

# Research Report 2019



THE UNIVERSITY OF  
SYDNEY

 **NHMR C**  
Clinical Trials Centre

# Research Report 2019

# Contents

<b>8</b>	Directors' report
<b>12</b>	Strategy
<b>16</b>	2019 awards
<b>18</b>	Oncology research
<b>20</b>	– Brain cancer (COGNO)
<b>22</b>	– Gastro-intestinal cancer (AGITG)
<b>24</b>	– Gynaecological cancer (ANZGOG)
<b>26</b>	– Lung cancer (ALTG)
<b>28</b>	– Urogenital cancer (ANZUP)
<b>30</b>	– Molecular screening and therapeutics program (MoST)
<b>32</b>	– Other cancer research
<b>34</b>	– Translational research
<b>36</b>	Cardiovascular research
<b>40</b>	Diabetes research
<b>44</b>	– Diabetes and islet biology
<b>46</b>	Neonatal and perinatal research
<b>50</b>	Health economics
<b>54</b>	Integrating evidence
<b>55</b>	– Australian New Zealand Clinical Trials Registry (ANZCTR)
<b>56</b>	– Cochrane Breast Cancer Group
<b>57</b>	– Health Technology Assessment group (HTA)
<b>58</b>	– Individual participant data and prospective meta-analysis (IPD/PMA)
<b>59</b>	– Medical test research (METRE)
<b>60</b>	Biostatistics
<b>64</b>	Business Group
<b>67</b>	Key Collaborators
<b>69</b>	CTC Community
<b>72</b>	Current CTC trials
<b>81</b>	Funding
<b>82</b>	Staff awards
<b>84</b>	Staff list
<b>87</b>	Publications
<b>92</b>	Glossary

Our mission:  
To improve global  
health outcomes  
through excellence  
in clinical trials and  
related research

## Our strengths



### Excellence

Leaders of quality globally recognised research in cancer, cardiovascular, diabetes, obesity and neonatal areas.



### Innovation

Developing new trial methods in design, biostatistics, risk modelling and health economics.



### Evidence

Integrating evidence for better decision making, guidelines implementation and policy.

## 2019 IN NUMBERS



90  
active  
trials



1,184  
patients  
recruited



177  
peer  
reviewed  
publications



+450  
active sites  
(globally)



1,790  
ANZCTR –  
all new trials  
registered

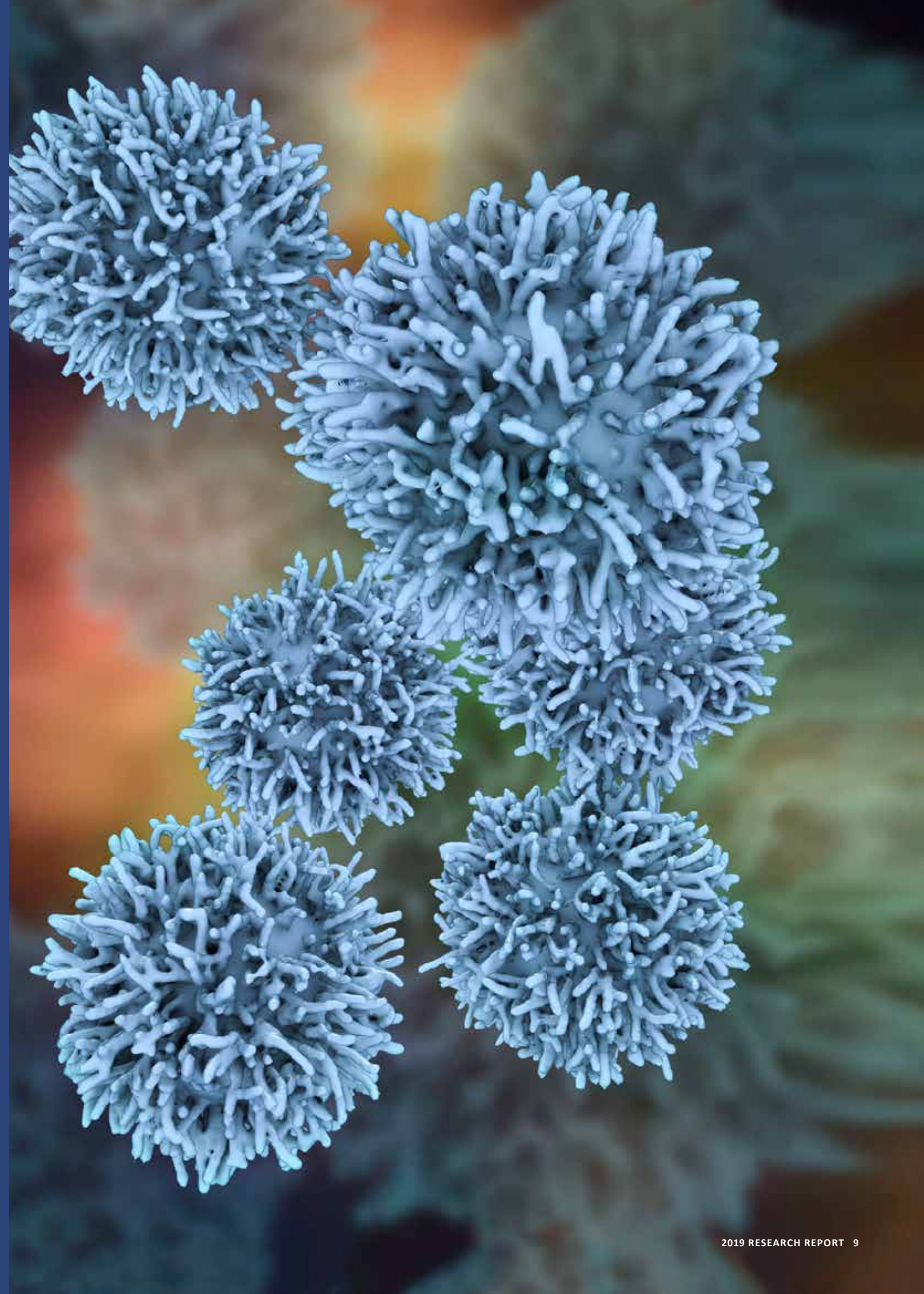


\$49.5m  
income  
received



+220  
staff







# Directors' report

The 2019 calendar year was one of continued growth for the Clinical Trials Centre (CTC). We started the year reflecting on some of our achievements with our collaborators as part of our 30th anniversary celebrations. The end of the year saw us preparing for external reviews of our centre that will help us plan our future strategy to continue to improve health outcomes for decades to come.

One highlight was our field-weighted citation impact (FWCI) measure of 3.35 for the last five years (2014-2019). This means that papers published by CTC authors have been cited 235% more frequently than similar publications in the field (the global FWCI mean is 1.0). This benchmark is often used to rank international research groups and is a great indication of the quality of clinical research we undertake across trials and trials methodology, and how highly valued it is by our peers globally.

On the clinical trials spectrum, major new findings have emerged that have shown the benefit of new treatment for an existing condition. In particular, the ENZAMET trial, a collaboration with the Australian and New Zealand Urogenital and Prostrate Cancer Trials Group (ANZUP), was one of those trials. This landmark Australian-led clinical trial, with participants in six countries, showed that hormone therapy with a drug called enzalutamide can improve the survival of some men with advanced prostate cancer. Primary results showed that enzalutamide could deliver a 33% survival improvement compared to men receiving standard care. The results published in the New England Journal of Medicine are already impacting on global practice.

Our Cardiovascular team received global ethics approvals to commence follow-up after the highly successful FOURIER trial. The FOURIER trial showed that patients – 27,564 across 49 countries - who received the active injection of evolocumab had a 15% reduction in further cardiovascular events over a 2.2 year period. The follow up in 10,000 participants will investigate the long-term effects of evolocumab over an additional five years to determine the long term safety profile and benefits of the drug. →

“We are planning our future strategy to continue to improve health outcomes for decades to come.”



**PROFESSOR JOHN SIMES**  
DIRECTOR

In partnership with our key collaborators, we are undertaking three major international trials that will seek to bring about new treatments for cancer patients worldwide with two to be launched in 2020. These are:

- **DASL HiCAP (with ANZUP)**: assessing the effectiveness of darolutamide as part of adjuvant androgen deprivation therapy (ADT) in men with localised prostate cancer at very high risk of recurrence;
- **DREAM3R (with ALTG)**: assessing if DuRvalumab with chemotherapy as first line treatment in advanced pleural mesothelioma (lung cancer) is beneficial for patients; and
- **INTEGRATE II (with AGITG)**: assessing whether Regorafenib is effective in prolonging survival in patients with advanced gastro-oesophageal carcinoma.

If positive, each of these trials is likely to have a major impact on future health care.

Assessing whether treatments will actually lead to improvements in standards of care and optimise existing treatments is also vital in the clinical trials space. New evidence from trials can also lead to recommending continuing current therapies or even stopping a routinely used treatment. For example:

- **VERTU (with COGNO)**: for patients with glioblastoma (GMB), the study showed that adding the drug veliparib to standard therapy with radiotherapy and in chemotherapy did not substantially improve outcomes. But further recommendations will await final results from this and other trials expected in 2020.
- **ALT GIST (with AGITG)**: The study's initial results showed no benefit in alternating imatinib and regorafenib treatment versus continuous imatinib in patients with gastrointestinal stromal tumour. In follow up, the trial is seeking to confirm these initial results.
- **WBRT**: Our Health Economics team were part of a trial that found Whole Brain Radiotherapy (WBRT) did not reduce the spread of melanoma in the brain. These results are likely to lead to changes in practice and savings for the healthcare system.

**PROFESSOR TONY KEECH**  
DEPUTY DIRECTOR



**AusTRIM will keep Australian researchers up to speed with global developments as well as help them lead on the world stage.**

While the CTC does not recruit participants to trials directly – hospital sites are responsible for patient recruitment – we look for ways to facilitate trial recruitment as best as we can. To improve recruitment of pre term babies to a trial assessing optimal oxygen levels, our Neonatal and Perinatal team partnered with a consumer body representing premature babies, the Miracle Babies Foundation. Together they obtained approval for waiver of consent, meaning all babies will benefit from entering the study, including those born at night or on weekends who were often excluded. For their efforts, they were awarded the 2019 Australian Clinical Trials Alliance (ACTA) Consumer Involvement Award.

Clinical trial designs are becoming more innovative. To help ensure innovations deliver value for patients and the healthcare system, Professor Ian Marschner and Associate Professor Chee Lee helped establish a newly funded NHMRC Centre of Research Excellence (CRE) called The Australian Trials Methodology Research Network (AusTriM). AusTriM is a collaboration with Monash University and research institutes in Melbourne, Perth, Adelaide and Brisbane. CTC will take the lead on the design and analysis of multi-stage adaptive trials, and the analysis of treatment mechanisms and surrogate outcomes, particularly in cancer studies. AusTriM will keep Australian researchers up to speed with global developments as well as help them to lead on the world stage.

One innovative way of researching is to conduct a prospective meta analysis (PMA). Little is known about this research method among many in the academic community. Its key feature is that studies/cohorts are identified for inclusion in the meta-analysis, and hypotheses and analysis strategies are specified, before results are known. To help the research community understand more, our PMA team published 'A guide to prospective meta-analysis' in the British Medical Journal. The guide describes how PMAs can help reduce research waste and bias, valuable outcomes as governments look for more efficient returns on grant spending.

Many other trials and achievements in this report demonstrate our effort to advance the boundaries of care and treatment, with the wellbeing of trial participants front of mind. These and other successes would not be possible without our highly valued collaborators, including the cancer cooperative groups, the Australian Genomics Cancer Medicine Centre, the cardiovascular, diabetes and perinatal networks, our many international partners as well as government, industry, ACTA, and hospitals and patients. Thanks to all for your participation and commitment to better healthcare.

**John Simes and Tony Keech**



# Strategy

As part of the CTC's Strategic Plan 2017-21, we have six core strategic objectives to help us achieve our vision. Here is a snapshot of the progress we made in each of these objectives in 2019.

## 1 BRING TOGETHER WORLD-CLASS EXPERTISE IN TRIAL METHODS AND CONDUCT, CLINICAL DISCIPLINES, BIOSTATISTICS, HEALTH ECONOMICS, BIOCHEMICAL AND MOLECULAR SCIENCES

- Our research leaders received prestigious peer awards for outstanding contributions in their fields, including Professor Martin Stockler (Oncology), Professor Alicia Jenkins (Diabetes), Professor Rachael Morton (Health Economics) and Professor Val Gebski (Biostatistics). See p.16 for more.
- Our Cardiovascular team are known worldwide for running one of the largest statin trials in the world (FOURIER) to help patients at risk of cardiovascular events. They were awarded a \$4.2 million cohort studies grant from the NHMRC to investigate the ability of colchicine to inhibit atherosclerosis-associated inflammation.
- Together with the Garvan Institute, our MoST team, which is investigating targeting the genes and proteins of patients with rare cancers instead of their tumours, expanded screening sites nationally to every state and territory. Nine sites across Australia have screened 1,952 patients for eligibility in four trials targeting immunotherapy and lung cancer using precision medicine (p.30).
- Our Neonatal and Perinatal team received the 2019 ACTA Consumer Involvement Award for their pioneering partnership with Miracle Babies Foundation that increased recruitment of pre term babies to a trial assessing the optimal level of oxygen (p.46).

## 2 BUILD INTERNATIONAL COLLABORATIONS

- In partnership with cancer cooperative groups, we presented results from cutting edge trials to international audiences, promoting our expertise and inviting future collaboration. Results from ENZAMET (with ANZUP; see p.28), VERTU (with COGNO; p.20), ALT GIST (with AGITG; p.22) and PHAEDRA (with ANZGOG; p.24) were presented at the American Society of Clinical Oncology meeting, the Society of NeuroOncology (US), and ESMO Asia.
- To help improve standard clinical practice for mesothelioma (lung cancer) patients, we kicked off Phase III of the international trial, DREAM3R (p.27). Together with ALTG, we are working with partners across Australia and New Zealand (30 planned hospital sites), and in the US (30 planned hospital sites) to recruit and run the trial.
- We partnered with ALTG and the Taiwan Cooperative Oncology Group on the ILLUMINATE trial (p.26), a phase II trial for lung cancer. The trial is on target to recruit 50 patients in Australia and Taiwan.
- The Fame 1 Eye study (p.42), which is testing whether fenofibrate can protect against eye damage in patients with type I diabetes, sees us working with partners across four countries (Australia, New Zealand, Hong Kong and Northern Ireland) and 18 hospital sites that are currently open for recruitment.

DANIELLE MILLER  
BUSINESS DIRECTOR



TONY KEECH  
DEPUTY  
DIRECTOR



## 2019 CTC Executive Team

JOHN SIMES  
DIRECTOR



BURCU VACHAN  
DIRECTOR CLINICAL  
TRIAL OPERATIONS



## 3 EMBED TRANSLATIONAL STUDIES INTO OUR RESEARCH

- Our collection of oncology biological marker samples, that may help predict a patient's response to treatment and progress understanding of precision medicine, doubled its number of samples in 2019 to nearly 30,000 from 65 hospitals. Grants totalling \$4.92 million were received.
- The TR team partnered with four cancer cooperative trials groups (ALTG, ANZGOG, ANZUP, COGNO) in the AUTO-CHECK translational research study, which aims to discover why some cancer patients get severe autoimmune side-effects from anti-cancer immunotherapy. The study completed recruitment in 2019.

- The Islet Biology team identified gene variants that can predict the quality of human islets before their isolation from a cadaveric donor pancreas (p.44).
- They also identified a set of microRNAs that can improve future Type 2 diabetes risk prediction in women who had gestational diabetes (p.44).



#### 4 DELIVER QUALITY EDUCATION, TRAINING, TEACHING AND DEVELOPMENT PROGRAMS

- Our research leaders supervised 25 PhD students and 14 summer students investigating and studying clinical trials research, helping the next generation to advance the quality of clinical trials research globally.
- Our research leaders continued to teach postgraduate courses in the Master of Clinical Trials Research and the Controlled Trials Unit of the Master of Public Health and Master of Clinical Epidemiology programs at the University of Sydney.
- The CTC-based Biostatistics Collaboration of Australia continues to deliver the Master of Biostatistics program, encouraging future biostatisticians to advance the future of clinical trial design and methodology.
- Throughout the year, we ran short courses in critical appraisal and study design methods in the Basic Sciences in Oncology workshop and the Statistical Methods, Evidence Appraisal & Research for Trainees (SMART) workshop, through the Royal Australian & New Zealand College of Radiologists. Workshops are run for professionals, academics and researchers from a range of backgrounds, increasing awareness and encouraging interest in clinical trials and related research.

Our research leaders supervised 25 PhD students and 14 summer students, helping the next generation to advance the quality of clinical trials research globally.

#### 5 EXTEND OUR METHODOLOGICAL WORK IN ADAPTIVE TRIAL DESIGNS, PATIENT REPORTED OUTCOMES (PROMS), PROGNOSTICATION, DIAGNOSTIC TEST EVALUATION AND COST-EFFECTIVENESS ANALYSIS IN PRACTICAL APPLICATION

- We looked to advance our understanding and use of PROMs in the SWIFT study, where PROMs were collected to see if the quality of life for patients with kidney disease can be improved. PROMs and PREMs (patient reported experience measures) were assessed for 177 patients across Australia and New Zealand (p.50).
- Professor Ian Marschner and A/Prof Chee Lee helped establish The Australian Trials Methodology Research Network (AusTriM), a newly funded NHMRC Centre of Research Excellence (CRE) in clinical trials methodology. AusTriM will link leading methods researchers across the country to help enable innovative trial designs and make sure they deliver valuable insights for patients (p.62).
- Professor Ian Marschner and colleagues published a position paper in the Medical Journal of Australia calling for greater investment in the discipline of Biostatistics in the big data era. Big data places greater emphasis on fundamental statistical concepts and methods to extract valuable evidence.
- In the British Medical Journal, the Integrating Evidence team were lead authors on 'A guide to prospective meta-analysis', a guide for researchers about this rare and often misunderstood research method that can help reduce research waste and bias. The team is a world-leader in prospective meta-analysis.



#### 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

- The Health Economics team were part of a trial with ANZMTG that found Whole Brain Radiotherapy trial (WBRT) did not reduce the spread of melanoma in the brain. This practice-changing outcome is likely to result in significant cost savings in the healthcare system (p.52).
- In the EPOCH trial, the Integrating Evidence team established that early intervention is best for reducing childhood obesity-related behaviour. With NHMRC funding, they will now investigate which interventions are most effective and efficient in reducing obesity rates, with potential benefits for patients and healthcare systems globally.
- Reviews from the Cochrane Breast Cancer Group, which CTC hosts, have been used in at least 34 consensus or practice guidelines, including those for the European Society of Medical Oncology and National Institute for Health and Care Excellence (UK). The Cochrane Breast Cancer Group continues to influence clinical practice by publishing relevant and useful Cochrane reviews.
- Our Medical Test Research team, in partnership with Abbott Laboratories, completed a systematic review on the value of high-sensitivity troponin to guide primary prevention of cardiovascular disease.

Image Top Right:  
Research Committee  
meeting



## February



→ **Emma Scott, Prof Alicia Jenkins** and colleagues contributed a chapter to the published book *'Comprehensive Cardiovascular Medicine in the Primary Care Setting'*.

## March

→ **The Biostatistics Collaboration of Australia (Erica Jobling, Emily Higginson and Gillian Heller)** were awarded the *2019 President's Award for Leadership in Statistics* from the Statistical Society of Australia.



→ **Chee Lee** was promoted to Associate Professor in recognition of his outstanding contribution to cancer research.

→ **Luke Carroll** received the *European Foundation for the Study of Diabetes Albert Renold Travel Fellowship*, which enabled him to undertake telomere related research in Helsinki with the Finnish FinnDiane Type 1 diabetes cohort.

## May



→ **Prof William Tarnow-Mordi & Torpedo 30/60 trial team** received the *ACTA Inaugural Consumer Involvement Award* recognising their groundbreaking partnership with the consumer-focussed Miracle Babies Foundation in trial recruitment.



→ **Prof Martin Stockler** received the *MOGA-Novartis Cancer Achievement Award* recognising his outstanding contributions to cancer research and control in Australia.

## July



→ **Luke Carroll** received the *Health and Infrastructure Award* at the Sydney Innovation and Research Symposium.

### 2019 AWARDS

Here is a selection of the external awards received by CTC staff in 2019.

## August



→ **Prof Val Gebski** received the *John Zalberg OAM Award for Excellence in AGITG Research* in recognition of over 28 years of contribution to the group as a senior statistician.



→ **Dr Emma Scott** was awarded the *Best Clinical Presentation*, and was a finalist in the *Young Clinical Investigators Award* at the Australian Diabetes Congress.

## October



→ **Dr Karen Bracken** was awarded the degree of *Doctor of Philosophy* at the University of Sydney.

## November



→ **Prof Rachael Morton** received the *FMH Supervisor of the Year Award* from the University of Sydney Postgraduate Representative Association.



→ **The Medidata Implementation Team** (Ilka Kolodziej, Mark Maclean, Salma Fahridin, Sarah Chinchin, Hannora Jurkovic, Martin Stockler, Seshu Atluri, Colin Sutton, Wendy Hague, Rachel O'Connell, Chris Brown, Kristy Robledo, David Espinoza) received the *FMH Award for Outstanding Contribution to Research Excellence* from the University of Sydney.

## December

→ **Prof Rachael Morton** received the *Mid-Career Distinguished Investigator Award* from HSRAANZ for her formidable research output (+140 papers) and making advances in healthcare for end-stage kidney disease treatment, migrant screening for disease in EU, and the diagnostic imaging of cancer patients.

# Oncology trials and other research

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

The CTC works collaboratively with five of the 13 national cancer cooperative groups 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.

## 2019 IN NUMBERS



53  
active  
trials



1867  
patients  
recruited



36  
peer  
reviewed  
publications

“It’s so important to work on things you are genuinely interested in and passionate about. It’s even more important to find excuses and opportunities to work with people you like, respect, and admire.”



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.



## 2019 IN NUMBERS

 **4**  
active trials

 **34**  
patients recruited

 **28**  
active sites

## 2019 HIGHLIGHTS

- VERTU trial: results were presented at the Society of NeuroOncology (SNO) conference in Phoenix, Arizona and at ASCO 2019. The trial was selected for discussion in the SNO daily highlights that featured the most cutting edge science from the day (see trial in focus).
- MAGMA trial: awarded a \$2.4m MRFF grant over five years to assess a number of options in the standard of care for the management of glioblastoma.
- PICCOG-PARP trial: awarded \$1.4m MRFF grant over five years to determine the activity of a PARP inhibitor and an immune checkpoint inhibitor (nivolumab) against relapsed IDH-mutant high-grade glioma.
- Three trials (CODEL, LUMOS and MAGMA) moved from development stage into operations stage, with plans to open trials in 2020.



## BRAIN CANCER IN AUSTRALIA

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

**31%**  
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: VERTU

How effective is Veliparib as a new treatment for glioblastoma (GBM)?

### CHALLENGE

GBM is a brain cancer that is almost always fatal. Treatment includes surgical removal followed by six weeks of chemoradiotherapy (CRT) followed by six months of chemotherapy (temozolomide).

### TRIAL

We know GBM cells contain an enzyme called MGMT which may be switched 'on' or 'off'. In the 'on' position, MGMT protects GBM cells from CRT. The VERTU clinical trial will assess if adding veliparib to CRT improves survival in patients with the 'on' MGMT enzyme.

This study aims to evaluate the safety and effectiveness of a combination of veliparib with radiotherapy, followed by a combination of veliparib with temozolomide (a chemotherapy), compared with temozolomide alone, to treat patients with newly diagnosed GBM.

The trial opened to recruitment in October 2015 and recruited 125 patients across 17 sites within Australia.

### IMPACT

Preliminary data was reported at two prestigious meetings (ASCO and SNO conferences) in 2019. Preliminary results demonstrated that treatment is safe and tolerable, and does not negatively impact the patient's quality of life. Final analysis with updated results is expected in 2020.

The translational correlative science component (studying biomarkers in the tissue and blood of patients) means that regardless of the study outcome, significant and novel knowledge will be added to existing efforts to find effective treatments for GBM.

### TRIAL SNAPSHOT

**STATUS: IN FOLLOW-UP**

**START DATE: 2015**

**PATIENTS RECRUITED: 125**

**SITES: 17**

# Gastro-Intestinal Cancer

Partner: Australasian Gastro-Intestinal Trials Group

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

Together we have completed over 58 trials involving more than 6,600 patients. Our research has changed treatment practices and improved patient life expectancy and quality of life.



Dr Katrin Sjoquist,  
Senior Research Fellow  
and Clinical Lead

## 2019 IN NUMBERS

 13  
active  
trials

 333  
patients  
recruited

 305  
active  
sites

## 2019 HIGHLIGHTS

- MASTERPLAN trial: opened to recruitment. This is the first published randomised trial that explores stereotactic radiotherapy for pancreatic cancer, with ten sites in ANZ.
- LIBERATE trial: completed recruitment of 101 patients at 14 sites in Australia, helping develop less invasive testing for predicting and evaluating treatment response to targeted therapies.
- ALT GIST trial: primary endpoint results were presented at ASCO19. The study's initial results showed no benefit in alternating imatinib and regorafenib treatment versus continuous imatinib in 76 patients with gastrointestinal stromal tumour. The trial continues in follow-up to assess secondary endpoints.
- INTEGRATEII trial: Due to the ever-evolving treatment landscape, the study design for this trial was amended substantially with the addition of immunotherapy to the intervention arm. In preparation for the amended study design, the trial established two new collaborations with groups in Taiwan and Germany.
- TOPGEAR trial: reached recruitment milestone of 500 patients. This trial investigates whether the addition of chemoradiotherapy to neoadjuvant chemotherapy is superior to chemotherapy alone for patients with operable gastric cancer.



## TRIAL IN FOCUS: DOCTOR

Is the addition of docetaxel chemotherapy +/- radiotherapy to pre-operative treatment with cisplatin and 5-fluorouracil chemotherapy, beneficial in the treatment of cancer of the oesophagus?

### CHALLENGE

Patients who show a metabolic response to pre-operative chemotherapy have consistently demonstrated better survival, while patients who do not respond on PET after 14 days generally have poor outcomes. There is a clinical need to find a treatment to improve outcomes for patients who do not demonstrate an early metabolic response to pre-operative chemotherapy.

### TRIAL

DOCTOR compared the effectiveness of pre-operative treatment with cisplatin, 5-fluorouracil and docetaxel +/- radiotherapy, in patients demonstrating a poor early response to standard chemotherapy for operable oesophageal cancer.

The trial commenced in 2009 and completed in 2019. Study results demonstrated that early metabolic response is associated with favourable survival and a low rate of local recurrence. Adding docetaxel to standard chemotherapy for metabolic non-responders may augment histological response rate, but survival and local

recurrence outcomes remained inferior. However, the combination of docetaxel, radiotherapy and standard chemotherapy showed favourable histological response rate and survival/local recurrence outcomes, matching outcomes for early metabolic responders. Hence, this combination may have closed the gap in survival between metabolic responders and non-responders. A larger study will be needed to confirm these findings.

### IMPACT

DOCTOR is the first study to focus on finding a treatment to improve survival rates for patients who do not show early metabolic response to standard chemotherapy. This study demonstrated the potential to individualise therapy related to tumour characteristics shown on PET scans, also known as "tailored therapy".

### TRIAL SNAPSHOT

**STATUS: COMPLETED 2019**  
**START DATE: 2009**  
**PATIENTS: 126**  
**SITES: 10**

## GASTRO-INTESTINAL CANCER IN AUSTRALIA

28,880  
estimated number  
of new cases  
diagnosed each year

38  
estimated number  
of deaths from of  
GI cancer each day

GI cancer includes: oesophageal, liver, stomach, gallbladder & biliary tract, pancreatic, gastro-intestinal stromal tumour (GIST), neuroendocrine tumours, colorectal, small bowel and anal.

Source: Australian Government, Australian Institute of Health and Welfare



# Gynaecological Cancer

Partner: Australia New Zealand  
Gynaecological Oncology Group



The Australia 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.



## GYNAECOLOGICAL CANCER IN AUSTRALIA

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

**9.3%**  
estimated % of all  
female deaths from  
cancer in 2019

**70%**  
chance of surviving  
at least five years  
(2011-2015)

Source: Australian Government,  
Cancer Australia

### 2019 HIGHLIGHTS

- Three new trials opened in Australia and New Zealand to investigate ovarian cancer (SOLACE2), perioperative care in ovarian cancer surgery (TIPS), and prevention of ovarian cancer in women with germline BRCA 1 or BRCA 2 mutations (STICs and STONeS).
- PHAEDRA trial: oral presentations were delivered at international and national scientific meetings (ASCO ASM 2019, ESMO Asia 2019 and MOGA 2019; the latter under the 'best of the best' research session). (See trial in focus).
- OUTBACK trial: disparities abstract was presented at international and national scientific meetings (ESMO 2019 and COSA ASM 2019; the latter under the 'best of the best posters' in clinical research). This study looks at whether the addition of adjuvant chemotherapy to standard cisplatin-based chemoradiation improves outcomes in women with locally advanced cervical cancer.
- A number of international trials were published in top-tier journals: PORTEC-3 trial manuscript in The Lancet Oncology; ICON8 progression-free survival analysis results in the Lancet Oncology; ANZGOG-1103 manuscript in Cancer Chemotherapy and Pharmacology; and PARAGON had three manuscripts published in Gynecologic Oncology (endometrial cancer and recurrent low grade ovarian cancer) and Journal of Gynecologic Oncology (asymptomatic patients with a rising CA125 after first-line chemotherapy and GCIG defined CA125 progression).
- In recognition of the Symptom Benefit Study and quality of life research in ovarian cancer trials, CTC fellows were invited to be authors for a book chapter titled "Integrating patient-reported outcomes into routine clinical care of patients with ovarian cancer to identify symptoms and to optimise management" in 100 Key Questions in Ovarian Cancer 2019.

### 2019 IN NUMBERS

**11**  
active trials

**102**  
patients recruited

**46**  
active sites

### TRIAL IN FOCUS: PHAEDRA

How safe and effective is the immunotherapy drug durvalumab in the treatment of advanced endometrial cancer?

**CHALLENGE**  
The management of advanced and recurrent endometrial cancer has been challenging. Advanced endometrial cancer (AEC) progressing after one or more lines of chemotherapy is an area of unmet need, with limited response rates to subsequent lines of chemotherapy of 20% or lower. There is a clear need to explore novel therapeutic options.

**TRIAL**  
DNA mismatch repair (MMR) deficiency, seen in approximately 15% of AEC, is associated with a high mutational load, a characteristic that may be associated with response to immune checkpoint inhibition.

The PHAEDRA trial utilises the immunotherapy drug, Durvalumab, to assess its effect on women with advanced endometrial cancer and the subsequent tumour response to immune checkpoint inhibition.

**IMPACT**  
Durvalumab monotherapy showed promising activity and safety in advanced endometrial cancer (AEC) with mismatch repair deficient (dMMR) disease regardless of prior lines of chemotherapy, but there was limited evidence of activity in AEC with mismatch repair proficient (pMMR) disease.

Durvalumab shows activity for AEC with dMMR, but not of AEC with pMMR. The treatment is well-tolerated and warrants further exploration in AEC with dMMR.

**TRIAL SNAPSHOT**  
**STATUS: IN FOLLOW-UP**  
**START DATE: 2017**  
**PATIENTS RECRUITED: 71**  
**SITES: 12**



# Lung Cancer

**Partner: Australasian Lung Cancer Trials Group**

The CTC collaborates with the Australasian Lung Cancer Trials Group (ALTG) to facilitate high quality clinical research in Australia and New Zealand.

In recent years, the partnership has expanded into new trials looking at immunotherapy and targeted therapies for lung cancers, as well as renewed interest in mesothelioma, and most recently expanding into genomic profiling to deliver personalised precision medicine.



Michelle Parry,  
Research Development  
Lead (ALTG)

## 2019 IN NUMBERS

**7**  
active  
trials

**+ 95**  
patients  
recruited

**50**  
active  
sites

## 2019 HIGHLIGHTS

- DREAM3R trial: this international phase 3 clinical trial is the follow on from the successful ALTG phase 2 DREAM trial. The DREAM3R trial has the capacity to change standard practice for mesothelioma patients worldwide (see trial in focus).
- ILLUMINATE trial: recruitment began with 10 out of 50 patients recruited in Australia by the end of 2019. ILLUMINATE examines advanced EGFR mutant-squamous NSCLC and is a unique partnership between ALTG/CTC and the Taiwan Cooperative Oncology Group, the first of its kind. We are on target to recruit 50 patients in Taiwan by early 2021.
- BR.31 trial: an international trial with our long-standing collaborators the Canadian Cancer Trials Group (CCTG) exceeded its' enrolment target, finishing at 111/100 participants.
- Nine new concepts were presented at the ALTG Scientific Advisory Committee meeting in November 2019, demonstrating the high level of engagement and enthusiasm throughout the ALTG membership.



## LUNG CANCER IN AUSTRALIA

**12,817**  
estimated number of  
new cases of lung cancer  
diagnosed in 2019

**18%**  
estimated % of all deaths  
from cancer in 2019

**17%**  
chance of surviving  
at least five years  
(2011-2015)

Source: Australian Government, Cancer Australia

## TRIAL IN FOCUS: DREAM3R

Is upfront immunotherapy (durvalumab) with chemotherapy effective in treating mesothelioma?

### CHALLENGE

Australia has one of the highest incidence rates of pleural mesothelioma in the world, with over 700 people diagnosed each year. Mesothelioma is a rare and aggressive cancer, and its primary cause is exposure to asbestos. Mesothelioma survival rates are very low and this has not changed over time.

### TRIAL

The results of the ALTG DREAM phase 2 trial were promising, and the phase 3 DREAM3R builds on this research. The DREAM3R trial aims to determine the effectiveness of adding durvalumab to standard chemotherapy for the treatment of malignant pleural mesothelioma.

Participants will be randomly allocated to receive either durvalumab plus standard chemotherapy, or to receive standard chemotherapy alone. Participants will be regularly assessed to evaluate whether the cancer is responding to treatment or whether it is worsening.

This will allow us to determine whether the addition of durvalumab immunotherapy to standard chemotherapy for mesothelioma is beneficial for survival time and cancer response to treatment, and whether it is cost effective.

### IMPACT

This trial aims to provide important information on whether adding durvalumab immunotherapy to standard chemotherapy is effective at improving survival, cancer response, patient quality of life and other outcomes in mesothelioma. If so, the trial may assist in making the drug more accessible for mesothelioma patients in future.

### TRIAL SNAPSHOT

**STATUS: IN START-UP**

**PLANNED START DATE: Q2 2020**

**PLANNED PATIENTS: 480 (240 ANZ, 240 USA)**

**PLANNED SITES: 60 (30 ANZ, 30 USA)**



# 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.



Xanthi Coskinas,  
Project Lead on  
the ENZAMET and  
ENZARAD trials

## 2019 IN NUMBERS

 **8**  
active trials

 **313**  
patients recruited

 **37**  
active sites

## 2019 HIGHLIGHTS

- ENZAMET trial: primary results were presented at ASCO19 and were simultaneously published in the New England Journal of Medicine. The study shows that hormone therapy could deliver a 33% survival benefit for men with metastatic prostate cancer (see trial in focus).
- TheraP trial: reached its recruitment target of 200 patients three months early. This study will provide further information about the risks and benefits of Lu-PSMA compared with cabazitaxel in men with prostate cancer.
- Pain-free TRUSB study: reached its recruitment target of 420 patients. This study will determine if the discomfort of prostate biopsies can be reduced by giving men inhaled methoxyflurane (the green whistle) in addition to their standard injections of local anaesthetic.



## PROSTATE CANCER IN AUSTRALIA

**19,508**  
estimated number of new cases of prostate cancer in 2019

**12%**  
estimated % of all male deaths from cancer in 2019

**95%**  
chance of surviving at least five years (2011-2015)

Source: Australian Government, Cancer Australia

## TRIAL IN FOCUS: ENZAMET

How effective is the hormone therapy enzalutamide versus NSAA, in the treatment of men with metastatic prostate cancer?

### CHALLENGE

Prostate cancer is the most commonly diagnosed cancer in Australian men. Approximately 3,300 men died 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 aim of this study is to see if a new drug, enzalutamide, can improve outcomes for patients with metastatic prostate cancer compared with the current best standard treatment. This is a randomised controlled trial meaning that half the trial participants receive enzalutamide and the other half receive the current best standard treatment. All participants receive active treatment for their cancer.

### IMPACT

Findings from the ENZAMET trial have shown that hormone therapy with a drug called enzalutamide can improve the survival of some men with advanced, hormone-sensitive prostate cancer, and men with this sort of cancer who receive enzalutamide with standard treatment have a 33% improvement in overall survival and a 60% improvement in progression-free survival, compared to men receiving standard treatment alone.

### TRIAL SNAPSHOT

**START DATE: 2014**  
**PATIENTS RECRUITED: 1,125**  
**SITES: 83**

The trial enrolled 1,125 participants from Australia, New Zealand, Canada, Ireland, United Kingdom and the USA.

# Molecular Screening and Therapeutics program

The Molecular Screening and Therapeutics program (MoST) is an innovative approach bringing new treatment options for advanced and incurable cancers. New treatment options are targeted (or personalised) to the genes and proteins of the patient, instead of their cancer type.

Support from government and partnerships with hospitals, collaborative groups, industry and philanthropy have grown the program from a NSW pilot into a leading source of treatments for cancer patients in Australia.

The MoST program has established drug and funding partnerships 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 over \$17.9 million.

The CTC is a founding member of a not for profit company called the Australian Genomic Cancer Medicine Centre (AGCMC) through which MoST will continue to grow, together with new national member centres. The company has attracted over \$70 million in funding.

## 2019 HIGHLIGHTS

- National expansion to every state and territory. This will increase screening and treatment capacity and provide greater access to studies for patients Australia-wide.
- Completed recruitment to two immunotherapy studies MoST 2 (durvalumab + tremelimumab) expansion and MoST 3 (olaparib + durvalumab).
- 1,952 patients screened and almost 200 patients treated since the program began.
- ASPIRATION study: The MoST program is facilitating genomic screening in lung cancer patients with metastatic disease through a collaboration with government, the Australian Lung Trial Group and Roche. The program’s approach is a world first design in that we are also providing treatment options for patients with a genomic target.



## RARE CANCER IN AUSTRALIA

**42,000**  
estimated number of people diagnosed with a rare or less common cancer each year

**22,000**  
estimated number of deaths from rare or less common cancer each year

**1 in 5**  
cancers diagnosed is a rare or less common cancer

Source: Rare Cancer Australia

New treatment options are targeted (or personalised) to the genes and proteins of the patient, instead of their cancer type.

## 2019 IN NUMBERS



Lucille Sebastian, MoST Program Manager & Sarah Chinchin, MoST Associate Program Manager





# Other oncology research

In addition to our extensive work with the cooperative trial groups (CTGs), the CTC conducts a range of quality research both independently, or in collaboration with multiple CTG's. Examples include the long-running SNAC trials, conducted in collaboration with the Australian Breast Cancer Trials (BCT) group, and the CannabisCINV trial, performed in collaboration with Chris O'Brien Lifehouse and the Lambert Initiative for Cannabinoid Therapeutics (see trial in focus).

The CTC also delivers the Cancer Australia-funded Genomics Cancer Clinical Trials Initiative (GCCTI) technical service in collaboration with ZEST Health Strategies. The aim of the GCCTI is to support the 13 national CTGs to develop cancer clinical trial protocols (grant applications) for studies involving two or more cancer types and two or more cooperative trials groups. It is funded under Cancer Australia's Support for Cancer Clinical Trials program.



## 2019 IN NUMBERS

 6  
active trials

 38  
patients recruited

 29  
active sites



Martijn Oostendorp,  
Clinical Trials  
Program Manager

The CTC also conducts a range of quality research both independently, or in collaboration with multiple CTG's.

## TRIAL IN FOCUS: CANNABISCINV

Can the use of medicinal cannabinoids help to treat cancer treatment related symptoms, such as nausea and vomiting?

### CHALLENGE

Nausea and vomiting are common and debilitating side effects of chemotherapy. Despite recent advances in managing nausea and vomiting in this setting, these two symptoms remain among the most distressing and feared consequences of chemotherapy.

### TRIAL

The aim of this trial is to determine if the addition of an oral medicinal cannabis medication is effective in preventing chemotherapy-induced nausea and vomiting (CINV) for people who have experienced nausea and/or vomiting during a previous cycle of chemotherapy despite the use of guideline recommended nausea prevention drugs (prophylaxis).

The active drug contains a combination of tetra-hydrocannabinol (THC) and cannabidiol (CBD) in a capsule form and is taken 3 times a day.

Patients must be 18 years and over with a known malignancy of any stage, requiring at least two further cycles of moderate to highly emetogenic intravenous chemotherapy and experiencing significant CINV during previous cycles.

The study consists of a pilot phase 2 crossover design component, which recruited 81 participants, followed by a definitive phase 3 parallel component that will recruit a further 170 participants. Recruitment to the

pilot phase was completed in June 2019 and with the recommendation of an independent data safety monitoring committee the definitive phase opened to recruitment in July 2019. The results of the pilot phase are planned for publication in 2020.

Participants enrolled in the definitive trial will be randomly allocated (by chance) to receive the active study drug or placebo for the first five days of their next two or three chemotherapy cycles following enrolment. All participants will be given the opportunity to move onto active drug after the first cycle if symptom control is not satisfactory. Participants will be asked to complete a number of questionnaires relating to their nausea and vomiting, quality of life and any side effects of the treatment.

### IMPACT

It is hoped that this trial will provide preliminary (pilot study) information, followed by more definitive information showing how effective the THC/CBD capsules are at preventing CINV. This study could help reduce the terrible side effects of chemotherapy and improve the quality of life of cancer patients.

### TRIAL SNAPSHOT

**START DATE:** 2016  
**PATIENTS RECRUITED:** 91  
**SITES:** 11

# Translational research (oncology)

Translational research studies examine patient samples from CTC trials for biological markers. These markers may help predict a patient’s response to a specific treatment, or they can help better forecast survival. These markers can 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 donate tissue and blood samples for this research. Samples are studied with research partners around the world. Cutting-edge techniques known as ‘omics’ are used to study genes (genomics), proteins (proteomics) and mRNA (transcriptomics).



Sonia Yip, Oncology Translational Research Manager


## 2019 HIGHLIGHTS

- More than twice as many samples shipped in 2019 than the previous year
- Five grants were awarded \$4.92 million from Cancer Council WA, Australian Brain Cancer Mission - MRFF and Cure Brain Cancer.
- The AUTO-CHECK translational research study completed recruitment of 257 patients. This study aims to discover why some cancer patients get severe autoimmune side-effects from anti-cancer immunotherapy. Led by the CTC and centre for Personalised Immunology, this study involves samples from trials in brain, endometrial, lung, mesothelioma and renal cancers (trials include: NUTMEG, PHAEDRA, ILLUMINATE, KEYPAD, DREAM)



Markers can be used as a tool to select the right treatment, delivered at the right time for the individual patient - the basis of precision medicine.


## 2019 IN NUMBERS



68  
oncology trials have translational research activities



29,290  
samples (tissue and blood from patients) shipped from 65 hospitals



22  
research labs collaborating on translational research studies

## STUDY IN FOCUS: TRANSLATIONAL RESEARCH STUDIES OF THE CABARET TRIAL

Are there any biomarkers that can help identify which glioblastoma patients do better on two treatments, bevacizumab or bevacizumab plus carboplatin?

### STUDY OVERVIEW

Tumour tissue samples from patients with glioblastoma on the COGNO trial, CABARET, were analysed in several translational research studies.

The CABARET trial recruited 122 Australian patients with glioblastoma from 18 hospitals. While the trial showed no difference in overall survival between patients randomized to the two treatments, bevacizumab or bevacizumab plus carboplatin, we were interested to see if there were any tissue biomarkers, such as genes or proteins that help to identify which patients were likely to do better on these treatments.

### IMPACT

A small group of three patients who had a prolonged survival of over 30 months showed an abnormality of a chromosome (extra parts of their chromosome 19) when compared with patients with poor survival. None of the 19 proteins tested in the tissue were associated with longer overall survival of patients. These interesting findings require further examination in a larger group of patients with glioblastoma. Results were published in the Journal of Clinical Neuroscience in 2019.



# Cardiovascular trials and other research

Cardiovascular disease (CVD) 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 trials 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.

## 2019 HIGHLIGHTS

- COLCARDIO ACS trial: awarded a \$4.2 million Clinical Trial and Cohort Study Grant from the NHMRC to investigate the ability of colchicine, a safe and commonly used anti-inflammatory drug, to inhibit atherosclerosis-associated inflammation. Sites have been activated in ANZ, with the goal of recruiting the first patient by April 2020.
- COBRRA trial: awarded a \$1.05 million MRFF International Clinical Trial Collaborations Grant comparing outcomes using apixaban versus rivaroxaban for the treatment of acute venous thromboembolism (blood clots in legs or lungs). This trial is in start-up with activation planned for Q2 2020.
- FOURIER Legacy trial: received global ethics approvals to commence the follow-up of up to 10,000 patients in 29 countries who completed the FOURIER trial (see trial in focus).

## 2019 IN NUMBERS

 6  
active  
trials

 15  
peer  
reviewed  
publications

“Statin therapy has been shown to prevent cardiovascular disease in a wide range of people. We recently found it is safe and effective for people aged 75 years and over with prior heart disease or stroke.”



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





Rebecca Mister,  
Clinical Trials  
Program Manager

## CARDIOVASCULAR DISEASE IN AUSTRALIA

4.2m

Australians are  
affected by CVD

43,477

deaths attributed to  
CVD in 2017

119

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

Source: heartfoundation.org

### TRIAL IN FOCUS: FOURIER LEGACY

What are the long term effects of evolocumab treatment for patients with cardiovascular disease?

#### CHALLENGE

The FOURIER OUTCOMES trial average individual patient participation lasted 2.2 years. The results were promising and showed that patients who received the active injection of evolocumab had a 15% reduction in further cardio-vascular events, compared with patients who received the placebo alongside conventional therapy who had an additional 5% further cardio-vascular event each year. There is a need to gather more data on these patients to support the long-term safety profile of the drug and to see whether longer term benefits emerge.

#### TRIAL

The FOURIER LEGACY study will follow patients who took part in the FOURIER OUTCOMES trial (closed December 2016) for five extra years to look at their longer-term cardiovascular outcomes. The FOURIER OUTCOMES trial compared a new cholesterol-lowering drug, evolocumab, with a placebo in patients with cardiovascular disease and high cholesterol levels despite being treated with statins.

This study will follow up to 10,000 patients in 29 countries. Participants will regularly be asked to complete a simple questionnaire detailing their cardiovascular outcomes since last follow-up. Surveys can be completed

either online or by telephone at enrolment and annually to 60 months after the FOURIER OUTCOMES trial closed.

The CTC is the Global Co-ordinating Centre and also the Regional Co-ordinating Centre for the Asia Pacific region. Other Regional Co-ordinating Centres are based in the UK, USA and Norway.

#### IMPACT

It is not uncommon to underestimate the long-term benefits of clinical trials, even appearing after treatment has stopped. The FOURIER Legacy study is looking for a reduction in deaths from cardio-vascular disease that might emerge beyond the original trial period. This study has the potential to significantly improve outcomes for patients with cardio-vascular disease by understanding the long-term safety profile and benefits of evolocumab treatment.

#### TRIAL SNAPSHOT

**STATUS: IN START-UP**

**PLANNED START DATE: FEB 2020**

**PLANNED PATIENTS: 10,000**

**COUNTRIES: 29**



# Diabetes trials and other research

Type 1 and Type 2 diabetes are major causes of morbidity and premature death globally. The Diabetes group takes a multi-faceted approach, studying both common 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 can improve outcomes for people with diabetes.

## 2019 HIGHLIGHTS

- T4DM study: the results of the study will be published in 2020. As well as being the first randomised trial of testosterone for diabetes prevention, it is also the largest randomised trial of testosterone, in any indication, ever to be conducted anywhere in the world.
- Hybrid Closed Loop (HCL) Adult study: reached a significant milestone, with the final two adult participants (of 120) completing their last study visits. The study aims to determine if the world's most advanced insulin pump improves glucose control and other factors, such as sleep, quality of life, mental well-being and vascular risk factors. Results are expected to be published by mid 2020.
- Fame 1 Eye study: continues to recruit with 18 sites open across three countries, with approximately one third of the 450 required participants enrolled (see study in focus).
- Prof Alicia Jenkins received the 2019 Kellion Award from the Australian Diabetes Society and the Kellion foundation for her outstanding contribution to diabetes research in Australia.
- Alicia was also elected as co-Director for the Precision Medicine Flagship of the Australian Cardiovascular Alliance and was also elected to the International Diabetes Federation Western Pacific Region Executive Council.
- PhD candidate Sharon Atkinson Briggs and her primary supervisor Dr Laima Brazionis tested a new model of care for testing eye health in primary care settings for Indigenous Australians with Type 2 diabetes, achieving very high screening rates.

## 2019 IN NUMBERS

**5**  
active trials

**38**  
peer reviewed publications

**21**  
active sites

“Our research aims to improve diabetes outcomes through the use of technology, such as insulin pumps and telehealth, and repurposing existent drugs to ameliorate diabetes and its complications.”



**PROFESSOR ALICIA JENKINS,**  
PROFESSOR, DIABETES AND  
VASCULAR MEDICINE





Diabetes  
Clinical Team

## DIABETES IN AUSTRALIA

280

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

10,000

Australians have developed diabetes in the past year

1.7m

estimated number of Australians with diabetes

\$14.6b

estimated total annual cost impact of diabetes in Australia

Source: diabetesaustralia.com.au

### TRIAL IN FOCUS: FAME-1 EYE

Does the blood fat -lowering drug, fenofibrate, protect against the progression of eye damage in adults with type 1 diabetes and early diabetes related?

#### CHALLENGE

People with type 1 diabetes, the insulin dependent type of diabetes that often begins in childhood, are at high risk of developing damage to the blood vessels and nerves in their eyes which, if severe, can cause vision loss. Diabetes is the leading cause of adult onset blindness globally.

#### TRIAL

We already know that fenofibrate reduces the risk of sight-threatening diabetes related eye damage in people with Type 2 diabetes, independent of blood fat levels. The drug is approved for such use in Australia and 18 other countries. Can fenofibrate develop similar results in people with Type 1 diabetes and existent early eye damage?

FAME-1 Eye is the first Type 1 diabetes specific trial of fenofibrate and protection against eye damage. It aims to determine if at least three years of a once daily tablet of fenofibrate can protect against progression of eye damage in adults with existent early retinopathy. Effects on other organs such as the kidneys and heart will also be recorded.

Vision testing and non-invasive photography and scanning of the eyes each year is used to assess the impact of the trial (fenofibrate or placebo) tablets.

The trial is planned to run in 25 centres in Australia, New Zealand, Hong Kong and Northern Ireland. It is seeking 450 trial participants aged 18 years and over with type 1 diabetes and existent mild to moderate eye damage (retinopathy) in at least one eye.

#### IMPACT

It is hoped that a daily fenofibrate tablet can slow the progression of diabetes related eye damage. If it does the drug, which is already available and usually well-tolerated, could be promptly translated into clinical practice around the world.

#### TRIAL SNAPSHOT

**STATUS: RECRUITING**

**PLANNED START DATE: 2016**

**PATIENTS: 139**

**SITES: 25**



# 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 metabolic health and disease; identifying biomarkers for predicting complications in diabetes and assessing epigenetic regulators of insulin gene transcription.



Prof Anand Hardikar,  
Head of Islet Biology  
and Diabetes Group



Dr Mugdha Joglekar,  
Head of Molecular Biology  
and Epigenetics group

## 2019 HIGHLIGHTS

- Whole transcriptome (discovery) analyses using a next-generation sequencing platform and machine learning workflows, identified gene variants that can accurately predict the quality of human islets, before their isolation from a cadaveric donor pancreas. These studies were published in JCI Insight 2019.
- Identified a set of microRNAs that can improve future Type 2 diabetes risk prediction in women with gestational diabetes. This was selected for oral presentation at the American Diabetes Association 2020 meeting and a manuscript is in preparation.
- Identified and validated circulating microRNA biomarkers of Type 1 diabetes and of therapies that aim to retard islet beta-cell function in individuals with newly diagnosed Type 1 diabetes. A subset of these microRNAs was confirmed to regulate factors that promote insulin gene transcription. Data related to some of these studies is being prepared for publication.

## 2019 IN NUMBERS

8
 projects

6
 peer reviewed publications

9
 key collaborators





# 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 babies and pregnancies, and in developing interventions to promote healthy survival.

Our 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 babies and women.

## 2019 HIGHLIGHTS

- CTC's partnership with Miracle Babies Foundation - a consumer body representing parents of premature and sick newborns - received the Australian Clinical Trials Alliance's inaugural award for consumer engagement (see trial in focus).
- The Advancing Large, collectively Prioritised trials of Health outcomes Assessment (ALPHA) collaboration is prioritising core questions for a new generation of affordable therapies and international trials that seek to improve disability-free survival using digital technology.
- Published in the American Journal of Obstetrics and Gynecology, a Phase II trial in 300 women in normal term labour showed that Sildenafil Citrate (Viagra) halved the rate of operative birth for foetal distress by emergency Caesarean Section or vaginal forceps or vacuum delivery.
- Neonatal and perinatal trials coordinated at CTC have generated more than \$22million in project grants.
- Over 7,000 babies recruited to date.

## 2019 IN NUMBERS

**7**  
active trials

**626**  
babies recruited

**67**  
active sites

“We need a new generation of large, collectively prioritised, efficient international trials to improve disability free survival – as envisaged by the ALPHA Collaboration, which was designed to preserve trial integrity in pandemics.”



**PROFESSOR WILLIAM  
TARNOW-MORDI**  
PROFESSOR, NEONATOLOGY



Neonatal and  
Perinatal team

## PRE-TERM BABIES IN AUSTRALIA

**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: Australia Institute of Health  
and Welfare, 2016

## TRIAL IN FOCUS: TORPIDO 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 stopped in 2016 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 TORPIDO 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. The waiver of consent means TORPIDO could finally answer the question around the best oxygen level for preterm babies after 30 years of research, helping babies to survive and lead healthy lives.

### TRIAL SNAPSHOT

**STATUS: RECRUITING**

**START DATE: 2015**

**PATIENTS: 148**

**SITES: 7**





# Health economics

The Health Economics team facilitates 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 healthcare programs to enable policy decision-making across oncology, cardio-metabolic disease and perinatal medicine. They also develop new methods of outcome assessment and resource measurement, and conduct studies to determine patient, clinician and community preferences for healthcare.

Recently the Health Economics team has been exploring ways to improve the design and efficiency of new trials through pre-trial modelling and value of information (VOI) analysis.

## 2019 HIGHLIGHTS

- Whole Brain Radiotherapy trial (WBRT): Prof Rachael Morton was part of the investigator team on this trial that found WBRT did not reduce the spread of melanoma in the brain. The findings from this trial are practice-changing and likely to save costs to the health system (see trial in focus).
- SWIFT study: A total of 177 patients were recruited to determine whether patient reported outcome measures (PROMs) collected at regular intervals can improve quality of life for patients with kidney disease. An audit was conducted on kidney hospitals across ANZ to ascertain current use of PROMs and patient reported experience measures (PREMs).
- The Health economics team completed four health economic analysis plans for trials in infants with cerebral palsy (GAME), prostate cancer (ENZAMET), cancer of the rectum (A La CART), and melanoma genomics (Managing your Risk), providing a detailed plan for data collection, analysis and modelling.
- The team supported two MSAC contracted health technology assessments
- Prof Rachael Morton was elected as co-chair for AHRA's Health Services Research Working Group, and as a Board Director for ACTA.
- The team were investigators on \$10.7m worth of grants awarded from MRFF, WAHTN and the NHMRC.

## 2019 IN NUMBERS

**28**  
active  
projects

**4**  
HEAPS  
(Health economics  
analysis plans)

**17**  
peer  
reviewed  
publications

“Publishing trials with negative outcomes is incredibly important to guide disinvestment in healthcare practices that are not effective or cost-effective. The WBRT trial is a good example of a practice-changing, negative trial.”



**PROFESSOR RACHAEL MORTON**  
PRINCIPAL RESEARCH FELLOW  
HEALTH ECONOMICS



Health  
Economics team

## HEALTH ECONOMICS IN AUSTRALIA

# \$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

Source: Clinical trials alliance, 2017

### STUDY IN FOCUS: WHOLE BRAIN RADIOTHERAPY TRIAL

Can whole brain radiotherapy improve disease control and quality of life in melanoma patients?

#### CHALLENGE

More than 60% of all Stage IV melanoma patients will develop brain metastases at some point. Until recently, melanoma brain metastases carried a poor prognosis, with a median overall survival of about four to five months.

#### TRIAL

This randomised phase III trial aimed to assess the value of treating brain metastases in patients with melanoma using post-operative whole brain radiotherapy (WBRT) in the hope of improving disease control, and quality of life, while maintaining satisfactory cognition.

The primary objective was to determine the effect of WBRT (after localised treatment for melanoma brain metastases) on distant intracranial control, as assessed by MRI scanning. From a health economics perspective the aims were to investigate the costs and health effects of WBRT, and assess the impact of melanoma brain metastases on a person's employment and household income.

Utility-based quality of life of adults treated for melanoma brain metastases was calculated using European Organisation for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30) scores, and transforming them to utilities using the new EORTC Quality of Life Utility Measure-Core 10 dimensions (QLU-C10D) instrument.

This trial was an international, prospective multi-centre, open-label, phase III randomised controlled trial, undertaken in Norway, UK, USA and Australia. Patients aged 18 years or older with 1-3 brain metastases excised and/or stereotactically irradiated and an Eastern Cooperative Oncology Group (ECOG) status of 0-2 were eligible. This trial aimed to provide evidence that was currently lacking in treatment decision-making for patients with melanoma brain metastases.

#### IMPACT

This trial will change oncologists' approach to the treatment of brain metastases of metastatic melanoma. WBRT after resection or stereotactic radiosurgery (SRS) of melanoma brain metastases did not improve outcomes, and therefore oncologists will no longer treat such patients with WBRT. Whether resection and/or SRS is necessary as opposed to combination immunotherapy remains to be determined and will soon be studied in another Australian-based randomized controlled trial. Decisions will have to be individualized, but it is likely patients will be treated with immunotherapy initially, and local WBRT treatment reserved for those who relapse.

#### TRIAL SNAPSHOT

**STATUS: ACTIVE**

**START DATE: 2007**

**PATIENTS: 215**

**SITES: 23**





# Integrating evidence



PROFESSOR LISA ASKIE  
PRINCIPAL RESEARCH  
FELLOW

“We have pushed the boundaries of new evidence synthesis methods so we can continue to improve research transparency and get reliable evidence to consumers and healthcare professionals faster.”

## Australian New Zealand Clinical Trials Registry

The CTC hosts the ANZCTR which is a key piece of national and international research infrastructure. It allows researchers to register their studies prospectively, in order to comply with their scientific and ethical obligations, and to update these registration records regularly as new information comes to hand.



ANZCTR team

### 2019 HIGHLIGHTS

- A study which assessed the ‘Associations between industry involvement and study characteristics at the time of trial registration in biomedical research’ (Seidler AL, Hunter K, Chartres N, Askie L), published in PLoS ONE, provided insight into industry-related clinical trials, assessing whether industry involvement was related to study characteristics. The authors found that industry trials were more likely to focus on treatment and to be prospectively registered when compared to non-industry trials.
- Addition of a map function: This function allows users to more easily find studies occurring near their chosen location, directly facilitating improved recruitment to existing trials.
- Addition of an Excel download function: This function allows users to download into Excel format all publicly available data from all studies registered on the ANZCTR.

### 2019 IN NUMBERS

1,790  
new trials  
registered

3,571  
updates of  
registered  
trials

18,664  
trials now  
registered  
in total on  
ANZCTR

292,403  
unique  
visitors to  
ANZCTR

# Cochrane Breast Cancer Group

For trusted and reliable evidence on questions of health care, the international Cochrane Library is the leading information source. 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. They build on the enthusiasm of authors by providing quality support during protocol and review development, and train new contributors in Cochrane methods.



Cochrane Breast Cancer team

## 2019 HIGHLIGHTS

- Conducted of a priority-setting survey to decide on the most important breast cancer topics to cover in the Cochrane Library. Almost 200 responses were received from doctors, consumers, researchers, nurses, guideline developers and funders from around the world. The survey responses generated a top 10 list of breast cancer topics to meet the needs of our readers.
- An audit of 260 Cochrane reviews showed that most reviews report searching clinical trial registries for information, but do not use this information to help assess bias or describe the completeness of the body of evidence on the review topic. The findings from this audit was accepted as a long oral presentation at the Cochrane Colloquium 2019.
- Cochrane reviews have been used in at least 34 consensus or practice guidelines, including those for the European Society of Medical Oncology and National Institute for Health and Care Excellence (UK). The Cochrane Breast Cancer Group continues to influence clinical practice by publishing relevant and useful Cochrane reviews.
- The 2018 Impact Factor for the Cochrane Breast Cancer Group is 7.375 (16 publications cited 118 times).

## 2019 IN NUMBERS

697

volunteers

(617 authors, 23 editors, 57 consumers)

5

Reviews published

3

Protocols published

1

Priority review published and funded by National Institute of Health Research (UK)



HTA team



# Health Technology Assessment (HTA) Group

The HTA group undertakes systematic reviews, health technology assessments and economic evaluations under contracts with the Commonwealth Department of Health and the National Health and Medical Research Council (NHMRC). The Department of Health work primarily assists the Medical Services Advisory Committee to make decisions on new listings for the Medical Benefits Schedule.

For NHMRC, the HTA group also reviews evidence and provides methodological expertise which is then used to develop health guidelines for Australians.

## 2019 HIGHLIGHTS

- Involved with 25% (3/12) of all HTAs discussed at the most recent Evaluation Sub Committee meeting. This is a significant achievement as 20 HTA groups could potentially do assessments for the Department. If these MSAC assessments are given a positive recommendation, these listings would affect hundreds of thousands of patients.
- Reviews in oncology, cardiovascular, and respiratory medicine.



# Individual participant data and prospective meta-analysis

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 meta-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.

## 2019 HIGHLIGHTS

- The team was awarded a highly competitive NHMRC Ideas Grant for their TOPCHILD project, which aims to bring together researchers from around the world to transform early childhood obesity prevention. This is an outstanding achievement as only 11% of grant applications were funded and TOPCHILD was among the top 5% of the most highest-ranked applications.
- The team published a prestigious Research Methods and Reporting article in the British Medical Journal entitled 'A guide to prospective meta-analysis'. This paper created a high impact in a short time reaching the top 5% of all research outputs scored by Altmetric.
- The team's poster, 'The advantages of prospective meta-analyses in health research', received an award for best moderated poster in category at the ACTA International Clinical Trials Symposium.
- The team's work was accepted for four oral presentations at the 2019 Cochrane Colloquium.
- A long awaited update to a Cochrane review on antiplatelet agents for preventing pre-eclampsia was published by members of the team in the Cochrane Database of Systematic Reviews. The review found that low doses of aspirin in pregnant women reduced the risk of pre-eclampsia and its complications.

IPD/PMA team

METRE team

# 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 European Federation of Clinical Chemistry and Laboratory Medicine Test Evaluation Working Group (EFLM).

## 2019 HIGHLIGHTS

- In collaboration with Abbott Laboratories, the team completed a systematic review on the value of high-sensitivity troponin to guide primary prevention of cardiovascular disease.
- Sally Lord was lead author on the paper 'Setting clinical performance specifications to develop and evaluate biomarkers for clinical use' in collaboration with the EFLM Test Evaluation Working Group.
- Sally Lord was an Investigator on a Health Research Council of New Zealand Project Grant funded project, 'iCare-FASTER'. This multisite study will evaluate the implementation of point-of-care troponin testing in the management of suspected acute myocardial infarction in the Emergency Department.

# 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.

## 2019 HIGHLIGHTS

- The ANZUP trial ENZAMET (see trial in focus, pp 32) achieved its primary objective earlier than planned, using a statistical stopping rule for early termination of the study. The statistical analysis was led by A/Prof Andrew Martin and was published in the NEJM.
- The Australian Trials Methodology Research Network (AusTriM), a newly funded NHMRC Centre of Research Excellence (CRE) in clinical trials methodology, was established to look at ways to enable innovative trial designs, and make sure they deliver valuable results. The CRE will support post-doc and PhD students at the CTC. Professor Ian Marschner and A/Prof Chee Lee are the CRE's Chief Investigator and Associate Investigator.
- Professor Ian Marschner and colleagues published a position paper in the MJA titled, 'Biostatistics: a fundamental discipline at the core of modern health data science', arguing for greater investment in the discipline of Biostatistics.
- This year marked the 10th anniversary of the two day biostatistics workshop for radiation oncology trainees to help them understand trial design and analysis. Now a part of the trainee's formal accreditation process, this year focused on evidence appraisal and time-to-event concepts and was the largest ever attended.

## 2019 IN NUMBERS

**+50**  
trials  
received  
biostatistics  
support

**+9**  
outreach  
partnerships  
with Sydney  
hospitals

**+50**  
peer  
reviewed  
publications

“The newly funded AusTriM will ensure local expertise is taking an international leadership role on methodological innovations for clinical trials.”



**PROFESSOR IAN MARSCHNER**  
PROFESSOR OF BIOSTATISTICS,  
CO-DIRECTOR OF BIOSTATISTICS





Biostats team

## OUTREACH

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

Outreach services are provided to:

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

## TEACHING

CTC Biostatisticians also play a key role in delivering:

- The postgraduate courses of the Master of Clinical Trials Research and the Controlled Trials Unit of the Master of Public Health and Master 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 & Research for Trainees (SMART) workshop, through the Royal Australian & New Zealand College of Radiologists.
- Supervision to postgraduate studies (PhD) and summer research students.

## AUSTRIM: A NEW CENTRE SUPPORTING INNOVATIVE TRIALS

The CTC will perform a key role in a newly funded Centre of Research Excellence (CRE) in clinical trials methodology. The Australian Trials Methods Research Network (AusTriM) has been established in response to a rapidly increasing number of innovative trials designs. The new NHMRC CRE will link leading biostatisticians and methods researchers across the country to help enable innovative trial designs and make sure they

deliver valuable insights for patients. Professor Ian Marschner is one of AusTriM's chief investigators, and Associate Professor Chee Lee is an Associate Investigator. They will be joined by biostatisticians and methods researchers from the administrative hub at Monash University, as well as at other research institutes in Melbourne, Perth, Adelaide and Brisbane.





# Business group

- Approximately 30 staff in the Business Group provide expertise in a range of support areas, including:
- human resources, workforce planning and management (HR team led by Cynthia Carr)
  - financial planning and management (Finance team led by Paul Smyth)
  - data systems, IT infrastructure support (Data and Informatics team led by Mark Maclean)
  - pre and post award grant coordination and contract management (Grants and Contracts team led by Nicole Wong)
  - internal and external communications (Communications team led by Ben Falkenmire)
  - executive and administration support (Administration team led by Susan Lohan).

The Business Group partners with trials staff to provide tailored support and resources to research projects and programs. Their efforts underpin the CTC's achievements and its status as a leading clinical trials centre in Australia and internationally.



Cynthia Carr, HR Manager



Finance team

“The CTC Business Group helps to ensure that the Centre’s strategy is well defined and implemented and that our team of ~220 academic and professional research staff are well supported to do their best work.”



DANIELLE MILLER  
BUSINESS DIRECTOR



# University of Sydney

The CTC is a highly respected research centre within the University's Faculty of Medicine and Health (FMH). CTC researchers work collaboratively with researchers within the FMH and across the University to advance the quality and effectiveness of research. CTC Business Group staff work in partnership with University departments, providing operational support and receiving support in key areas, such as contracts and grants, ethics and regulation, and communications and marketing. CTC's research leaders supervise PhD and Masters students from the University, and they teach subjects in the biostatistics and clinical trials research programs as well as tailored short courses.



## Key collaborators

### AUSTRALIAN CLINICAL TRIALS ALLIANCE

The CTC is a full member of the Australian Clinical Trials Alliance (ACTA), the national body supporting and representing clinician researchers conducting clinical trials, clinical trial registries and coordinating clinical trial centres.

CTC Director Professor John Simes and CTC Deputy Director Professor Tony Keech played lead roles in the establishment of ACTA in 2013. The CTC participates in and supports ACTA events to help advance clinical trial research and make it more integrated with healthcare. The CTC's Professor Rachael Morton is an ACTA Board Director.

### CANCER COOPERATIVE GROUPS

The CTC works collaboratively with key national cancer cooperative groups to design and run clinical trials. The cancer cooperative groups are made up of clinicians and researchers addressing specific types of cancer. Often they will champion the trial with the CTC advising on trial design and coordinating the trial from start to finish, including assessing results. We have collaborated with cancer cooperative groups in over 180 projects with the aim of improving global health outcomes for cancer patients.

We also run the Genomics Cancer Clinical Trials Initiative (GCCTI), funded by Cancer Australia, that supports the 14 national cooperative cancer clinical trial groups to run mutation-specific trials across two or more cancer types or collaborative groups. The GCCTI helps these groups to develop clinical trial protocols by facilitating interaction, and providing support around development of concepts and grant applications through personal consultation and workshops.

### GOVERNMENT

Since its beginnings in 1988, the CTC has received foundational funding from the National Health and Medical Research Council. Funding has typically been provided by the NHMRC in five year blocks. The most recent funding provided by the NHMRC is for the period 2017-2021. The CTC receives funding and support from other government agencies at federal and state levels, including peer reviewed grants for projects and infrastructure from Cancer Australia. It also undertakes health technology assessment services for the federal government's Medical Services Advisory Committee (MSAC).

### HOSPITAL SITES

In the CTC's role as coordinator of trials, our trials operations teams work collaboratively with hospitals across Australia and New Zealand to establish and run trials. This includes working with a hospital's ethics committee that oversee trials, providing information about the trial to encourage hospitals to recruit patients to trials, and coordinating the trial process to ensure each hospital is aware of its responsibilities.

## INDUSTRY

Clinical trials research supported by the pharmaceutical industry is crucial for making many of the advances in healthcare associated with new and existing medicines. The CTC and its academic partners undertake investigator-initiated trials with a number of pharmaceutical companies in key clinical trial areas, where pharmaceutical companies provide funding support and/or investigational product. This investigator-initiated research funded by industry is of clinical and public health importance, where CTC / academic study investigators remain responsible for how the research is conducted, analysed and reported on. Each Trial Management Committee (TMC), comprised of researchers and clinicians, is responsible for key decisions that affect a trial. Publications featuring trial results are drafted and published by leading researchers on the trial. Pharmaceutical companies are given the opportunity to provide input, but ownership of publication content rests with trial researchers. Industry funding accounted for around 40% of CTC funding in 2019. See page p. 88 for a list of companies we work with.

## CONSUMERS

Consumers are people who have lived experience of a health issue. They include patients, families and friends, carers and members of the general public.

As part of the CTC's mission to improve global health outcomes, we engage with consumers around the investigation, design and running of trials to increase a trial's likelihood of making a positive impact on consumers and the health care system in a number of ways.

→ **Oncology:** The CTC works closely with five cancer cooperative groups and their Consumer Advisory Panels that comprise cancer survivors, patients and carers. These panels provide a consumer's perspective on trials, helping to review new trial concepts, identify gaps in research, assist with trial information dissemination, and advise on recruitment strategies.



Melinda Cruz,  
Miracle babies

→ **Diabetes:** The CTC works with consumer advisors on technology-based diabetes studies, in particular the Hybrid Closed Loop and Fame-1 Eye studies (see diabetes section). Consumers provide input into the challenges faced by type 1 diabetes patients and the type of research that is important to them. They also provide feedback on consent forms and, where appropriate, present at forums and talk to the media.

→ **Neonatal & Perinatal:** To improve recruitment of pre term babies to key trials, the CTC is partnered with Miracle Babies Foundation (MBF), a consumer body representing parents of sick newborns. In the current TORPEDO 30/60 trial, MBF helped secure a waiver of consent for the trial, a critical step that sees premature babies – particularly those born at night or on weekends who were often excluded from participating – automatically included in the trial.

→ **Health Economics:** The CTC is working in partnership with consumers to enrich study design and impact in the Melanoma Genomics Managing Your Risk study, the PET/CT melanoma surveillance study, and the symptom monitoring with feedback trial (SWIFT). Consumers help review study designs, lay summaries and manuscripts, and members of a consumer panel in the SWIFT trial participated in grant applications and co-authored publications.

→ **Integrating Evidence:** To help consumers find trials occurring near their physical location, the team behind the Australian New Zealand Clinical Trial Registry recently added a map function to their registry website. The map function allows users to search for trials by location. A consumer can pass on this information to their doctor to help assess their eligibility for a trial.

# CTC community

## 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.

The Centre brings together over 700 outstanding researchers and clinicians from leading NSW institutions to work 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.

## 2019 HIGHLIGHTS

- 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. In 2019, the program reached an exciting milestone by recruiting its 1,000th patient.
- Sydney Catalyst is committed to supporting the development of new concepts and projects through its Pilot and Seed Program. Since 2011, 40 pilot research studies have been funded with many going on to leverage funding from external partners such as the NHMRC. Training and development opportunities are supported through the annual Scholarships and Awards Program.
- New research opportunities were initiated by Research Fellows, Drs Alison Young and Emma Ramsay. Alison's projects focus on smoking cessation and genetic mainstreaming, while Emma is investigating procoagulant platelets as a diagnostic predictor of thrombosis in lung cancer patients.







#### PROFESSOR PHILIP HOGG

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.

#### BIostatISTICS COLLABORATION OF AUSTRALIA

The Biostatistics Collaboration of Australia (BCA) is a consortium of biostatistical experts from around Australia. Representatives from universities, government and the pharmaceutical industry combine to offer a program of distance postgraduate courses via an alliance of six universities. The BCA Coordinating Office is hosted by the CTC.

In the second semester of 2019, 323 students were enrolled (44 new). Since 2003, 658 students have graduated from BCA courses (including 375 Masters awards). We have also delivered one or more BCA units to over 300 non-award students. These graduates will contribute to solving the shortage of well qualified biostatisticians in Australia and internationally.

In 2019, the BCA was awarded the 2019 President's Award for Leadership in Statistics from the Statistical Society of Australia for its' outstanding contribution to statistics since 2001. The BCA has provided Australia with much needed skills in biostatistics, including research in genetics, clinical trials and public health.



# Current CTC trials

As at December 2019

Trial	Participants	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	250	91
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	10
Leep: a Randomised controlled Phase II trial of the pharmacodynamic effects of CDK4/6 inhibitor LEE011 in high risk, localised prostate cancer	Adult males with localised prostate cancer and at least clinical stage T3a Or Gleason score of between 8 and 10 Or Preoperative PSA greater than or equal to 20 ng/ml AND planned for radical prostatectomy	47	8
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	305
GASTRO-INTESTINAL CANCER (COLLABORATING WITH AGITG)			
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	50 (ANZ) 781 (Int'l)	19 (ANZ) 516 (Int'l)
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	460 (ANZ) 1,575 (Int'l)	400 (ANZ) 1,460 (Int'l)
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	90 (ANZ) 350 (Int'l)	65 (ANZ) 112 (Int'l)
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	0
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	14

Trial	Participants	Target	Accrual
CURRENT TRIALS			
NABNEC: Phase II study of nab-paclitaxel and carboplatin as first-line treatment (AGITG and CTC study)	Patients with advanced gastro-intestinal neuroendocrine carcinoma	58	36
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	37
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	280 (ANZ) 570 (Int'l)	231 (ANZ) 524 (Int'l)
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	30 (ANZ) 76 (Int'l)	21 (ANZ) 78 (Int'l)
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	58	36
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	101
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 neuroendocrine tumours	72	75
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
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	246
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)	25 (ANZ) 80 (Int'l)



Trial	Participants	Target	Accrual
CURRENT TRIALS			
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	17
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)	0 (ANZ) 36 (Int'l)
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	0
TRIALS IN FOLLOW-UP			
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)	67 (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) 919 (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)	341 (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)

UROGENITAL CANCER (COLLABORATING WITH ANZUP)

TRIALS IN START-UP			
DASL-HiCaP: Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (ANZUP1801). A randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer.	Men aged 18 years and older, with pathological diagnosis of adenocarcinoma of the prostate	1100	N/A

Trial	Participants	Target	Accrual
CURRENT TRIALS			
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	48
TRIALS IN FOLLOW-UP			
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	30
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	127

MOLECULAR SCREENING AND THERAPEUTICS PROGRAM (MOST) (COLLABORATING WITH AGCMC)

TRIALS IN START-UP			
MoST 6: Single arm, open label, signal seeking, phase IIa trial of the activity of larotrectinib in patients with advanced NTRK1-3 positive tumours	Please complete	32	N/A
MoST 7: Single arm, open label, signal seeking, phase IIa trial of the activity of Tremelimumab in patients with advanced rare or neglected cancers	Patients with advanced rare or neglected cancers	48	N/A
MoST 8: Single arm, open label, signal seeking, phase IIa trial of the activity of trastuzumab emtansine (T-DM1) in patients with tumours harbouring HER2 amplifications or mutations	Patients with tumours harbouring HER2 amplifications or mutations	32	N/A

CURRENT TRIALS			
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	8
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	4

Trial	Participants	Target	Accrual
<b>LUNG CANCER (COLLABORATING WITH ALTG)</b>			
<b>CURRENT TRIALS</b>			
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)	11 (ANZ)
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)	111 (ANZ)
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	91
<b>TRIALS IN FOLLOW-UP</b>			
BR34: A Randomized Trial of Durvalumab and Tremelimumab +/- Platinum Based Chemotherapy in Patients with Metastatic (Stage IV) Squamous or Non-Squamous Non-Small Cell Lung Cancer (NSCLC)	Patients with Metastatic (Stage IV) Squamous or Non-Squamous Non-Small Cell Lung Cancer (NSCLC)	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	100 (ANZ) 1,360 (Int'l)	111 (ANZ)
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	120	50
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	49
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)	5 (ANZ) 151 (Int'l)
<b>BRAIN CANCER (COLLABORATING WITH COGNO)</b>			
<b>TRIALS IN START-UP</b>			
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	36 (ANZ) 360 (Int'l)	N/A
LUMOS: Low & Intermediate Grade Glioma Umbrella Study of Molecular Guided Therapies (Pilot study)	Adults, aged 18 years and older, with histological confirmed grade 2 or 3 glioma at initial diagnosis.	10	N/A
MAGMA: Multi-Arm GlioblastoMa Australasia Trial	Adults, aged 18 years and older, with newly diagnosed histologically confirmed grade IV malignant glioblastoma	300	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	33 (ANZ) 180 (int'l)	N/A

Trial	Participants	Target	Accrual
<b>CURRENT TRIALS</b>			
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	48
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	30
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	127
<b>TRIALS IN FOLLOW-UP</b>			
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	30
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	127
<b>MOLECULAR SCREENING AND THERAPEUTICS PROGRAM (MOST) (COLLABORATING WITH AGCMC)</b>			
<b>TRIALS IN START-UP</b>			
MoST 6: Single arm, open label, signal seeking, phase IIa trial of the activity of larotrectinib in patients with advanced NTRK1-3 positive tumours	Please complete	32	N/A
MoST 7: Single arm, open label, signal seeking, phase IIa trial of the activity of Tremelimumab in patients with advanced rare or neglected cancers	Patients with advanced rare or neglected cancers	48	N/A
MoST 8: Single arm, open label, signal seeking, phase IIa trial of the activity of trastuzumab emtansine (T-DM1) in patients with tumours harbouring HER2 amplifications or mutations	Patients with tumours harbouring HER2 amplifications or mutations	32	N/A
<b>CURRENT TRIALS</b>			
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	8
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	4



Trial	Participants	Target	Accrual
TRIALS IN FOLLOW-UP			
MoST 1: Single-arm open-label signal-seeking Phase Ib/Ila 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
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	114
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	49

## CARDIOMETABOLIC 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)	N/A
FOURIER Legacy: Long-term Study of LDL-c Lowering with Evolocumab: Observational Follow-up after the FOURIER Outcomes Study	Participants in the FOURIER OUTCOMES trial	10,000 (Int'l)	N/A

CURRENT TRIALS			
RESTORE-MI: 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	Adults with STEMI	800 (1,666 registered)	18 registered 8 randomised
SWIFT (Pilot): Symptom monitoring with feedback trial (SWIFT) Pilot: A feasibility and acceptability study of ANZDATA e-PROMS data capture and feedback.	Adults with end-stage kidney disease receiving in-centre haemodialysis.	318	163

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

## 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	209 registered 145 randomised
Hybrid closed loop — paediatric cohort: Performance of closed-loop artificial pancreas at home compared with best available technology	People with Type 1 diabetes: paediatric cohort	160	171 registered 135 randomised

Trial	Participants	Target	Accrual
TRIALS IN FOLLOW UP			
Hybrid closed loop — adult cohort: Performance of closed-loop artificial pancreas at home compared with best available technology	People with Type 1 diabetes: Adult cohort	120	148 registered 120 randomised

## NEONATAL AND PERINATAL

CURRENT TRIALS			
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	43
LEAP: Lactoferrin evaluation in anaemia in pregnancy (CTC-led study)	Pregnant women with anaemia	800	289
PAEAN: Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy (CTC-led study)	Newborn infants with signs of brain damage	300	237
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	129
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	417

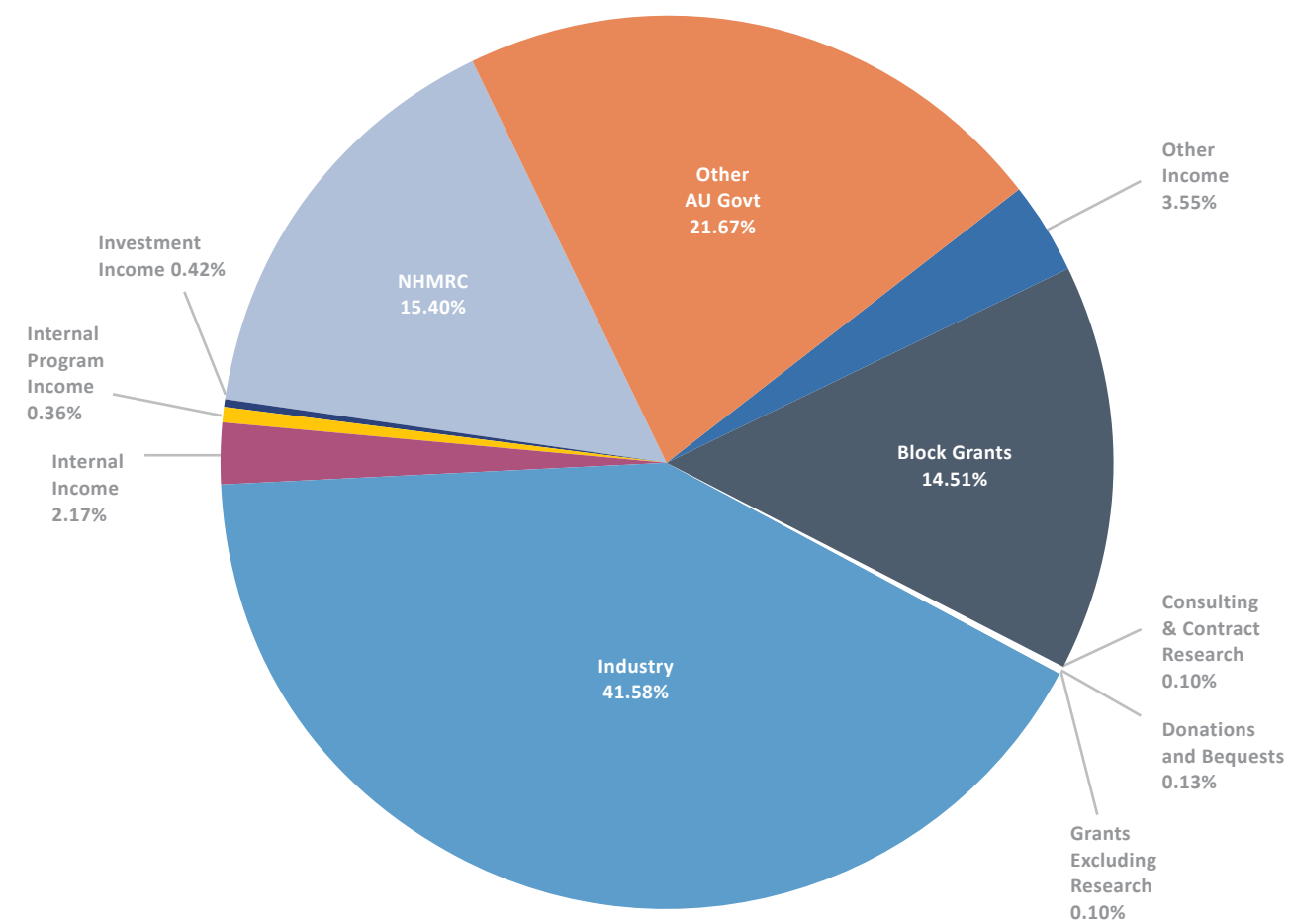
TRIALS IN FOLLOW-UP			
APTS: Australian placental transfusion study (CTC-led study)	Neonates born before 30 weeks gestation	1,600	1,634
LIFT: Lactoferrin infant feeding trial (CTC-led study)	Infants born weighing under 1,500g	1,100	1,542



# Funding

The CTC continues to receive highly sought-after national and international peer reviewed funding, as well as pharmaceutical industry support.

- Our 2019 annual income of \$49.5m reflects:
- the quality of our research
  - the strength of our collaborations
  - our innovative edge in academic clinical trials





# CTC staff awards

The following CTC staff were recognised in 2019 for their outstanding contribution to the CTC.



## ACADEMIC AWARD FOR RESEARCH EXCELLENCE: Alicia Jenkins, Professor, Diabetic and Vascular Medicine

→ Alicia started the year with the publication of a chapter in a book on Cardiovascular medicine in primary care settings and finished the year with the most grants submitted, papers published, and students mentored. She was also active in outreach activities as President of Insulin for Life, with IDF Life for a Child, Diabetes Australia, as the Western Pacific Region Executive Council member of IDF, and in her primary investigator role on a funded IDF Global grant.



## ACADEMIC AWARD FOR A RISING STAR: Lene Seidler, Systematic Reviews Biostatistician

→ Lene leaped ahead this year in her work researching and sharing knowledge around the next generation of systematic reviews, prospective meta-analysis (PMA). She was lead author on the BMJ paper 'A guide to PMA', which

has been read over 7,000 times since its publishing date, she co-presented at the Cochrane Colloquium in Chile on PMA, was co-author on a paper on the prevalence of trial registration, and was a major reason the ideas grant TOPCHILD was awarded NHMRC funding.



## RESEARCH AWARD FOR PROFESSIONAL STAFF: Hannora Jurkovic, Clinical Trials Program Manager (Oncology)

→ Hannora championed instrumental process improvements throughout the year to make CTC trial operations more effective and robust, including spearheading the selection and implementation of the Clinical Trials Management System (CTMS) and an electronic Trial Master File system (eTMF), refining trial operations roles to be more focussed and meaningful, leading excellent relationships with our collaborative trial groups, in particular with ANZGOG and ALTG, and fostering a positive and supportive team environment for Oncology trials staff.



## LEADERSHIP AWARD: Martijn Oostendorp, Clinical Trials Program Manager (Oncology)

→ Martijn has demonstrated outstanding leadership skills and unwavering commitment to the CTC, resulting in significant improvements in clinical trial operations including: revision of Position Descriptions for trials staff, development of a 'distinct trials' stream in the Oncology Program, input into generic eCRFs, the eTMF and CTMS, and much more. Martijn's expertise in clinical trials enables him to provide invaluable advice to his colleagues and his team, he is a great listener and he frequently goes above and beyond to ensure projects are completed on time and to the highest standard.



## ACHIEVEMENT AWARD FOR PROFESSIONAL STAFF: Lena Germinarios, CTC Workforce Coordinator

→ Lena covered two roles for lengthy periods in 2019, willingly taking on additional duties above her current workload and identifying new processes that improved processing and tracking. Lena frequently worked from home after hours and over weekends to make sure that all

CTCHR deadlines were met and there was minimal impact or disruption, and she also took on the supervision of our receptionists and other administrative staff.



## ACHIEVEMENT AWARD FOR PROFESSIONAL STAFF: Emily Tu, Senior Trial Operations Coordinator

→ Emily demonstrated strong leadership skills managing multiple priorities on the ENZAMET trial in a very challenging year and delivering on time. Emily's ability to maintain a consistent and sharp focus on high priority areas was greatly appreciated by her colleagues, as was her high degree of professionalism when dealing with stakeholders and collaborators of the ENZAMET and ENZARAD trials.



## MAKING A DIFFERENCE AWARD: Carlos Sterling, Finance Officer

→ Carlos went above and beyond in his role as Finance Officer in 2019, mentoring Sydney Catalyst staff to develop their finance and budgeting skills and make crucial strategic decisions. He invested countless hours explaining

complex processes to staff, made time to answer questions, and helped ensure smooth transitions for senior staff changes, all with enthusiasm and a positive attitude, making Sydney Catalyst forget they are only one of the many groups Carlos assists.

## TEAM SPIRIT AWARD: Prospective Meta-Analysis Methods team

→ The PMA team had a ground breaking year publishing 'A guide to PMA' in the BMJ which has been read more than 7,000 times since October. They also won best moderated poster at ACTA, featured two posters at the NHMRC Symposium and three posters at the Cochrane Colloquium, and received NHMRC funding for ideas grant TOPCHILD.



## INNOVATION AWARD: Salma Fahridin, Head of Clinical Data Management

→ Salma calved out a new operations team at the CTC this year - Clinical Data Management – which is the missing link between Trials Operations, Clinical Data Systems and Biostatistics. The new team will ease the process of extracting data from trial databases to garner operational insights. Salma turned ideas into positions, creating a team of eleven staff from scratch and coordinating the creation of new Trials Data Committee which will address key data issues each team encounters.

## INNOVATION AWARD (TEAM): MoST team

→ The MoST team moved across to the Medidata platform in 2019, collaborating with other teams to create a platform for MoST that will deliver value for years to come. This involved refining data, reviewing reference materials, creating reports to complement Medidata, and contributing to materials that will be widely beneficial for CTC staff.



## LIVING OUR VALUES AWARD: Chris Brown, Clinical Biostatistician - Research Fellow

→ Chris played a pivotal role in helping the Clinical Data Systems team to create solutions for the Clinical Trial Operations team. Chris went beyond his job description, sharing his expertise in statistics and lateral thinking, to help find solutions that will benefit anyone working with trial data. He also performed a mentor role to members of the Clinical Data Systems team in the process, demonstrating his leadership skills, selflessness, and commitment to an even smarter, more efficient CTC.

CTC Executive

John Simes, Director  
Tony Keech, Deputy Director  
Danielle Miller, Business Director  
Burcu Vachan, Director Clinical Trial Operations Development

Strategic Development

Wendy Hague, Clinical Trials Strategic Development Director

Executive Support

Paulette Anderson, Executive Assistant  
Susan Lohan, Executive Assistant

Oncology Trials Program Managers

Hannora Jurkovic, Clinical Trials Program Manager  
Martijn Oostendorp, Clinical Trials Program Manager  
Lucille Sebastian, Clinical Trials Program Manager (MoST)  
Kate Wilson, Research Development Manager

Oncology Clinical Trial Operations Leads

Christine Aiken, Clinical Trial Operations Lead (AGITG)  
Sandra Bahamad, Clinical Trial Operations Lead (AGITG)  
Karen Bracken, Clinical Trial Operations Lead (DASL-HiCaP)  
Sarah Chinchén, Clinical Trial Operations Lead (MoST)  
Xanthi Coskinas, Clinical Trials Program Manager (ENZAMET/ENZARAD)  
Katrina Diamante, Clinical Trial Operations Lead (ANZGOG)  
Kate Ford, Clinical Trial Operations Lead (ANZUP)  
Merryn Hall, Clinical Trial Operations Lead (COGNO)  
Anthony Jaworski, Clinical Trial Operations Lead (INTEGRATEII)  
Eric Tsobanis, Clinical Trials Operations Lead (INTEGRATEII)  
Mariya Walker, Clinical Trial Operations Lead (ALTG)  
Anna Walsh, Clinical Trial Operations Lead (CannabisCINV)

Oncology Research Development Leads

Candace Carter, Research Development Lead (COGNO)  
Margot Gorzeman, Research Development Lead (ANZUP)  
Ann Livingstone, Research Development Lead (Oncology Support)  
Jenna Mitchell, Research Development Lead (ALTG)  
Michelle Parry, Research Development Lead (ALTG)  
Kate Wilson, Research Development Manager (AGITG)  
Sarah York, Research Development Lead (ANZGOG)

Oncology Trials Staff

Amasy Alkhateeb, Senior Trial Operations Coordinator  
Lisa Bailey, Senior Trial Operations Coordinator  
Kirston Barton, Trial Operations Coordinator  
Anjali Bhardwaj, Senior Trial Operations Coordinator  
Nathan Bradshaw, Trials Operations Coordinator  
Lesley Brassel Ngo, Senior Trial Operations Coordinator  
Hannah Cahill, Senior Trial Operations Coordinator  
Mariam Chendeb, Clinical Trials Assistant  
Yvonne (Ching Loong) Cheung, Trial Operations Coordinator  
Wiza Chileshe, Clinical Trials Assistant  
Jennifer Chong, Trial Operations Coordinator  
Frances Daley, Trial Operations Coordinator  
Sarah Finlayson, Senior Trial Operations Coordinator  
Lauren Fisher, Senior Trial Operations Coordinator  
Kathleen Harwood, Clinical Trials Assistant  
Stephanie Hollis, Trial Operations Coordinator  
Marzena Kucharska-Kelly, Trial Operations Coordinator  
Ashneeta Kumar, Trial Operations Coordinator  
Lenna Lai, Clinical Trials Assistant  
Ailsa Langford, Senior Trials Operations Coordinator  
Loc (Phuoc) Le, Trial Operations Coordinator  
Margaret Lett, Trial Operations Coordinator  
Joseph Levitt, Senior Trial Operations Coordinator  
Tracy Liaw, Trial Operations Coordinator  
Anneliese Linaker, Clinical Trials Assistant  
Juanita Lopez Gaitan, Clinical Trials Assistant  
Magda Luciuk, Clinical Trials Assistant  
Kristen McParland, Trial Operations Coordinator  
Catherine O'Connor, Trial Operations Coordinator  
Muslima Rahman, Clinical Trials Assistant  
Aliko Rasmiena, Trial OperationsCoordinator  
Tet (Marie Antonette) Ricafort, Trial Operations Coordinator  
Georgia Rook, Clinical Trials Assistant  
Timothy Roque, Clinical Trials Assistant  
Hayley Thomas, Clinical Trials Assistant  
Evonne Tim, Senior Trial Operations Coordinator  
Jason Todd, Senior Trial Operations Coordinator  
Emily Tu, Senior Trial Operations Coordinator  
Diana Winter, Senior Trial Operations Coordinator  
Shirley Yung, Senior Trial Operations Coordinator  
Amy Zhong, Trial Operations Coordinator

Oncology Translational Research Team

**Led by Sonia Yip, Oncology Translational Research Manager**  
Garry Chang, Senior Translational Research Operations Officer  
Kathleen Harwood, clinical Trials Assistant  
Michelle Parry, Senior Translational Research Operations Officer  
Georgia Rook, Clinical Trial Assistant  
Timothy Roque, Clinical Trial Assistant

Oncology Clinical Team

**Led by Martin Stockler, Co-Director of Cancer Trials**  
Chee Lee, Clinical Lead  
Hao-Wen Sim, Clinical Lead  
Katrin Sjoquist, Clinical Lead  
Belinda Kiely, Senior Research Fellow  
Chen (Yeh Chen) Lee, Oncology Research Fellow  
Peey-Sei Kok, Oncology Research Fellow  
Benjamin Kong, Oncology Research Fellow  
Rebecca Merceica-Bebber, NHMRC Early Career Fellow  
Antony Mersiades, Oncology Research Fellow  
Sayeda Naher, Oncology Research Fellow  
Felicia Roncolato, Research Fellow  
Zarka Samoon, Oncology Research Fellow  
Shalini Subramaniam, Oncology Research Associate  
Alison Zhang, Oncology Research Fellow

Cardiovascular/Diabetes Trials Staff

**Led by Rebecca Mister, Clinical Trials Program Manager**  
San Yip Chan, Clinical Trials Assistant  
Li Ping Li, Project Manager  
Helen Pater, Project Manager  
Jessie Payne, Trial Operations Coordinator  
Portia Westall, Trial Operations Coordinator  
Annie Yeung, Clinical Trial Operations Lead

Cardiovascular/Diabetes Clinical Team

**Led by Alicia Jenkins, Professor, Diabetes & Vascular Medicine**  
Sharon Atkinson-Briggs, PhD student  
Laima Brazionis, Senior Lecturer  
Luke Carroll, Research Assistant  
Fahmida Ema, Research Assistant Molecular Biology  
Anandwardhan Hardikar, JDRF Career Devt Fellow; Associate Professor, Genetics and Epigenetics  
Andrzej Januszewski, Senior Research Fellow  
Mugdha Joglekar, JDRF Postdoctoral Fellow  
Hilary Richardson, Developer/Programmer  
Chris Ryan, Developer/Programmer  
Wilson Wong, Postdoctoral Research Fellow  
Emma Scott, PhD student

Neonatal and Perinatal Trials Team

**Led by Alpana Ghadge, Clinical Trials Program Manager**  
Rebecca Brown, Senior Trial Operations Coordinator  
Sarah Finlayson, Senior Trial Operations Coordinator  
Shannon Hunt, Trial Operations Coordinator  
Jessie Payne, Trial Operations Coordinator  
Isabella Richardson, Clinical Trials Assistant  
Carbo (Ka Yan) Yeung, Trial Operations Coordinator

Neonatal and Perinatal Clinical Team

William Tarnow-Mordi, Professor, Neonatology

Ethics and Regulatory

Rebecca Mister, Ethics Lead  
Lara Hall, Senior Ethics and Regulatory Coordinator  
Hira Saud, Ethics and Regulatory Coordinator  
Cecilia Taing, Clinical Trials Assistant, Ethics and Regulatory

Health Economics

**Led by Rachael Morton, Professor Health Economics**  
Kathleen Dempsey, Research Fellow  
Mbathio Dieng, Research Fellow  
Nikita Khanna, Research Assistant  
Stephen Law, Senior Research Fellow  
Ann Livingstone, PhD Candidate  
Karan Shah, Health Economist

Systematic Reviews

**Led by Lisa Askie, Principal Research Fellow Health Economics**  
Blaise Agresta, Health Technology Assessment Lead  
Hannah Ahern, Systematic Reviews - Project Administrator  
Angie (Ekaterina) Barba Malespin, Senior Project Officer  
Slavica Berber, Project Officer - Health Technology Assessment Team  
Vendula Blaya-Novakova, Project Officer - Health Technology Assessment Team  
Saskia Cheyne, Senior Evidence Analyst  
Kylie Hunter, Senior Systematic Reviews Project Officer  
Sally (Sarah) Lord, Senior Research Fellow  
Lene (Anna) Seidler, Systematic Reviews Biostatistician (Research Fellow)  
Lukas Staub, Clinical Epidemiologist  
Ava Tan-Koay, Senior Project Officer  
Melina Willson, Project Manager  
Matthew Wynn, Systematic Reviews Coordinator

Biostatistics

**Led by Val GebSKI & Ian Marschner, Co-Directors of Biostatistics and Research Methodology**  
Nanda Aryal, Biostatistician  
Rebecca Asher, Biostatistician  
Liz (Elizabeth) Barnes, Research Fellow  
Chris Brown, Research Fellow  
Kate Brewer, Biostatistician  
Karen Byth Wilson, Biostatistician  
Vanessa Cochrane, Admin Officer  
David Espinoza, Biostatistician  
Gillian Heller, Professor of Biostatistics  
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, Program Coordinator, Sydney Catalyst  
Bea Brown, Manager, EnRICH Program  
Michael Boyer, Director, Sydney Catalyst  
Spoorthi Gowda, Clinical Data Coordinator, EnRICH Program  
Merylín Heuschkel, Manager, Sydney Catalyst  
Kimberley Mander, Research Officer, EnRICH Program  
Cara McFarlane, Events and Communications Officer, Sydney Catalyst  
Alison Young, T1T2 Research Fellow, Sydney Catalyst

COGNO

**Led by Jenny Chow, ExecutivE Officer**  
Yi Feng, Project Officer  
Danielle Massey, Project Officer  
Mythily Sachchithananthian, Senior Project Officer, BCBA, COGNO

Clinical Quality and Compliance

**Led by Kate Sawkins, Clinical Quality and Compliance Manager**  
Karen Wilkinson, Program Co-Ordinator  
Quality Assurance and Auditor

Clinical Data Management Group

**Led by Salma Fahrudin, Head of Clinical Data Management**  
Leanna Cheung, Clinical Data Manager  
Georgina Dukoska, Clinical Data Manager  
Vevian Evans, Clinical Data Manager  
Tara Flores, Clinical Data Manager  
Savita Iyer, Senior Clinical Data Manager  
Shradha Kadam, Clinical Data Programmer  
Ashneeta Kumar, Clinical Data Manager  
Sandra Lee, Clinical Data Manager  
Talia Palacios, Senior Clinical Data Manager  
Raynelle Penafior, Clinical Data Manager  
Thida Thein, Clinical Data Manager  
Lisa Valenti, Clinical Data Programmer

Data & Informatics Group (DIG) & Informatics

DIG: Clinical Data Systems

**Led by Ilka Kolodziej, Clinical Data Systems Manager**  
Danielle Parker, Clinical Data Systems Coordinator  
Nicole McKay, Clinical Data Systems Coordinator  
Louisa Muhuthia, Clinical Data Systems Coordinator  
Sharmila Siriragavan, Clinical Data Systems Coordinator

DIG: Information Systems Development

Seshu Atluri, Software Developer  
Colin Sutton, IT Systems Development Manager  
Anh Tai Nguyen, Database Manager

DIG: Information Systems and Support

Ha (Manh Ha) Le, Desktop Support Officer  
Asanka Perera, Infrastructure Support  
Dinh Tran, Manager, IS&S Infrastructure Support

Business Group

**Led by Danielle Miller, Business Director**  
Rebecca Blain, Receptionist/Admin Assistant  
Ellen Brodie, CTC Research Support Co-ordinator  
Cynthia Carr, HR/Admin Manager  
Libby (Elizabeth) Cregan, Receptionist/Admin Assistant  
Suzanne Everett, Business Support Coordinator  
Ben Falkenmire, Communication Specialist  
Lena (Magdalena) Germinarios, CTC Workforce Coordinator  
Sherilyn Goldstone, Medical Writer  
Yumi Guo, Contracts & Grants Coordinator  
Agnes Ho, Finance Officer  
Maki Joseph, Finance Officer  
Sarah Munro, Communications Officer  
Paul Smyth, Finance Manager  
Carlos Sterling, Finance Officer  
Nicole Wong, Contracts and Grants Manager  
Marina Zadonskaia, Admin Officer, Business Group



# Supervision of postgraduate research

## Professor John Simes

**PhD:** Saskia Cheyne, Doah Cho, Xanthi Coskinos, Anna-Lene Seidler, Katrin Sjoquist, Monica Tang

## Professor Lisa Askie

**PhD:** Karen Bracken (completed), Saskia Cheyne, Anna Lene Seidler  
**Summer students:** Zachary Blood, Dinneth Fonseka, Danai Modi, Anooj Ghadge, Aidan Tan, Gemma Xu

## Professor Val Gebski

**PhD:** Alan Garner (completed), Katherine Francis

## Anand Hardikar

**PhD:** Luke Carroll, Ho Pham, Vijit Saini, Dr Emma Scott  
**Masters:** Cody Lee Maynard  
**Summer students:** Alissa Chaitarvornkit, Mariah Taleb

## Andrzej Januszewski

**PhD:** Dr Emma Scott  
**Summer students:** Benjamin Rao

## Professor Alicia Jenkins

**PhD:** Dr Emma Scott, Sharon Atkinson-Briggs, Jason Chiang  
**DMedSci:** Dr Graham Ogle  
**Summer students:** Hayden Young, Benjamin Rao, David Chen, Sabrina Chia, Stefanie Law

## Mugdha Joglekar

**PhD:** Ho Pham  
**Masters:** Cody Lee Maynard  
**Summer students:** Alissa Chaitarvornkit, Mariah Taleb

## Professor Anthony Keech

**PhD:** Karen Bracken (completed).

## Professor Chee Lee

**PhD:** Katherine Francis, Peey-Sei Kok, Doah Cho, Angelina Tjokwidjaja, Monica Tang  
**Masters:** Jovana Babic

## Sally Lord

**PhD:** Doah Cho, PeeySei Kol, AngelinaTjokrowidjaja, Katherine Francis, Ziad Al-Rubaie  
**Masters:** Jovana Babic

## Professor Rachael Morton

**PhD:** Anu Agarwal, Ann Livingstone, Marcus Sellars, Barney Hole, Laverne Lok  
**Summer students:** Dinneth Fonseka, Zachary Blood

## INDUSTRY PARTNERS

The following companies provided funding, drugs or services to CTC-coordinated trials in 2019:

Abbott Laboratories  
AbbVie  
Amgen  
Apotex  
Aspen Pharmacare  
Astellas Scientific and Medical Affairs  
AstraZeneca  
Australia’s Nuclear Science and Technology Organisation  
Bayer  
BGP Products Operations  
Bionomics Ltd  
Boston Biomedical  
Bristol Myers Squibb  
Eisai Inc  
Eli Lilly and Company  
Epworth Healthcare  
European Thoracic Oncology Platform  
Fournier  
Hammondcare Health and Hospitals Limited  
Health Education & Training Institute  
Macquarie Stem Cells Pty Ltd  
MD Anderson Cancer Centre  
Medical Developments International Limited  
Medtronic  
Merck  
Mylan  
Novartis  
Omegapharm  
Pharmaceutical Packaging Professionals  
PharmaCo  
PCI Pharma Services  
Roche  
Sanofi-Aventis  
Specialised Therapeutics (STA)  
Tilray

# Publications

For the 2019 calendar year

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88 CLINICAL TRIALS CENTRE

2019 RESEARCH REPORT 89

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# Glossary

<b>ACTA</b>	Australian Clinical Trials Alliance
<b>AGCMC</b>	Australian Genomic Cancer Medicine Centre
<b>AGITG</b>	Australasian Gastro-Intestinal Trials Group
<b>ALTG</b>	Australasian Lung Cancer Trials Group
<b>ANZCTR</b>	Australian New Zealand Clinical Trials Registry
<b>ANZGOG</b>	Australia and New Zealand Gynaecological Oncology Group
<b>ANZUP</b>	Australian and New Zealand Urogenital and Prostate Cancer Trials
<b>ASCO</b>	American Society of Clinical Oncology
<b>AusTriM</b>	Australian Trials Methodology Research Network
<b>BCA</b>	Biostatistics Collaboration of Australia
<b>BCT</b>	Australian Breast Cancer Trials Group
<b>CCTG</b>	Canadian Cancer Trials Group
<b>COGNO</b>	Cooperative Trials Group for Neuro-Oncology
<b>CRE</b>	Centre of Research Excellence
<b>CTC</b>	Clinical Trials Centre
<b>GCCTI</b>	Genomics Cancer Clinical Trials Initiative
<b>HTA</b>	Health Technology Assessment
<b>IPD/PMA</b>	Individual Participant Data and Prospective Meta-analysis
<b>METRE</b>	Medical Test Research
<b>MoST</b>	Molecular Screening and Therapeutics Program
<b>MRFF</b>	Medical Research Future Fund
<b>MSAC</b>	Medical Services Advisory Committee
<b>NHMRC</b>	National Health and Medical Research Council
<b>PREMs</b>	Patient Reported Experience Measures
<b>PROMs</b>	Patient Reported Outcome Measures
<b>SNO</b>	Society of Neuro-Oncology
<b>TR</b>	Translational Research





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