancer) by the European Network for Gynaecological Oncology (ENGOT).

Statistical analysis of the study evaluating disease-free survival in patients treated with laparoscopic surgery for operable cervical cancer (MD Anderson Cancer Care Centre Texas and the Royal Hospital for Women, Brisbane). The results were published in the New England Journal of Medicine and were practice-changing.

Manuscript on data maturity and time-to-event outcomes published in the International Journal of Epidemiology.

Andrew Martin promoted to Associate Professor; PhD awarded to Kristy Robledo by Macquarie University.

Susan Lohan

Business group

Finance team

The Business Group provides local services and resources to CTC's trial and research teams. Working together with internal and external stakeholders, including the University of Sydney, the Business Group tailors services and resources for individual teams, underpinning the CTC's achievements and status as a leading clinical trials centre in Australia.

Approximately 30 staff in the Business Group provide expertise in a range of support areas, including human resources, workforce planning and management (HR, led by Cynthia Carr); financial planning and management (Finance, led by Paul Smyth); clinical data systems (DSD led by Mark Maclean, working in close collaboration with clinical data management led by Salma Fahridin); pre and post award grant coordination and contract management (Grants and Contracts, led by Nicole Wong); IS infrastructure and internal helpdesk support (IS, led by Dinh Tran); internal and external communications (Communications, including Ben Falkenmire and Sarah Munro); and executive and administration support (Administration, led by Suzanne Everett and Susan Lohan).

Cynthia Carr

IS team

CTC Community

We are privileged to work closely with a number of specialist organisations, some of which began life at the CTC or are currently co-located at the CTC.

Sydney Catalyst

Sydney Catalyst is the Translational Cancer Research Centre of central Sydney and regional NSW, and aims to improve outcomes for people affected by cancer.

Sydney Catalyst brings together over 700 outstanding researchers and clinicians from leading NSW institutions working across the full translational research continuum and provides a rich forum for members to connect and collaborate.

The Sydney Catalyst central office is housed within the CTC. This has provided an important opportunity for the groups to work closely together across a range of translational research projects and activities, challenging institutional and work culture boundaries. Co-location also provides Sydney Catalyst staff with a unique opportunity to experience the inner workings of the CTC, enriching their understanding of clinical research.

Sydney Catalyst team

Professor Philip Hogg

Cancer work

The Embedding Research (and Evidence) in Cancer Healthcare (EnRICH) Study is Sydney Catalyst's major flagship research program and is an important example of translational research collaboration between the CTC and Sydney Catalyst. The program is led by CTC Director, Professor John Simes.

EnRICH is assembling a clinical cohort of 1,000 patients with lung cancer to:

- Describe the natural history of and patterns of care for lung cancer
- Better define, treat and care for patients across Sydney Catalyst member hospitals, including the Lifehouse
- Create a platform for researchers across the T1–T3 translational research spectrum to develop and initiate clinical research and intervention studies to address gaps

Significant new research opportunities have been made possible by EnRICH, enabling Sydney Catalyst members to use the resource to improve outcomes for people affected by cancer. A number of sub-studies using biospecimens and data from the EnRICH cohort are currently being undertaken.
www.sydneycatalyst.org.au

Professor Philip Hogg, centenary cancer research centre

Professor Philip Hogg is an NHMRC Senior Principal Research Fellow. He currently holds the Sydney Catalyst Chair in Translational Cancer Research and is Director of the Australian Cancer Research Foundation (ACRF) Centenary Cancer Research Centre at the Centenary Institute.

In partnership with the ACRF and Sydney Catalyst, the new ACRF Centenary Cancer Research Centre expands the capabilities of the Centenary's cancer research stream. The Centre has four core strategic aims: i) making key discoveries about disease mechanisms; ii) their effective translation into the clinic; iii) catalysing medical research by collaborations and iv) local and international recognition.

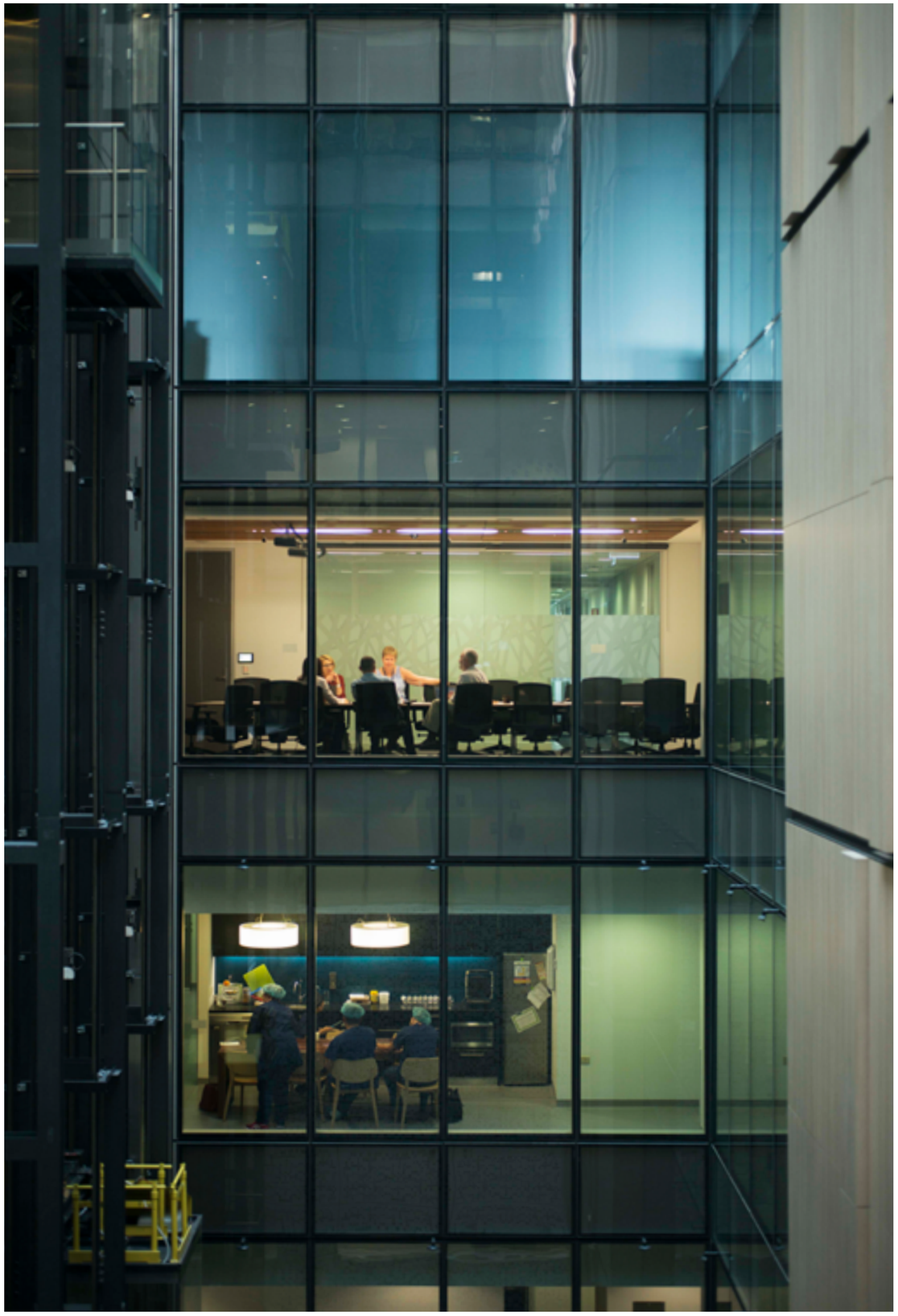
The Centre is located within the University of Sydney's Charles Perkins Centre and will be the first dedicated cancer biology research centre in the Royal Prince Alfred Hospital and the University of Sydney Precinct — a health precinct that is technically excellent, clinically innovative and directly connected to patients.

BCA team

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 program of postgraduate courses via an alliance of six universities. The BCA Coordinating Office is hosted by the CTC.

The BCA program is delivered entirely by distance. At the end of Semester 2 2018, around 300 students were enrolled, 141 new in 2018 (of which 73 were enrolled in award courses and 68 in single units of study). Since 2003, 568 students have graduated from BCA courses (130 Graduate Certificates, 85 Graduate Diplomas, 344 Masters). These graduates will contribute to solving the shortage of well qualified biostatisticians in Australia and internationally.
www.bca.edu.au



Current CTC trials

As at December 2018

Group	Participant	Target	Accrual
ONCOLOGY			
CURRENT TRIALS			
Cannabis CINV: Pilot and definitive trials of cannabis extract for prevention of secondary nausea and vomiting (CTC, Lambert, NSW Health, Tilray)	Adults with cancer with significant nausea or vomiting during Cycle 1 of intravenous chemotherapy	330	66
EMBRACE: Phase II clinical trial of the PARP inhibitor, olaparib, in HR-deficient advanced breast and ovarian cancer (GCCTI, including ANZGOG and CCT)	Patients with either: a) metastatic TNBC; or b) relapsed platinum-sensitive HGSOC; who have an eligible tumour molecular analysis result and have not received prior treatment for metastatic/ relapsed disease	60	2
Breast cancer (collaborating with the Royal Australasian College of Surgeons)			
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	1,000	1,088
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	1,012	326
Gastro-intestinal cancer (collaborating with AGITG)			
TRIALS IN START-UP			
MASTERPLAN: A randomised Phase II study of MFOLFIRINOX And Stereotactic Radiotherapy (SBRT) for Pancreatic Cancer With High-Risk and Locally Advanced Disease (AGITG and CTC study)	Adults aged 18–75 years with histologically proven high-risk, borderline resectable pancreatic cancer or locally advanced pancreatic cancer suitable for neoadjuvant or definitive chemotherapy and SBRT. High risk is defined as any patient with tumour >4cm, extrapancreatic extension or node positive disease	120	N/A
CURRENT TRIALS			
ACTICCA-1: Phase III trial of adjuvant gemcitabine and cisplatin chemotherapy compared with standard treatment (AIO-led (Germany), AGITG and CTC study)	Patients with biliary tract cancer after resection	781 (Int'l) 50 (ANZ)	331 (Int'l) 5 (ANZ)
ASCOLT: Aspirin for Dukes C and high-risk Dukes B CRCs (National Cancer Institute (Singapore)-led, AGITG and CTC study)	Patients with CRC who have completed surgery and other treatment	1,500 (Int'l) 460(ANZ)	1,334 (Int'l) 326 (ANZ)
INTEGRATE II: Phase III trial comparing regorafenib and placebo for oesophagogastric cancer (AGITG and CTC-led international study)	Patients with refractory advanced oesophageal or gastric cancer	350 (Int'l) 90 (ANZ)	98 (Int'l) 40 (ANZ)
LIBERATE: A phase II study evaluating liquid biopsies to profile metastatic CRC (AGITG and CTC study)	Male and female patients aged ≥18 years with chemotherapy naïve metastatic CRC	100	36
MONARCC: A randomised Phase II study of panitumumab monotherapy and panitumumab plus 5-fluorouracil as first-line therapy for RAS and BRAF wild-type metastatic CRC (AGITG and CTC study)	Elderly patients, >70 years, with histologically confirmed RAS and BRAF wild-type metastatic CRC who have not have previously received chemotherapy and/or targeted therapy for their metastatic disease who are suitable for panitumumab alone or panitumumab plus 5-FU	80	4
NABNEC: Phase II study of nab-paclitaxel and carboplatin as first-line treatment (AGITG and CTC study)	Patients with advanced gastro-intestinal neuroendocrine carcinoma	70	27
SPAR: A randomised, placebo-controlled Phase II trial of simvastatin in addition to standard chemotherapy and radiation in preoperative treatment for rectal cancer (AGITG and CTC study)	Patients aged >18 years with biopsy-proven rectal adenocarcinoma (or high-grade dysplasia on biopsy with radiological evidence of invasive tumour) planned for concurrent long-course pCRT using fluoropyrimidine-based chemotherapy	222	6
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	620 (Int'l) 280 (ANZ)	458 (Int'l) 206 (ANZ)
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
ALT-GIST: Imatinib alternating with regorafenib compared to imatinib alone for GIST (AGITG, SSG, EORTC and CTC study)	Adults with previously untreated metastatic gastro-intestinal stromal tumours	76 (Int'l) 30 (ANZ)	78 (Int'l) 21 (ANZ)
CONTROL NETS: Phase II open-label trial of lutetium-177 octreotate added to capecitabine and temozolomide for neuroendocrine tumours (AGITG and CTC study)	Patients with pancreatic or midgut neuroendocine tumours	72	75
DOCTOR: Phase II trial of preoperative cisplatin, 5-fluorouracil and docetaxel with or without radiotherapy for oesophageal cancer (AGITG and CTC study)	Patients with resectable adenocarcinoma of the oesophagus not responsive to chemotherapy	120	124
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
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	90 (Int'l) 20 (ANZ)	91 (Int'l) 3 (ANZ)
Gynaecological cancer (collaborating with ANZGOG)			
TRIALS IN START-UP			
AtTEND: Phase III double-blind randomised placebo-controlled trial of atezolizumab in combination with paclitaxel and carboplatin in women with advanced/recurrent endometrial cancer (MaNGO-led, ANZGOG and CTC study)	Newly diagnosed advanced stage (III/IV) endometrial cancer patients with residual disease after surgery, or recurrent endometrial cancer patients who have not been treated with systemic therapy in the advanced/recurrent setting	80 (ANZ) 550 (Int'l)	N/A
SOLACE2: A Phase II randomised trial comparing immune priming by low-dose oral cyclophosphamide plus olaparib versus priming by olaparib alone, prior to combination therapy with olaparib plus durvalumab, versus single agent olaparib alone, in asymptomatic platinum-sensitive recurrent ovarian, fallopian tube or primary peritoneal cancers with homologous recombination repair defects (ANZGOG and CTC study)	Women with platinum-sensitive high-grade serous carcinoma of the ovary, fallopian tube or primary peritoneum, at first asymptomatic CA125 progression	114	N/A

Group	Participant	Target	Accrual
ONCOLOGY continued			
STICs and STONEs: A randomised Phase II double-blind placebo-controlled trial of acetylsalicylic acid in prevention of ovarian cancer in women with BRCA 1/2 mutations (CCTG-led, ANZGOG and CTC study)	Women with documented germline BRCA 1/2 mutations, scheduled to undergo risk-reducing surgery within six months to two years after the date of randomisation	70 (ANZ) 414 (Int'l)	N/A
TIPS: Testing individual interventions to optimise perioperative care in ovarian cancer surgery (ANZGOG and CTC study)	Women undergoing surgery for advanced or, suspected advanced malignancy of the ovary, fallopian tubes or primary peritoneum. Neoadjuvant chemotherapy is allowed	60	N/A
CURRENT TRIALS			
ECHO: Exercise during chemotherapy for ovarian cancer (ANZGOG and CTC study)	Women with newly diagnosed ovarian cancer starting treatment	304	185
ICON9: An international Phase III randomised study to evaluate the efficacy of maintenance therapy with olaparib and cediranib or olaparib alone in patients with relapsed platinum-sensitive ovarian cancer following a response to platinum-based chemotherapy (UCL-led, ANZGOG and CTC study)	Women with high-grade serous or endometrioid carcinoma of the ovary, fallopian tube or peritoneum, progressing ≥6 months after Day 1 of the last cycle of first-line chemotherapy and requiring platinum-based chemotherapy for first relapse	110 (ANZ) 618 (Int'l)	1 (ANZ) 8 (Int'l)
STATEC: A randomised trial of non-selective versus selective adjuvant therapy in high-risk apparent Stage 1 endometrial cancer (UCL-led, ANZGOG and CTC study)	Women aged 16 years or above, that have histologically confirmed high-risk apparent International Federation of Gynecology and Obstetrics Stage I endometrial cancer	240 (ANZ) 2,000 (Int'l)	6 (ANZ) 29 (Int'l)
TRIALS IN FOLLOW-UP			
ICON 6: Safety and efficacy of cediranib in combination with standard chemotherapy (MRC-led, ANZGOG and CTC study)	Women with platinum-sensitive relapsed ovarian cancer	400 (Int'l)	17 (ANZ) 486 (Int'l)
ICON 8: Dose-fractionated chemotherapy compared with three-weekly chemotherapy for ovarian cancer (MRC-led, ANZGOG and CTC study)	Women with ovarian, fallopian tube or primary peritoneal cancer	145 (ANZ) 1,485 (Int'l)	70 (ANZ) 1,566 (Int'l)
OUTBACK: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer (ANZGOG- and CTC-led international study)	Women with locally advanced cervical cancer	150 (ANZ) 900 (Int'l)	168 (ANZ) 926 (Int'l)
OVAR2.21: Non-inferiority Phase III trial of bevacizumab + gemcitabine and carboplatin compared with bevacizumab + doxorubicin and carboplatin (GCIG-led, ANZGIG and CTC study)	Women with recurrent cancer sensitive to platinum-based treatment	120 (ANZ) 654 (Int'l)	76 (ANZ) 680 (Int'l)
OVAR 16: Pazopanib versus placebo for ovarian cancer (AGO-led, ANZGOG and CTC study)	Women without disease progression after chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer	50 (ANZ) 900 (Int'l)	65 (ANZ) 940 (Int'l)
PARAGON: Phase II study of anastrozole in gynaecological cancers (ANZGOG- and CTC-led international study)	Women with potentially hormone-responsive gynaecological cancers	350 (Int'l)	226 (ANZ) 333 (Int'l)
PHAEDRA: Durvalumab (MEDI-4736) in endometrial cancer progressing after one or more lines of chemotherapy: a Phase II trial in mismatch repair deficient (MMR-d) and mismatch repair competent (MMR-c) cohorts (ANZGOG and CTC study)	Adult women with advanced, unresectable endometrial cancer that is either MMR-proficient and progressing after 1–3 lines of chemotherapy, or MMR-deficient and progressing after 0–3 lines of chemotherapy. Key eligibility criteria include known MMR status, one or more target lesions according to RECIST 1.1, ECOG performance status 0–2, adequate organ function, and no contraindication to treatment with durvalumab	70	71
PORTEC 3: Chemoradiation and adjuvant chemotherapy compared with pelvic radiation alone in high-risk endometrial carcinoma (ANZGOG- and CTC-led international study)	Women with advanced endometrial carcinoma	120 (ANZ) 670 (Int'l)	122 (ANZ) 688 (Int'l)

Group	Participant	Target	Accrual
ONCOLOGY continued			
REZOLVE: Phase II study to evaluate the safety and potential palliative benefit of intraperitoneal bevacizumab (DGOG-led, ANZGOG and CTC study)	Women with symptomatic ascites due to advanced chemotherapy-resistant ovarian cancer	24	24
Genitourinary cancer (collaborating with ANZUP)			
CURRENT TRIALS			
BCG+MMC: Phase III trial of adding mitomycin C to BCG as adjuvant intravesical therapy for bladder cancer (ANZUP and CTC study)	Patients with high-risk, non-muscle-invasive bladder cancer	500	188
P3BEP: Phase III trial of accelerated versus standard BEP (ANZUP, CUH (UK), CTI (IRL), COG/CHOP/NIH (USA) and CTC study)	Patients with intermediate and poor-risk metastatic germ cell tumours	150	72 (Int'l) 47 (ANZ)
Pain Free TRUS B: Phase III trial of methoxyflurane with periprostatic local anaesthesia to reduce discomfort of transrectal ultrasound-guided prostate biopsy (ANZUP and CTC study)	Men scheduled to undergo first TRUS biopsy of the prostate	420	330
KEYPAD: Denosumab and pembrolizumab in clear cell renal carcinoma: a Phase II trial (ANZUP and CTC study)	Adults with unresectable or metastatic ccRCC progressing after treatment with a VEGFR TKI. Key eligibility criteria include target lesion(s) according to RECIST 1.1, good performance status (ECOG PS 0–2), no history of significant autoimmune disease, tumour sample available (archival or recent biopsy), and no previous treatment with immunotherapy	70	16
TheraP: Randomised Phase II trial of 177Lu labelled PSMA-DKFZ-617 versus cabazitaxel in men with progressive metastatic castration-resistant prostate cancer (ANZUP and CTC study)	Men with castration-resistant prostate cancer suitable for chemotherapy with cabazitaxel (surgical or medical castration, and previous chemotherapy with docetaxel. Previous enzalutamide and/or abiraterone is permitted), ECOG performance status 0–2. ^{68}Ga-PSMA PET/CT must show high PSMA avidity without discordant disease on FDG PET/CT	200	103
Tiger: A randomised Phase III trial comparing conventional-dose chemotherapy using paclitaxel, ifosfamide, and cisplatin (TIP) with high-dose chemotherapy using mobilising paclitaxel plus ifosfamide followed by high-dose carboplatin and etoposide (TI-CE) as first salvage treatment in relapsed or refractory germ cell tumours	Men, aged ≥14 years on the date of randomisation with histologically or cytologically confirmed germ cell tumour and who relapsed or were refractory to one prior line of cisplatin based chemotherapy for GCT	420 (Int'l) 60 (ANZ)	2 (Int'l) 2 (ANZ)
TRIALS IN FOLLOW-UP			
ENZAMET: Phase III trial of enzalutamide in androgen-deprivation therapy for metastatic prostate cancer (ANZUP and CTC international study)	Men with metastatic prostate cancer	1,100 (Int'l)	684 (ANZ) 1,125 (Int'l)
ENZARAD: Phase III trial of enzalutamide in androgen-deprivation therapy with radiation therapy for high-risk, clinically localised prostate cancer (ANZUP and CTC study)	Men with high-risk localised prostate cancer	800 (Int'l)	802 (Int'l); 503 (ANZ)
SORCE: Adjuvant sorafenib for renal cell carcinoma (MRC-led, ANZUP and CTC trial)	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ) 1,656 (Int'l)	168 (ANZ) 1,711 (Int'l)

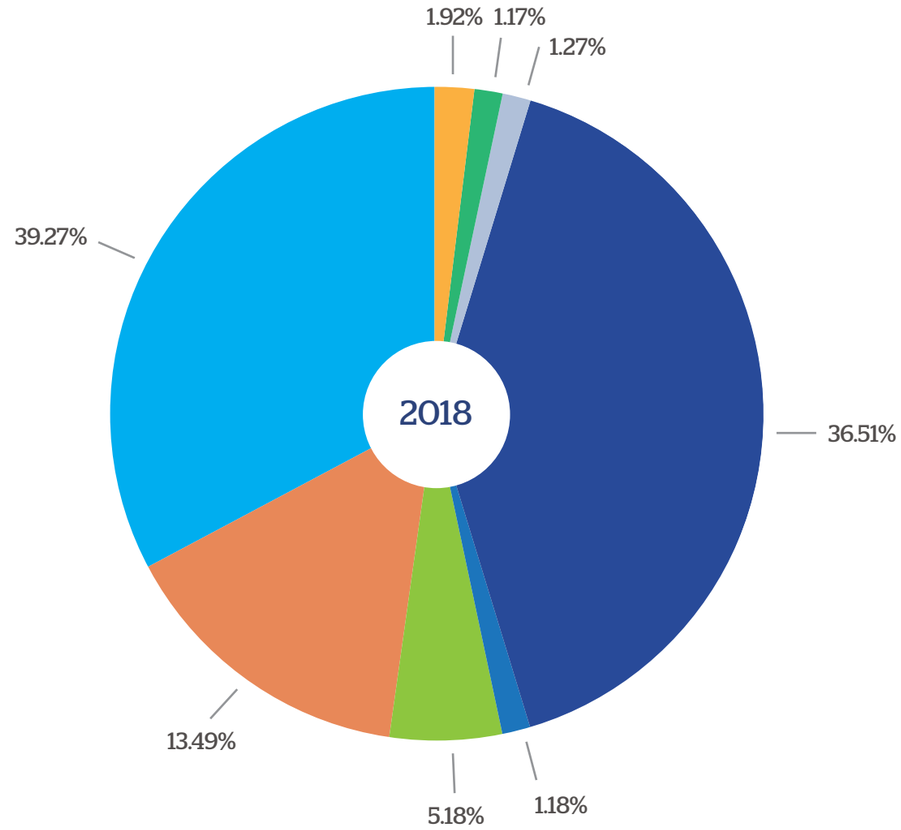
Group	Participant	Target	Accrual
ONCOLOGY continued			
Lung cancer (collaborating with ALTG)			
TRIALS IN START-UP			
ILLUMINATE: A Phase II trial of durvalumab (MEDI4736) and tremelimumab with chemotherapy in metastatic EGFR mutant NSCLC following progression on EGFR tyrosine kinase inhibitors (ALTG, CTC and National Taiwan University Hospital study)	Adults with relapsed EGFR-mutated non-squamous NSCLC	50 (ANZ) 100 (Int'l)	0
CURRENT TRIALS			
BR.31: Phase III study of adjuvant MEDI4736 (CCTG-led, ALTG and CTC study)	Patients with resected primary Stage IB (>4 cm), II or IIIA NSCLC	100 (ANZ) 1,360 (Int'l)	88 (ANZ) 982 (Int'l)
BR34: A randomised trial of durvalumab and tremelimumab +/- platinum-based chemotherapy in patients with high-risk metastatic (Stage IV) squamous or non-squamous NSCLC (CCTG-led, ALTG and CTC study)	Patients with documented evidence of metastatic (Stage IV per 4.1.2) squamous or non-squamous NSCLC and be planned for standard first-line therapy	80 (ANZ) 300 (Int'l)	53 (ANZ) 300 (Int'l)
NIVORAD: Nivolumab and stereotactic ablative body radiotherapy (SABR) versus nivolumab alone (ALTG and CTC study)	Patients with advanced NSLC progressing after chemotherapy	120	38
OSCILLATE: Alternating osimertinib and gefitinib in patients with EGFR T790M positive NSCLC (ALTG and CTC study)	Adults with advanced, EGFR-mutated NSCLC that have acquired resistance to first or second generation EGFR-TKIs and are EGFR-T790M mutation positive	45	36
PEARL: Palliative care Early in Advanced Lung cancers (ALTG and CTC study)	The target population is adults with advanced NSCLC, SCLC or MPM that has been newly diagnosed within the last 60 days	200	58
STIMULI: A randomised open-label Phase II trial of consolidation with nivolumab and ipilimumab in limited-stage SCLC after chemoradiotherapy (ETOP-led, ALTG and CTC study)	Radically treated limited-stage SCLC following completion of thoracic radiotherapy concomitant to chemotherapy and PCI	50 (ANZ) 260 (Int'l)	0
TRIALS IN FOLLOW-UP			
DREAM: A Phase II trial of durvalumab with first-line chemotherapy in mesothelioma with a safety run-in (ALTG and CTC study)	Adults commencing first-line doublet chemotherapy with cisplatin and pemetrexed for MPM	54	55
Brain cancer (collaborating with COGNO)			
TRIALS IN START-UP			
CODEL: Phase III Intergroup study of radiotherapy with concomitant and adjuvant temozolomide versus radiotherapy with adjuvant PCV chemotherapy in patients with 1p/19q co-deleted anaplastic glioma or low-grade glioma (ALLIANCE-led, EORTC, COGNO and CTC study)	Patients with newly diagnosed co-deleted 1p/19q anaplastic glioma or high-risk low-grade glioma	360	N/A
PersoMed-1: Personalised targeted therapy for adolescent and young adult medulloblastoma patients (EORTC, COGNO and CTC study)	Post-pubertal patients with newly diagnosed medulloblastoma	180 (Int'l) 33 (ANZ)	N/A
SEQUITUR – BRAIN: SEQUential ImmunoTherapy in patients with Underserved Rare cancers (COGNO and CTC study)	Adults with advanced cancers who have received standard of care treatments and progressed, or where there is no evidence-based effective treatment option	60	N/A
CURRENT TRIALS			
ACED: Phase II study of acetazolamide + dexamethasone v dexamethasone alone for cerebral oedema (COGNO and CTC study)	Adults with recurrent or progressive high-grade glioma, who require dexamethasone or dose increase for cerebral oedema	84	23

Group	Participant	Target	Accrual
ONCOLOGY continued			
NUTMEG: A randomised Phase II study of nivolumab and temozolomide vs temozolomide in newly diagnosed elderly GBM patients (COGNO and CTC study)	Newly diagnosed patients with histologically confirmed supratentorial GBM (Grade IV astrocytoma), aged 65 years or older who have not received any treatment for GBM other than surgery	102	21
TRIALS IN FOLLOW-UP			
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy for anaplastic glioma (EORTC, COGNO and CTC study)	Patients with non-1p/19q-deleted anaplastic glioma	100 (ANZ) 748 (Int'l)	82 (ANZ) 751 (Int'l)
VERTU: Veliparib, radiotherapy and temozolomide in unmethylated MGMT GBM (COGNO and CTC study)	Patients with newly diagnosed resected GBM with an unmethylated MGMT gene promoter	120	128
Molecular Screening and Therapeutics Program (MoST) (collaborating with AGCMC)			
TRIALS IN START-UP			
MOST 5: Single-arm open-label signal-seeking Phase IIa trial of the activity of eribulin in patients with advanced CD31 positive angiosarcoma and selected CD31 positive sarcomas	Patients with advanced CD31 positive angiosarcoma and selected CD31 positive sarcomas	16	N/A
CURRENT TRIALS			
MOST 2: Single-arm open-label signal-seeking Phase IIa trial of the activity of durvalumab (MEDI4736) in combination with tremelimumab in patients with advanced rare or neglected cancers (CTC-led study)	Patients with advanced rare or neglected cancers	112	71
MOST 3: Single-arm open-label signal-seeking Phase IIa trial of the activity of olaparib in combination with durvalumab in patients with tumours with homologous recombination repair defects (CTC-led study)	Patients with tumours with homologous recombination repair defects	48	6
MOST 4: Single-arm open-label signal-seeking Phase IIa trial of the activity of vismodegib in patients with tumours harbouring PTCH1 or SMO mutations	Patients with tumours with PTCH1 or SMO mutations	16	3
TRIALS IN FOLLOW-UP			
MOST 1: Single-arm open-label signal-seeking Phase Ib/IIa trial of the CDK4/6 inhibitor palbociclib in patients with tumours with amplified D-type cyclins or CDK4 or inactivation of CDKN2A (CTC-led study with the Garvan Institute)	Patients with tumours with amplified D-type cyclins or CDK4 or inactivation of CDKN2A	16	16
CARDIOVASCULAR DISORDERS			
TRIALS IN START-UP			
Colchicine Cardiovascular Outcomes in Acute Coronary Syndrome Study — a randomised clinical trial (COLCARDIO-ACS)	Adult patients with acute coronary syndrome	3,000 (Int'l)	
Long-term Study of LDL-c Lowering with Evolocumab: Observational Follow-up after the FOURIER Outcomes Study (FOURIER LEGACY)	Participants in the FOURIER OUTCOMES trial	10,000 (Int'l)	

Group	Participant	Target	Accrual
CARDIOVASCULAR DISORDERS continued			
CURRENT TRIALS			
Restoring Microcirculatory Perfusion in ST-Elevation Myocardial Infarction: A randomised trial to evaluate the efficacy of low-dose intracoronary tenecteplase in STEMI patients with high microvascular resistance post-PCI (RESTORE-MI)	Adults with STEMI	800 (1,666 registered)	3
TRIALS IN FOLLOW-UP			
FIELD: Fenofibrate Intervention and Event Lowering in Diabetes (CTC-led study)	Patients with Type 2 diabetes	8,000	9,795
LIPID: Long-term intervention with pravastatin in ischaemic disease (CTC-led study)	Patients with a history of coronary heart disease	9,000	9,014
T4DM: A randomised, placebo-controlled, Phase III trial adding testosterone to a lifestyle programme to prevent Type 2 diabetes (University of Adelaide and CTC-led study)	Men with prediabetes or newly diagnosed diabetes and low testosterone	1,000	1,007
DIABETES			
CURRENT TRIALS			
FAME1-Eye: Fenofibrate and microvascular events in Type 1 diabetes (CTC-led study)	Adults with Type 1 diabetes and non-proliferative retinopathy	450	6
Performance of closed-loop artificial pancreas at home compared with best available technology (St Vincent's Hospital Melbourne, JDRF, Medtronic, CTC study)	People with Type 1 diabetes: paediatric cohort adult cohort	120 160	39 41
NEONATAL AND PERINATAL			
TRIALS IN START-UP			
ESPRESSO: Can esomeprazole improve outcomes in women at high risk of pre-eclampsia? A Phase II placebo-controlled randomised, multicentre clinical trial (CTC-led study)	Pregnant women at high risk of pre-eclampsia	500	0
CURRENT TRIALS			
LEAP: Lactoferrin evaluation in anaemia in pregnancy (CTC-led study)	Pregnant women with anaemia	800	101
PAEAN: Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy (CTC-led study)	Newborn infants with signs of brain damage	300	170
TORPIDO: Targeted oxygenation in the respiratory care of premature infants at delivery: effects on developmental outcome (CTC-led study)	Neonates born before 29 weeks gestation	1,470	19
PROTECT: Can pentoxifylline improve long-term outcomes in pre-term infants with late-onset sepsis or necrotising enterocolitis? A pragmatic, randomised, placebo-controlled trial	Infants born less than 29 weeks gestation with suspected sepsis or necrotising enterocolitis	1,800	211
TRIALS IN FOLLOW-UP			
APTS: Australian placental transfusion study (CTC-led study)	Neonates born before 30 weeks gestation	1,600	1,634
LIFT: Lactoferrin infant feeding trial (CTC-led study)	Infants born weighing under 1,500 g	1,100	1,542

Funding

The CTC continues to receive highly sought-after national and international peer reviewed funding, as well as pharmaceutical industry support. Our 2018 annual income of $40 million reflects the quality of our research, the strength of our collaborative relationships and our innovative edge in academic clinical trials.



Staff profiles

Congratulations to the following people who received a staff award for their outstanding contribution to the CTC in 2018.

Andrew Martin

What do you do at the CTC?

I am Principal Research Fellow in Biostatistics and have over 20 years' experience in clinical trials research, gained from senior roles within research-based pharmaceutical organisations and the University of Sydney.

What do you love about working for the CTC?

Working together with great colleagues on interesting and important projects!

If you didn't work in clinical trials what would you like to do?

Hmm, maybe I could become a botanist!

Burcu Vachan

What do you do at the CTC?

Before becoming the Director of Clinical Trial Operations in 2018, I led the CTC oncology program for 15 years.

What do you love about working for the CTC?

The intelligent and committed people both internally and externally.

If you didn't work in clinical trials what would you like to do?

Something else in medicine or health. I love working in this field.

Ha Le

What do you do at the CTC?

As part of the IT team, I provide and coordinate support and facilities to CTC staff and trials.

What do you love about working for the CTC?

The people!

If you didn't work in clinical trials what would you like to do?

Hike around the globe!

Ilka Kolodziej

What do you do at the CTC?

I work in the Clinical Data Systems team.

What do you love about working for the CTC?

I am passionate about working on clinical trials.

If you didn't work in clinical trials what would you like to do?

I am very interested in research so would definitely stay in research but in a different area.

Sarah Finlayson

What do you do at the CTC?

I have worked as a trial coordinator across oncology and neonatalogy since 2014, coordinating large, international multicentre studies.

What do you love about working for the CTC?

Everyone is so committed to what they do, the projects they work on and the patients at the end of it.

If you didn't work in clinical trials what would you like to do?

I'm completing my MPH at the moment, and am really interested in the way the general public receive, process and interact with scientific information.

Staff

As at December 2018

CTC Executive

John Simes, Director
Tony Keech, Deputy Director
Burcu Vachan, Director Clinical Trial Operations
Vera Terry, Business Director

Consultant
Wendy Hague, Clinical Trials Strategic Consultant

Executive Support
Paulette Anderson, Executive Assistant
Susan Lohan, Executive Assistant

Oncology Trials Managers

AGITG
Christine Aiken, Associate Oncology Program Mgr
Martijn (Martinus) Oostendorp, Associate Oncology Program Mgr
Kate Wilson, Associate Oncology Program Mgr

ALTG
Sarah Chinchen, Associate Oncology Program Mgr
Hannora Jurkovic, Associate Oncology Program Mgr
Jenna Mitchell, Associate Oncology Program Mgr

ANZGOG
John Andrews, Associate Oncology Program Mgr
Candace Carter, Associate Oncology Program Mgr

ANZUP
Kate Ford, Associate Oncology Program Mgr
Margot Gorzeman, Associate Oncology Program Mgr

COGNO
Merryn Hall, Associate Oncology Program Mgr
Candace Carter, Associate Oncology Program Mgr

MoST
Lucille Sebastian, MoST Program Mgr
Ann Livingstone, Associate Oncology Program Mgr

Oncology Trials Staff

Amasy Alkhateeb, Senior Trials Coordinator
Lisa Bailey, Senior Trials Coordinator
Anjali Bhardwaj, Senior Trials Coordinator
Nathan Bradshaw, Clinical Trials Coordinator
Lesley Brassel Ngo, Group Coordinator
Hannah Cahill, Clinical Trials Coordinator
Mariam Chendeb, Clinical Trials Assistant
Yvonne (Ching Loong) Cheung, Clinical Trials Coordinator
Jennifer Chong, Clinical Trials Assistant
Andrea (Lay Fong) Chiu, Clinical Trials Assistant
Xanthi Coskinas, Senior Project Mgr
Georgina Dukoska, Clinical Trials Assistant
Lauren Fisher, Clinical Trials Coordinator
Tara Flores, Clinical Trials Coordinator
Kathleen Harwood, Clinical Trials Assistant
Stephanie Hollis, Clinical Trials Coordinator
Savita Iyer, Clinical Trials Coordinator
Marzena Kucharska-Kelly, Clinical Trials Coordinator
Lenna Lai, Clinical Trials Assistant
Ailsa Langford, Senior Trials Coordinator
Loc (Phuoc) Le, Clinical Trials Coordinator
Sandra Lee, Clinical Trials Assistant
Margaret Lett, Clinical Trials Coordinator
Joseph Levitt, Senior Trials Coordinator
Anneliese Linaker, Clinical Trials Assistant
Juanita Lopez Gaitan, Clinical Trials Assistant
Angus McDonald, Clinical Trials Coordinator
Kristen McParland, Clinical Trials Coordinator
Raewyn O'Connor, Admin Assistant
Catherine O'Connor, Clinical Trials Assistant
Danielle Parker, Clinical Trials Coordinator
Raynelle Penaflor, Clinical Trials Coordinator
Aliki Rasmiena, Clinical Trials Assistant
Tet (Marie Antonette) Ricafort, Clinical Trials Coordinator
Thida Thein, Clinical Trials Coordinator
Evonne Tim, Clinical Trials Coordinator
Eric Tsobanis, Senior Project Mgr
Emily Tu, Senior Trials Coordinator
Jaclyn Verghis, Senior Clinical Trials Coordinator
Mariya Walker, Senior Clinical Trials Coordinator
Anna Walsh, Senior Trials Coordinator
Portia Westall, Clinical Trials Assistant
Diana Winter, Senior Trials Coordinator
Nicole Wong, Senior Project Manager
Sarah York, Senior Trials Coordinator
Shirley Yung, Senior Trials Coordinator

Oncology Translational Research Team

Led by Sonia Yip, Oncology Translational Research Manager
Michelle Parry, Associate Oncology Program Mgr, Translational Research
Garry Chang, Clinical Trials Coordinator, Translational Research

Oncology Clinical Team

Led by Martin Stockler, Co-Director of Cancer Trials
Mustafa Khasraw, MRFF Career Development Fellow
Belinda Kiely, Senior Research Fellow
Nicola Lawrence, Oncology Research Fellow
Chee Lee, Clinical Lead
Chen (Yeh Chen) Lee, Oncology Research Fellow
Rebecca Merceica-Bebber, NHMRC Early Career Fellow
Antony Mersiades, Oncology Research Fellow
Sayeda Naher, Oncology Research Fellow
Felicia Roncolato, Research Fellow
Hao-Wen Sim, Oncology Research Fellow
Katrin Sjoquist, Clinical Lead
Alison Zhang, Oncology Research Fellow

Cardiovascular/Diabetes Trials Staff

Led by Rebecca Mister, Program Manager
Karen Bracken, Project Manager
San Yip Chan, Admin Assistant
Li Ping Li, Project Manager
Sarah Mulray, Clinical Trials Coordinator
Helen Pater, Project Manager
Jessie Payne, Clinical Trials Coordinator
Caitlin van Holst Pellekan, Clinical Trials Coordinator
Annie Yeung, Senior Trials Coordinator

Collaborator

Chris Ryan, Telehealth Program Manager

Cardiovascular/Diabetes Clinical Team

Led by Alicia Jenkins, Professor, Diabetes & Vascular Medicine
Anandwardhan Hardikar, JDRF Career Devt Fellow; Associate Professor, Genetics and Epigentics
Andrzej Januszewski, Senior Research Fellow
Mugdha Joglekar, JDRF Postdoctoral Fellow
Wilson Wong, Postdoctoral Research Fellow

Neonatal and Perinatal Trials Team

Led by Alpana Ghadge, Project Manager
Rebecca Brown, Senior Trials Coordinator
Catherine Lu, Clinical Trials Assistant
Sarah Finlayson, Senior Clinical Trials Coordinator

Neonatal and Perinatal Clinical Team

William Tarnow-Mordi, Professor, Neonatology

Ethics and Regulatory

Lara Hall, Senior Ethics and Regulatory Coordinator
Jade Lor-Chan, Ethics and Regulatory Coordinator
Hira Saud, Clinical Trials Assistant, Ethics and Regulatory

Health Economics

Led by Rachael Morton, Principal Research Fellow Health Economics
Mbathio Dieng, Research Fellow
Nikita Khanna, Research Assistant
Mai Nguyen, Project Officer
Karan Shah, Health Economist
Anh Tran, Research Fellow

Systematic Reviews

Led by Lisa Askie, Principal Research Fellow Health Economics
Lukas Staub, Clinical Epidemiologist
Melina Willson, Project Manager
Mark (Peter) Ayson, Project Officer
Angie (Ekaterina) Barba Malespin, Project Administrator
Slavica Berber, Project Officer
Vendula Blaya-Novakova, Project Officer
Saskia Cheyne, Project Officer
Kylie Hunter, Senior Systematic Reviews Project Officer
Lene (Anna) Seidler, Systematic Reviews Biostatistician (Research Fellow)
Ava Tan-Koay, Systematic Reviews Project Officer
Matthew Wynn, Systematic Reviews Project Administrator
Sally (Sarah) Lord, Senior Research Fellow
Jenny Chow, Coordinator, Systematic Reviews

Biostatistics

Led by Val Gebski, Director, Biostatisics and Research Methodology
Nanda Aryal, Biostatistician
Rebecca Asher, Biostatistician
Liz (Elizabeth) Barnes, Research Fellow
Chris Brown, Research Fellow
Karen Byth Wilson, Biostatistician
Vanessa Cochrane, Admin Officer
David Espinoza, Biostatistician
Adrienne Kirby, Senior Research Fellow
Ian Marschner, Professor Biostatistics
Andrew Martin, Senior Research Fellow
James Murray, Biostatistician
Rachel O'Connell, Senior Research Fellow
Kristy Robledo, Research Fellow

BCA

Emily Higginson, Senior Admin Officer
Erica Jobling, Executive Officer

Sydney Catalyst

Ellen Brodie, Coordinator Sydney Catalyst Program
Bea Brown, EnRICH Program Manager
Joyce Chiu, Research Fellow
Anthony Don, Principal Research Fellow, Tumour Metabolism
Merilyn Heuschkel, Sydney Catalyst Research Manager
Philip Hogg, Chair Translational Cancer Research
Tracy Liaw, Clinical Trials Coordinator
Magda Luciuk, Clinical Trials Assistant
Kimberley Mander, Research Officer, EnRICH
Cara McFarlane, Sydney Catalyst Project Officer, Education and Communications
Talia Palacios, Clinical Trials Coordinator
Emma Ramsay, Postdoctural Research Associate, T1T2 Translational Research
Eve Simons, Sydney Catalyst Project Officer, Education and Communication
Alison Young, Postdoctoral Research Associate

COGNO

Mythily Sachchithananthian, BCBA Senior Project Officer
Jenny Chow, Executive Officer
Yi Feng, Clinical Trials Admin Assistant
Catherine Bullivant, BCBA

Quality Assurance

Kate Sawkins, Clinical Quality and Compliance Manager
Karen Wilkinson, Auditor

Data Management

Salma Fahridin, Clinical Data Project Manager

Data Systems Development

Mark Maclean, Head Data Management
Nicole McKay, Clinical Data Coordinator
Louisa Muhuthia, Clinical Data Coordinator
Sharmila Siriragavan, Clinical Data Coordinator

Information Systems and Support

Seshu Atluri, Software Developer
Ha (Manh Ha) Le, Desktop Support Officer
Anh Tai Nguyen, Database Administrator
Asanka Perera, Infrastructure Support
Colin Sutton, IT Systems Development Manager
Dinh Tran, Manager, ISS Infrastructure Support

Business Group

Rebecca Blain, Receptionist/Admin Assistant
Cynthia Carr, HR/Admin Manager
Libby (Elizabeth) Cregan, Receptionist/Admin Assistant
Suzanne Everett, Business Support Coordinator
Ben Falkenmire, Communication Specialist
Lena (Magdalena) Germinarios, Admin Officer, Business Group
Sherilyn Goldstone, Medical Writer
Agnes Ho, Finance Officer
Maki Joseph, Finance Officer
Sarah Munro, Communications Officer
Emma Rackley, Communication Specialist
Paul Smyth, Finance Manager
Carlos Sterling, Finance Officer
Nicole Wong, Contracts and Grants Admin Manager
Gillian Woodhouse, Contracts and Grants Admin Manager
Marina Zadonskaia, Admin Officer, Business Group

Publications

As at December 2018

1. Agbata EN, Morton RL, Bisoffi Z, Bottieau E, Greenaway C, Biggs BA, Montero N, Tran A, Rowbotham N, Arevalo-Rodriguez I, Myran DT, Noori T, Alonso-Coello P, Pottie K, Requena-Mendez A. Effectiveness of screening and treatment approaches for schistosomiasis and strongyloidiasis in newly-arrived migrants from endemic countries in the EU/EEA: A systematic review. *International Journal of Environmental Research and Public Health*. 2018;16(1).
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NHMRC CLINICAL TRIALS CENTRE UNIVERSITY OF SYDNEY | Locked Bag 77 Camperdown NSW 1450 Australia
92-94 Parramatta Road, Camperdown NSW 2050 | 119-143 Missenden Road, Camperdown NSW 2050
T: +61 2 9562 5000 | F: +61 2 9565 1863 | E: enquiry@ctc.usyd.edu.au | W: www.ctc.usyd.edu.au