

# 2020 Research Report



THE UNIVERSITY OF  
SYDNEY



# 2020 Research Report



We acknowledge the tradition of custodianship and law of the Country on which the University of Sydney campuses stand. We pay our respects to those who have cared and continue to care for Country.







## CONTENTS

<b>8</b>	Directors' Report
<b>12</b>	Strategy
<b>16</b>	2020 Awards
<b>18</b>	Oncology Research
	– Oncology Research Development
	– Brain cancer (COGNO)
	– Gastro-intestinal cancer (AGITG)
	– Gynaecological cancer (ANZGOG)
	– Lung cancer (ALTG)
	– Urogenital cancer (ANZUP)
	– Molecular screening and therapeutics program (MoST)
	– Other cancer research
	– Novel collaborations
	– Translational research
<b>40</b>	Cardiovascular research
<b>44</b>	Diabetes research
<b>45</b>	Kidney health research
<b>50</b>	Neonatal and perinatal research
<b>54</b>	Health economics
<b>57</b>	Health technology assessment
<b>58</b>	Evidence Integration
	– Australian New Zealand Clinical Trials Registry (ANZCTR)
	– Cochrane Breast Cancer Group
	– Next Generation Methods
<b>64</b>	Biostatistics
<b>66</b>	Business group
<b>69</b>	Key Collaborators
<b>71</b>	CTC Community
<b>74</b>	Current CTC trials
<b>84</b>	Staff awards
<b>86</b>	Staff list
<b>89</b>	Publications

## 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.

### Evidence

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

### Innovation

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

## 2020 in numbers



## DIRECTORS' REPORT

Since our establishment in 1988, the CTC has grown from an initial staff of 10 to more than 240 staff members in 2020, working with over 1000 collaborators around Australia and internationally. Today, over 30 years later, our initial mission remains unchanged: to improve practice, policy and health outcomes through the better use of clinical trials research.

A measure of the impact of the CTC's research is our field-weighted citation impact (FWCI). The global FWCI mean is set at 1.0, and this benchmark is often used to rank international research groups. Over the past 10 years, the CTC's FWCI measure was 3.52, which compares favourably with many other research organisations. This is an excellent indication of the quality and impact of the research we undertake across trials and trials methodology, and how highly valued it is by our peers globally.

Clinical trials research is a huge undertaking, and our achievements would not be possible without the enormous collaborative efforts of our team and partners—from clinical investigators, trial coordinators, data managers and consumers, to those with expertise in trial design, biostatistics, health economics and translational sciences. Our partnerships with national cancer cooperative groups, other international cardiovascular, diabetes and perinatal trial networks, the OMICO collaboration and our many international partners as well as government, industry, the Australian Clinical Trials Network (ACTA) and hospitals and patients have been key to our research effort this year.

Some of the highlights of 2020 include three new clinical trial initiatives: the DREAM3R, INTEGRATE IIB and COLCARDIO-ACS studies.

- DREAM3R is an international multi-centre trial of chemo-immunotherapy in patients with advanced malignant pleural mesothelioma, with the CTC and the Thoracic Oncology Group of Australasia (TOGA) leading the trial in Australia and New Zealand. Pleural mesothelioma is a particularly aggressive cancer, with most patients surviving less than a year after diagnosis. Current treatment involves surgery and chemotherapy, and two earlier small-scale studies have indicated that adding durvalumab, an immunotherapeutic agent, to standard chemotherapy can benefit these patients. DREAM3R aims to determine whether combined treatment with this immunotherapeutic agent and standard chemotherapy can improve survival time in these patients.
- INTEGRATE IIB is an international multi-centre trial of the combination of regorafenib and nivolumab that aims to determine whether this combination therapy can prolong survival in patients with advanced gastro-oesophageal cancer who have not responded to earlier chemotherapies. These patients have a very poor prognosis, and as yet, there is no established treatment for this group. This international trial is being coordinated by the CTC in collaboration with the Australasian Gastro-Intestinal Trials Group (AGITG) and follows on from the successful international phase II INTEGRATE trial, which first indicated that regorafenib may be useful in this cancer type. →

“Today, over 30 years later, our initial mission remains unchanged: to improve practice, policy and health outcomes through the better use of clinical trials research.”



PROFESSOR JOHN SIMES, DIRECTOR



- The COLCARDIO-ACS study, led by the CTC's Cardiovascular team, aims to determine whether giving daily low-dose colchicine, a commonly prescribed anti-inflammatory drug, as well as standard medical care reduces the rate of subsequent cardiac events in people who have had an initial cardiac event, and who have persistently high levels of inflammatory markers in their blood 4–6 weeks after their first heart attack. These patients are at high risk of having another heart attack and are expected to gain the most benefit from colchicine. The results of this trial will contribute a major addition to the evidence about treating this high-risk group and could provide a cheap and effective therapy option to those with the greatest need.

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

In another highlight for 2020, the ENZAMET trial, a collaboration between the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) and the CTC, was awarded the ACTA Trial of the Year Award, the ACTA STInG Award for Excellence in Trial Statistics and the Consumer Involvement Award. This landmark study has shown that hormone therapy with enzalutamide can significantly improve the survival of men with advanced prostate cancer; and the results are already changing global practice in the treatment of prostate cancer.

In February 2020, the CTC underwent an external review to help plan our future strategy and allow us to continue to improve health outcomes for decades to come. The review was conducted by a panel of experts: Professor Lesley Seymour, Director of Investigational New Drug Program, Deputy Director of the Canadian Cancer Trials Group; Professor John McNeil, Professor of Epidemiology and Preventive Medicine at Monash University; Dr Anna Lavelle, Chair of Medicines Australia; and Mr Marc Buyse, the Chief Scientific Officer of the International Drug Development Institute in San Francisco. The review concluded that the CTC is a world-class academic research organisation with skills across multiple modalities and disease areas and is a unique and valuable resource. However, it also highlighted that the CTC faces a number of challenges in today's rapidly changing, internationally competitive clinical trials landscape.

Key recommendations from the reviewers included the development of strategies for attracting and retaining researchers interested in academic high quality clinical trials, models of working with industry, and developing more efficient and responsive trial systems and capability in the university environment. We also welcome greater recognition and support from the University as we launch our new strategic initiatives informed by the findings of this review.

A particularly exciting path for future clinical trials will see more routine embedding of clinical trials in health care. Pragmatic trial design, such as the SOCRATES trial, designed to evaluate standard of care protocols in routine care, and registry-based trials, such as the SWIFT trial, will be important here. Greater incorporation of molecular profiling or biomarker-directed therapies, as exemplified by the MOST program, will be key to developing personalised therapeutic approaches. Wider use of digital health, in both trials and health care more broadly, will greatly expand access to health care, as well as the reach and range of trials by facilitating the integration of routine care with clinical research.

2020 has seen many unique challenges as a result of the COVID-19 pandemic. As an organisation, we have had to adapt, rethink and change our ways of working to allow our



The adaptability, flexibility and ongoing commitment to continuing our research under constantly changing conditions shown by our team members has been outstanding.

Incoming Director Prof Meg Jardine, Deputy Director Prof Tony Keech and Director Prof John Simes

research to continue. The adaptability, flexibility and ongoing commitment shown by our team members to continuing our research under constantly changing conditions has been outstanding. We are enormously grateful for their dedication, professionalism, and invaluable contributions that have meant that we have not only survived, but thrived, in this pandemic year.

The trials and achievements outlined 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 collaborators, and most of all, without the efforts of our outstanding team of dedicated, committed, enthusiastic trial staff with their shared vision of making a difference. We thank you all for your participation and commitment to better healthcare.

Finally, 2020 marks the final year with Professors John Simes and Anthony Keech as directors, and we very much welcome Professor Meg Jardine as the Incoming Director for 2021 and beyond. We have every confidence that the CTC, with such an outstanding team of researchers working in partnership with key collaborators, will continue to make a profound impact on future practice and health.

## 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 2020.

### 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 John Simes (Oncology), Associate Professor Andrew Martin (Biostatistics), Professor Meg Jardine (Kidney Health), Professor Angela Webster (Evidence Integration), and Professor Val GebSKI (Biostatistics) (p.16).
- 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, have grown the program from an NSW pilot into a leading source of cancer treatments for advanced cancer patients throughout Australia. 11 sites across Australia have screened over 3,000 patients for eligibility in seven active trials targeting immunotherapy and lung cancer using precision medicine (p.30).
- The Enzamet study, in partnership with ANZUP, was highlighted as a Clinical Cancer Advance in the ASCO 2020 Annual Report on Progress Against Cancer. Results have led to changes to ESMO Clinical Practice Guidelines on prostate cancer and the American Urological guidelines (p.38).

### 2 BUILD INTERNATIONAL COLLABORATIONS

- We presented results from cutting edge trials to international audiences, promoting our expertise, and inviting future collaboration. Results from ACED (with COGNO; p.xx) were presented at the Society for Neuro-Oncology (SNO) Annual Meeting 2020 in USA, ILLUMINATE (with ALTG; p.26) featured a 'Trials in Progress' poster at the American Society of Clinical Oncology Annual Meeting, and SWIFT presented results at the American Society of Nephrology.
- The TOPCHILD Collaboration, established by our NextGen team, has brought researchers from around the world together to transform the thinking and practices around early childhood obesity prevention. 38 trials, with data from over 30,000 participants have joined the collaboration and shared their data.
- The Fame 1 Eye study (p.42), which is testing whether fenofibrate can protect against eye damage in patients with type 1 diabetes, sees us working with partners across four countries (Australia, New Zealand, Hong Kong and the United Kingdom) and 21 hospital sites that are currently open for recruitment.



# 2020 CTC Executive Team





### 3 EMBED TRANSLATIONAL STUDIES INTO OUR RESEARCH

- Our collection of oncology biological samples from trial patients, used in translational research to help predict a patient's response to treatment and progress understanding of precision medicine, increased in 2020 with over 33,000 shipped from over 65 hospitals. Grants totalling \$5.88 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 blood sample collections from its 257 patients in 2020.
- Two new studies opened where patient tumours undergo molecular profiling using next generation sequencing. Profile results guide the patient's treatment: LUMOS study (glioma) and ASPIRATION study (lung cancer – see Novel Collaborations p.32).

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

- Our research leaders supervised 12 PhD students and 5 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.

### 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. We completed the pilot study, and the main trial set is to open in early 2021.
- In the CARSK study, the Health Economics team are evaluating the cost-effectiveness of regular coronary artery disease (CAD) screening compared with no further screening and the subsequent economic impact of CAD-related expenditure from a health system perspective. The trial is currently underway and recruiting in Australia, New Zealand, Canada, and Spain. The pre-trial model has identified an area of significant potential cost-savings to the Australian health system. (p.54).
- Our NextGen 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. Methods developed by the team have been applied by researchers in Australia and globally across health research fields, including obesity, midwifery, COVID-19, and prostate cancer.



### 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 first published value of information analysis (VOI) came from the Whole Brain Radiotherapy trial for Melanoma. The Health Economics team were part of this trial with ANZMTG which found Whole Brain Radiotherapy (WBRT) did not reduce the spread of melanoma in the brain.
- The individual participant data on Cord Management at Preterm Birth Collaboration (iCOMP), established and run by the NextGen Team since 2019, grew in 2020 – with 74 trials (including data from 12,350 preterm infants) agreeing to provide data. The iCOMP protocol was also published in BMJ open.
- 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.

## 2020 AWARDS

A selection of the external awards received by CTC staff in 2020



### JANUARY

→ **Prof John Simes** received an Order of Australia Award in the Australia Day Honours List for his service to cancer research and clinical trials.



→ **Saskia Cheyne** received an NHMRC scholarship for her study of next generation systematic reviews & meta-analysis.



### MAY

→ **Prof Alicia Jenkins** and **Prof Tony Keech** received a Certificate of Achievement Award from Internal Medicine Journal (IMJ) for their paper on the diagnosis



and management of statin intolerance which generated immediate impact and was among the top 10% most downloaded papers between Jan 2018 and Dec 2019.



### JUNE

→ **Prof Ian Marschner's** paper and findings on 'back-projection' for COVID19 were published in the Sun Herald. The study shows waiting another week to introduce border closures and physical distancing measuring could have led to a five-fold increase in Australia's current infections.



### JULY

→ **Prof Meg Jardine** awarded the ANZSN 2020 TJ Neale Award, which honours Members who have made a significant contribution to Nephrological science.



→ **Prof Angela Webster** awarded the ANZSN 2020 TJ Neale Award, which honours Members who have made a significant contribution to Nephrological science.



→ **Dr Wilson Wong** received the Lindsey Baudnet Rising Star Award in Type 1 Diabetes Research for his research project on 'Assessment of the long non-coding RNA MALAT1 to predict pancreatic islet isolation outcome'.



### OCTOBER

→ **Prof Lisa Askie** appointed a Fellow of the Australian Academy of Health and Medical Sciences.



### NOVEMBER

→ **Prof John Simes** named one of 443 Sydney researchers in the top two percent in the world according to a study led by Stanford University and published in PLOS Biology.



### DECEMBER

→ **A/Prof Andrew Martin** accepted the ACTA (Australian Clinical Trials Alliance) STInG award for excellence in trial statistics on behalf of the ANZUP ENZAMET trial team. The ENZAMET trial scooped the pool at the ACTA trial of the Year Awards Ceremony winning all three awards: Trial of the Year, STInG, and Consumer Involvement.



## ONCOLOGY 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 of cancer patients. We are a leader in developing and conducting novel trial designs, including adaptive designs, genomics-driven screening and inclusion of translational research that helps predicting treatment benefits, future health status and survival.

The CTC works collaboratively with leading cancer clinicians, national cancer cooperative groups and international cancer research centres to design and run cancer clinical trials, with a focus on the areas of breast, gastro-intestinal, lung, gynaecological, neurological, and urogenital cancers.

We have collaborated in over 200 cancer clinical trials, which thousands of cancer patients have joined.



“Progress in cancer research, treatment, and outcomes is accelerating. It’s wonderful to be part of a team at the forefront of these advances.”

### 2020 in numbers



55  
ACTIVE  
TRIALS



485  
ACTIVE  
SITES



800  
PATIENTS  
RECRUITED



60  
PEER REVIEWED  
PUBLICATIONS



## ONCOLOGY RESEARCH DEVELOPMENT

The Oncology Research Development (ORD) team supports the development of new clinical trials and research activities at the CTC. The team works closely with the five cancer collaborative groups based at CTC, as well as Clinical Fellows, Clinical Leads and Statisticians and external academic partners. They develop early concepts into a final study design, assess feasibility and equipoise, develop study budgets, obtain drug supply and manage the legal agreement processes. With extensive experience in clinical trial development and conduct, the team provides study design recommendations and identifies areas for special consideration during the concept and protocol development stage.

With extensive experience in clinical trial development and conduct, the team provides study design recommendations and identifies areas for special consideration during the concept and protocol development stage.

The ORD team is responsible for developing trial protocols which include the associated sub-studies such as quality of life, health economics, translational research, and preparing consent forms for trials. Once finalised, the new studies are handed over to the Trial Operations team for opening to recruitment. The ORD team coordinates the preparation and submission of grant applications to government and philanthropic grant schemes working with external and internal academics. They also work alongside lead investigators and collaborative groups for discussions and negotiations with the pharmaceutical industry for trial support. Working with clinical trialists to write manuscripts for trial protocol publications and dissemination of results and preparing abstracts and presentations for national and international conferences are activities that round out the work done by this expert team.



## 2020 HIGHLIGHTS

- Brain Cancer (partnering with COGNO): The IDH mutated 1p/19q intact lower grade glioma following resection: Wait or Treat? (IWOT) study was awarded funding by Cancer Australia and the Australian Brain Cancer Mission, with funding provided by the Mark Hughes Foundation. IWOT will commence recruitment in 2021.
- Gastrointestinal Cancer (partnering with AGITG): RoLaCaRT-1 Study. Development work for planned study planned to open in 2021. RoLaCaRT1 is an international randomised phase II trial comparing robotic-assisted right hemicolectomy versus laparoscopic-assisted hemicolectomy for resection of adenocarcinoma of the caecum, ascending or proximal transverse colon. RoLaCaRT-1 will recruit from ten Australian sites and two in the UK and two in the US.
- Gynaecological Cancer (partnering with ANZGOG): Assisted in the development and writing of three successful MRFF grant submissions in the Rare Cancers, Rare Diseases and Unmet Need for Reproductive Cancers Scheme for the ADELE, HyNOVA and PARAGON-II studies and supported development of the three corresponding protocols and consent forms.
- Lung Cancer (partnering with ALTG/TOGA): Secured funding and drug supply for five ASPIRATION Study treatment substudies, developed the six corresponding protocols (the molecular screening subprogram, and five treatment substudies), and handed these over to the Operations teams for activation.
- Urogenital and Prostate Cancer (partnering with ANZUP): Assisted with the development and writing of NHMRC Clinical Trials and Cohort Studies and Cancer Australia grant applications for the WATER Study and supported concept development and budgeting of the proposed EVOLUTION trial.
- COVID-19: Led the research development activities for the BEAT COVID-19 Trial, a bayesian adaptive randomised controlled trial platform to evaluate the efficacy of interventions for high-risk older patients with COVID-19 in reducing the risk of hospital admission or death, a new collaboration with internal and external clinical academics in response to the pandemic.



ONCOLOGY RESEARCH DEVELOPMENT TEAM



## 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.



MERRYN HALL, CLINICAL TRIAL OPERATIONS LEAD



## 2020 TRIAL HIGHLIGHTS

- ACED (high grade glioma): results were presented at the Society for Neuro-Oncology (SNO) Annual Meeting 2020 in USA. This study explores whether the addition of oral acetazolamide allows for dexamethasone dose reduction without clinical deterioration in performance status in the management of raised intracranial pressure in recurrent and/or progressive High-Grade Glioma (HGG).
- MAGMA (multi-arm glioblastoma): opened ten out of 30 sites and recruited 25 of 300 participants since activation in September 2020. This study looks at diverse options in the standard of care for the management of glioblastoma.
- NUTMEG (elderly patients with glioblastoma): reached 79% of its recruitment target and opened at Duke University in USA. NUTMEG evaluates whether the combination of adjuvant nivolumab with temozolomide improves overall survival outcomes of GBM patients who are 65 years of age or older.
- LUMOS (low and intermediate grade brain tumours): reached 80% of target for the pilot study and submitted a grant for the main study. LUMOS matches tumours on a molecular level with the best treatments and assists in accessing these drugs, including creating trials of new treatments (see trial in focus).
- Four trials (iWOT, PersoMed, CODEL and PICCOG) received funding in 2019 and 2020 and plan to open for recruitment in 2021.

## TRIAL IN FOCUS: LUMOS

### How feasible is it to match brain tumours on a molecular level with the best available treatments?

#### CHALLENGE

Low and intermediate grade brain tumours are the second largest group of fatal brain tumours in adults with almost no access to clinical trials. Interpretation of tumour mutations in individuals and matching this to available treatments is a complex process, which also needs to account for the unique biology of this rare tumour type and limited drug access across the blood-brain barrier.

#### TRIAL

We know that patients with relapsed low (grade 2) and intermediate (grade 3) brain tumours after prior treatment with radiotherapy and chemotherapy have a poor prognosis with no established standard of care treatment. The LUMOS pilot study aims to provide Australian patients with treatment options by matching patients with targeted therapies based on molecular testing using contemporaneous tumour tissue.

A panel of neuro-oncology and translational research experts with representation across Australia and USA formed the Molecular Tumour Advisory Panel to provide guidance on the interpretation of molecular testing results, including review of each report and

providing guidance about potential treatment recommendations for clinicians.

The pilot study is to demonstrate proof of concept and to evaluate whether this testing model might be feasible.

The trial opened to recruitment in April 2020 and recruited nine patients across five Australian sites in less than 12 months.

#### IMPACT

Nine out of 10 patients are now in follow-up to collect information about the turnaround times of the testing model, whether patients received targeted therapy based on molecular testing and whether they responded well to treatment.

We hope results from this pilot study will provide invaluable information for subsequent studies using tumour tissue to provide targeted treatment options for patients with low and intermediate grade brain tumours.

### Trial snapshot

Status: Follow-up  
Start date: April 2020  
Patients recruited: 9  
Sites: 5



BRAIN CANCER TEAM (COGNO)

## 2020 in numbers

6 ACTIVE TRIALS

4 TRIALS IN START-UP

67 PATIENTS RECRUITED

28 ACTIVE SITES



## 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 5,200 patients. Our research has changed treatment practices and improved patient life expectancy and quality of life.



### 2020 TRIAL HIGHLIGHTS

- MONARCC (colorectal cancer): recruited seven patients in three months and opened three Teletrial sites. This study aims to investigate the activity of anti-EGFR monotherapy, or combined with infusional 5FU, in a molecularly selected, elderly patient population with metastatic colorectal cancer.
- NABNEC (NeuroEndocrine tumours): received philanthropic funding to conduct a translational research sequencing study. Blood, tissue, and other biomarkers will be collected for translational research that will help increase our understanding of neuroendocrine carcinomas. The study aims to establish if carboplatin and nab-paclitaxel combination is an effective and tolerable chemotherapy treatment for grade 3 advanced gastrointestinal NECs.
- MASTERPLAN (pancreatic cancer): randomised its first patient in February 2020. This trial investigates whether SBRT in addition to modern chemotherapy is superior to the current standard of chemotherapy alone in both the neoadjuvant and definitive setting (see trial in focus).
- GAP (pancreatic cancer): results were published in Annals of Surgical Oncology. The trial has added to current evidence that gemcitabine and nab-paclitaxel before surgery is a worthwhile treatment for pancreatic cancer.
- INTEGRATE IIa (advanced gastro-oesophageal cancer): recruited 225 participants globally, surpassing projected recruitment total of 200 participants for this phase of the INTEGRATE platform. INTEGRATE IIb received HREC (Human Research Ethics Committee) approval and amendment rolled out to clinical sites around the world. The study will determine whether the drug Regorafenib is effective in prolonging survival in patients with Advanced Gastro-Oesophageal Cancer.
- PETACC-6 (locally advanced rectal cancer): results were published in the Journal of Clinical Oncology. This study explored whether intensifying chemotherapy before and after curative surgery can reduce the risk of cancer returning and improve survival. It compared capecitabine and oxaliplatin based treatment to standard capecitabine based treatment before and after curative surgery.

## 2020 in numbers



## TRIAL IN FOCUS: MASTERPLAN

Is the addition of Stereotactic Radiotherapy (SBRT) to standard chemotherapy safe and beneficial to patients with locally advanced/borderline resectable pancreatic cancer?

### CHALLENGE

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

The five-year survival for patients with pancreatic cancer is only 8% and half of all patients experience loco-regional recurrence (LRR) within 12 months after initial treatment.

### TRIAL

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

MASTERPLAN is the first Australasian randomised trial that explores SBRT for pancreatic cancer. The trial includes 15 sites across Australia and New Zealand.

Funding has been provided through a grant from the Medical Research Future Fund for Low Survival Cancers and Diseases. This highly competitive grant opportunity is awarded to innovative clinical trials of the highest quality design that address low survival cancers. New Zealand secured funding this year from the Gut Cancer Foundation and Christchurch Oncology Trust Funds, to support participation in the trial.

### IMPACT

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

The trial is currently recruiting in Australia with nine sites open and ten patients enrolled at 31 Dec 2020. New Zealand is expected to open in 2021. Recruitment is expected to remain open until 2023.



### Trial snapshot

Status: Recruiting  
Start date: October 2019  
Patients recruited: 10  
Sites Open: 9

GI CANCER TEAM (AGITG)



## GYNAECOLOGICAL CANCER

Partner: Australia New Zealand Gynaecological Oncology Group

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

ANZGOG and CTC collaborate to develop and conduct clinical trials that test interventions designed to improve care and outcomes for people affected by gynaecological cancer.



### 2020 TRIAL HIGHLIGHTS

- AtTEnd (advanced/recurrent endometrial cancer): activated its first ANZ site and recruited seven participants within four months of activation. This international study will assess whether the use of the immunotherapy, atezolizumab, is of additional benefit to current first line chemotherapy combination (carboplatin and paclitaxel) in women with advanced or recurrent endometrial cancer.
- STICs and STONEs (prevention of ovarian cancer): activated all sites in ANZ and recruited its first participant. This international study will provide a better understanding of how ovarian and fallopian tube cancers start in women carrying germline BRCA1/2 mutation and whether aspirin might be a useful risk-reducing medication.
- TIPS (primary ovarian cancer): activated all sites in ANZ and recruited its first participants. The TIPS study aims to assess the two interventions to enhance recovery after surgery – preoperative carbohydrate-loading and perioperative pregabalin – in patients with primary ovarian cancer.
- ECHO (primary ovarian cancer): received a CCQLD AACR grant, which will see the study through to the end with a total 500 participants. The trial will identify whether incorporation of an exercise program into the current standard of care for people undergoing chemotherapy for primary ovarian cancer is a clinically effective and cost-effective way to improve health outcomes in this patient group.
- SOLACE2 (recurrent ovarian cancer): reached its 50% accrual milestone. The trial aims to investigate different strategies to prime the immune system and enhance response to durvalumab and olaparib in patients with asymptomatic platinum-sensitive recurrent ovarian cancer.

## 2020 in numbers



## TRIAL IN FOCUS: PARAGON-II (ANZGOG1913): PHASE II BASKET STUDY OF AN AROMATASE INHIBITOR PLUS PI3KCA INHIBITOR OR CDK4/6 INHIBITOR IN WOMEN WITH HORMONE RECEPTOR POSITIVE RECURRENT/METASTATIC GYNAECOLOGICAL NEOPLASMS

Does combining letrozole with alpelisib in PIK3CA-mutated tumours, and letrozole and ribociclib in PIK3CA non-mutated tumours, have a role in selected patients with potentially hormone-responsive, recurrent, or metastatic gynaecological cancers?

### CHALLENGE

Many gynaecological cancers carry molecular mutations in PIK3CA and CDK4/6 pathway. These cancers also express hormone receptors, and hormonal therapies have modest benefit in treating these cancers as shown in our previous study PARAGON. Drawing from the results in breast cancer studies, adding drugs that target the PIK3CA pathway (alpelisib) or the CDK4/6 pathway (ribociclib) to hormonal therapy (letrozole) may improve the response rate in treating these cancers.

### TRIAL

PARAGON-II is a basket trial that enables patients with uncommon/rare gynaecological cancers to be enrolled into a series of six separate phase 2 studies, all embedded within a single protocol. It will include participants with hormone receptor positive gynaecological cancers which include ovarian cancers, endometrial cancers, and sarcomas. The tumour sample will be tested centrally for PIK3CA mutation and participants will receive letrozole plus alpelisib if PIK3CA mutation is detected, or letrozole plus ribociclib if PIK3CA mutation is not detected. Participants will continue trial treatment until disease progression or unacceptable toxicity.

PARAGON-II is an open-label study and all trial participants will receive one of the two trial drug combinations. There are translational research questions embedded in this study to identify potential biomarkers associated with treatment response.

### IMPACT

PARAGON-II is an academic study investigating if combinational drug strategy can overcome intrinsic resistance to hormonal therapy in endometrial cancer and other rare gynaecological cancers. Although hormonal therapies are widely used in gynaecological cancers, the associated benefit is modest as shown in the PARAGON trial. PARAGON-II builds on the success of the PARAGON trial and is supported by a solid scientific foundation of preclinical as well as clinical research in hormone positive breast cancers with PIK3CA and CDK4/6 inhibitors. The PARAGON-II trial will address new and important research questions including biomarker-driven treatment selection, supporting the implementation of personalised medicine.



### Trial snapshot

Status: In start-up  
 Start date: Q2 2021  
 Target accrual:  
 182 patients

GYNAECOLOGICAL  
 CANCER TEAM  
 (ANZGOG)



## LUNG CANCER

Partner: Australasian Lung Cancer Trials Group (until 4-Nov-2020) and the Thoracic Oncology Group of Australasia (from 5-Nov-2020)

The CTC collaborated with the Australasian Lung Cancer Trials Group (ALTG) until the transition to the newly formed Thoracic Oncology Group of Australasia (TOGA) in late 2020.

The high-quality clinical research delivered by these partnerships in Australia and New Zealand includes trials looking at immunotherapy and targeted therapies for lung cancers, new trials in mesothelioma, and most recently expanding into genomic profiling to deliver personalised precision medicine.



### 2020 TRIAL HIGHLIGHTS

- **ASPIRATION** (lung cancer): this ground-breaking national multicentre cohort study will screen 1,000 newly diagnosed metastatic, non-squamous, non-small cell lung cancer (NSCLC) patients using tissue-based comprehensive genomic profiling (CGP). The study will assess the clinical impact of CGP and feasibility of implementing CGP nationally (See trial in focus, pxx).
- **DREAM** (mesothelioma): promising results were published in The Lancet Oncology journal, showed that the combination of durvalumab and standard chemotherapy was active and safe in malignant pleural mesothelioma, and affirmed that further research of chemoimmunotherapy in this population is warranted.
- **DREAM3R** (mesothelioma): following encouraging results from the DREAM trial, our research team is working together with researchers in the USA to conduct a larger phase 3 trial that will directly compare the combination of standard chemotherapy plus durvalumab versus standard chemotherapy alone in 480 people with malignant pleural mesothelioma.
- **ILLUMINATE** (lung cancer): recruited its first patient in Taiwan and featured a 'Trials in Progress' poster at the American Society of Clinical Oncology Annual Meeting. This unique partnership with the National Health Research Institutes (NHRI) in Taiwan is the first of its kind. (see trial in focus).
- **PEARL** (palliative care): completed recruitment with 113 participants. This trial aims to determine if early referral to palliative care improves outcomes for patients with advanced thoracic malignancies in the Australian healthcare setting.
- **BR.31** (lung cancer): exceeded its target recruitment at 114 out of 100 planned participants. This international trial with CTC's long-standing collaborators the Canadian Cancer Trials Group (CCTG) looks at the effectiveness of adjuvant therapy with durvalumab in patients with completely resected NSCLC.

## 2020 in numbers



## TRIAL IN FOCUS: ILLUMINATE

Is a new treatment strategy that combines immunotherapy (durvalumab and tremelimumab) with chemotherapy active in treating epidermal growth factor receptor (EGFR) mutation positive advanced NSCLC?

### CHALLENGE

Lung cancer is the leading cause of cancer-related mortality worldwide and most patients present with advanced disease at diagnosis. Approximately 85% have non-small cell lung cancer (NSCLC) and a subset of these patients harbour an EGFR mutation, a driver mutation that promotes cell proliferation and cancer growth. Despite initial response to targeted treatments, resistance is inevitable and response to palliative chemotherapy is modest at best. Whilst single-agent immunotherapy has been shown to significantly prolong survival in advanced NSCLC, its role in lung tumours with driver mutations, such as EGFR, is unclear.

Participants will receive induction treatment comprising two immunotherapy agents - durvalumab plus tremelimumab - with platinum-pemetrexed chemotherapy. This will be followed by maintenance treatment with durvalumab and pemetrexed. Participants will be regularly assessed to evaluate the safety and activity of the treatments.

ILLUMINATE is conducted in collaboration with National Health Research Institutes (NHRI) in Taiwan, establishing a unique equal partnership model.

### IMPACT

ILLUMINATE will establish the role of chemoimmunotherapy in a well-defined patient population who have progressed on targeted treatment with limited subsequent therapeutic options. The results from this study will have an immediate impact on 15-25% of cases of advanced NSCLC diagnosed in Australia, and approximately 50% of all advanced NSCLC diagnosed in Asia. Furthermore, ILLUMINATE is a model for future trials of other NSCLC that harbour oncogenic driver mutations.



### Trial snapshot

Status: Recruiting  
Patients recruited: 25  
Sites open: 19

LUNG CANCER TEAM (TOGA)



## 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 in genitourinary oncology. This research aims to identify and promote better treatments to raise survival rates and enhance the quality of life of people affected by urogenital and prostate cancers.



### 2020 TRIAL HIGHLIGHTS

- ENZAMET (prostate cancer): won the 2020 ACTA Trial of the Year Award, the ACTA STInG Award for Excellence in Trial Statistics and the Consumer Involvement Award! The study was also highlighted as a Clinical Cancer Advance in the ASCO 2020 Annual Report on Progress Against Cancer. Results have led to changes to ESMO Clinical Practice Guidelines on prostate cancer and the American Urological guidelines. ENZAMET investigates the effectiveness of the hormone therapy enzalutamide versus NSAA, in the treatment of men with metastatic prostate cancer.
- DASL-HiCaP (prostate cancer): opened in March 2020 and accruing ahead of projections. The purpose of this study is to see if darolutamide, a novel oral anti-androgen, combined with the current best treatments, can improve outcomes for people with high-risk prostate cancer being treated with radiation therapy (see trial in focus).
- ENZA-P (prostate cancer): opened in August 2020. This study will compare determine the activity of Lu-PSMA in combination with enzalutamide, versus enzalutamide alone, in advanced prostate cancer.
- BCGMMC (bladder cancer): accruing well in Australia and opened a major site in the UK This study will determine the effects of adding mitomycin to standard treatment with BCG on recurrence, survival, side effects, and quality of life for people with bladder cancer.
- KEYPAD (kidney cancer): successfully passed its halfway point and first interim analysis. This study will determine if denosumab, a drug most used to prevent osteoporosis can improve the activity of immunotherapy with pembrolizumab in advanced kidney cancer.
- P3BEP (testicular and ovarian germ cell tumours): successfully passed its 70-participant interim analysis for safety, and 150-participants for its first interim analysis of activity. This study will determine if giving the main drugs every 2 weeks (accelerated) is better than giving them every 3 weeks (standard) results in better control of the cancer, survival, and quality of life.

### 2020 in numbers



### TRIAL IN FOCUS: DASL-HICAP

## Does darolutamide improve recurrence rates when added to standard androgen deprivation therapy and radiation in high risk, localised prostate cancer?

#### CHALLENGE

Prostate cancer is the most common cancer in Australian men and caused around 3,300 deaths in 2019. The best standard treatment for prostate cancer that is localised, but considered at high risk of recurrence, includes radiation therapy plus androgen deprivation therapy. The risk of recurrence within five years is approximately 15% even with this best standard treatment. This trial will determine if darolutamide, a novel anti-androgen tablet, can further reduce the risk of recurrence when added to best standard treatment.

#### TRIAL

DASL-HiCaP is a randomised controlled trial. All participants are treated with best standard treatment including radiation therapy and androgen deprivation. In addition to best standard treatment, half the participants are also treated with darolutamide, while the other receive a placebo (an inactive tablet that looks like darolutamide). The trial has enrolled 94 participants in 2020 of a planned 1100 from Australia, New Zealand, Canada, Ireland, the United Kingdom, and the USA.

#### IMPACT

If darolutamide improves recurrence rates in this trial, then its adoption in routine clinical practice could save thousands of lives per year worldwide.



#### Trial snapshot

Start date: 31 March 2020  
 Patients recruited: 94  
 Sites: 24 sites activated

UROGENITAL AND PROSTATE CANCER TEAM (ANZUP)



## 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's cancer, 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 advanced cancer patients throughout Australia.

The MoST program has established drug and funding partnerships with an expanding list of pharmaceutical companies (including Pfizer, AstraZeneca, 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), now known as OMICO, through which MoST will continue to grow, together with new national member centres. The company has attracted over \$70 million in funding.

### 2020 HIGHLIGHTS

The MoST program is a successful national platform that provides profiling of tumours to identify actionable molecular targets, paired with a growing pipeline of clinical studies matching treatment to molecular signals. In 2020, we continued to expand this national framework for precision oncology clinical trials together with partners in the Australian Genomic Cancer Medicine Centre. The framework initially focused on a tumour agnostic approach to rare and treatment refractory cancer. Through 2020, over 3000 patients with rare and treatment refractory cancers were screened and over 200 patients received treatment. In 2020, we leveraged this existing infrastructure and expertise in

molecular screening to incorporate two additional subprograms:

1. ASPIRATION: a screening program for metastatic lung cancer patients, led by the Thoracic Oncology Group of Australasia (TOGA) (see Trial in Focus p.35)
2. MOSTLTY: a screening program specific to haematological cancers. Also in 2020, we grew our pipeline of therapeutic substudies, incorporating treatment options for the ASPIRATION and haematology subprograms, with achievements that included:

- Doubling the number of studies from ten at the end of 2019 to 20 at the end of 2020.
- Over 3,000 patients screened, and 208 patients treated since the program began.

- Opening 3 new trials in the rare and treatment refractory cancer treatment portfolio: MoST 6 larotrectinib, MoST 7 tremelimumab and MoST 8 trastuzumab emtansine.
- Continuing development of 5 new trials for the rare and treatment refractory cancer portfolio, and two trials for the haematology portfolio
- Embarking on the ASPIRATION subprogram for lung cancer, including development of five trials.

The demand for cancer therapeutics was unabated even against the backdrop of COVID-19, a testament to the importance of the MoST program.

## 2020 in numbers

**7**  
ACTIVE TRIALS

**7**  
TRIALS IN START-UP

**22**  
PATIENTS RECRUITED

**11**  
ACTIVE SITES



**Pan Cancer Subprogram**

> 3000 screened  
208 patients treated  
8 studies active  
6 studies in development

**ASPIRATION (Lung)**

1000 to be screened  
4+ substudies in development

**MoSTLTY (Haematology)**

240 to be screened  
2+ substudies in development

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



MOLECULAR SCREENING AND THERAPEUTICS TEAM (MoST)



## OTHER ONCOLOGY RESEARCH

In addition to our extensive work with the national cancer cooperative trial groups that focus on brain, gastro-intestinal, gynaecological, urogenital and lung cancer research, the CTC conducts a range of quality research both independently, or in collaboration with multiple cooperative groups. Examples include the long-running SNAC trials, conducted in collaboration with the Royal Australasian College of Surgeons, and the CannabisCINV trial, performed in collaboration with Chris O'Brien Lifehouse and the Lambert Initiative for Cannabinoid Therapeutics.

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 14 national cooperative cancer clinical trials groups funded under Cancer Australia's Support for Cancer Clinical Trials program to develop cancer clinical trial protocols (grant applications) for studies involving two or more cancer types and two or more cooperative trials groups.



## 2020 in numbers

5  
ACTIVE  
TRIALS

43  
PATIENTS  
RECRUITED

39  
ACTIVE  
SITES

## 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 OVERVIEW

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

The active drug is a combination of tetra-hydrocannabinol (THC) and cannabidiol (CBD) in capsules taken three times a day. Participants must be 18 years or older 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.

#### IMPACT

The preliminary (pilot study) results showed that addition of an oral THC/CBD had activity preventing CINV, indicating that the THC/CBD capsules have the potential to reduce the side effects of chemotherapy and improve quality of life. The pilot study results attracted considerable attention when the results were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in May 2020 and published in the Annals of Oncology scientific journal in December 2020. The pilot phase 2, crossover design results confirmed the importance of proceeding with definitive, phase 3, parallel-design component of the trial, which is ongoing.



#### Trial snapshot

Start date: 23 Nov 2016  
Patients recruited: 113  
(81 in phase 2 pilot study; 32 in  
definitive phase 3 study)  
Sites: 15

ORPHAN  
TRIALS TEAM



## NOVEL COLLABORATIONS

Transformations often arise when different streams of expertise merge. No-one appreciates that more keenly than those of us involved with clinical trials. CTC understands that successful clinical trials are built by teams of people with diverse skills and backgrounds.

As trial scientists, we know that meetings with new partners inspire exciting conversations that stimulate leaps in innovation and excellence, providing unique solutions and advancing trial science.

CTC is proud to work with five incredible partners on the ASPIRATION program (see trial in focus), and we are continually engaging in novel collaborations to advance trial science and improve health outcomes in the future.

## TRIAL IN FOCUS: ASPIRATION

An observational cohort study to assess the clinical impact of comprehensive genomic profiling in metastatic lung cancer patients.

### CHALLENGE

Lung cancer is the leading cause of cancer death in Australia and worldwide, with a five-year survival rate of only 17 per cent.

### STUDY

The ASPIRATION program is a pioneering 5-way partnership between Government, industry, and academia. The program is led by the Thoracic Oncology Group of Australasia (TOGA) [and formerly the Australasian Lung Cancer Trials Group (ALTG)], in collaboration with the Australian Genomic Cancer Medicine Centre (AGCMC) and the NHMRC Clinical Trials Centre (CTC). The program is jointly funded by the federal government's Medical Research Future Fund (MRFF) and Roche, as well as in-kind support through access to Roche medicines in 4 of the program's therapeutic clinical trials.

### IMPACT

The ASPIRATION study is the first of its kind in Australia to generate high-quality, real-world data about the impact and value of comprehensive genomic profiling (CGP) to deliver precision medicine and personalised healthcare, by identifying actionable molecular targets and treating these patients in a suite of therapeutic substudies using novel targeted treatments.

### PROGRESS

Molecular screening for ASPIRATION commenced in late 2020. Five therapeutic substudies are approved, and development is ongoing to bring more therapeutic substudies online in 2021.



### Trial snapshot

Status: Recruiting  
Start date: December 2020  
Patients screened: 1  
Sites: 15 planned

ASPIRATION  
TEAM



## TRANSLATIONAL RESEARCH (ONCOLOGY)

Translational research (TR) involves searching for biological markers to help predict a patient's response to a specific treatment, or to help better forecast survival. Markers might be found in biological samples from patients on CTC trials. 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 samples like tissue, blood, and saliva for this research. Samples are studied with research partners around the world. Innovative techniques known as 'omics' are used to study genes (genomics), proteins (proteomics) and mRNA (transcriptomics).



## 2020 TRIAL HIGHLIGHTS

- TR studies awarded grants:
  - ENZAMET- lipidomics sub study (prostate cancer) – Cancer Australia grant
  - CONTROL-NETS genomics sub study (neuroendocrine cancer) and the MASTERPLAN microbiome sub study (pancreas cancer) – AGITG Innovation grants
- The AUTO-CHECK translational research study completed blood sample collections from its 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 the Centre for Personalised Immunology, this study analyses samples from trials in brain, endometrial, lung, mesothelioma, and renal cancers (trials include: NUTMEG, PHAEDRA, ILLUMINATE, KEYPAD, DREAM).
- New studies opened where patient tumours undergo molecular profiling using next generation sequencing. Profile results guide the patient's treatment: LUMOS study (glioma) and ASPIRATION study (lung cancer – see Novel Collaborations p.35).

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

### Are there biomarkers that can help identify which patients with mesothelioma do better on the anti-cancer immunotherapy durvalumab?

Results of the DREAM trial and translational research were published in the Lancet Oncology 2020.

### STUDY OVERVIEW

Tumour tissue from 54 patients with mesothelioma on the DREAM trial were studied to learn more about the PD-L1 protein. These translational research results were presented with the DREAM trial results showing that durvalumab plus chemotherapy is a promising anticancer treatment combination. The remaining tumour and bloods from DREAM patients are being analysed in several other TR studies.

### IMPACT

The PD-L1 protein in tumour tissue samples from patients was examined. PD-L1 acts like a 'brake' to keep a person's immune responses under control. No link was found between levels and patterns of PD-L1 protein in a patient's tissue with how well they benefited from durvalumab treatment. This result mirrors what other researchers found in mesothelioma trials testing different anti-cancer immunotherapies. Further TR studies of DREAM tissues and bloods are underway, studying the expression of genes and proteins involved with the immune system. These will generate new hypotheses that may be tested in our larger international mesothelioma trial, DREAM3R (recruiting 480 patients).

## 2020 Awards

**71**  
ONCOLOGY TRIALS WITH TR ACTIVITIES

**33,138**  
SAMPLES (TISSUE AND BLOOD FROM PATIENTS) SHIPPED FROM 65+ SITES

**19**  
RESEARCH LABS COLLABORATING ON TR STUDIES

**7**  
GRANTS TOTTALLING \$5.88 MILLION, INCLUDING FROM MRFF, COMMENCED; SUPPORTING TRIALS AND STUDIES WITH TR COMPONENTS



TRANSLATIONAL RESEARCH TEAM



## CARDIOVASCULAR 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.

### 2020 TRIAL HIGHLIGHTS

- CASPER trial (stroke & heart attack): awarded \$3M study grant from MRFF to investigate whether the drug colchicine, a safe and commonly used anti-inflammatory drug, is safe and effective for patients with persistent inflammation after a stroke event.
- IMPACTICO trial (COVID19): awarded +\$1M from MRFF to investigate whether both immune-modifying nanoparticles and low-dose anti-inflammatory colchicine treatment, alone and together, will reduce injury to the lungs and heart caused by COVID-19.

“The recent discovery that inflammation appears to play a key role in cardiovascular events provides a new opportunity to explore how anti-inflammatory treatments might help reduce the burden.”



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



### 2020 in numbers

2  
ACTIVE TRIALS

11  
PATIENTS RECRUITED

2  
ACTIVE SITES

12  
PEER REVIEWED PUBLICATIONS



## TRIAL IN FOCUS: COLCARDIO-ACS

Can a small daily dose of colchicine, a common anti-inflammatory medication, reduce the risk of further heart attacks after a first cardiac event?

### CHALLENGE

One Australian dies from a heart attack every 51 minutes; it is the leading cause of death worldwide, and of disease burden in high income countries. Despite current best treatments, many people remain at high risk of future heart attacks, predominantly because current therapies do not specifically target the inflammatory component of atherosclerosis. A previous study has shown that canakinumab, a drug targeting inflammation around the heart, reduced repeat cardiovascular events in high-risk patients; however, this medication is expensive to produce and not well tolerated. Colchicine is an approved anti-inflammatory treatment for gout and is also commonly used in treating pericarditis. It is inexpensive, well tolerated and readily available, and thus may be an appropriate therapy to reduce the risk of repeat heart attacks.

### TRIAL

The COLCARDIO-ACS study aims to determine whether giving daily low-dose colchicine as well as standard medical care reduces the rate of subsequent cardiac events after an initial heart attack. The study will be conducted in 3000 adults from Australia and overseas who have experienced an initial acute cardiac event and have persistently high levels of inflammatory markers in their blood 4–6 weeks after their first heart attack. These patients are at highest risk of having another heart attack and are expected to get the most benefit from colchicine. Participants will take a daily tablet containing either colchicine (0.5mg) or placebo tablets for 3 years and will be followed up regularly to collect information about cardiac events.

### IMPACT

The results of this trial will contribute a major addition to the evidence about treating this high-risk group, over and above ongoing trials, and will provide a cheap and effective therapy option to those with the greatest need.



JESSIE PAYNE AND REBECCA MISTER

### Trial snapshot

Status: In start-up  
Planned start date: 2021  
Planned patients: 3,000





## DIABETES RESEARCH

Type 1 and Type 2 diabetes are major causes of morbidity and premature death globally, particularly for the estimated 79% of people with diabetes who live in disadvantaged regions. The Diabetes group takes a multi-faceted approach, studying both common types of diabetes in human observational studies and clinical trials and in model systems in the laboratory.

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



DR ANDRZEJ JANUSZEWSKI, SENIOR RESEARCH FELLOW, AND DR NICOLA QUINN, POST-DOCTORAL FELLOW

### 2020 TRIAL HIGHLIGHTS

- Hybrid Closed Loop (HCL) insulin pump trials in people with Type 1 diabetes: Aligned trials in adults and youth showed that 6-months use of a 'hybrid closed loop' insulin pump system improves glucose control and quality of life compared to standard care of multiple daily insulin injections or less advanced insulin pumps. Adult study results were published in the leading diabetes journal Diabetes Care and presented at the annual meetings of the American Diabetes Association and the Australian Diabetes Congress.
- Tested a novel nurse lead model of care combining eye screening and diabetes education in Indigenous Australian adults with diabetes in regional Australia.
- T4DM study (Type 2 Diabetes in men): Positive results were published in Lancet Diabetes and Endocrinology. The study found two years of testosterone treatment together with a lifestyle program decreased the risk of type 2 diabetes more than the lifestyle program alone did.
- FAME-1 Eye trial: The study investigates whether the blood fat-lowering drug, fenofibrate, protects against progression of eye damage in adults with type 1 diabetes. The study continues to recruit with 21 sites open across three countries, with over 250 subjects enrolled and over 180 (of the required 450) randomised to fenofibrate or placebo.
- Three PhD candidates were awarded higher research degrees and a visiting post-doctoral fellow from the UK completed and published several studies.

“Our research aims to provide practical solutions for common problems relevant to people with Type 1 diabetes and people with or at risk of Type 2 diabetes.”



PROFESSOR ALICIA JENKINS, PROFESSOR, DIABETES AND VASCULAR MEDICINE

### 2020 in numbers

2  
ACTIVE  
TRIALS

26  
ACTIVE  
SITES

19  
PEER REVIEWED  
PUBLICATIONS



## TRIAL IN FOCUS 2020: HYBRID CLOSED LOOP (INSULIN PUMP) USE IN ADULTS WITH TYPE 1 DIABETES

Can an advanced integrated insulin pump and glucose sensor improve glucose, cognition and sleep in adults with Type 1 diabetes.

### CHALLENGE

Achieving excellent glucose control reduces the risk of long-term eye, kidney, nerve and heart damage in people with diabetes, but this is often difficult, particularly in people with Type 1 diabetes. This type of diabetes often begins in childhood and requires daily insulin injections for life. Cognition, sleep quality and mental well-being are key aspects of life that may also be disrupted by diabetes.

### TRIAL

The trial was run in seven specialist hospital diabetes clinics in Australia and included 120 adults with Type 1 diabetes. For a six-month test period, half of the subjects were randomised to the world's most advanced clinically available integrated insulin pump and continuous glucose monitoring system, called a Hybrid Closed Loop system, and half continued standard care with multiple daily injections or a less advanced insulin pump without a glucose sensor. Effects on blood glucose, memory, sleep quality and mental well-being were assessed.

### IMPACT

Hybrid closed loop use significantly improved all aspects of glucose control, and also improved some aspects of mental well-being, with no adverse effects on sleep quality or memory. User satisfaction was high. This system is available for clinical use but ensuring equitable access for all who may benefit and desire this therapy is an ongoing challenge.

### Trial snapshot

Status: Completed  
Patients: 120  
Sites: 7



DIABETES  
TEAM





## KIDNEY HEALTH RESEARCH

Established in 2020 with the appointment of Professor Meg Jardine as Director, the CTC's Kidney Health research program concentrates on identifying and addressing key knowledge gaps that will improve patient lives, lead to better treatments for those with kidney disease, and open new avenues for the global research community to pursue.

All activities of the Kidney Health research program are grounded in three guiding principles:

- 1 Patient-centricity:** Research is designed in collaboration with patients, consumer advocacy groups or other relevant community stakeholders.
- 2 Global impact:** Research will be delivered in collaboration with global experts in nephrology and other relevant fields. The Kidney Health program aims to generate evidence relevant to, and impactful for those with the greatest burden of disease, not only in Australia, but internationally.
- 3 Research efficiency:** The Kidney Health research program collaborates with global experts in novel and adaptive clinical trial methodology to ensure that all research ventures are established utilising optimal designs. A fit-for-purpose design allows streamlined, cost-effective evidence generation, with minimisation of any burden of participation.



KIDNEY  
HEALTH  
TEAM

“We are stepping into a new era of evidence generation for kidney disease, an oft-silent condition that affects up to one in seven adults. Multiple new candidate therapies are emerging to treat kidney disease and better manage its complications.”



PROFESSOR MEG JARDINE, INCOMING DIRECTOR AND DIRECTOR OF KIDNEY HEALTH



## NEONATAL AND PERINATAL 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.



ALPANA GHADGE, PROGRAM MANAGER

### 2020 TRIAL HIGHLIGHTS

- LIFT trial (premature infants): hospital outcomes published in Lancet Child and Adolescent Health in May 2020. When this trial was combined with 12 others, in a total of over 5,000 very low birthweight infants, lactoferrin reduced the risk of infection by a fifth and there were no safety concerns.
- LEAP-1 trial (Anaemia in pregnancy): has recruited 583 patients and is now two thirds of the way to its target of 800 with 13 Australian based sites and 1 in Pakistan. The study aims to see if bovine lactoferrin administration during pregnancy improves foetal growth and neonatal iron status at birth.
- PAEAN trial (lack of oxygen to brain at birth): has almost reached its recruitment target of 300 patients (97% recruited). PAEAN aims to find out whether erythropoietin in addition to the standard of care treatment increases survival without moderate to severe disability at 2 years of age. 57% of patients have reached their two-year outcomes.
- APTS trial (delayed cord clamping): Completed its two-year patient follow-up. Data has been analysed and writing is in progress. APTS aimed to find out whether immediate cord clamping (clamping within 10 seconds of delivery) or delayed cord clamping (waiting at least 60 seconds before clamping) was better for premature babies in the short term and the long term.

“We need a new generation of large, collectively prioritised, efficient international trials – run at least ten times larger and faster at one tenth the cost.”



PROFESSOR WILLIAM TARNOW-MORDI, PROFESSOR, NEONATOLOGY

### 2020 in numbers



7  
ACTIVE  
TRIALS



719  
PATIENTS  
RECRUITED



118  
ACTIVE  
SITES



## TRIAL IN FOCUS: LACTOFERRIN INFANT FEEDING TRIAL (LIFT)

### Does lactoferrin improve survival free from morbidity in very low birth weight infants?

#### CHALLENGE

Very low birthweight infants are at increased risk of late-onset sepsis (infection), necrotising enterocolitis, and death. LIFT assessed whether supplementing the enteral diet of very low-birthweight infants with the antimicrobial protein lactoferrin reduces death or major morbidity. This was a critical gap in the evidence.

#### TRIAL

LIFT, a multicentre, double-blind, randomised controlled trial, seeks to find out the effect of lactoferrin supplementation on death or major morbidity in very low birthweight infants.

1542 infants of birth weight <1500 g in 16 Australian and New Zealand neonatal units were assigned 200 mg/kg pasteurised bovine lactoferrin in feeds once daily or none until 34 weeks postmenstrual age to assess its effects on death or major morbidity, i.e., brain injury, necrotising enterocolitis, late-onset sepsis, or retinopathy. A pre-specified, PRISMA-compliant meta-analysis of this and other RCTs was conducted to

estimate more precisely the effects of lactoferrin on infection, necrotising enterocolitis, and survival. The study was conducted to a high standard in fidelity with the research protocol and statistical analysis plan, which were pre-published in BMJ Open in 2017.

#### IMPACT

This randomised trial found that supplementing feeds with lactoferrin, a dairy protein with antimicrobial properties, did not improve survival or complications in about 1500 very low birthweight infants. But lactoferrin reduced the risk of infection by a fifth when this trial was combined with 12 others, in a total of over 5,000 very low birthweight infants. There were no safety concerns.

The next step is to identify the most effective lactoferrin products.

To confirm findings like this more quickly in future we need international collaboration in a new generation of trials which can rapidly recruit thousands of infants.



#### Trial snapshot

Status: in follow up  
Start date: 2013  
Patients: 1542  
Sites: 16

NEONATAL  
TEAM



## 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 and kidney 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, efficiency, and impact of new trials through pre-trial modelling and value of information (VOI) analysis.

### 2020 HIGHLIGHTS

- 26 publications in high impact journals including BMJ, Nature Reviews Nephrol and Annals of Oncology.
- The first published value of information analysis (VOI) came from the Whole Brain Radiotherapy trial for Melanoma.
- 21 grant applications. More than half of the teams' work involved CTC lead studies, and the others were in partnership with The University of Sydney or national and international collaborators.
- SWIFT trial (kidney dialysis): completed the pilot study and presented results at American Society of Nephrology. This is the CTC's first registry-based, cluster, randomised control trial. The main trial is set to open in early 2021 in NSW.
- Instigated an interview-style webinar series to answer the critical issues in health economics. Attendance records exceeded expectations with over 100 people from outside the CTC joining each discussion.



HEALTH ECONOMICS TEAM

### 2020 in numbers

**33**  
ACTIVE PROJECTS (INCLUDING  
17 RANDOMISED TRIALS;  
6 COHORT STUDIES;  
4 MODELLING STUDIES;  
6 SYSTEMATIC REVIEWS)

**26**  
PEER REVIEWED  
PUBLICATIONS

**21**  
GRANT  
APPLICATIONS

“A value of information (VOI) framework could be helpful in developing criteria for when to replicate and when not to replicate prior systematic reviews.”



PROFESSOR RACHAEL MORTON, DIRECTOR HEALTH ECONOMICS AND HEALTH TECHNOLOGY ASSESSMENT



## STUDY IN FOCUS: CANADIAN-AUSTRALASIAN RANDOMIZED CONTROLLED TRIAL OF SCREENING KIDNEY TRANSPLANT CANDIDATES FOR CORONARY ARTERY DISEASE (CARSK)

### Is further screening of waitlisted kidney transplant recipients effective and cost-effective?

#### CHALLENGE

Current guidelines recommend 12 to 24-monthly screening of waitlisted transplant candidates for coronary artery disease (CAD). Multiple randomized controlled trials (RCTs) in patients without kidney failure have failed to demonstrate a survival benefit for screening asymptomatic patients for CAD. Additionally, no studies have evaluated the cost-effectiveness of screening patients on the transplant waitlist for asymptomatic CAD.

#### PRE-TRIAL ECONOMIC MODEL

An NHMRC and CIHR-funded randomised phase III trial including investigators from the CTC, Morton and Webster aims to test the hypothesis that after waitlist entry, no further screening for asymptomatic CAD is non inferior (with a margin of a 25% increase or 1.5% absolute difference) to regular screening for CAD in preventing major adverse cardiac events. A key outcome of CARSK is to evaluate the cost-effectiveness of regular CAD screening compared with no further screening and the subsequent economic impact of CAD-related expenditure from a health system perspective.

The trial is currently underway and recruiting in Australia, New Zealand, Canada, and Spain. A pre-trial economic model was constructed to estimate the likelihood of cost-effectiveness for the CAD screening strategies; and determine where the CARSK randomised trial needed to focus its data collection efforts.

In modelling the costs and benefits of CAD (Coronary Artery Disease) screening, we also aimed to identify variables that may change the results of the final within-trial economic evaluation.

We developed a Markov microsimulation model to replicate the natural history of a theoretical cohort of Australian kidney transplant candidates aged 18 to 69 years. Microsimulation modelling tracks a patient's duration on the waitlist, thereby generating a more accurate probability of death for any given year and increasing the overall validity of the model. All patients

were deemed eligible for transplantation, entered the model at the time of waitlist activation for deceased donor kidney transplantation, and were followed up until death (lifetime time horizon) using an annual cycle length. We constructed the model using TreeAGE Pro2018 software.

#### IMPACT

The pre-trial model has identified an area of significant potential cost-savings to the Australian health system, as well as pinpointing the trial variables that need focused attention for data collection. Our model predicted 'no further screening' to be cost-effective when compared with annual or second yearly screening for CAD. No further screening increased survival by 0.49 life-year or 0.35 QALY. One-way sensitivity analyses identified the costs of transplantation in the first year and CAD prevalence as the most influential variables on the cost-effectiveness result. Probabilistic sensitivity analyses showed that 94% of the simulations were cost-effective below a willingness-to-pay threshold of \$50,000 per QALY gained. No further screening for CAD after waitlisting is likely to be cost-effective and may improve survival. This model has identified that complete and accurate data in CARSK are needed around CAD prevalence estimates and healthcare resource use.

#### Trial snapshot

Status: Active  
Start date: 2016  
Patients: 1000  
Sites: 13

## 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.



HEALTH  
TECHNOLOGY  
ASSESSMENT  
TEAM

## 2020 HIGHLIGHTS

- Involved with 25% of all HTAs discussed in the most recent MSAC meeting
- Involved in projects and decision making in oncology, cardiovascular disease, infectious diseases, CNS, and diagnostic tests
- Increased value and number of projects by 35% compared with previous year.
- Involved with the clinical care guidelines for Covid-19



## EVIDENCE INTEGRATION

The Evidence Integration team works across multiple projects developing and applying methods of data synthesis, including individual patient data meta-analysis, prospective meta-analysis and network meta-analysis. We are the Editorial base for the Cochrane Breast Cancer group and the Prospective Meta-analysis Methods Group and manage the Australia and New Zealand Clinical Trials Registry. We also perform research on research, often drawing on the ANZCTR to describe the landscape of trial activity in our region.

Our focus is on collaborating to maximise the value of existing data and generate new evidence to improve health outcomes. Our vision is to shape the generation of new evidence using innovative methodologies.



EVIDENCE  
INTEGRATION  
TEAM

“I formed the Evidence Integration team when I joined the CTC in 2020. I am looking forward to pushing methods of evidence synthesis further to inform policy and practice and make a difference to health outcomes for all.”



PROFESSOR ANGELA WEBSTER, DIRECTOR EVIDENCE INTEGRATION



## AUSTRALIAN NEW ZEALAND CLINICAL TRIALS REGISTRY (ANZCTR)

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

## 2020 HIGHLIGHTS

- Created COVID-19 specific search function and resources for public use
- Directly linked to the National COVID-19 Clinical Evidence Taskforce. The Taskforce develops evidence-based clinical guidelines and continually monitors data from clinical trial registries including the ANZCTR
- Reviewed the characteristics of COVID-19 clinical trials in Australia. The analysis identified gaps in critical topics and outcomes and highlighted a need for better co-ordination of research effort. Key findings were presented to the Australian Government and clinical trials research community
- Substantially contributed to a nationwide initiative on improving the re-use of existing healthcare data. The initiative is being coordinated by the Health Studies Australian National Data Asset (HeSANDA), Australian Research Data Commons (ARDC), with the ANZCTR seen as an integral piece of infrastructure in this initiative.



ANZCTR TEAM

## 2020 in numbers



## 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 develops and co-ordinates the review of evidence from breast cancer research and publishes the findings. These reviews include synthesising evidence from randomised and non-randomised studies of interventions, diagnostic test accuracy studies and prognosis studies.

They build on the enthusiasm of authors by providing quality support during protocol and review development and contribute to training authors in synthesis methods.

## 2020 HIGHLIGHTS

- At least 34 consensus or practice guidelines used Cochrane breast cancer reviews, 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 Impact Factor for the Cochrane Breast Cancer Group rose from 7.375 to 12.167 (12 publications cited 146 times), meaning that a review published by the Breast Cancer Group in 2017 and 2018 was cited, on average, 12.167 times in 2019.



COCHRANE BREAST CANCER TEAM

## 2020 in numbers





## NEXT-GENERATION EVIDENCE SYNTHESIS

2020 was an exciting and defining year for the newly named Next-generation Evidence Synthesis (NextGen) Team, which evolved from the previously known Individual Participant Data and Prospective Meta-Analysis (IPD/PMA) Team. The NextGen 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 conduct methodological research, provide methods support and advice to national and international external research teams, and co-convene the Cochrane Prospective Meta-Analysis Methods Group.



NEXTGEN  
TEAM

## 2020 HIGHLIGHTS

- The individual participant data on Cord Management at Preterm Birth Collaboration (iCOMP), established and run by the NextGen Team since 2019, grew in 2020 – with 74 trials (including data from 12,350 preterm infants) agreeing to provide data. The iCOMP protocol was also published in BMJ open.
- The Transforming Obesity Prevention for Children (TOPCHILD) Collaboration was established by members of the NextGen team, after being awarded a highly competitive NHMRC Ideas Grant (ranked in the top 5% of applications). By year end, 38 trials, including data from >30,000 participants, had agreed to join the TOPCHILD Collaboration and share their data. Protocols for both the individual participant data meta-analysis and deconstructing interventions projects were submitted to BMJ Open in December 2020 and have been published as preprints on MedRxiv.
- Methods developed by the team have been applied by researchers in Australia and globally across health research fields, including obesity, midwifery, COVID-19, and prostate cancer.
- The Cochrane Collaboration invited the team to write an editorial on their methods developments, and to present their methods to Cochrane Editors and Methods Specialists.

## 2020 in numbers



7  
PEER  
REVIEWED  
PUBLICATIONS



3  
COMPETITIVE  
GRANTS  
AWARDED



2  
PHD THESES  
SUBMITTED



1  
PHD  
COMMENCED



## BIostatISTICS

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

### OUTREACH

CTC biostatisticians support several 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 – Medical Oncology
- 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
- Sydney Adventist Hospital

### TEACHING

CTC Biostatisticians also play a key role in delivering:

- The postgraduate courses of the Master of Clinical Trials Research and 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 research studies (PhD).



## 2020 HIGHLIGHTS

- ENZAMET trial (enzalutamide in metastatic prostate cancer): won the ACTA STinG Award for Excellence in Trial Statistics. The trial looked at whether adding enzalutamide to hormone therapy at the beginning of treatment would improve the survival of men with metastatic prostate cancer.
- Made various contributions to the COVID19 research and surveillance effort. Contributed to four COVID-19 study designs for potential treatments and was involved in a range of data analytics projects to help inform monitoring and control of the pandemic.
- Delivered a two-day workshop on Bayesian adaptive randomised clinical trials in collaboration with AusTriM (Australian Trials Methodology Research Network).
- Prof Gillian Heller gave the Statistical Society of Australia annual lecture on "The new normal: distributional regression."

“The ACTA award for Excellence in Trial Statistics was a major milestone rewarding the high quality of CTC Biostatistics and the leadership of Andrew Martin on the ENZAMET study.”



## 2020 in numbers

**50+**  
TRIALS RECEIVED  
BIostatISTICS  
SUPPORT

**10**  
OUTREACH  
PARTNERSHIPS WITH  
SYDNEY HOSPITALS

**50+**  
PEER REVIEWED  
PUBLICATIONS



## BUSINESS GROUP

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.

Over 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 showed agility and resilience in 2020 in response to the pandemic. We transitioned over 240 staff to work remotely and maintained a high standard of support, helping academic and professional staff to continue achieving good together.”





## UNIVERSITY OF SYDNEY

The CTC is a highly respected research centre within the University's Faculty of Health and Medicine (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

### 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).

### HOSPITALS

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.



### AUSTRALIAN CLINICAL TRIALS ALLIANCE

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

CTC Founding 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 Professors Meg Jardine and Rachael Morton are ACTA Board Directors.

### CANCER COOPERATIVE GROUPS

The CTC works collaboratively with key national cancer cooperative groups to design and run clinical trials. Often the collaborative groups, made up of clinicians and researchers addressing specific types of cancer, 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 support around development of concepts and grant applications through personal consultation and workshops.



## INDUSTRY

Participation in clinical trials research by the pharmaceutical industry is crucial for making advances in healthcare. At the CTC, we have the support of several pharmaceutical companies in key clinical trial health areas, with industry funding accounting for around 40% of 2019 funding. We have always had firm contractual and operating procedures in place for trials involving industry support (funding and/or provision of therapeutic goods). How the study is conducted, analysed, and reported on is the responsibility of study investigators, and is independent of the pharmaceutical company. Any key decisions around the trial are made by a trial Management Committee, where a company does not have voting rights. Results are analysed, published, and disseminated independent of the pharmaceutical company. See page [xx.] for a list of companies.

## CONSUMERS

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

The CTC is not directly involved in recruiting consumers as participants to clinical trials. Recruitment is the responsibility of hospital sites involved in a trial. A consumer's doctor will advise on which sites might be appropriate, and a consumer can look up trial sites on the CTC-run Australian New Zealand Clinical Trials Registry.

As part of the CTC's mission to improve global health outcomes, we engage with consumers to inform our research particularly 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.

- **Oncology:** The CTC works closely with five cancer cooperative groups and their Consumer Advisory Panels that comprise cancer survivors, patients, and carers. The panel provides 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.
- **Diabetes:** The CTC works with consumer advisors on technology-based diabetes studies, in particular Hybrid Closed Loop and Fame-1 Eye. 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 TORPEDO 30/60 trial, MBF helped to secure a waiver of consent for the trial, a critical step that sees premature babies – particularly those born at nights or on weekends – automatically included in the trial.
- **Health Economics:** The CTC is working in partnership with consumers to enrich study design and impact 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 have a map function on their registry website. The map function allows users to see which trials are open and where they are located. A consumer may be able to pass on this information to their doctor to help assess their eligibility for the 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 770 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.



## 2020 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 founding CTC Director, Professor John Simes. There are now 1,600 patients enrolled in the EnRICH program with ten affiliated sub-studies.
- Our Research Fellows continued to strengthen Sydney Catalyst's translational research interests. Dr Alison Young's projects focused on smoking cessation and genetic mainstreaming, with collaborations across major clinical sites. Mark Schreuder investigated procoagulant platelets as a diagnostic predictor of thrombosis in lung cancer patients. He also commenced a new study that will explore if a theranostic protein can be used increase tumour cell death and therefore improve chemotherapy, radiotherapy, or immunotherapy efficacy.
- Despite major disruptions due COVID-19 Sydney Catalyst hosted an impressive 13 virtual workshops, seminars and events including their first ever hybrid event, the annual Postgraduate & Early Career Researcher Symposium. The Sydney Catalyst Mentoring Program ran for the second year, matching 18 mentees with experienced mentors.

MELINDA CRUZ, MIRACLE BABIES





**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 2020, 392 students were enrolled (97 new). Since 2003, 682 students have graduated from BCA courses (including 415 Masters awards). We have also delivered one or more BCA units to over 400 non-award students. These graduates will contribute to solving the shortage of professionally qualified biostatisticians in Australia and internationally. 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 2020

Trial	Participants	Target	Accrual
<b>ONCOLOGY</b>			
<b>OTHER ONCOLOGY RESEARCH</b>			
<b>CURRENT TRIALS</b>			
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	113
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	14
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	23
<b>BREAST CANCER (COLLABORATING WITH THE ROYAL AUSTRALASIAN COLLEGE OF SURGEONS)</b>			
<b>IN FOLLOW-UP</b>			
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
<b>GASTRO-INTESTINAL CANCER (COLLABORATING WITH AGITG)</b>			
<b>IN START-UP</b>			
RoLaCaRT-1: Robotic versus Laparoscopic Colon - a Randomized Trial. An international randomised phase II trial comparing robotic-assisted right hemicolectomy versus laparoscopic-assisted hemicolectomy for resection of adenocarcinoma of the caecum, ascending or proximal transverse colon.	Adults with adenocarcinoma (tumour or malignant polyp) of the caecum, ascending or proximal transverse colon.	50	N/A
<b>RECRUITING</b>			
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	40 (ANZ) 781 (Int'l)	29 (ANZ) 617 (Int'l)
ASCOLT: Aspirin for Dukes C and high-risk Dukes B Colorectal Cancers (CRCs) - National Cancer Institute (Singapore)-led, AGITG and CTC study)	Patients with CRC who have completed surgery and other treatment	460 (ANZ) 1,587 (Int'l)	453 (ANZ) 1,522 (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)	77 (ANZ) 226 (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	10

Trial	Participants	Target	Accrual
<b>RECRUITING</b>			
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	30
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	46
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	74
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)	238 (ANZ) 554 (Int'l)
<b>IN FOLLOW-UP</b>			
A La CART: Australian Phase III randomised trial of laparoscopy-assisted resection compared with open resection (AGITG and CTC study)	Patients with primary rectal cancer	470	475
ALT-GIST: Imatinib alternating with regorafenib compared to imatinib alone for GIST (AGITG, SSG, EORTC and CTC study)	Adults with previously untreated metastatic gastro-intestinal stromal tumours	30 (ANZ) 76 (Int'l)	21 (ANZ) 78 (Int'l)
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
<b>GYNAECOLOGICAL CANCER (COLLABORATING WITH ANZGOG)</b>			
<b>IN DEVELOPMENT</b>			
ADELE: Adjuvant tislelizumab plus chemotherapy after post-operative pelvic chemoradiation in high risk Endometrial cancer (ADELE): a randomised phase 2 trial	People (≥18 years) with stage II-IVa endometrial cancer planned for adjuvant pelvic chemoradiation followed by adjuvant chemotherapy after primary surgery, who are suitable to receive tislelizumab	135	N/A
HyNOVA: A randomised study comparing Hyperthermic and Normothermic intraperitoneal chemotherapy following interval cytoreductive surgery for stage III epithelial ovarian, fallopian tube and primary peritoneal cancer	Participants (≥18 years) with histologically or cytologically confirmed stage III epithelial ovarian, fallopian tube or peritoneal cancer following neoadjuvant chemotherapy with at least stable disease undergoing interval CRS with residual disease of <2.5mm	80	N/A
PARAGON 2: Phase 2 basket study of an ARomatase inhibitor plus PI3KCA inhibitor or CDK4/6 inhibitor in women with hormone receptor positive recurrent/metastatic Gynaecological Neoplasms (PARAGON-II)	Post-menopausal women with advanced (recurrent and/or metastatic) HR+ gynaecological cancers	182	N/A
<b>RECRUITING</b>			
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	40 (ANZ) 550 (Int'l)	7 (ANZ)
ECHO: Exercise during chemotherapy for ovarian cancer (ANZGOG and CTC study)	Women with newly diagnosed ovarian cancer starting treatment	500	308

Trial	Participants	Target	Accrual
<b>RECRUITING</b>			
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)	66 (ANZ)
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	63
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)	7 (ANZ)
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	20

#### IN FOLLOW-UP

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)
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) 686 (Int'l)

### UROGENITAL CANCER (COLLABORATING WITH ANZUP)

#### IN DEVELOPMENT

RAMPART: A phase II/III trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse.	Male subjects greater than 18 years of age with histologically-proven cancer of the prostate with at least one imaging- or histologically -proven metastasis to lymph nodes or bone.	200 (ANZ) 1,750 (Int'l)	N/A
---	--	-------------------------	-----

#### RECRUITING

ENZA-p: A randomised phase II trial using PSMA as a therapeutic agent and prognostic indicator in men with metastatic castrate-resistant prostate cancer treated with enzalutamide	Men with metastatic prostate cancer, progressing on androgen deprivation therapy, not previously treated with chemotherapy for castration-resistant disease, at high risk of early failure on enzalutamide	160	13
--	--	-----	----

Trial	Participants	Target	
<b>RECRUITING</b>			
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 "	400 (ANZ) 1100 (Int'l)	94 (ANZ)
BCG+MMC: Phase III trial of adding mitomycin C to BCG as adjuvant intravesical therapy for bladder cancer (ANZUP and CTC study)	Patients with high-risk, non-muscle-invasive bladder cancer	500	311
P3BEP: Phase III trial of accelerated versus standard BEP (ANZUP, CUH (UK), CTI (IRL), COG/ CHOP/NIH (USA) and CTC study)	Patients with intermediate and poor-risk metastatic germ cell tumours	500	147
KEYPAD: Denosumab and pembrolizumab in clear cell renal carcinoma: a Phase II trial (ANZUP and CTC study)	Adults with unresectable or metastatic ccRCC progressing after treatment with a VEGFR TKI. Key eligibility criteria include target lesion(s) according to RECIST 1.1, good performance status (ECOG PS 0–2), no history of significant autoimmune disease, tumour sample available (archival or recent biopsy), and no previous treatment with immunotherapy	70	42
Tiger: A randomised Phase III trial comparing conventional-dose chemotherapy using paclitaxel, ifosfamide, and cisplatin (TIP) with high-dose chemotherapy using mobilising paclitaxel plus ifosfamide followed by high-dose carboplatin and etoposide (TI-CE) as first salvage treatment in relapsed or refractory germ cell tumours	Men, aged ≥14 years on the date of randomisation with histologically or cytologically confirmed germ cell tumour and who relapsed or were refractory to one prior line of cisplatin based chemotherapy for GCT	60 (ANZ) 420 (Int'l)	9 (ANZ)

#### IN FOLLOW-UP

ENZAMET: Phase III trial of enzalutamide in androgen-deprivation therapy for metastatic prostate cancer (ANZUP and CTC international study)	Men with metastatic prostate cancer	1,100 (Int'l)	726 (ANZ) 1,125 (Int'l)
ENZARAD: Phase III trial of enzalutamide in androgen-deprivation therapy with radiation therapy for high-risk, clinically localised prostate cancer (ANZUP and CTC study)	Men with high-risk localised prostate cancer	800 (Int'l)	593 (ANZ) 802 (Int'l)
TheraP: Randomised Phase II trial of 177Lu labelled PSMA-DKFZ-617 versus cabazitaxel in men with progressive metastatic castration-resistant prostate cancer (ANZUP and CTC study)	"Men with castration-resistant prostate cancer suitable for chemotherapy with cabazitaxel (surgical or medical castration, and previous chemotherapy with docetaxel. Previous enzalutamide and/or abiraterone is permitted), ECOG performance status 0–2. 68Ga-PSMA PET/CT must show high PSMA avidity without discordant disease on FDG PET/CT "	200	201

### LUNG CANCER (COLLABORATING WITH ALTG)

#### IN DEVELOPMENT

DREAM3R: DuRvalumab (MEDI4736) with chemotherapy as first line treatment in advanced pleural Mesothelioma - A phase 3 Randomised trial	Adults with a histological diagnosis of malignant pleural mesothelioma that is not amenable to curative surgical resection.	480	N/A
ASPIRATION: An observational cohort study to assess the clinical impact of comprehensive genomic profiling in metastatic lung cancer patients	See the 'Novel Collaborations' section (pp XX)	1,000	N/A



Trial	Participants	Target	Accrual
<b>RECRUITING</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)	34
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	113
<b>IN FOLLOW-UP</b>			
BR.31: : Phase III prospective double blind placebo controlled randomised study of adjuvant MEDI4736 in completely resected non-small cell lung cancer	Patients with resected primary Stage IB (>4 cm), II or IIIA NSCLC	100 (ANZ) 1,360 (Int'l)	114 (ANZ) 1415 (Int'l)
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)	78 (ANZ) 300 (Int'l)
NIVORAD: Nivolumab and stereotactic ablative body radiotherapy (SABR) versus nivolumab alone (ALTG and CTC study)	Patients with advanced NSCLC progressing after chemotherapy	120	144
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>IN DEVELOPMENT</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
IWOT: IDH mutated 1p/19q intact lower grade glioma following resection: Wait Or Treat?	Histologically WHO grade II (diffuse) or III (anaplastic) astrocytoma, IDHmt without 1p/19q co-deletion (local diagnosis)	45 (ANZ) 624 (Int'l)	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	N/A
PICCOG: PARP and Immune Checkpoint inhibitor COmbination for relapsed IDH-mutant high-grade Glioma	Adults with histologically confirmed diagnosis of grade 3 or 4 glioma	62	N/A
<b>RECRUITING</b>			
MAGMA: Multi-Arm GlioblastoMa Australasia Trial	Adults, aged 18 years and older, with newly diagnosed histologically confirmed grade IV malignant glioblastoma	300	25
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	81

Trial	Participants	Target	Accrual
<b>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)
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	9
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
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>MOLECULAR SCREENING AND THERAPEUTICS PROGRAM (MOST) (COLLABORATING WITH AGCMC)</b>			
<b>IN DEVELOPMENT</b>			
MoST ASPIRATION: multi-centre prospective study of the clinical impact of personalised healthcare on the management and treatment of Australians with newly diagnosed, metastatic nonsquamous non-small cell lung cancer (NSCLC)	Patients with metastatic nonsquamous non-small cell lung cancer (NSCLC)	1000	1
MoST 9 Tucatinib plus Trastuzumab: Single arm, open label, signal seeking, phase IIa trial of the activity of MoST 09Trastuzumab emtansine (T-DM1) in patients with tumours harbouring HER2 amplifications or mutations	Patients with tumours harbouring HER2 amplifications or mutations	32	N/A
MoST 10: Single arm, open label, signal seeking, phase II trial of the activity of Palbociclib in combination with Avelumab in patients with tumours with amplified D-type cyclins or CDK4/6 or inactivation of CDKN2A.	Patients with advanced rare or neglected cancers	32	N/A
MoST 11: Single arm, open label signal seeking, phase II trial to study the clinical activity of Tildrakizumab in patients with advanced osteosarcoma and soft tissue sarcomas.	Patients with advanced osteosarcoma and soft tissue sarcomas.	32	N/A
MoST 12: Single arm, open label, phase II trial of vemurafenib and cobimetinib in patients with advanced tumours harbouring BRAF V600 mutations detected by comprehensive genomic profiling	Patients with tumours harbouring HER2 amplifications or mutations	64	N/A
MoST 13: A single-arm, open-label, phase II trial of entrectinib in patients with advanced tumours harbouring NTRK or ROS1 gene rearrangements detected by comprehensive genomic profiling	Patients with advanced tumours harbouring NTRK or ROS1 gene rearrangements	16	N/A
MoST 14 Alelectinib: A Single arm, open label, phase II trial of alectinib in patients with advanced tumours harbouring ALK gene alterations detected by comprehensive genomic profiling	Patients with advanced tumours harbouring ALK gene alterations	16	N/A
MoST 15 Durvalumab plus Acalabrutinib : A single arm, open label, signal seeking, phase II trial of the activity of Durvalumab in combination with Acalabrutinib in patients with high-grade B cell lymphoma	Patients with high grade B cell lymphoma	32	N/A



Trial			
<b>IN DEVELOPMENT</b>			
MoST 16 Pamiparib: Single arm, open label, signal seeking, phase II trial of pamiparib in patients with relapsed/ refractory myeloid haematological malignancy with aberrant germline or somatic DNA repair pathway function	Patients with aberrant germline or somatic DNA repair pathway function	16	N/A
MoST 17 Tepotinib: A single arm, open label, signal-seeking, phase II, trial of tepotinib in patients with advanced non-small cell lung cancer harbouring MET exon 14 skipping mutations detected by comprehensive genomic profiling	Patients with advanced non-small cell lung cancer harbouring MET exon 14 skipping mutations	32	N/A
MoST 18 Durvalumab plus chemo: A single-arm, open-label, signal-seeking, phase II trial of durvalumab and chemotherapy in patients with extra-pulmonary small cell carcinoma	Patients with extra-pulmonary small cell carcinoma	16	N/A
MoST 19: Single arm, open label, signal-seeking phase II study of Sotorasib (AMG-510) in patients with solid tumours harbouring KRAS G12C mutation	Patients with tumours harbouring KRAS G12C mutations	32	N/A
MoST CRESTONE: CRESTONE: A Phase 2 Study of Seribantumab in Adult Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors	Patients with Neuregulin-1 (NRG1) Fusion Positive Locally Advanced or Metastatic Solid Tumors	16	N/A
<b>RECRUITING</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	10
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	10
MOST 6: Single arm, open label, signal seeking, phase IIa trial of the activity of larotrectinib in patients with advanced NTRK1-3 positive tumours	Patients with advanced NTRK1-3 positive tumours	32	1
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	1
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	12
<b>TRIALS IN FOLLOW-UP</b>			
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 Olaparib: 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

Trial	Participants	Target	Accrual
<b>CARDIOMETABOLIC DISORDERS</b>			
<b>IN DEVELOPMENT</b>			
CASPER: Colchicine After Stroke to Prevent Event Recurrence will investigate the ability of colchicine, a safe and commonly used anti-inflammatory drug, to inhibit vascular disease-associated inflammation and improve clinical outcomes	Adults presenting with i) ischaemic stroke without major disability or clinical TIA with brain imaging evidence of acute infarction AND ii) hs-CRP >2 mg/L at 4-6 weeks post-event	1,500	N/A
COBRRA: A multi-centre, pragmatic, prospective randomised, open label, blinded end-point (PROBE) trial comparing bleeding outcomes using apixaban vs. rivaroxaban for the treatment of acute VTE	Adult patients with confirmed, newly diagnosed symptomatic acute VTE (proximal lower extremity DVT or segmental or greater PE)	600 (ANZ)	N/A
COLCARDIO-ACS: Colchicine Cardiovascular Outcomes in Acute Coronary Syndrome Study – a randomised clinical trial	Adult patients with acute coronary syndrome	3,000 (Int'l)	N/A
IMPACTICO: randomised, 2x2 factorial then adaptive multi-centre trial of Colchicine and IMP to improve clinical outcomes in adults with SARS CoV-2 COVID-19, hospitalised for hypoxia	Patients with SARS CoV2 COVID-19, who are in hospital and require oxygen support	1000 (Int'l)	N/A
SWIFT: A Registry-Based Cluster Randomised Controlled Trial to determine the clinical effectiveness and cost-effectiveness of symptom monitoring with feedback to clinicians compared with standard care in improving quality of life outcomes at 12 months for adults on haemodialysis	Adult patients on haemodialysis	3078 (Int'l)	N/A
<b>ACTIVE TRIALS</b>			
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)	972 (consented)
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)	42
<b>IN FOLLOW-UP</b>			
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
<b>DIABETES</b>			
<b>RECRUITINGS</b>			
FAME1-Eye: Fenofibrate and microvascular events in Type 1 diabetes (CTC-led study)	Adults with Type 1 diabetes and non-proliferative retinopathy	450	170
<b>IN FOLLOW-UP</b>			
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	130	171 registered 135 randomised



Trial	Eligibility Criteria	Target	Accrual
<b>NEONATAL AND PERINATAL</b>			
<b>IN DEVELOPMENT</b>			
iSEARCH: Can intrapartum Sildenafil safely Avert the Risks of Contraction-induced Hypoxia in labour? iSEARCH a pragmatic Phase 3 Randomised Controlled Trial	Women, in spontaneous or induced labour at term	3200	N/A
<b>RECRUITING</b>			
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	105
LEAP1: Lactoferrin evaluation in anaemia in pregnancy (CTC-led study)	Pregnant women with anaemia	800	564
PAEAN: Preventing adverse outcomes of neonatal hypoxic ischaemic encephalopathy (CTC-led study)	Newborn infants with signs of brain damage	300	299
TORPIDO 30/60: 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	287
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	587
<b>TRIALS IN FOLLOW-UP</b>			
APTS: Australian placental transfusion study (CTC-led study)	Neonates born before 30 weeks gestation	1,600	1,634
LIFT: Lactoferrin infant feeding trial (CTC-led study)	Infants born weighing under 1,500 g	1,100	1,542





## CTC STAFF AWARDS

The following CTC staff were recognised in 2020 for their outstanding contribution to the CTC.



PROFESSOR JOHN SIMES RECEIVING AN ORDER OF AUSTRALIA 2020



### ACHIEVEMENT AWARD FOR ACADEMIC STAFF

#### PROF MARTIN STOCKLER CTC Co-Director of Cancer Trials

Since joining the CTC over two decades ago, Martin has published 240 papers and attracted close to \$120M in funding. Key findings include the benefits of chemotherapy, targeted drugs, adjuvant therapy, and the best way to communicate prognoses to cancer patients. Martin is a key contributor to clinical guidelines, enhancing the standard of care in Australia and around the world.



### ACHIEVEMENT AWARD FOR PROFESSIONAL STAFF

#### SESHU ATLURI CTC Systems Architect Program Manager

Seshu can explain complex problems, produce creative solutions, and rise to the occasion every time. He goes above and beyond to ensure each assigned task is done in a prompt manner and all loose ends are completed. He has been essential to the success of the FOURIER LEGACY study, and this is true for all the studies and CTC systems he supports.



### MAKING A DIFFERENCE AWARD

#### SAVITA IYER Senior Clinical Data Manager

Savita uses her extensive data management experience to support others, she consistently displays a strong work ethic and commitment to her projects. Savita created the RECIST data cleaning training which is now in use in over 20 trials. She also led the technical specifications and testing of the imaging module for the DASL-HiCaP trial, paving the way for future trials.

### CHRIS AIKEN AWARD FOR LEADERSHIP

This award was created in recognition of Christine Aiken, who was a much loved and respected long standing member of staff who passed away in 2020.



#### SANDRA BAHAMAD Clinical Trial Operations Lead - Oncology

Sandra is a supportive, caring, and respectful manager who empowers her team to trust their knowledge and experience to work at their best output. She shows a strong commitment to her work, and her growing portfolio of trials. Sandra has actively developed more open and collaborative relationships with our stakeholders.

### TEAM SPIRIT AWARD

#### COVID-19 WORKING FROM HOME SWAT (STAFF WELLBEING ACTION TEAM)

Dinh Tran, Asanka Perera, Mark Maclean, Cynthia Carr, Lena Germinarios, Rebecca Blain, Monika Kodrun, Eric Tsobanis, Kate Sawkins, Colin Sutton, Seshu Atluri

The COVID-19 SWAT team transitioned over 240 CTC staff to work from home. They provided ongoing, comprehensive technical support and proactively ensured that workstations were set up correctly for returning staff. The team showed great resilience in performing pandemic-related work whilst under resourced.



# STAFF

As at December 2020

## CTC EXECUTIVE

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

## STRATEGIC DEVELOPMENT

Wendy Hague, Clinical Trials Strategic Development Director

## EXECUTIVE SUPPORT

Paulette Anderson, Executive Assistant  
Susan Lohan, Executive Assistant

## ONCOLOGY TRIALS PROGRAM MANAGERS

Eric Tsobanis, Head, Trial Management and Monitoring  
Hannora Jurkovic, Clinical Trials Program Manager  
Kate Wilson, Research Development Manager  
Lucille Sebastian, Clinical Trials Program Manager (MoST)  
Martijn Oostendorp, Clinical Trials Program Manager

## ONCOLOGY CLINICAL TRIAL OPERATIONS LEADS

Anna Walsh, Clinical Trial Operations Lead (CannabisCINV)  
Anthony Jaworski, Clinical Trial Operations Lead (INTEGRATEII)  
Izabella Pokorski, Clinical Trial Operations Lead (ANZUP)  
Karen Bracken, Clinical Trial Operations Lead (DASL-HiCaP)  
Kate Ford, Clinical Trial Operations Lead (DREAM3R)  
Katrina Diamante, Clinical Trial Operations Lead (ANZGOG)  
Lisa Bailey, Clinical Trial Operations Lead (AGITG)  
Mariya Walker, Clinical Trial Operations Lead (ALTG)  
Merryn Hall, Clinical Trial Operations Lead (COGNO)  
Sandra Bahamad, Clinical Trial Operations Lead (AGITG)  
Sarah Chinchin, Clinical Trial Operations Lead (MoST)  
Xanthi Coskinas, Clinical Trials Program Manager (ENZAMET/ENZARAD)

## ONCOLOGY RESEARCH DEVELOPMENT LEADS

Izabella Pokorski, Research Development Lead (ANZUP)  
Kate Wilson, Research Development Manager (AGITG)  
Kirston Barton, Research Development Lead (COGNO)  
Margot Gorzeman, Research Development Lead (ANZGOG)  
Michelle Cummins, Research Development Lead (ALTG/TOGA)

## ONCOLOGY TRIALS STAFF

Ailsa Langford, Senior Trials Operations Coordinator  
Anjali Bhardwaj, Senior Trial Operations Coordinator  
Amasy Alkhateeb, Senior Trial Operations Coordinator  
Catherine O’Connor, Trial Operations Coordinator  
Clarencia Lie, Clinical Trials Assistant  
Deepa Mathur, Trial Operations Coordinator  
Diana Winter, Senior Trial Operations Coordinator  
Emily Tu, Senior Trial Operations Coordinator  
Evan Buck, Trial Operations Coordinator  
Evyonne Tim, Senior Trial Operations Coordinator  
Frances Daley, Trial Operations Coordinator  
Hannah Cahill, Senior Trial Operations Coordinator  
Hayley Thomas, Clinical Trials Assistant  
Jason Todd, Senior Trial Operations Coordinator  
Jennifer Chong, Trial Operations Coordinator  
Joseph Levitt, Senior Trial Operations Coordinator  
Jovana Mijatovic, Trial Operations Coordinator  
Juanita Lopez Gaitan, Clinical Trials Assistant  
Kristen McParland, Senior Trial Operations Coordinator  
Lauren Fisher, Senior Trial Operations Coordinator  
Lenna Lai, Trial Operations Coordinator  
Lesley Brassel Ngo, Senior Trial Operations Coordinator  
Loc (Phuoc) Le, Trial Operations Coordinator  
Margaret Lett, Trial Operations Coordinator  
Mariam Chendeb, Clinical Trials Assistant  
Marzena Kucharska-Kelly, Trial Operations Coordinator

Muslima Rahman, Clinical Trials Assistant  
Nathan Bradshaw, Trials Operations Coordinator  
Nicolo Catapang, Clinical Trials Assistant  
Nikola Risteovski, clinical Trials Assistant  
Raewyn O’Connor, Admin Assistant (casual)  
Rose Estefanos, Clinical Trials Assistant  
Sandiya Sathiyaseelan, Trial Operations Coordinator  
Sarah York, Senior Trial Operations Coordinator  
Stephanie Attwell, Trial Operations Coordinator  
Stephanie Hollis, Trial Operations Coordinator  
Stephanie Winata, Trial Operations Coordinator  
Tara Flores, Trial Operations Coordinator  
Tet (Marie Antonette) Ricafort, Trial Operations Coordinator  
Timothy Roque, Clinical Trials Assistant  
Wiza Chileshe, Clinical Trials Assistant  
Yvonne Lee, Trial Operations Coordinator

## ONCOLOGY TRANSLATIONAL RESEARCH TEAM

**Led by Sonia Yip, Oncology Translational Research Manager**  
Estefania Martino Echarri, Translational Research Operations Officer  
Garry Chang, Senior Translational Research Operations Officer  
Rebecca Collins, Translational Research Operations Manager

## ONCOLOGY CLINICAL TEAM

**Led by Martin Stockler, Co-Director of Cancer Trials**  
Ahmad Sufian Ab Rahman, Oncology Research Fellow  
Alison Zhang, Oncology Research Fellow  
Angelina Tjokrowidaj, Oncology Research Fellow  
Antony Mersiades, Oncology Research Fellow  
Belinda Kiely, Senior Research Fellow  
Benjamin Kong, Oncology Research Fellow  
Chee Lee, Clinical Lead  
Chen (Yeh Chen) Lee, Oncology Research Fellow  
Derrick (Ho Wai) Siu, Research Associate  
Felicia Roncolato, Senior Research Fellow  
Frank Po-Yen, Research Fellow  
Hao-Wen Sim, Research Fellow  
Jane (Yeo Jeong) So, Clinical Research Fellow

Katrin Sjoquist, Clinical Lead  
Michael Burling, Research Fellow  
Peey-Sei Kok, Oncology Research Fellow  
Rebecca Merceica-Bebber, NHMRC Early Career Fellow  
Sayeda Naher, Oncology Research Fellow  
Shalini Subramaniam, Oncology Research Associate  
Subo (Subotheni) Thavaneswaran, Senior Research Fellow  
Zarka Samoon, Oncology Research Fellow

## CARDIOVASCULAR/DIABETES TRIALS STAFF

**Led by Rebecca Mister, Clinical Trials Program Manager**  
Annie Yeung, Clinical Trial Operations Lead  
Cat Van Kemenade, Clinical Trials Assistant  
Cecilia Taing, Trial Operations Coordinator  
Clare Toms, Trial Operations Coordinator  
Jessie Payne, Senior Trial Operations Coordinator  
Li Ping Li, Senior Trial Operations Coordinator  
Portia Westall, Trial Operations Coordinator  
Stephanie Obeid, Senior Trial Operations Coordinator  
Winnie (Wenxian) Zhang, Trial Operations Coordinator

## CARDIOVASCULAR/DIABETES CLINICAL TEAM

**Led by Alicia Jenkins, Professor, Diabetes & Vascular Medicine**  
Andrzej Januszewski, Senior Research Fellow  
Chris Ryan, Telehealth Program Manager  
Emma Scott, PhD Candidate  
Hilary Richardson, Developer/Programmer  
Luke Carroll, Postdoctoral Research Assistant  
Sharon Atkinson-Briggs, PhD Candidate

## KIDNEY HEALTH TEAM

**Led by Arlen Wilcox, Clinical Trials Program Manager**  
Nuria Zamora Solano, Senior Trial Operations Coordinator

## KIDNEY HEALTH CLINICAL TEAM

**Led by Meg Jardine, Professor, Kidney Health**  
Brendan Smyth, Research Fellow

## NEONATAL AND PERINATAL TRIALS TEAM

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

## NEONATAL AND PERINATAL CLINICAL TEAM

William Tarnow-Mordi, Professor, Neonatology

## ETHICS AND REGULATORY

**Led by Lara Hall, Senior Ethics and Regulatory Coordinator**  
Hira Saud, Ethics and Regulatory Coordinator

## HEALTH ECONOMICS

**Led by Rachael Morton, Professor Health Economics**  
Ann Livingstone, PhD Candidate  
Emma Zhang, Project Officer (casual)  
Enam (Mohammad) Hoque, Research Fellow  
Karan Shah, Health Economist  
Kathy Dempsey, Research Fellow  
Mbathio Dieng, Research Fellow  
Rashed (Rashidul) Mahumud, Postdoctoral Health Economist  
Samuel Herzog, Research Assistant (casual)  
Stephen Law, Senior Research Fellow

## HEALTH TECHNOLOGY ASSESSMENT

**Led by Blaise Agresta, Health Technology Assessment Program Manager**  
Nathan Fox, Senior Evidence Analyst  
Slavica Berber, Project Officer - Health Technology Assessment Team  
Smriti Raichand, Senior Evidence Analyst  
Vendula Blaya-Novakova, Project Officer - Health Technology Assessment Team

## EVIDENCE INTEGRATION

**Led by Angela Webster, Director Evidence Integration**  
Angie (Ekaterina) Turnbull, Senior Project Officer  
Ava Tan-Koay, Senior Project Officer  
Helen Towle, Admin Officer (casual)  
Jessica Falon, Admin Assistant ANZCTR (casual)  
Jonathan Williams, Research Assistant (casual)  
Julie Phan, Admin Assistant ANZCTR (casual)  
Kylie Hunter, Systematic Reviews Senior Project Officer  
Lene (Anna) Seidler, Systematic Reviews Biostatistician (Research Fellow)  
Lukas Staub, Clinical Epidemiologist  
Mason Aberoumand, Systematic Reviews Data Officer  
Melina Willson, Project Manager  
Peta Skeers, Project Officer  
Sally (Sarah) Lord, Senior Research Fellow  
Saskia Cheyne, Senior Evidence Analyst  
Sol Libesman, Systematic Reviews Data Officer

## BIostatISTICS

**Led by Ian Marschner & Val Gebski, Co-Directors of Biostatistics & Research Methodology**  
Adrienne Kirby, Senior Research Fellow  
Andrew Martin, Senior Research Fellow  
Anne Soerensen, Biostatistician  
Chris Brown, Research Fellow  
David Espinoza, Biostatistician  
Gillian Heller, Professor of Biostatistics  
James Murray, Biostatistician  
Karen Byth Wilson, Biostatistician  
Kristy Robledo, Research Fellow  
Liz (Elizabeth) Barnes, Research Fellow  
Nanda Aryal, Biostatistician  
Vanessa Cochrane, Admin Officer  
Rachel O’Connell, Senior Research Fellow  
Renee Eggins, Biostatistician  
Sandun Silva, Biostatistician

## BCA

Emily Higginson, Senior Admin Officer  
Erica Jobling, Executive Officer  
Karolina Kulczynska-Le Breton, Executive Officer



## SYDNEY CATALYST

Alison Young, Postdoctoral Research Associate  
Anthony Don, Principal Research Fellow, Tumour Metabolism  
Bea Brown, EnRICH Program Manager  
Cara McFarlane, Sydney Catalyst Project Officer, Education and Communications  
Divya Murthy, Coordinator Sydney Catalyst  
Gerry Tierney, Casual  
Henna Kuusisto, Trial Operations Coordinator (casual)  
Jean Adeline Yap, Research Assistant, EnRICH  
Joyce Chiu, Research Fellow  
Kimberley Mander, Research Officer, EnRICH  
Kirsty Galpin, Research Fellow, EnRICH  
Mark Schreuder, Research Associate  
Meryllyn Heuschkel, Sydney Catalyst Research Manager  
Mikaela Holmes, Casual  
Philip Hogg, Chair Translational Cancer Research  
Spoorthi Gowda, Clinical Data Coordinator, EnRICH

## COGNO

**Led by Jenny Chow, Executive Officer**  
Danielle Massey, Project Officer  
Mythily Sachchithananthian, Senior Project Officer, BCBA, COGNO  
Yi Feng, Project Officer  
Clinical Quality and Compliance  
Led by Kate Sawkins, Clinical Quality and Compliance Manager  
Karen Wilkinson, Program Co-Ordinator  
Quality Assurance and Auditor  
Sally Doyle, Clinical Quality & Compliance Officer

## CLINICAL DATA MANAGEMENT GROUP

**Led by Salma Fahridin, Head of Clinical Data Management**

Aliki Rasmiena, Clinical Data Manager  
Anneliese Linaker, Clinical Data Manager  
Ashneeta Kumar, Clinical Data Manager  
Georgina Dukoska, Clinical Data Manager  
Georgia Rook, Clinical Data Manager  
Kathleen Harwood, Clinical Data Manager  
Leanna Cheung, Clinical Data Manager  
Lisa Valenti, Clinical Data Programmer  
Savita Iyer, Senior Clinical Data Manager  
Shradha Kadam, Clinical Data Programmer  
Sandra Lee, Clinical Data Manager  
Talia Palacios, Senior Clinical Data Manager  
Tara Flores, Clinical Data Manager  
Thida Thein, Clinical Data Manager  
Vevian Evans, Clinical Data Manager  
Ying Pan, Clinical Data Program Manager

## DATA & INFORMATICS GROUP

**Led by Mark Maclean, Associate Director, Data & Informatics**

## CLINICAL DATA SYSTEMS

**Led by Ilka Kolodziej, Clinical Data Systems Manager**  
Danielle Parker, Clinical Data Systems Coordinator  
Jacinta Lourdesamy, Clinical Data Systems Officer  
Louisa Muhuthia, Clinical Data Systems Coordinator  
Nicole McKay, Clinical Data Systems Coordinator  
Sharmila Siriragavan, Clinical Data Systems Coordinator  
Information Systems Development  
Anish Khaleefa, Developer/Programmer  
Seshu Atluri, Systems Architect Program Manager  
Colin Sutton, IT Systems Development Manager  
Information Systems and Support  
Asanka Perera, Infrastructure Support  
Dinh Tran, Manager, IS&S Infrastructure Support  
Patrick Wangsa, Desktop Support Officer

## BUSINESS GROUP

**Led by Danielle Miller, Business Director**

Agnes Ho, Finance Officer  
Carlos Sterling, Finance Officer  
Cynthia Carr, HR/Admin Manager  
Ellen Brodie, CTC Research Support Co-ordinator  
Lena (Magdalena) Germinarios, CTC Workforce Coordinator  
Libby (Elizabeth) Cregan, Receptionist/Admin Assistant  
Marina Zadonskaia, Admin Officer  
Melissa Meng, Associate Finance Manager (casual)  
Molly Dias, Finance Officer  
Nicole Wong, Contracts and Grants Manager  
Paul Smyth, Finance Manager  
Rebecca Blain, Admin Officer  
Sarah Munro, Communications Officer  
Sherilyn Goldstone, Medical Writer  
Yumi Guo, Contracts & Grants Coordinator

# PUBLICATIONS

For the 2020 calendar year

1. Aji G, Huang Y, Ng ML, Wang W, Lan T, Li M, et al. Regulation of hepatic insulin signaling and glucose homeostasis by sphingosine kinase 2. *Proc Natl Acad Sci U S A*. 2020;117(39):24434-42.  
2. Alfelali M, Haworth EA, Barasheed O, Badahdah AM, Bokhary H, Tashani M, et al. Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial. *PLoS One*. 2020;15(10):e0240287.  
3. Al-Rubaie ZTA, Hudson HM, Jenkins G, Mahmoud I, Ray JG, Askie LM, et al. Prediction of pre-eclampsia in nulliparous women using routinely collected maternal characteristics: A model development and validation study. *BMC Pregnancy Childbirth*. 2020;20(1):23.  
4. Anderson KJ, Tan AC, Parkinson J, Back M, Kastelan M, Newey A, et al. Molecular and clonal evolution in recurrent metastatic gliosarcoma. *Cold Spring Harb Mol Case Stud*. 2020;6(1).  
5. Arnott C, Neuen BL, Heerspink HJL, Figtree GA, Kosiborod M, Lam CS, et al. The effects of combination canagliflozin and glucagon-like peptide-1 receptor agonist therapy on intermediate markers of cardiovascular risk in the CANVAS program. *Int J Cardiol*. 2020;318:126-9.  
6. Arnott C, Huang Y, Neuen BL, Di Tanna GL, Cannon CP, Oh R, et al. The effect of canagliflozin on amputation risk in the CANVAS program and the CREDENCE trial. *Diabetes Obes Metab*. 2020.  
7. Arnott C, Li Q, Kang A, Neuen BL, Bompont S, Lam CSP, et al. Sodium-glucose cotransporter 2 inhibition for the prevention of cardiovascular events in patients with type 2 diabetes mellitus: A systematic review and meta-analysis. *J Am Heart Assoc*. 2020;9(3):e014908.  
8. Askie LM, Espinoza D, Martin A, Daniels LA, Mhrshahi S, Taylor R, et al. Interventions commenced by early infancy to prevent childhood obesity - The EPOCH Collaboration: An individual participant data prospective meta-analysis of four randomized controlled trials. *Pediatr Obes*. 2020:e12618.  
9. Asztalos EV, Barrington K, Lodha A, Tarnow-Mordi W, Martin A. Lactoferrin infant feeding trial\_Canada (LIFT\_Canada): Protocol for a randomized trial of adding lactoferrin to feeds of very-low-birth-weight preterm infants. *BMC Pediatr*. 2020;20(1):40.

10. Athavale A, Morris J, Jardine M, Gallagher M, Sen S, Ritchie A, et al. Acute interstitial nephritis and nephrogenic diabetes insipidus following treatment with sulfamethoxazole-trimethoprim and temozolomide. *Nephrology (Carlton)*. 2020.  
11. Back M, Jayamanne D, Brazier D, Newey A, Bailey D, Schembri G, et al. Pattern of failure in anaplastic glioma patients with an IDH1/2 mutation. *Strahlenther Onkol*. 2020;196(1):31-9.  
12. Balegar VK, Jayawardhana M, Martin AJ, de Chazal P, Nanan RKH. Association of bolus feeding with splanchnic and cerebral oxygen utilization efficiency among premature infants with anemia and after blood transfusion. *JAMA Netw Open*. 2020;3(2):e200149.  
13. Barbour AP, Walpole ET, Mai GT, Barnes EH, Watson DI, Ackland SP, et al. Preoperative cisplatin, fluorouracil, and docetaxel with or without radiotherapy after poor early response to cisplatin and fluorouracil for resectable oesophageal adenocarcinoma (AGITG DOCTOR): Results from a multicentre, randomised controlled phase II trial. *Ann Oncol*. 2020;31(2):236-45.  
14. Barbour AP, Samra JS, Haghighi KS, Donoghoe MW, Burge M, Harris MT, et al. The AGITG GAP Study: A phase II study of perioperative gemcitabine and nab-paclitaxel for resectable pancreas cancer. *Ann Surg Oncol*. 2020.  
15. Barnes DR, Rookus MA, McGuffog L, Leslie G, Mooij TM, Dennis J, et al. Polygenic risk scores and breast and epithelial ovarian cancer risks for carriers of BRCA1 and BRCA2 pathogenic variants. *Genet Med*. 2020.  
16. Barraclough JY, Joglekar MV, Januszewski AS, Martinez G, Celermajer DS, Keech AC, et al. A microRNA signature in acute coronary syndrome patients and modulation by colchicine. *J Cardiovasc Pharmacol Ther*. 2020:1074248420922793.  
17. Bartos NSO, Hamilton S, Barnes E, Caldwell PHY. Toilet training children with special needs using a Potty Monkey toy device. *J Paediatr Child Health*. 2020.  
18. Bina S, Pacey V, Barnes EH, Burns J, Gray K. Interventions for congenital talipes equinovarus (clubfoot). *Cochrane Database Syst Rev*. 2020;5:CD008602.  
19. Bordewijk EM, Wang R, Askie LM, Gurrin LC, Thornton JG, van Wely M, et al. Data integrity of 35 randomised controlled

trials in women' health. *Eur J Obstet Gynecol Reprod Biol*. 2020.  
20. Bordewijk EM, Wang R, Askie LM, Gurrin LC, Thornton JG, van Wely M, et al. Letter of response (2) - Data integrity of 35 randomised controlled trials in women' health. *Eur J Obstet Gynecol Reprod Biol*. 2020.  
21. Bui KT, Willson ML, Goel S, Beith J, Goodwin A. Ovarian suppression for adjuvant treatment of hormone receptor-positive early breast cancer. *Cochrane Database Syst Rev*. 2020;3:CD013538.  
22. Burgess SN, Juergens CP, Nguyen TL, Leung M, Robledo KP, Thomas L, et al. Comparison of late cardiac death and myocardial infarction rates in women vs men with ST-elevation myocardial infarction. *Am J Cardiol*. 2020;128:120-6.  
23. Burgess SN, Juergens CP, Nguyen T, Leung M, Robledo KP, Thomas L, et al. Diabetes and incomplete revascularisation in ST elevation myocardial infarction. *Heart Lung Circ*. 2020.  
24. Butera D, Hogg PJ. Fibrinogen function achieved through multiple covalent states. *Nat Commun*. 2020;11(1):5468.  
25. Cannon CP, Perkovic V, Agarwal R, Baldassarre J, Bakris G, Charytan DM, et al. Evaluating the effects of canagliflozin on cardiovascular and renal events in patients with type 2 diabetes mellitus and chronic kidney disease according to baseline HbA1c, including those with HbA1c <7%: results from the CREDENCE trial. *Circulation*. 2020;141(5):407-10.  
26. Cao JY, Waldman B, O'Connell R, Sullivan DR, Scott RS, Aryal N, et al. Uric acid predicts long-term cardiovascular risk in type 2 diabetes but does not mediate the benefits of fenofibrate: The FIELD study. *Diabetes Obes Metab*. 2020.  
27. Cardoso F, Paluch-Shimon S, Senkus E, Curigliano G, Aapro MS, Andre F, et al. 5th ESO-ESMO international consensus guidelines for advanced breast cancer (ABC 5)(dagger). *Ann Oncol*. 2020.  
28. Chan L, Hwang SJE, Kyaw M, Byth K, Carlino MS, Chou S, et al. The oncological survival and prognosis of individuals receiving PD-1 inhibitor with and without immunologic cutaneous adverse events. *J Am Acad Dermatol*. 2020;82(2):311-6.  
29. Chen Z, Moore KH, Mansfield KJ, Ognenovska S, Allen W, Parkin K, et al. Effect of antibiotics on urine leakage in women



with refractory detrusor overactivity:

A phase IIb randomized trial. *NeuroUrol Urodyn.* 2020.

30. Chia PL, Russell P, Asadi K, Thapa B, GebSKI V, Murone C, et al. Analysis of angiogenic and stromal biomarkers in a large malignant mesothelioma cohort. *Lung Cancer.* 2020;150:1-8.

31. Chia PL, Parakh S, Russell P, Gan HK, Asadi K, GebSKI V, et al. Expression of EGFR and conformational forms of EGFR in malignant pleural mesothelioma and its impact on survival. *Lung Cancer.* 2020;153:35-41.

32. Chiang JI, Manski-Nankervis JA, Thuraisingam S, Jenkins A, O’Neal D, Mair FS, et al. Multimorbidity, glycaemic variability and time in target range in people with type 2 diabetes: A baseline analysis of the GP-OSMOTIC trial. *Diabetes Res Clin Pract.* 2020;169:108451.

33. Cipriani A, Ioannidis JPA, Rothwell PM, Glasziou P, Li T, Hernandez AF, et al. Generating comparative evidence on new drugs and devices after approval. *Lancet.* 2020;395(10228):998-1010.

34. Clark W, Bird P, Diamond T, Gonski P, GebSKI V. Vertebroplasty has an important role in managing patients with severe pain when performed early and with appropriate technique. *Intern Med J.* 2020;50(5):647-8.

35. Clark W, Bird P, Diamond T, Gonski P, GebSKI V. Cochrane vertebroplasty review misrepresented evidence for vertebroplasty with early intervention in severely affected patients. *BMJ Evid Based Med.* 2020;25(3):85-9.

36. Clase CM, Carrero JJ, Ellison DH, Grams ME, Hemmelgarn BR, Jardine MJ, et al. Potassium homeostasis and management of dyskalemia in kidney diseases: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int.* 2020;97(1):42-61.

37. Cohen PA, Leung Y, Anderson L, van der Griend R, Chivers P, Bilic S, et al. Excisional treatment comparison for in situ endocervical adenocarcinoma (EXCISE): A phase 2 pilot randomized controlled trial to compare histopathological margin status, specimen size and fragmentation after loop electrosurgical excision procedure and cold knife cone biopsy. *Gynecol Oncol.* 2020.

38. Condie AM, Allen TV, Ogle GD. Incidence and characteristics of childhood- and youth-onset diabetes in the Qalanderabad area in northern Pakistan. *Diabetes Res Clin Pract.* 2020;163:108155.

39. Coultas TA, Rustam YH, Song H, Qi Y, T eo JD, Chen J, et al. A novel function of

sphingosine kinase 2 in the metabolism of sphinga-4,14-diene lipids. *Metabolites.* 2020;10(6).

40. Cronin RS, Wilson J, Gordon A, Li M, Culling VM, Raynes-Greenow CH, et al. Associations between symptoms of sleep-disordered breathing and maternal sleep patterns with late stillbirth: Findings from an individual participant data meta-analysis. *PLoS One.* 2020;15(3):e0230861.

41. Cusimano MC, Sajewycz K, Nelson M, Jivraj N, Lee YC, Bowering V, et al. Supported self-management as a model for end-of-life care in the setting of malignant bowel obstruction: A qualitative study. *Gynecol Oncol.* 2020.

42. Diamond T, Clark W, Bird P, Gonski P, Barnes E, GebSKI V. Early vertebroplasty within 3 weeks of fracture for acute painful vertebral osteoporotic fractures: subgroup analysis of the VAPOUR trial and review of the literature. *Eur Spine J.* 2020.

43. Dieng M, Morton RL, Costa DSJ, Butow PN, Menzies SW, Lo S, et al. Benefits of a brief psychological intervention targeting fear of cancer recurrence in people at high risk of developing another melanoma: 12-month follow-up results of a randomized controlled trial. *Br J Dermatol.* 2020;182(4):860-8.

44. Dieng M, Khanna N, Nguyen MTH, Turner R, Lord SJ, Menzies AM, et al. Cost-effectiveness analysis of PET/CT surveillance imaging to detect systemic recurrence in resected stage III melanoma: study protocol. *BMJ Open.* 2020;10(11):e037857.

45. Dorio M, Hunter DJ, Collins JE, Asher R, Eckstein F, Guermazi A, et al. Association of baseline and change in tibial and femoral cartilage thickness and development of widespread full-thickness cartilage loss in knee osteoarthritis - data from the Osteoarthritis Initiative. *Osteoarthritis Cartilage.* 2020.

46. Duncanson E, Bennett PN, VieceLLi A, Dansie K, Handke W, Tong A, et al. Feasibility and acceptability of e-PROMs data capture and feedback among patients receiving haemodialysis in the Symptom monitoring With Feedback Trial (SWIFT) pilot: protocol for a qualitative study in Australia. *BMJ Open.* 2020;10(11):e039014.

47. Eisen T, Frangou E, Oza B, Ritchie AWS, Smith B, Kaplan R, et al. Adjuvant sorafenib for renal cell carcinoma at intermediate or high risk of relapse: Results from the SORCE randomized phase III Intergroup trial. *J Clin Oncol.* 2020;38(34):4064-75.

48. Felmingham CM, Adler NR, Ge Z,

Morton RL, Janda M, Mar VJ. The importance of incorporating human factors in the design and implementation of artificial intelligence for skin cancer diagnosis in the real world. *Am J Clin Dermatol.* 2020.

49. Foote C, Hockham C, Sukkar L, Campain A, Kang A, Young T, et al. EXamining outTcomEs in chroNic Disease in the 45 and Up Study (the EXTEND45 Study): Protocol for an Australian Linked Cohort Study. *JMIR Res Protoc.* 2020;9(4):e15646.

50. Frumovitz M, Obermair A, Coleman RL, Pareja R, Lopez A, Ribero R, et al. Quality of life in patients with cervical cancer after open versus minimally invasive radical hysterectomy (LACC): a secondary outcome of a multicentre, randomised, open-label, phase 3, non-inferiority trial. *Lancet Oncol.* 2020;21(6):851-60.

51. Fulcher J, Keech A, Simes J, Baigent C, Collins R. Questioning statin therapy for older patients - Authors’ reply. *Lancet.* 2020;395(10240):1832-3.

52. Fung AS, Tam VC, Meyers DE, Sim HW, Knox JJ, Zaborska V, et al. Second-line treatment of hepatocellular carcinoma after sorafenib: Characterizing treatments used over the past 10 years and real-world eligibility for cabozantinib, regorafenib, and ramucirumab. *Cancer Med.* 2020.

53. Furler J, O’Neal D, Speight J, Blackberry I, Manski-Nankervis JA, Thuraisingam S, et al. Use of professional-mode flash glucose monitoring, at 3-month intervals, in adults with type 2 diabetes in general practice (GP-OSMOTIC): A pragmatic, open-label, 12-month, randomised controlled trial. *Lancet Diabetes Endocrinol.* 2020;8(1):17-26.

54. Gencer B, Mach F, Guo J, Im K, Ruzza A, Wang H, et al. Cognition after lowering LDL-cholesterol with evolocumab. *J Am Coll Cardiol.* 2020;75(18):2283-93.

55. Gencer B, Mach F, Murphy SA, De Ferrari GM, Huber K, Lewis BS, et al. Efficacy of evolocumab on cardiovascular outcomes in patients with recent myocardial infarction: A prespecified secondary analysis from the FOURIER trial. *JAMA Cardiol.* 2020.

56. Gencer B, Marston NA, Im K, Cannon CP, Sever P, Keech A, et al. Efficacy and safety of lowering LDL cholesterol in older patients: a systematic review and meta-analysis of randomised controlled trials. *Lancet.* 2020;396(10263):1637-43.

57. Giugliano RP, Pedersen TR, Saver JL, Sever PS, Keech AC, Bohula EA, et al. Stroke prevention with the PCSK9 (Proprotein Convertase Subtilisin-Kexin Type 9) inhibitor

evolocumab added to statin in high-risk patients with stable atherosclerosis. *Stroke.* 2020;51(5):1546-54.

58. Goh A, Karine P, Kirby A, Williams C, Kapurubandara S. Day 1 to day 4 serum hCG change in predicting single-dose methotrexate treatment failure for tubal ectopic pregnancies. *Eur J Obstet Gynecol Reprod Biol.* 2020;255:105-10.

59. Goldstein D, Von Hoff DD, Chiorean EG, Reni M, Tabernero J, Ramanathan RK, et al. Nomogram for estimating overall survival in patients with metastatic pancreatic cancer. *Pancreas.* 2020;49(6):744-50.

60. Grimison P, Mersiades A, Kirby A, Lintzeris N, Morton R, Haber P, et al. Oral THC:CBD cannabis extract for refractory chemotherapy-induced nausea and vomiting: a randomised, placebo-controlled, phase II crossover trial. *Ann Oncol.* 2020.

61. Grunwald V, Chirovsky D, Cheung WY, Bertolini F, Ahn MJ, Yang MH, et al. Global treatment patterns and outcomes among patients with recurrent and/or metastatic head and neck squamous cell carcinoma: Results of the GLANCE Head and Neck study. *Oral Oncol.* 2020;102:104526.

62. Hallal S, Azimi A, Wei H, Ho N, Lee MYT, Sim HW, et al. A comprehensive proteomic SWATH-MS workflow for profiling blood extracellular vesicles: a new avenue for glioma tumour surveillance. *Int J Mol Sci.* 2020;21(13).

63. Hallal S, Ebrahim Khani S, Wei H, Lee MYT, Sim HW, Sy J, et al. Deep sequencing of small RNAs from Neurosurgical extracellular vesicles substantiates miR-486-3p as a circulating biomarker that distinguishes glioblastoma from lower-grade astrocytoma patients. *Int J Mol Sci.* 2020;21(14).

64. Handrinos L, Januszewski AS, Trimble E, Donelan N, Williams P, Jenkins AJ. Point-of-care testing of HbA1c, renal function and lipids in remote or disadvantaged regions. *Intern Med J.* 2020;50(12):1567-71.

65. Hendrieckx C, Halliday JA, Russell-Green S, Cohen N, Colman PG, Jenkins A, et al. Adults with diabetes distress often want to talk with their health professionals about it: Findings from an audit of four Australian specialist diabetes clinics. *Can J Diabetes.* 2020.

66. Hill RE, Wakefield CE, Cohn RJ, Fardell JE, Brierley ME, Kothe E, et al. Survivorship care plans in cancer: A meta-analysis and systematic review of care plan outcomes. *Oncologist.* 2020;25(2):e351-e72.

67. Hilvo M, Meikle PJ, Pedersen ER, Tell GS, Dhar I, Brenner H, et al. Development and validation of a ceramide- and phospholipid-

based cardiovascular risk estimation score for coronary artery disease patients. *Eur Heart J.* 2020;41(3):371-80.

68. Ho Shon I, Kumar D, Sathiakumar C, Berghofer P, Van K, Chicco A, et al. Biodistribution and imaging of an hsp90 ligand labelled with (111)In and (67)Ga for imaging of cell death. *EJNMMI Res.* 2020;10(1):4.

69. Hole B, Hemmelgarn B, Brown E, Brown M, McCulloch MI, Zuniga C, et al. Supportive care for end-stage kidney disease: an integral part of kidney services across a range of income settings around the world. *Kidney Int Suppl* (2011). 2020;10(1):e86-e94.

70. Horsley PJ, Perera L, Veness MJ, Stevens MJ, Eade TN, Back M, et al. Outcomes for elderly patients 75 years and older treated with curative intent radiotherapy for mucosal squamous cell carcinomas of the head and neck. *Head Neck.* 2020;42(1):25-32.

71. Isaacs D, Tarnow-Mordi WO, Sherwood J. Black Lives Matter movement: The time for nice words and good intentions is over. *J Paediatr Child Health.* 2020;56(9):1327-9.

72. J C, Manski-Nankervis JA, Thuraisingam S, Jenkins A, O’Neal D, Mair FS, et al. Multimorbidity, glycaemic variability and time in target range in people with type 2 diabetes: a baseline analysis of the GP-OSMOTIC trial. *Diabetes Res Clin Pract.* 2020;108451.

73. Jain A, Sjoquist K, Yip D. ESMO Localized colon cancer guidelines: “Can we improve on our surveillance protocols?”. *Ann Oncol.* 2020.

74. Jamieson LM, Sajiv C, Cass A, Maple-Brown LJ, Skilton MR, Kapellas K, et al. Lessons learned from a periodontal intervention to reduce progression of chronic kidney disease among Aboriginal Australians. *BMC Res Notes.* 2020;13(1):483.

75. Januszewski AS, Sachithanandan N, Ward G, Karschimus CS, O’Neal DN, Jenkins AJ. Estimated insulin sensitivity in Type 1 diabetes adults using clinical and research biomarkers. *Diabetes Res Clin Pract.* 2020;167:108359.

76. Januszewski AS, Xu D, Cho YH, Benitez-Aguirre PZ, O’Neal DN, Craig ME, et al. Skin autofluorescence in people with type 1 diabetes and people without diabetes: An eight-decade cross-sectional study with evidence of accelerated aging and associations with complications. *Diabet Med.* 2020:e14432.

77. Jardine MJ, Zhou Z, Mahaffey KW, Oshima M, Agarwal R, Bakris G, et al. Renal, cardiovascular, and safety outcomes of

canagliflozin by baseline kidney function:

A secondary analysis of the CREDENCE randomized trial. *J Am Soc Nephrol.* 2020;31(5):1128-39.

78. Joglekar MV, Satoor SN, Wong WKM, Cheng F, Ma RCW, Hardikar AA. An optimised step-by-step protocol for measuring relative telomere length. *Methods Protoc.* 2020;3(2).

79. Kang A, Sukkar L, Hockham C, Jun M, Young T, Scaria A, et al. Risk factors for incident kidney disease in older adults: an Australian prospective population-based study. *Intern Med J.* 2020.

80. Kasherman L, Siu DHW, Lee KWC, Lord S, Marschner I, Lewis CR, et al. Efficacy of immune checkpoint inhibitors in older adults with advanced stage cancers: A meta-analysis. *J Geriatr Oncol.* 2020;11(3):508-14.

81. Keall P, Nguyen DT, O’Brien R, Hewson E, Ball H, Poulsen P, et al. Real-time image guided ablative prostate cancer radiation therapy: Results from the TROG 15.01 SPARK trial. *Int J Radiat Oncol Biol Phys.* 2020.

82. Kelly CB, Wagner CL, Shary JR, Leyva MJ, Yu JY, Jenkins AJ, et al. Vitamin D metabolites and binding protein predict preeclampsia in women with type 1 diabetes. *Nutrients.* 2020;12(7).

83. Khandkar C, Vaidya K, Penglese R, Cai K, Shin JS, Hunyor I, et al. Rare case of infiltrative cardiomyopathy secondary to scleromyxoedema. *Intern Med J.* 2020;50(1):127-8.

84. Khou V, De La Mata NL, Morton RL, Kelly PJ, Webster AC. Cause of death for people with end-stage kidney disease withdrawing from treatment in Australia and New Zealand. *Nephrol Dial Transplant.* 2020.

85. Kiely BE, Stockler MR. When should oncologists use the words hope and cure? *JNCI Cancer Spectr.* 2020;4(6):pkaa066.

86. Kok PS, Cho D, Yoon WH, Ritchie G, Marschner I, Lord S, et al. Validation of progression-free survival rate at 6 months and objective response for estimating overall survival in immune checkpoint inhibitor trials: a systematic review and meta-analysis. *JAMA Netw Open.* 2020;3(9):e2011809.

87. Krishnasamy R, Hawley CM, Jardine MJ, Roberts MA, Cho Y, Wong M, et al. A trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients: A safety device study. *Blood Purif.* 2020;49(4):468-78.

88. Kurra P, Brazionis L, Gale J, Chen K, Lake S, Robledo KP, et al. Visual outcomes in the management of diabetic maculopathy in



Central Australia. *Ophthalmic Epidemiol.* 2020;1-7.

89. Lee KWC, Lord SJ, Kasherman L, Marschner I, Stockler M, Gralla R, et al. The impact of smoking on the effectiveness of immune checkpoint inhibitors - a systematic review and meta-analysis. *Acta Oncol.* 2020;59(1):96-100.

90. Lee MH, Vogrin S, Paldus B, Jayawardene D, Jones HM, McAuley SA, et al. Glucose and counterregulatory responses to exercise in adults with Type 1 diabetes and impaired awareness of hypoglycemia using closed-loop insulin delivery: A randomized crossover study. *Diabetes Care.* 2020;43(2):480-3.

91. Lee A, Arasaratnam M, Chan DLH, Khasraw M, Howell VM, Wheeler H. Anti-epidermal growth factor receptor therapy for glioblastoma in adults. *Cochrane Database Syst Rev.* 2020;5:CD013238.

92. Leonardi M, Robledo KP, Goldstein SR, Benacerraf BR, Condous G. International survey finds majority of gynecologists are not aware of and do not utilize ultrasound techniques to diagnose and map endometriosis: it is time to improve education and change guidelines. *Ultrasound Obstet Gynecol.* 2020.

93. Leonardi M, Robledo KP, Espada M, Vanza K, Condous G. SonoPODography: A new diagnostic technique for visualizing superficial endometriosis. *Eur J Obstet Gynecol Reprod Biol.* 2020;254:124-31.

94. Levett KM, Lord SJ, Dahlen HG, Smith CA, Giosi F, Downe S, et al. The AEDUCATE Collaboration. Comprehensive antenatal education birth preparation programmes to reduce the rates of caesarean section in nulliparous women. Protocol for an individual participant data prospective meta-analysis. *BMJ Open.* 2020;10(9):e037175.

95. Levin A, Agarwal R, Herrington WG, Heerspink HL, Mann JFE, Shahinfar S, et al. International consensus definitions of clinical trial outcomes for kidney failure: 2020. *Kidney Int.* 2020;98(4):849-59.

96. Lheureux S, Oaknin A, Garg S, Bruce JP, Madariaga A, Dhani NC, et al. EVOLVE: A multicenter open-label single-arm clinical and translational phase ii trial of cediranib plus olaparib for ovarian cancer after PARP inhibition progression. *Clin Cancer Res.* 2020.

97. Li C, Zhou Z, Neuen BL, Yu J, Huang Y, Young T, et al. Sodium-glucose co-transporter-2 inhibition and ocular outcomes in patients with type 2 diabetes: A systematic review and meta-analysis. *Diabetes Obes Metab.* 2020.

98. Lintzeris N, Mills L, Dunlop A, Copeland J, McGregor I, Bruno R, et al. Cannabis use in patients 3 months after ceasing nabiximols for the treatment of cannabis dependence: Results from a placebo-controlled randomised trial. *Drug Alcohol Depend.* 2020;215:108220.

99. Liu B, Amaratunga R, Veness M, Wong E, Abdul-Razak M, Coleman H, et al. Tumor depth of invasion versus tumor thickness in guiding regional nodal treatment in early oral tongue squamous cell carcinoma. *Oral Surg Oral Med Oral Pathol Oral Radiol.* 2020;129(1):45-50.

100. Livingstone A, Morton RL. ASO Author Reflections: Important factors for adjuvant immunotherapy treatment decisions for stage II-IV melanoma patients and their clinicians. *Ann Surg Oncol.* 2020;27(2):585-6.

101. Livingstone A, Agarwal A, Stockler MR, Menzies AM, Howard K, Morton RL. Preferences for immunotherapy in melanoma: A systematic review. *Ann Surg Oncol.* 2020;27(2):571-84.

102. Lo SN, Smit AK, Espinoza D, Cust AE, Managing Your Risk Study G. The Melanoma Genomics Managing Your Risk Study randomised controlled trial: statistical analysis plan. *Trials.* 2020;21(1):594.

103. Luen SJ, Asher R, Lee CK, Savas P, Kammler R, Dell'Orto P, et al. Identifying oncogenic drivers associated with increased risk of late distant recurrence in post-menopausal, estrogen receptor-positive, HER2-negative early breast cancer: results from the BIG 1-98 study. *Ann Oncol.* 2020.

104. Malesu R, Martin AJ, Lyons JG, Scolyer RA, Chen AC, McKenzie CA, et al. Nicotinamide for skin cancer chemoprevention: Effects of nicotinamide on melanoma in vitro and in vivo. *Photochem Photobiol Sci.* 2020.

105. Manera KE, Ju A, Baumgart A, Hannan E, Qiao W, Howell M, et al. Patient-reported outcome measures for life participation in peritoneal dialysis: a systematic review. *Nephrol Dial Transplant.* 2020.

106. Marschner IC, Askie LM, Schou IM. Sensitivity analyses assessing the impact of early stopping on systematic reviews: Recommendations for interpreting guidelines. *Res Synth Methods.* 2020.

107. Marschner IC. Back-projection of COVID-19 diagnosis counts to assess infection incidence and control measures: analysis of Australian data. *Epidemiol Infect.* 2020;148:e97.

108. Marston NA, Kamanu FK, Nordio F, Gurmu Y, Roselli C, Sever PS, et al. Predicting benefit from evolocumab therapy in patients with atherosclerotic

disease using a genetic risk score: Results from the FOURIER trial. *Circulation.* 2020;141(8):616-23.

109. Marston NA, Gurmu Y, Melloni GEM, Bonaca M, Gencer B, Sever PS, et al. The effect of PCSK9 inhibition on the risk of venous thromboembolism. *Circulation.* 2020.

110. Martin JH, Hill C, Walsh A, Efron D, Taylor K, Kennedy M, et al. Clinical trials with cannabis medicines-guidance for ethics committees, governance officers and researchers to streamline ethics applications and ensuring patient safety: considerations from the Australian experience. *Trials.* 2020;21(1):932.

111. McAuley SA, Lee MH, Paldus B, Vogrin S, de Bock MI, Abraham MB, et al. Six months of hybrid closed-loop versus manual insulin delivery with fingerprick blood glucose monitoring in adults with type 1 diabetes: A randomized, controlled trial. *Diabetes Care.* 2020;43(12):3024-33.

112. McNamara MG, Goyal L, Doherty M, Springfield C, Cosgrove D, Sjoquist KM, et al. NUC-1031/cisplatin versus gemcitabine/cisplatin in untreated locally advanced/metastatic biliary tract cancer (NuTide:121). *Future Oncol.* 2020.

113. Meads DM, Martin A, Griffiths A, Kelley R, Creese B, Robinson L, et al. Cost-effectiveness of dementia care mapping in care-home settings: Evaluation of a randomised controlled trial. *Appl Health Econ Health Policy.* 2020;18(2):237-47.

114. Mercieca-Bebber R, Stockler MR. Patient-reported outcomes and localized prostate cancer management. *Nat Rev Urol.* 2020;17(5):257-8.

115. Morton RL, Lioufas N, Dansie K, Palmer SC, Jose MD, Raj R, et al. Use of patient-reported outcome measures and patient-reported experience measures in renal units in Australia and New Zealand: A cross-sectional survey study. *Nephrology (Carlton).* 2020;25(1):14-21.

116. Morton RL, Thompson JF. Evidence-based follow-up schedules after primary cancer treatment. *Ann Surg Oncol.* 2020.

117. Mullins RJ, Campbell DE, Barnes EH, Camargo CA, Jr. The relationship between latitude and allergic gastroenteritis hospital admissions in New Zealand infants. *Ann Allergy Asthma Immunol.* 2020;124(1):96-7.

118. Murray Brunt A, Haviland JS, Wheatley DA, Sydenham MA, Alhasso A, Bloomfield DJ, et al. Hypofractionated breast radiotherapy for 1 week versus 3 weeks (FAST-Forward): 5-year efficacy and late normal tissue effects results from a multicentre, non-inferiority, randomised, phase 3 trial. *Lancet.*

2020;395(10237):1613-26.

119. Nassar ZD, Mah CY, Dehairs J, Burvenich IJ, Irani S, Centenera MM, et al. Human DECR1 is an androgen-repressed survival factor that regulates PUFA oxidation to protect prostate tumor cells from ferroptosis. *Elife.* 2020;9.

120. Neuen BL, Ohkuma T, Neal B, Matthews DR, de Zeeuw D, Mahaffey KW, et al. Relative and absolute risk reductions in cardiovascular and kidney outcomes with canagliflozin across KDIGO risk categories: findings from the CANVAS program. *Am J Kidney Dis.* 2020.

121. Neuen BL, Jardine MJ, Perkovic V. Sodium-glucose cotransporter 2 inhibition: which patient with chronic kidney disease should be treated in the future? *Nephrol Dial Transplant.* 2020;35(Suppl 1):i48-i55.

122. Noori T, Hargreaves S, Greenaway C, van der Werf M, Driedger M, Morton RL, et al. Strengthening screening for infectious diseases and vaccination among migrants in Europe: What is needed to close the implementation gaps? *Travel Med Infect Dis.* 2020;101715.

123. Nowak AK, Findlay M, Culjak G, Stockler MR. Tamoxifen for hepatocellular carcinoma. *Cochrane Database Syst Rev.* 2020;8:CD001024.

124. Nowak AK, Lesterhuis WJ, Kok PS, Brown C, Hughes BG, Karikios DJ, et al. Durvalumab with first-line chemotherapy in previously untreated malignant pleural mesothelioma (DREAM): a multicentre, single-arm, phase 2 trial with a safety run-in. *Lancet Oncol.* 2020;21(9):1213-23.

125. Obermair A, Asher R, Pareja R, Frumovitz M, Lopez A, Moretti-Marques R, et al. Incidence of adverse events in minimally invasive versus open radical hysterectomy in early cervical cancer: results of a randomized controlled trial. *Am J Obstet Gynecol.* 2020;222(3):249.e1-.e10.

126. O'Halloran P, Noble H, Norwood K, Maxwell P, Murtagh F, Shields J, et al. Nurse-led advance care planning with older people who have end-stage kidney disease: feasibility of a deferred entry randomised controlled trial incorporating an economic evaluation and mixed methods process evaluation (ACReDiT). *BMC Nephrol.* 2020;21(1):478.

127. O'Hara DV, Neuen BL, Jardine MJ. Kidney and cardiovascular protection with SGLT2 inhibitors: lessons from cardiovascular outcome trials and CREDENCE. *J Nephrol.* 2020.

128. O'Lone E, Viecelli AK, Craig JC, Tong A, Sautenet B, Herrington WG, et al. Establishing core cardiovascular outcome

measures for trials in hemodialysis: Report of an international consensus workshop. *Am J Kidney Dis.* 2020;76(1):109-20.

129. O'Lone E, Howell M, Viecelli AK, Craig JC, Tong A, Sautenet B, et al. Identifying critically important cardiovascular outcomes for trials in hemodialysis: an international survey with patients, caregivers and health professionals. *Nephrol Dial Transplant.* 2020;35(10):1761-9.

130. Ong KL, Wu L, Januszewski AS, O'Connell RL, Xu A, Rye KA, et al. Relationships of adipocyte-fatty acid binding protein and lipocalin 2 with risk factors and chronic complications in type 2 diabetes and effects of fenofibrate: A fenofibrate Intervention and event lowering in diabetes sub-study. *Diabetes Res Clin Pract.* 2020;169:108450.

131. Oshima M, Neuen BL, Li J, Perkovic V, Charytan DM, de Zeeuw D, et al. Early change in albuminuria with canagliflozin predicts kidney and cardiovascular outcomes: A post hoc analysis from the CREDENCE trial. *J Am Soc Nephrol.* 2020.

132. Pammi M, Preidis GA, Tarnow-Mordi WO. Evidence from systematic reviews of randomized trials on enteral lactoferrin supplementation in preterm neonates. *Biochem Cell Biol.* 2020.

133. Ping Loh T, Lord SJ, Bell K, Kathryn Bohn M, Yee Lim C, Markus C, et al. Setting minimum clinical performance specifications for tests based on disease prevalence and minimum acceptable positive and negative predictive values: Practical considerations applied to COVID-19 testing. *Clin Biochem.* 2020.

134. Pottie K, Magwood O, Rahman P, Concannon T, Alonso-Coello P, Jaramillo Garcia A, et al. Validating the "feasibility, acceptability, cost, and equity" instrument using stakeholder perceptions of feasibility, acceptability, cost, and equity in guideline implementation. *J Clin Epidemiol.* 2020;131:133-40.

135. Price T, Burge M, Chantrill L, Gibbs P, Pavlakis N, Shapiro J, et al. Trifluridine/tipiracil: A practical guide to its use in the management of refractory metastatic colorectal cancer in Australia. *Asia Pac J Clin Oncol.* 2020;16 Suppl 1:3-12.

136. Quinn N, Yang F, Ryan C, Bursell SE, Keech A, Atkinson-Briggs S, et al. Screening for diabetic retinopathy and reduced vision among Indigenous Australians in Top End primary care health services: a TEAMSnet sub-study. *Intern Med J.* 2020.

137. Quinn N, Jenkin A, Ryan C, Januszewski A, Peto T, Brazionis L. Imaging the eye and its relevance to diabetes care. *J Diabetes*

Investig. 2020.

138. Rapport F, Smith AL, Cust AE, Mann GJ, Watts CG, Gyorki DE, et al. Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: protocol paper for a mixed methods study. *BMJ Open.* 2020;10(2):e032636.

139. Rhee JJ, Jardine MJ, Chertow GM, Mahaffey KW. Dedicated kidney disease-focused outcome trials with sodium-glucose cotransporter-2 inhibitors: Lessons from DAPA-HF, DAPA-CKD, and EMPA-KIDNEY. *Diabetes Obes Metab.* 2020;22 Suppl 1:46-54.

140. Robbins SR, Melo LRS, Urban H, Deveza LA, Asher R, Johnson VL, et al. Is a stepped-care intervention effective in overweight and obese people with medial tibiofemoral osteoarthritis? The STReAMline study: A randomised controlled trial. *Arthritis Care Res (Hoboken).* 2020.

141. Roncolato FT, O'Connell RL, Joly F, Lanceley A, Hilpert F, Buizen L, et al. Predictors of progression free survival, overall survival and early cessation of chemotherapy in women with potentially platinum sensitive (PPS) recurrent ovarian cancer (ROC) starting third or subsequent line(>=3) chemotherapy - The GCIG symptom benefit study (SBS). *Gynecol Oncol.* 2020;156(1):45-53.

142. Sanjida S, Obermair A, GebSKI V, Armfield N, Janda M. Long-term quality of life outcomes of women treated for early-stage endometrial cancer. *Int J Gynecol Cancer.* 2020.

143. Satgunaseelan L, Allanson BM, Asher R, Reddy R, Low HTH, Veness M, et al. The incidence of squamous cell carcinoma of the oral tongue is rising in young non-smoking women: An international multi-institutional analysis. *Oral Oncol.* 2020;110:104875.

144. Scheinberg T, Kench J, Stockler M, Mahon KL, Sebastian L, Stricker P, et al. Pharmacodynamics effects of CDK4/6 inhibitor LEE011 (ribociclib) in high-risk, localised prostate cancer: A study protocol for a randomised controlled phase II trial (LEEP study: LEE011 in high-risk, localised Prostate cancer). *BMJ Open.* 2020;10(1):e033667.

145. Scott ES, Jenkins AJ, Fulcher GR. Challenges of diabetes management during the COVID-19 pandemic. *Med J Aust.* 2020.

146. Seidler AL, Duley L, Katheria AC, De Paco Matallana C, Dempsey E, Rabe H, et al. Systematic review and network meta-analysis with individual participant data on cord management at preterm birth



- (iCOMP): study protocol. *BMJ Open*. 2020;10(3):e034595.
147. Seidler AL, Hunter KE, Johnson BJ, Ekambareshwar M, Taki S, Mauch CE, et al. Understanding, comparing and learning from the four EPOCH early childhood obesity prevention interventions: A multi-methods study. *Pediatr Obes*. 2020:e12679.
148. Sever P, Gouni-Berthold I, Keech A, Giugliano R, Pedersen TR, Im K, et al. LDL-cholesterol lowering with evolocumab, and outcomes according to age and sex in patients in the FOURIER trial. *Eur J Prev Cardiol*. 2020:2047487320902750.
149. Shah KK, Murtagh FEM, McGeechan K, Crail SM, Burns A, Morton RL. Quality of life among caregivers of people with end-stage kidney disease managed with dialysis or comprehensive conservative care. *BMC Nephrol*. 2020;21(1):160.
150. Shaman AM, Smyth B, Arnott C, Palmer SC, Mihailidou AS, Jardine MJ, et al. Comparative efficacy and safety of BP-lowering pharmacotherapy in patients undergoing maintenance dialysis: a network meta-analysis of randomized, controlled trials. *Clin J Am Soc Nephrol*. 2020;15(8):1129-38.
151. Shihana F, Joglekar MV, Raubenheimer J, Hardikar AA, Buckley NA, Seth D. Circulating human microRNA biomarkers of oxalic acid-induced acute kidney injury. *Arch Toxicol*. 2020.
152. Shihana F, Mohamed F, Joglekar MV, Hardikar AA, Seth D, Buckley NA. Urinary versus serum microRNAs in human oxalic acid poisoning: Contrasting signals and performance. *Toxicol Lett*. 2020;334:21-6.
153. Sim HW, Nowak AK, Lwin Z, Khasraw M. Management of glioblastoma: An Australian perspective. *Chin Clin Oncol*. 2020.
154. Sivashanmugarajah A, Fulcher J, Sullivan D, Elam M, Jenkins A, Keech A. Author reply. *Intern Med J*. 2020;50(4):507-8.
155. Smith-Uffen MES, Johnson SB, Martin AJ, Tattersall MHN, Stockler MR, Bell ML, et al. Estimating survival in advanced cancer: a comparison of estimates made by oncologists and patients. *Support Care Cancer*. 2020;28(7):3399-407.
156. Smyth B, Chan CT, Grieve SM, Puranik R, Zuo L, Hong D, et al. Response to: Loutradis et al. Longer dialysis sessions improve cardiac systolic function by reducing myocardial stunning. *J Card Fail*. 2020.
157. Smyth B, Zuo L, Gray NA, Chan CT, de Zoysa JR, Hong D, et al. No evidence of a legacy effect on survival following randomization to extended hours dialysis in the ACTIVE Dialysis trial. *Nephrology (Carlton)*. 2020;25(10):792-800.
158. Smyth B, Chan CT, Grieve SM, Puranik R, Zuo L, Hong D, et al. Predictors of change in left-ventricular structure and function in a trial of extended hours hemodialysis. *J Card Fail*. 2020;26(6):482-91.
159. Snell KIE, Allotey J, Smuk M, Hooper R, Chan C, Ahmed A, et al. External validation of prognostic models predicting pre-eclampsia: individual participant data meta-analysis. *BMC Med*. 2020;18(1):302.
160. Snyders K, Cho D, Hong JH, Lord S, Asher R, Marschner I, et al. Benchmarking single-arm studies against historical controls from non-small cell lung cancer trials - an empirical analysis of bias. *Acta Oncol*. 2020;59(1):90-5.
161. Sridar P, Kennedy NJ, Quinton AE, Robledo K, Kim J, Nanan R. Normative ultrasound data of the fetal transverse thalamic diameter derived from 18 to 22 weeks of gestation in routine second-trimester morphology examinations. *Australasian Journal of Ultrasound in Medicine*. 2020;23(1):59-65.
162. Sridhar SS, Blais N, Tran B, Reaume MN, North SA, Stockler MR, et al. Efficacy and safety of nab-paclitaxel vs paclitaxel on survival in patients with platinum-refractory metastatic urothelial cancer: The Canadian cancer trials group BL.12 randomized clinical trial. *JAMA Oncol*. 2020.
163. Sriravindrarajah A, Kotwal SS, Sen S, McDonald S, Jardine M, Cass A, et al. Impact of supplemental private health insurance on dialysis and outcomes. *Intern Med J*. 2020;50(5):542-9.
164. Stamatakis E, Koster A, Hamer M, Rangul V, Lee IM, Bauman AE, et al. Emerging collaborative research platforms for the next generation of physical activity, sleep and exercise medicine guidelines: the Prospective Physical Activity, Sitting, and Sleep consortium (ProPASS). *Br J Sports Med*. 2020;54(8):435-7.
165. Staub LP, Aghayev E, Skrivankova V, Lord SJ, Haschtmann D, Mannion AF. Development and temporal validation of a prognostic model for 1-year clinical outcome after decompression surgery for lumbar disc herniation. *Eur Spine J*. 2020.
166. Subramaniam N, Robledo KP, Dietz HP. Anal sphincter imaging: better done at rest or on pelvic floor muscle contraction? *Int Urogynecol J*. 2020;31(6):1191-6.
167. Sukkar L, Kang A, Hockham C, Young T, Jun M, Foote C, et al. Incidence and associations of chronic kidney disease in community participants with diabetes: A 5-year prospective analysis of the EXTEND45 Study. *Diabetes Care*. 2020;43(5):982-90.
168. Surr CA, Holloway I, Walwyn REA, Griffiths AW, Meads D, Martin A, et al. Effectiveness of dementia care mapping to reduce agitation in care home residents with dementia: An open-cohort cluster randomised controlled trial. *Aging Ment Health*. 2020:1-14.
169. Tang M, Schaffer A, Kiely BE, Daniels B, Simes RJ, Lee CK, et al. Correction: Treatment patterns and survival in HER2-positive early breast cancer: a whole-of-population Australian cohort study (2007-2016). *Br J Cancer*. 2020.
170. Tarnow-Mordi WO, Abdel-Latif ME, Martin A, Pammi M, Robledo K, Manzoni P, et al. The effect of lactoferrin supplementation on death or major morbidity in very low birthweight infants (LIFT): a multicentre, double-blind, randomised controlled trial. *Lancet Child Adolesc Health*. 2020;4(6):444-54.
171. Tendal B, Vogel JP, McDonald S, Norris S, Cumpston M, White H, et al. Weekly updates of national living evidence-based guidelines: Methods for the Australian Living Guidelines for Care of People with COVID-19. *J Clin Epidemiol*. 2020.
172. Tian H, Deng W, Law C, Zhao Q, Xiaoniuliang, Wu W, et al. Adverse life events and late-life cognitive decline in a Chinese cohort: The Shanghai Aging Study. *Int J Geriatr Psychiatry*. 2020.
173. Tjokrowidjaja A, Goldstein D, Hudson HM, Lord SJ, GebSKI V, Clarke S, et al. The impact of neutrophil-lymphocyte ratio on risk reclassification of patients with advanced renal cell cancer to guide risk-directed therapy. *Acta Oncol*. 2020;59(1):20-7.
174. Tjokrowidjaja A, Lee CK, Friedlander M, GebSKI V, Gladieff L, Ledermann J, et al. Concordance between CA-125 and RECIST progression in patients with germline BRCA-mutated platinum-sensitive relapsed ovarian cancer treated in the SOLO2 trial with olaparib as maintenance therapy after response to chemotherapy. *Eur J Cancer*. 2020;139:59-67.
175. Toussaint ND, Pedagogos E, Lioufas NM, Elder GJ, Pascoe EM, Badve SV, et al. A randomized trial on the effect of phosphate reduction on vascular end points in CKD (IMPROVE-CKD). *J Am Soc Nephrol*. 2020.
176. Tran C, Heng B, Teo JD, Humphrey SJ, Qi Y, Coultas TA, et al. Sphingosine 1-phosphate but not fingolimod protects neurons against excitotoxic cell death by inducing neurotrophic gene expression in astrocytes. *J Neurochem*. 2020;153(2):173-88.
177. Tugwell P, Welch VA, Karunanathan S, Maxwell LJ, Akl EA, Avey MT, et al. When to replicate systematic reviews of interventions: consensus checklist. *BMJ*. 2020;370:m2864.
178. Turner J, Dunn L, Tarnow-Mordi W, Flatley C, Flenady V, Kumar S. Safety and efficacy of sildenafil citrate to reduce operative birth for intrapartum fetal compromise at term: A Phase 2 randomized controlled trial. *Am J Obstet Gynecol*. 2020.
179. Turner S, Pham T, Robledo K, Turner S, Brown C, Sundaresan P. Rapid adaptation of cancer education in response to the COVID-19 pandemic: Evaluation of a live virtual statistics and research skills workshop for oncology trainees. *J Cancer Educ*. 2020.
180. Van Biesen W, Jha V, Abu-Alfa AK, Andreoli SP, Ashuntantang G, Bernieh B, et al. Considerations on equity in management of end-stage kidney disease in low- and middle-income countries. *Kidney Int Suppl* (2011). 2020;10(1):e63-e71.
181. van der Tol A, Stel VS, Jager KJ, Lameire N, Morton RL, Van Biesen W, et al. A call for harmonization of European kidney care: dialysis reimbursement and distribution of kidney replacement therapies. *Nephrol Dial Transplant*. 2020.
182. Vasista A, Ryan L, Naher S, Moylan E, Stockler MR, Wilcken N, et al. Survival and cardiac toxicity in patients with HER2-positive, metastatic breast cancer treated with trastuzumab in routine clinical practice. *Asia Pac J Clin Oncol*. 2020;16(1):34-8.
183. Vasista A, Stockler MR, Martin A, Lawrence NJ, Kiely BE. Communicating prognostic information: what do oncologists think patients with incurable cancer should be told? *Intern Med J*. 2020.
184. Velayutham V, Craig ME, Liew G, Wong TY, Jenkins AJ, Benitez-Aguirre PZ, et al. Extended zone retinal vascular caliber and risk of diabetic retinopathy in adolescents with type 1 diabetes. *Ophthalmol Retina*. 2020.
185. Venkatesh N, Paldus B, Lee MH, MacIsaac RJ, Jenkins AJ, O'Neal DN. COVID-19, type 1 diabetes clinical practice, research, and remote medical care: a view from the land down-under. *J Diabetes Sci Technol*. 2020:1932296820929708.
186. Wang M, Kirby A, Gibbs E, Gidaszewski B, Khajehei M, Chua SC. Risk of preterm birth in the subsequent pregnancy following caesarean section at full cervical dilatation compared with mid-cavity instrumental delivery. *Aust N Z J Obstet Gynaecol*. 2020;60(3):382-8.
187. Wang N, Fulcher J, Abeyasuriya N, Park L, Kumar S, Di Tanna GL, et al. Intensive LDL cholesterol-lowering treatment beyond current recommendations for the prevention of major vascular events: A systematic review and meta-analysis of randomised trials including 327 037 participants. *Lancet Diabetes Endocrinol*. 2020;8(1):36-49.
188. Wang X, Yeo RX, Hogg PJ, Goldstein D, Crowe P, Dilda PJ, et al. The synergistic inhibitory effect of combining therapies targeting EGFR and mitochondria in sarcomas. *Oncotarget*. 2020;11(1):46-61.
189. Wang R, Seidler AL, Askie L, Norman RJ, Bhattacharya S, van Wely M, et al. Network meta-analyses in reproductive medicine: challenges and opportunities. *Hum Reprod*. 2020;35(8):1723-31.
190. Ward R, West K, Latty D, Beldham-Collins R, Jia D, Wang W, et al. Patient-specific heart constraint: A tool for optimisation and evaluation of mean heart dose in breast cancer patients. *Pract Radiat Oncol*. 2020.
191. Watts CG, Smith AL, Robinson S, Chang CS, Goumas C, Schmid H, et al. Australian general practitioners' attitudes and knowledge of sentinel lymph node biopsy in melanoma management. *Aust J Gen Pract*. 2020;49(6):355-62.
192. West K, Schneider M, Wright C, Beldham-Collins R, Coburn N, Tiver K, et al. Radiation-induced oesophagitis in breast cancer: Factors influencing onset and severity for patients receiving supraclavicular nodal irradiation. *J Med Imaging Radiat Oncol*. 2020;64(1):113-9.
193. Whitford HS, Kalinowski P, Schembri A, Grimison P, Stockler M, Martin A, et al. The impact of chemotherapy on cognitive function: a multicentre prospective cohort study in testicular cancer. *Support Care Cancer*. 2020;28(7):3081-91.
194. Wijetunga A, Jayamanne D, Cook R, Parkinson J, Little N, Curtis J, et al. Hypofractionated adjuvant surgical cavity radiotherapy following resection of limited brain metastasis. *J Clin Neurosci*. 2020;82(Pt A):155-61.
195. Williams MD, Joglekar MV, Hardikar AA, Wong WKM. Directed differentiation into insulin-producing cells using microRNA manipulation. *Open Med (Wars)*. 2020;15(1):567-70.
196. Wiltink LM, King M, Muller F, Sousa MS, Tang M, Pendlebury A, et al. A systematic review of the impact of contemporary treatment modalities for cervical cancer on women's self-reported health-related quality of life. *Support Care Cancer*. 2020.
197. Wyld MLR, Morton RL, Aouad L, Magliano D, Polkinghorne KR, Chadban S. The impact of comorbid chronic kidney disease and diabetes on health-related quality-of-life: a 12-year community cohort study. *Nephrol Dial Transplant*. 2020.
198. Xie Y, Baker J, Young T, Jun M, Sukkar L, Campaign A, et al. Therapy escalation following an elevated HbA1c in adults aged 45 years and older living with diabetes in australia: a real-world observational analysis. *Diabetes Care*. 2020.
199. Ying T, Tran A, Webster AC, Klarenbach SW, Gill J, Chadban S, et al. Screening for asymptomatic coronary artery disease in waitlisted kidney transplant candidates: a cost-utility analysis. *Am J Kidney Dis*. 2020;75(5):693-704.
200. Yu J, Zhou Z, Mahaffey KW, Matthews DR, Neuen BL, Heerspink HJL, et al. An exploration of the heterogeneity in effects of SGLT2 inhibition on cardiovascular and all-cause mortality in the EMPA-REG OUTCOME, CANVAS Program, DECLARE-TIMI 58, and CREDENCE trials. *Int J Cardiol*. 2020.
201. Zen M, Padmanabhan S, Zhang K, Kirby A, Cheung NW, Lee VW, et al. Urinary and serum angiogenic markers in women with preexisting diabetes during pregnancy and their role in preeclampsia prediction. *Diabetes Care*. 2020;43(1):67-73.



**NHMRC Clinical Trials Centre University of Sydney**

Locked Bag 77 Camperdown NSW 1450 Australia  
92–94 Parramatta Road, Camperdown NSW 2050  
119–143 Missenden Road, Camperdown NSW 2050

**T** +61 2 9562 5000

**F** +61 2 9565 1863

**E** [ctc.enquiry@sydney.edu.au](mailto:ctc.enquiry@sydney.edu.au)

[www.ctc.usyd.edu.au](http://www.ctc.usyd.edu.au)