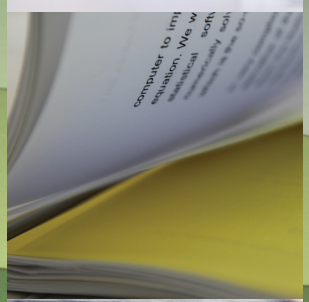
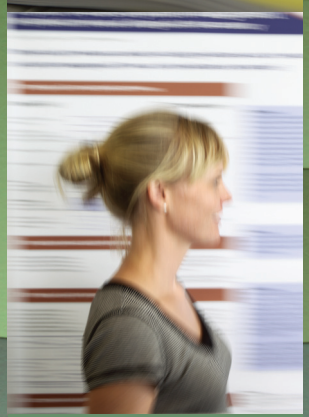
NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY

RESEARCH REPORT 2010





The NHMRC Clinical Trials Centre has the mission to improve health outcomes in Australia and internationally through the use of clinical trials research.

'Every person treated internationally for heart attack, diabetes and most cancers will have at least some of the care determined because of trial evidence generated by CTC investigators.'

— Anthony Keech, deputy director, CTC

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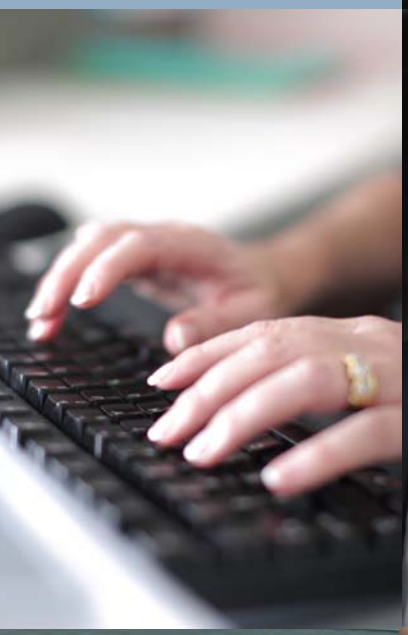
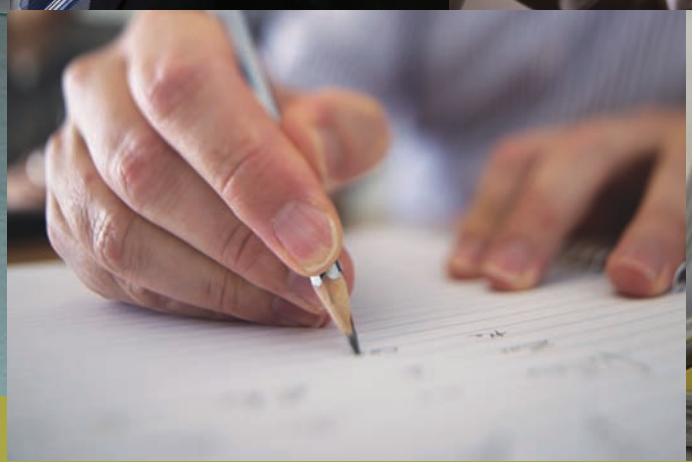
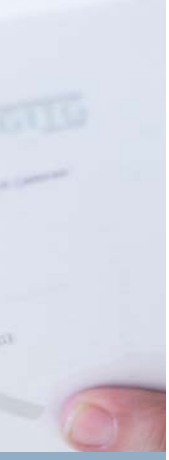


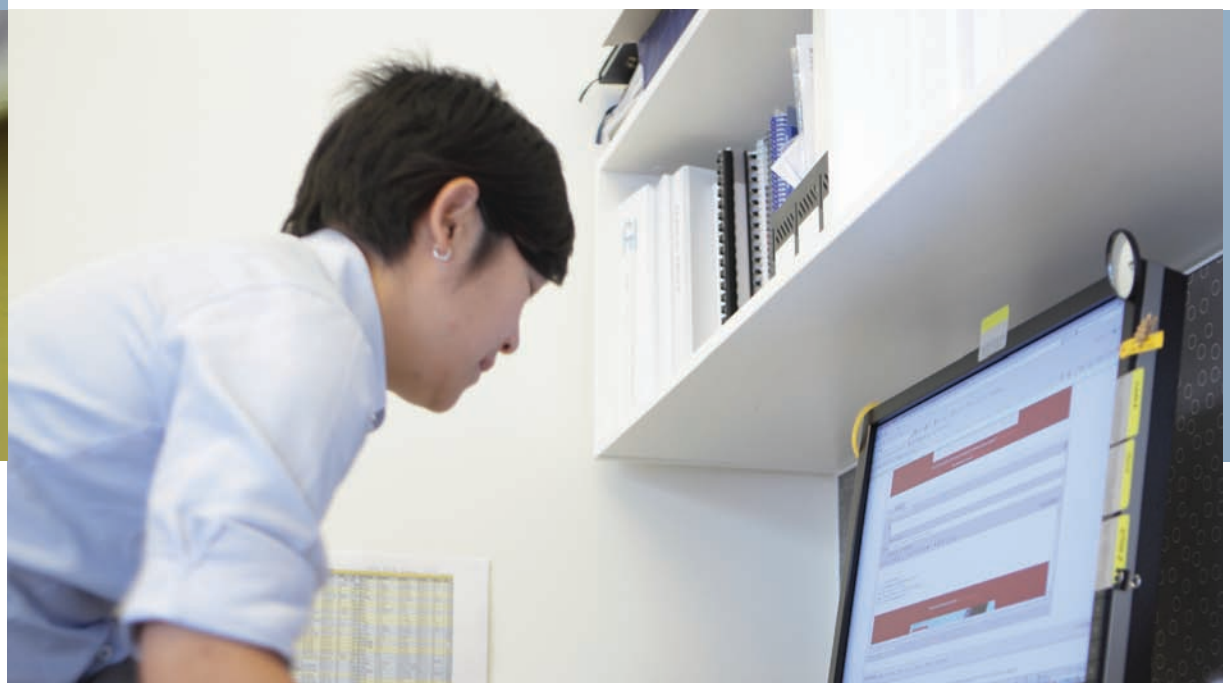
The NHMRC Clinical Trials Centre at the University of Sydney conducts large multicentre investigator-initiated clinical trials, takes part in trials of national and international collaborative trial groups and contributes expertise to trials run by others. It also:

- takes a lead in proposing new directions for trial research in Australia, particularly with regard to integrating clinical trials with national policy and clinical practice
- undertakes methodological research in relation to clinical trials
- reviews and synthesises evidence from completed trials and is at the forefront of developments in methods, such as prospective meta-analysis
- advises on trial design and operation, and randomises patients and analyses data for other groups conducting trials
- offers postgraduate supervision in all of these areas
- offers a postgraduate program in clinical trials research by distance education
- runs short courses in the design and conduct of clinical trials as part of its undertaking to train people for Australian medical research

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

The CTC is at two sites in Camperdown in inner Sydney — the Medical Foundation Building on Parramatta Road and on Mallett Street.

This report covers the CTC's achievements for 2010.



DIRECTORS' REPORT

The CTC continues to provide intellectual leadership, evidence from trials-related research, and operational expertise in clinical trials to improve clinical practice and health outcomes in Australia and elsewhere. In 2010, we made many important steps toward improving health through trials research. We continue to work in partnership and collaboration with many Australian and international investigators, without whom these and other major advances would not be possible.

A theme of this year's report is to highlight some of the important work of early-career investigators, who are future research leaders at the CTC and elsewhere. We trust that others will be as impressed as we are by their achievements and ideas.

Our oncology group, managed by Burcu Vachan, has grown to over 40 staff working with 7 national collaborative groups and currently undertaking 35 projects. Trials now cover almost all cancer disease areas, corresponding to our aim to conduct research in areas of need in Australia. The results of MAX, initiated by the Australasian Gastro-Intestinal Trials Group (AGITG) in partnership with the CTC, showed significant improvements in progression-free survival with newer combination therapy. Further analyses will cover genetic studies of tumour tissue and quality of life. Other concluded gastrointestinal studies in 2010 include ATTAX, a trial of treatment for oesophagogastric cancer, and the biliary tract study. Testicular cancer is largely curable, and the current optimum treatment has been defined by the 2010 results of the BEP germ-cell trial conducted by the CTC and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). With the Sydney Cancer Centre, we conducted the first randomised trial comparing inpatient and outpatient administration of chemotherapy, which showed that outpatient treatment was preferred by most patients, appeared safe, and reduced the strain on hospital systems. Research into patients' preferences and quality of life are continuing as an important strand of oncology research: a breast cancer study concluded that wellbeing was related to response to chemotherapy and that quality of life should be a routine clinical assessment for patients entering clinical trials.

We have advanced in our aim of providing evidence for tailoring treatments to individual patients. We integrate molecular sciences into clinical trials design where possible. Identifying genetic and molecular markers can lead to optimising treatment for individual patients. One recently published exploratory study, using data from several trials including CO.17, showed that colorectal tumours with mutations at a specific locus might be treatable by cetuximab. In cardiovascular disease, blood samples from the completed FIELD and LIPID prevention trials are the subject of extensive laboratory studies. FIELD continues to generate new research questions answerable from its large diabetes dataset; in 2010, we published important findings on renal disease and silent myocardial infarction.

Many of the CTC's collaborative projects are international prospective meta-analyses. Typically, these studies combine data from a CTC trial with data from other similar trials for aggregate analysis. Neonatal studies, in particular, usually require large numbers of patients for valid analysis; recently published examples are MAPPiNO and PreVILIG. The CTC's BOOST II trial is part of the international NeOProM meta-analysis. Dr Lisa Askie, head of the CTC's systematic reviews and health technology assessment group, is a leader in neonatal studies. MetaGIST, a meta-analysis of trials of the AGITG and international collaborators, revealed important results on the optimum therapy for some patients with stomach cancers. Cardiovascular meta-analyses have recently generated important evidence to underpin treatment of patients with acute coronary syndromes; examples are Primary Coronary Angioplasty versus Thrombolysis-2 and the HERO-2 study of international differences. The Cholesterol Treatment Trialists' Collaboration analysed data from 170 000 patients to show that the greater the lowering of LDL cholesterol at any level the greater the reductions in cardiovascular risk.

The CTC is at the forefront of research into clinical trials methodology. Much of this work is being done by the CTC's biostatisticians, led by Professor Val

Gebski. A recent study developed models to predict the rates of intramammary lymph node metastasis in breast cancer. Another breast cancer study provided evidence that historical cross-trial and other non-randomised comparisons have limited validity and confirmed the importance of randomised trials. In cardiovascular disease, data from the LIPID trial were used to develop a method to analyse recurrent events, and data from FIELD to devise a method for adjusting the size of the effect of the study drug for changes in background treatment in long-term trials. As part of the CTC's technology assessment research, a new clinical sign was evaluated — the nerve root sedimentation sign — which appears to be useful in clinical practice to distinguish lumbar spinal stenosis from low back pain from other causes.

A new health economics team has been established at the CTC, led by Professor Deborah Schofield. This group is implementing aspects of our continuing policy to incorporate measures of benefit, harm and cost into trials. They are also improving methods for analysing cost-effectiveness and cost-utility in trials and have published a series of studies on the financial effects of chronic illness.

In 2010, we developed a new postgraduate course in clinical research, which starts enrolment in the first semester of 2011. The new course complements our long-running program of seminars and short courses as well as our in-house supervision of research students. The process was helped by our earlier experience in the groundwork of the successful biostatistics postgraduate program of the Biostatistics Collaboration of Australia.

In summary, our research program is focused on addressing research questions relevant to improving clinical practice and health outcomes in major disease areas. We have continued to work with collaborative trial groups, helped build new networks and groups in areas of need, and added value to the results of trials through substudies and methodological research. The skill and experience of our research teams and collaborators in biostatistics, clinical research design and trial conduct, clinical epidemiology, and health economics, and the dedication of CTC staff have been essential to our success.

CTC executive

CTC operations and research are led by the Executive: John Simes, director; Tony Keech, deputy director; Wendy Hague, trials program director; and Kim Russell-Cooper, general manager.

Professor John Simes is the foundation director of the CTC and represents the CTC on many national and international committees. In 2010 he received the 2010 Medical Oncology Group of Australia Award to recognise an outstanding contribution to medical oncology in Australia through the scientific study of cancer.

Professor Anthony Keech is Professor of Medicine, Cardiology and Epidemiology at the University of Sydney. He is chairman of the international FIELD study on heart disease and diabetes and directs the CTC's research program.

Dr Wendy Hague is primarily responsible for the successful conduct of the CTC's large-scale, multicentre clinical trials and ensuring that trials systems, procedures and methods are of the highest standard.

Kim Russell-Cooper works with the CTC executive, managers and research staff toimprove the business process in the areas of clinical trial research governance, risk assessment, financial planning, management and reporting.

John Simes

Anthony Keech

Wendy Hague

Kim Russell-Cooper

New qualification is a foundation for a career in clinical research

MASTERS IN CLINICAL TRIALS

A major achievement of the CTC in 2010 is the launching of a new postgraduate course in clinical trials research at the University of Sydney, which is enrolling students from the first semester of 2011. It is for doctors, researchers, consultants, health care professionals, data managers and nurse practitioners who are working in or planning to pursue opportunities in clinical research.

The course will equip graduates with the skills to design and lead clinical trials, including specifically:

- developing trial concepts
- choosing optimal trial designs
- leading protocol development
- implementing trial protocols
- developing operational strategies for trial conduct
- collecting and critically analysing trial data
- presenting, reporting and interpreting trial results
- evaluating trial designs and methods
- leading systematic reviews and meta-analyses
- identifying funding options
- assessing patient outcomes
- identifying and interpreting issues related to health economic outcomes

In summary, the course will provide a solid understanding of research methods, clinical trials literature, and the clinical trials process (such as trial design, scheduling of interventions, doses of treatment, and statistical and ethical considerations).

Teaching is by distance education. The course is offered part-time, with the options of pursuing a graduate certificate, graduate diploma or masters degree, or studying individual units for interest or professional development.

Opportunities to learn about clinical trials from the experts

Courses over one to five days provide opportunities for people wanting to learn about specific aspects of clinical trials.

In 2010 the CTC presented its introductory course for new clinical trials staff: 'Introduction to clinical trials', which has two 2-day modules, one on methods and design and one on trial management. Participants learned from CTC presenters with experience and state-of-the-art knowledge in the development and management of trials, trial design and statistical analysis.

Concept development workshops for people pursuing clinical research were run at intervals over the year. This one-day workshop helps investigators to develop existing concepts for new trials. It covers objectives, population, interventions, study design, outcome measures, sample size, the analysis plan and funding strategies. Participants work on their proposed concepts throughout the day and present them for discussion in small-group sessions supported by faculty experts.

CTC shares knowledge for research into Aboriginal health

The CTC and Menzies School of Health Research have begun a long-term research collaboration. Menzies has a national reputation in conducting important Indigenous health research and understands the special health needs and culturally appropriate methods for research involving Indigenous populations. Menzies conducts trials in respiratory disease, kidney disease and paediatric disorders.

CTC biostatisticians and trials staff are lending their skills and knowledge in trials management and aspects of design and methods, including randomising patients, sources of patients, sample size, and measuring outcomes.

This emerging collaboration will allow the CTC to broaden its clinical trials expertise in the methodologically challenging area of Aboriginal health and is expected to lead to future joint public health research initiatives.

menzies school of health research

Biostatistics Collaboration of Australia

After 10 years, the BCA is now well established as a postgraduate coursework program delivered by distance education, serving the need for qualified biostatisticians in Australia and elsewhere. The BCA has an annual enrolment of around 250 students. The CTC was a key contributor in the establishment of the BCA, which is administered from the CTC.

www.bca.edu.au

Health economics

Health economics researchers at the CTC, led by Professor Deborah Schofield, and their collaborators, have undertaken a series of studies on cost-effectiveness and the economic impacts of illness.

COST-EFFECTIVENESS STUDIES

The health economics team work closely with clinicians in fields including oncology, neonatal care and cardiovascular disease in evaluating cost-effectiveness of medical interventions. In one such study, a Markov model has been developed to assess the long-term effectiveness and cost-effectiveness of the sentinel node biopsy procedure in women with early breast cancer. The model provides estimates of cost and effectiveness of the treatment over a 20-year period, and is able to identify priorities for future research in this area.

Professor Deborah Schofield, pictured above.

ECONOMIC BURDEN OF ILLNESS

The health economics team and partners at the university of Canberra (NATSEM) have developed a microsimulation model used for a series of studies which generates information on employment, income, social security, taxation and poverty called Health&WealthMOD,

Diabetes and cardiovascular disease, both research priorities of the CTC, are important causes of early retirement. In an investigation of the financial vulnerability of people with diabetes, it was found that those retiring from the labour force early because of diabetes had significantly less wealth and 90% less chance of accumulating wealth than others. People with cardiovascular disease were in a similarly difficult situation: nearly 20% of those who retired early had no income-producing assets.

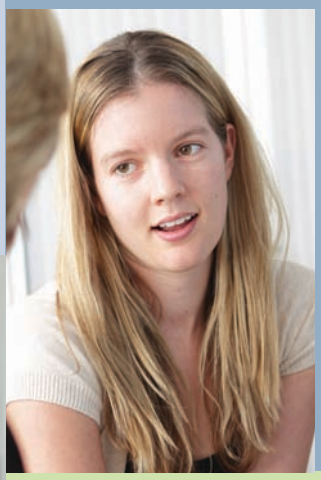
Another study, published in the *British Journal of Psychiatry,* quantified the lost savings and lesser wealth of people who retire early because of depression or other mental illness. People who retired early because of mental illness had 93% less accumulated wealth than people who continued to work. Preventing common chronic diseases and increasing workforce participation would help many people to self-finance the costs of retirement and ageing.

COSTS OF PREMATURE MORTALITY IN AUSTRALIA

Decisions to publicly fund effective health interventions in Australia are generally based on costs that occur in the health sector alone. But premature mortality also reduces household income, savings and superannuation, tax revenue and economic productivity. This research will highlight the costs to individuals and society as a whole, which may have significant implications for how decision makers choose to allocate scarce resources.

Hannah Verry hopes her work will provide a valid method of incorporating societal costs into economic evaluations of health interventions and also that it will signal the economic benefits of disease prevention.

'I wanted to be able to combine my background in pure economics with my current work in health research, in particular clinical trials. My research topic allows me to make use of both these sets of skills and experience', Hannah says.



Hannah Verry

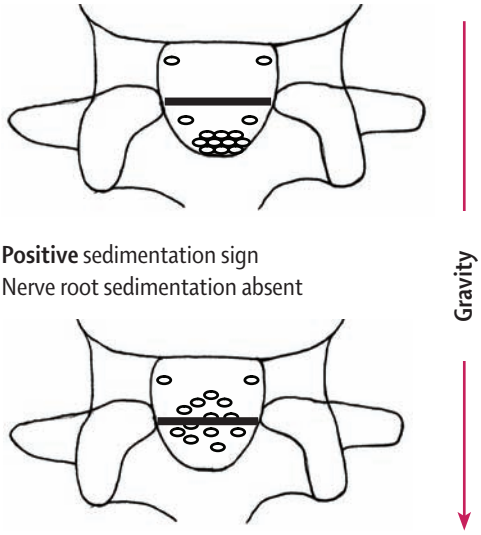
Left:
Health economics researchers: Deborah Schofield, Hannah Verry and Emily Callendar.

Clinical validity of diagnostic tests

A strand of the CTC's research is evaluation of new tests and technology to obtain evidence of their value in clinical decision making and policy.

In a study published in *Spine* in 2010, PhD student Lukas Staub, epidemiologist Sally Lord and their colleagues addressed the difficulty of distinguishing lumbar spinal stenosis, which can be treated by surgery, from low back pain from other causes. Magnetic resonance imaging with the patient lying down had shown that without spinal stenosis, the nerve roots move toward the back because of gravity. In patients with stenosis, the nerve roots do not move. This was termed the 'sedimentation sign'. The performance of this sign was tested in a large group of patients; it was 100% successful in excluding spinal stenosis, but slightly less successful in identifying it. The study has provoked further research in this area: Is the sedimentation sign applicable to a broader range of patients? Can this sign identify patients who will benefit from surgery? Is it related to clinical symptoms?

Negative sedimentation sign
Normal nerve root sedimentation



Normally, nerve roots fall towards the back in a patient lying supine because of gravity. In patients with stenosis, the roots do not move. A positive sedimentation sign indicates no gravitational movement.

Symposium panellists: Alex Barratt, John Simes, Les Irwig (obscured); Paul Glasziou, Tracy Merlin, Frederick Khafagi, Andrew Mitchell, George Koumantakis

METHODS FOR EVALUATING NEW TESTS

Dr Lukas Staub, with epidemiologist Sally Lord, is developing new methods of clinical test evaluation. He previously worked in orthopaedic research at the MEM Research Center, University of Bern, Switzerland, but realised that his main interest lay in clinical trials methodology.

His PhD project is about bridging the gap between two broad research domains—studies of diagnostic test accuracy and clinical trials of treatment effectiveness.

Demonstrating how new tests affect treatment selection and subsequent outcomes will lead to both better health of patients and more efficient use of health expenditures. He hopes that, after completing his PhD, he will continue to develop and publish these ideas in order to improve the evidence base on which clinicians make decisions about the use of medical tests in everyday practice.

Lukas says: 'The main driver for moving to Sydney was the CTC's international reputation, although other factors, such as my wife's career, were important for this decision too. It is a very satisfying experience to work at the CTC. I'm allowed to work with the top experts in my field, in a highly motivating and supportive environment'.

Dr Lukas Staub

'The main driver for moving to Sydney was the CTC's international reputation. I'm allowed to work with the top experts in my field, in a highly motivating and supportive environment.'

Symposium on test evaluation

The Test Evaluation Symposium at the University of Sydney in September 2010, attended by 70 people, had an agenda of the frameworks, criteria and evidence requirements for assessing the clinical effectiveness and economic impact of medical tests.

It was organised by the CTC's Systematic Reviews and Health Care Assessment group with support from the Screening and Test Evaluation Program at the School of Public Health. Speakers, including clinicians, researchers and government decision makers, represented a wide range of views.

Tailoring the treatment to an individual patient

Clinical trials have traditionally determined the effectiveness of treatments in large samples of patients. Modern researchers attempt to build on trial results to elucidate the best treatment for individual patients. Individual responses to treatment depend on various factors, including genes, quality of life, psychological factors, lifestyle, and the level of risk of the disease or disorder. At the CTC, this research has three strands: first, detecting genetic and molecular markers in tumour tissues or blood that may modulate the effect of a treatment (that is, translational research); second, determining individual risk where a treatment is more effective for patients at high risk; and third, identifying the characteristics of the patient that may correlate with benefit of treatment, such as quality of life and psychological factors.

An example is a study published in the *British Journal of Cancer*, in which Chee Lee and colleagues sought to identify patients in three breast cancer trials who were more or less likely to respond to chemotherapy on the basis of their reported quality of life. The results showed the value of using quality-adjusted outcomes in trials and revealed a need for trials of new treatment approaches for women with poor quality of life. Current work includes developing a prognostic nomogram to predict overall survival by using available clinical and laboratory data and identifying individual gene expression that predicts sensitivity or resistance to treatment for colorectal cancer.

TRANSLATIONAL RESEARCH: BENCH TO BEDSIDE

Translational research is the application of laboratory discoveries to improvements in treatment and care of patients. The CTC and its collaborative groups aim to build translational research into trials as far as possible.

Currently, most trials the CTC coordinates include an option for patients to consent to biological samples being used in research or being banked for future research.

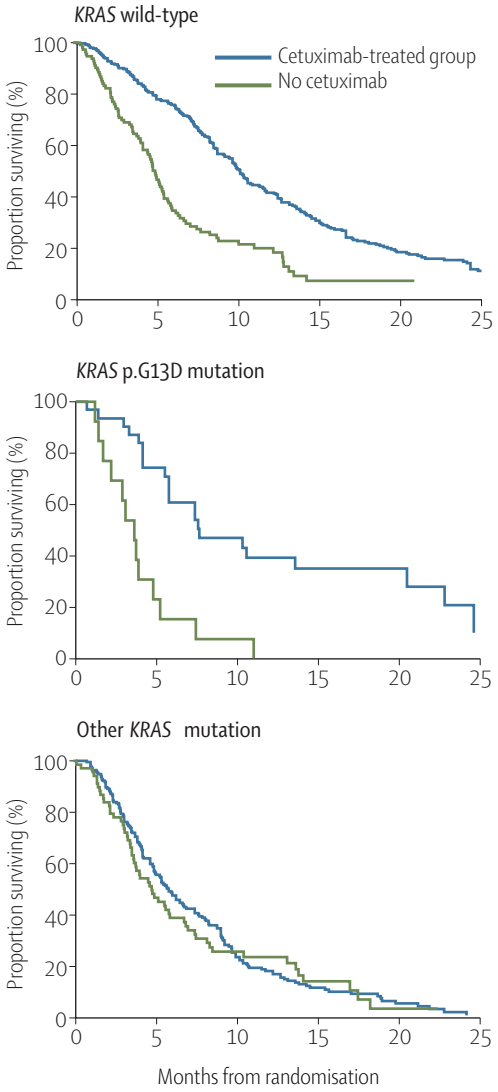
Typically, samples of blood or tumour tissue are collected, then analysed in the laboratory. Individual biomarkers that correlate with a patient's clinical outcomes may forecast survival or predict the response of a patient to a particular treatment. Sometimes genetic testing is done before selecting patients for a trial because the treatment is already known to benefit some patients and not others, depending on their genetic profile.

TRANSLATIONAL RESEARCH IN ONCOLOGY: LABORATORY STUDIES HELP TO MATCH TREATMENT TO PATIENTS

A previous genetic study of patients from one of the CTC's collaborative trials, CO.17, showed that treatment with a monoclonal antibody, cetuximab, improved survival only in colorectal cancer patients whose tumours had the *KRAS* wild-type gene, not the mutated gene. A collaboration of the National Cancer Institute of Canada (NCIC) and the Australasian Gastro-Intestinal Trials Group (AGITG) recently re-examined the *KRAS* genetic marker in tumour tissue from over 500 patients in this and similar trials.

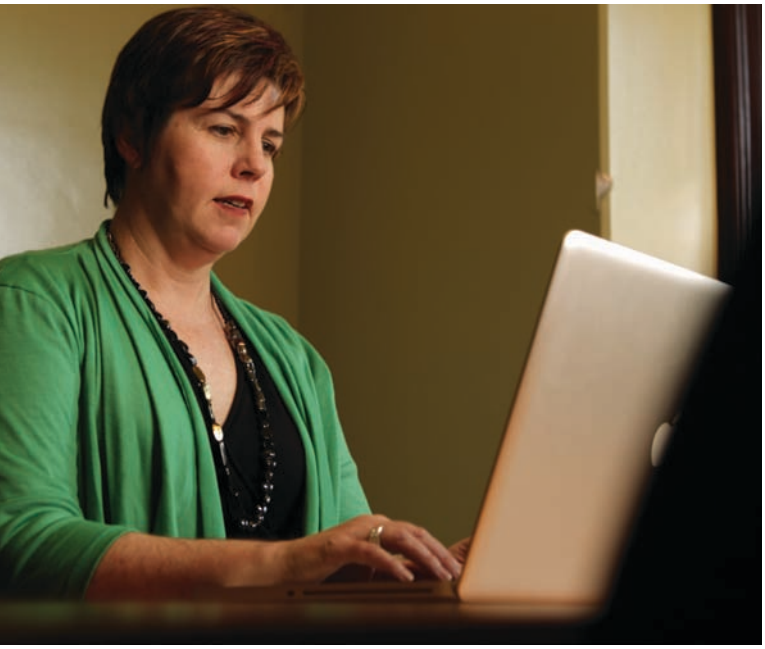
The results, published in *JAMA* in 2010, showed that even within the group of patients with *KRAS* mutations, cetuximab prolongs the survival of patients with the specific *KRAS* p.G13D mutation, but not those with other kinds of *KRAS* mutations. They observed the same responses of the mutated tumours to the drug in laboratory studies in cell lines, and now the overall result remains to be confirmed in prospective clinical trials.

Another study, MetaGIST, was an international meta-analysis of data from Australia, Europe and the United States, which showed that gastrointestinal stromal tumour patients with a particular mutation (KIT exon 9) have delayed disease recurrence with high-dose imatinib treatment (p. 14).



Survival in patients with advanced colorectal cancer in different KRAS genetic groups, from a collaborative study using data from CO.17 and other similar trials.

Prospective meta-analysis of trial data



Dr Lisa Aslie, director of systematic reviews and a leader in meta-analyses in neonatal disorders

MetaGIST: HIGHER OR LOWER DOSAGE FOR GASTROINTESTINAL STROMAL TUMOURS?

Gastrointestinal stromal tumours are relatively common stomach cancers. A proven treatment is imatinib, which targets mutated genes in the tumour. A trial by the Australasian Gastro-Intestinal Trials Group and its European collaborators had shown that over the short term, about 2 years, imatinib twice a day prevented disease recurrence more effectively than the standard daily treatment. However, this difference was not sustained over a longer period, leading to uncertainty about the best treatment regimen. The results of this trial were combined with results from an American trial in a meta-analysis based on 1640 patients. This confirmed that the higher dose did not prolong survival or have any advantage for most patients. These results may guide clinicians in choosing the best treatment regimen for patients with this disease.

META-ANALYSIS OF DATA FROM NEONATAL VENTILATION TRIALS

The PreVILIG (Prevention of Ventilator Induced Lung Injury Collaborative Study) Group recently published a systematic review and meta-analysis of data from 10 trials comparing controversial high-frequency oscillatory ventilation (HFOV) and conventional ventilation for preterm infants, finding that HFOV appeared just as effective as conventional ventilation.

This meta-analysis was a collaborative effort involving investigators from the original trials, who worked together to plan the analysis and interpret the results. Use of individual patient's data improved the assessment of the treatment effect because outcomes with varied definitions could be redefined. The large number of participants (3229) meant that subgroup characteristics, such as gestational age and the extent of lung disease, could be analysed as well.

Neonatal and paediatric studies typically require large cohorts of patients to show subtle effects, so meta-analyses of data from similar trials are becoming common. The CTC is leading or participating in several such studies: NeOProM (Neonatal Oxygenation Prospective Meta-Analysis), EPOCH (Early Prevention of Obesity in Children), MAPPiNO (Nitric Oxide in Assisted Ventilation) and PARIS (Antiplatelets for Preventing Pre-Eclampsia).

ACUTE MYOCARDIAL INFARCTION

The CTC is part of the Primary Coronary Angioplasty versus Thrombolysis-2 Trialists Collaborators group, which has conducted a series of meta-analyses of trials comparing percutaneous procedures (such as insertion of stents and balloons) with drug treatment for restoring blood flow in coronary arteries in patients with acute myocardial infarction. These have shown that percutanous procedures are better for patients at high risk, but they are often withheld from older patients because of uncertainty about the harms and benefits of treatment in this group.

A recent study pooling data from 22 trials found that, for elderly patients well enough to be selected for clinical trials, the advantage of percutaneous procedures after myocardial infarction was similar in older and younger patients. Therefore, age is not a reason to exclude patients from the better treatment.

INTERNATIONAL CHOLESTEROL-LOWERING COLLABORATION

The Cholesterol Treatment Trialists' Collaboration is one of the largest international prospective meta-analysis groups. It was established in 1994 to analyse data from all relevant large-scale randomised trials of cholesterol-lowering therapy, so that data from similar trials could be combined to study specific outcomes and subgroups of patients. The LIPID trial (Long-Term Intervention with Pravastatin in Ischaemic Disease), coordinated by the CTC since 1990, contributes data from 9014 Australian and New Zealand patients.

The second cycle of planned analyses incorporated more trials and has involved nearly 170 000 patients from 26 trials (published in 2010 in *The Lancet*). The study analysed data from individual patients to assess the effect and safety of reducing LDL cholesterol to very low concentrations. Intensive statin therapy reduced the vascular risk, even for patients with initially very low LDL cholesterol, without cancer risk. The investigators recommended that for people at high risk of vascular disease, LDL cholesterol should be reduced as far as possible, preferably with modern statins or with combinations of statins and other drugs.

The CTC and the Clinical Trial Service Unit at Oxford University coordinate the collaboration.

Reviews of evidence in the Cochrane Library

The CTC is the editorial base of the Cochrane Breast Cancer Group, an international team of volunteers who prepare, maintain and update Cochrane reviews on breast cancer. The CTC staff who form the editorial base coordinate these activities and maintain a specialised register of breast cancer research references.

SPECIAL COLLECTION FOR THE LIBRARY

During October 2010, to coincide with Breast Cancer Awareness Month, the Cochrane Breast Cancer Group, with the Cochrane Editorial Unit in the UK, prepared a special edition on metastatic breast cancer. The collection features 18 Cochrane reviews and focuses on the range of treatments available for metastatic breast cancer, including chemotherapy, endocrine therapy, psychosocial interventions and supportive care. The special edition can be found at:

http://www.thecochranelibrary.com/details/collection/857471/Metastatic-Breast-Cancer.html

Melina Willson, project manager, Cochrane Breast Cancer Group

EVIDENCE IN A UNIVERSAL HEALTH CARE SYSTEM

Henry Ko, project officer for systematic reviews at the CTC, was one of 30 finalists in an international essay competition for young researchers by the Global Forum for Health Research and *The Lancet*.

His essay 'Fostering better shared decision-making in universal health coverage in the face of hype, hope, and evidence' argued for the need for and methods to provide evidence-based decision-making when it comes to medical therapies in a universal health care system.

Health systems research is rapidly emerging as one of the most dynamic and complex areas of research for health. The finalists' essays are anthologised at http://www.globalforumhealth.org.

Australian New Zealand Clinical Trials Registry

The Australian New Zealand Clinical Trials Registry (ANZCTR) since 2005 has been providing public data on clinical trials conducted in Australia, New Zealand and neighbouring regions. It is a primary registry in the World Health Organization's registry network.

New trials submitted for registration averaged 102 per month in 2010—an increase from the 2009 average of 90 per month. The total number of registered studies has now reached 4772.

AUSTRALIAN CANCER TRIALS WEBSITE LAUNCHED IN NOVEMBER 2010

Staff of the ANZCTR have been working with others on Australian Cancer Trials, a consumer-friendly website providing information about cancer trials in Australia. The University of Sydney, Cancer Australia, Cancer Voices and other consumer groups and the CTC collaborated in this project. The site was officially launched on 11 November during the COSA Annual Scientific Meeting. Website data are sourced from the ANZCTR and clinicaltrials.gov in the United States.

www.australiancancertrials.gov.au

www.anzctr.org.au

www.clinicaltrials.gov

Neonatal trials

BOOST II: a major advance in therapy for very premature babies

For over 50 years, the best level of oxygenation for maximising survival without disability in infants born at under 28 weeks' gestation has remained unknown. The accepted range of oxygen saturation has varied from 85% to 95%.

BOOST II is a trial comparing disability-free survival at 2 years in 1135 infants randomly assigned to low (85–89%) or high (91–95%) oxygen saturation targets. BOOST II is also part of the Australian-led international NeOProM Collaboration, a pooled meta-analysis of several trials comprising 4959 infants.

In mid-2010, the United States trial, which recruited 1316 infants, reported marginally better short-term survival with the high target range.

The local data monitoring committee reviewed outcomes for 1352 infants in the Australian and New Zealand trials and found no reason to discontinue recruitment. However, joint analysis of the Australasian, United Kingdom and United States trials confirmed better survival on the high target, by 21% in all 3631 infants and by 65% in a prespecified group of 1055 infants enrolled after oximeters were upgraded with new software. With such definitive interim results, BOOST II closed to recruitment in December 2010. A report will be published in 2011.

BOOST II is continuing in follow-up of patients and analysis of results.

Lucille Sebastian, INIS manager

INIS: study of immunoglobulin to prevent disability after neonatal infection

2010 was a big year for the International Neonatal Immunotherapy Study (INIS). The first patient was enrolled in February 2002. Nine years and 1398 Australian recruits later, the data for 2 years of follow-up were sent to the National Perinatal Epidemiology Unit at Oxford University for amalgamation with data from other countries. Australian and New Zealand study sites were closed. The results will be published in 2011.

APTS: cord blood for premature babies

The benefit to a newborn premature infant of promoting blood flow from the placenta just after birth is unclear. The Australian Placental Transfusion Study completed a pilot study of delayed cord clamping and cord milking in 2010, and the protocol for the main study was finalised. The main study will start initially in 10 tertiary centres in Australia.

CTC devises new methods within trials research

A MODEL TO PREDICT RISK OF RECURRENT EVENTS IN THE LIPID CARDIOVASCULAR TRIAL

Traditional methods for analysing clinical and epidemiological data have focused on the first occurrence of the outcome or event being measured. These methods can be unsuitable for analysing recurring events because a first event may signal another one; that is, recurrent events are not independent of each other.

A recent methodological study used the dataset of the CTC's multicentre trial, LIPID, which had shown that lipid-lowering with a statin prevented a coronary event, such as a heart attack. The LIPID study is still following up patients, many years after the main trial closed (p.26).

The new study focused on recurring events and risk factors and and whether the risk factors were different for first and recurrent events. Several potentially useful statistical models were applied to the data. A semiparametric proportional-hazards model and a parametric conditional model were both found to be useful tools for exploring the biological cardiovascular process.The analysis also showed that the study drug, pravastatin, prevented first and second cardiovasacular events to a similar degree.

A METHOD TO ADJUST FOR DIFFERENTIAL BACKGROUND TREATMENTS IN LONG-TERM TRIALS

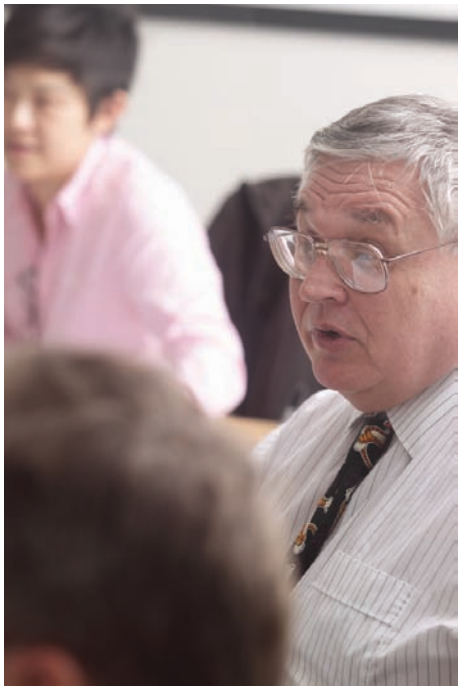
An advance in trial methodology arose from difficulties in the statistical analysis of the FIELD diabetes trial (p. 26). In this large international trial, 9795 patients were randomly assigned to fenofibrate or placebo and followed up for an average of 5 years. Cardiovascular outcomes were measured.

Over the 5 years of the trial, many patients started taking newly approved cholesterol-lowering drugs, confounding the effect of the study drug. FIELD investigators and CTC statisticians devised a novel method using the results of other clinical trials to adjust the estimates of efficacy of the study drug —a method with potential for wide application in long-term trials.

Adrienne Kirby and Kristy Mann, biostatisticians

MODELS TO PREDICT BREAST CANCER METASTASIS TO INTERNAL MAMMARY NODES

An important prognostic factor in breast cancer is the status of the internal mammary lymph nodes, that is, whether there is tumour in the nodes near the middle of the chest. These nodes are less accessible than axillary lymph nodes and less likely to be visualised with radio-isotope mapping or to be biopsied. Models to predict metastasis in these lymph nodes have been developed on the basis of anatomy and tumour biology. These will assist cancer clinicians to make decisions about treatment when the status of these lymph nodes is not known.



Val Gebski, director, Biostatistics

Clinical Trials Development Unit, an Australian collaboration for cancer trial infrastructure

The Clinical Trials Development Unit (CTDU) harnesses the experience and expertise of the CTC and the Centre for Biostatistics and Clinical Trials, Peter MacCallum Cancer Centre, in Melbourne. The CTDU has been supported since 2008 by Cancer Australia. It is an important formal structure for sharing information, ideas and resources, thereby adding value to what could be provided by each institution in isolation.

The unit provides expert advice and trial development services for recently established cancer trials groups, including the Cooperative Trials Group for Neuro-Oncology (COGNO), the Primary Care Collaborative Cancer Clinical Trials Group (PC4) and the Australasian Sarcoma Study Group (ASSG). The CTDU's activities include:

- expert design of trials, and biostatistical and operational advice for new trials
- developing research grant applications and preparation and management of budgets and finances
- advice on case report forms and design of databases for various trials
- standard operating procedures, forms and processes to initiate and conduct cancer trials
- procedures for quality assurance, particularly in relation to data quality
- contributions to collaborative group executive and scientific committees.

The CTC's oncology story: a better life for cancer patients

It has been nearly 25 years since the CTC began its first oncology trial, a randomised comparative study of surgery versus radiotherapy and chemotherapy in patients with squamous cell carcinoma of the head and neck. Much has changed in the world of clinical trials since then. The early trials were straightforward head-to-head comparisons, with simple randomisation to one treatment or the other. Now, trials are multidisciplinary studies of surgery, chemoradiation and a targeted biological agent (or two), sometimes a second randomisation when the patient's disease progresses, and usually value-added translational substudies (tissue and blood collection) and substudies on quality of life, health economics and patient preferences. Eighty trials and 5 collaborative groups coordinated through the CTC have recruited nearly 20 000 patients.

Much of this success is owed to staff at the CTC and at the trial sites—the principal investigators, nurses, data managers, pharmacists, radiologists and others—who have contributed to the research for patients and their families living with cancer.

Burcu Vachan, oncology program manager

HIGHLIGHTS OF ONCOLOGY RESEARCH FOR 2010

MAX: TREATMENT FOR ADVANCED COLORECTAL CANCER

MAX was an investigation comparing capecitabine chemotherapy alone with capecitabine plus a genetically engineered monoclonal antibody, bevacizumab (with or without mitomycin), for patients with advanced colorectal cancer, particularly older patients. Bevacizumab blocks the growth of the tumour's blood supply. Patients in the bevacizumab arms of the trial survived without recurrence on average about 8.5 months, or 3 months longer than without this treatment. Further analyses of the trial data are continuing, and will cover the cost-effectiveness of this treatment regimen in the Australian health setting, genetic studies of tumour tissue, and patients' quality of life

MAX was initiated and sponsored by the Australasian Gastro-Intestinal Trials Group (AGITG). Results were published in the *Journal of Clinical Oncology*.

> *"It is therefore heartening to see that in the Tebbutt study the addition of bevacizumab to single-agent oral fluoropyrimidine (capecitabine) ... does indeed improve PFS and suggests that this combination is a reasonable alternative for patients who cannot tolerate ... the augmented toxic effects of dual-agent chemotherapy."*
>
> —Yanagisawa and Midgley, *Nature Reviews: Clinical Oncology*, October 2010

***Streptomyces verticillus*, source of bleomycin, used to treat testicular cancer**
(Reprinted with permission. By T Harada and M Hamada, ©Society for Actinomycetes, Japan)

HIGH-DOSE BLEOMYCIN, ETOPOSIDE AND CISPLATIN (BEP) ESTABLISHED AS THE BEST CHEMOTHERAPY FOR TESTICULAR CANCER

Testicular cancer is curable in over 95% of cases with treatment regimens that have been around for many years. A trial conducted in the early days of the CTC comparing a 3-cycle higher-dose BEP regimen with a 4-cycle lower-dose regimen showed after less than 3 years of follow-up that the former had better outcomes than the latter. Patients have continued to be followed up, and an analysis of their outcomes 9 years later was published in the *Journal of the National Cancer Institute*. The survival rate continued to be better for patients treated with the shorter, more intense regimen. The study helped to establish the best regimen for testicular cancer, which is now included in clinical guidelines.

The CTC undertakes investigator-initiated trials with the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP).

> *"The thorough article by Grimison et al, with the careful attention to long-term follow-up, in our view, should bring an end to clinical investigations of alternatives..."*
>
> — Nichols and Killmannsberger, editorial, *JNCI*, 18 August 2010.

TESTING NEW TREATMENT FOR OESOPHAGOGASTRIC CANCER

The phase II trial, ATTAX, evaluated two new regimens for oesophagogastric cancer, adding docetaxel to either the standard therapy (cisplatin and fluorouracil) or to capecitabine. Both regimens appeared promising and showed that weekly docetaxel regimens are feasible. This AGITG-sponsored trial appeared in the *British Journal of Cancer*.

OVARIAN CANCER

The standard treatment for women with advanced ovarian cancer has been chemotherapy with paclitaxel and carboplatin, but patients having a second round of this treatment after relapse may be troubled by cumulative side-effects. CALYPSO compared a newer drug, pegylated liposomal doxorubicin (with carboplatin) with the standard therapy. This combination was not only as good as, but better than, the standard treatment in prolonging progression-free survival. The new treatment is a more effective, less toxic alternative for these patients. The report appeared in the *Journal of Clinical Oncology*.

The CTC is the statistical centre for GINECO's CALYPSO, the largest international trial of therapy for relapsed ovarian cancer, with 976 patients worldwide. The CTC's conducts its gynaecological trials in collaboration with the Australia New Zealand Gynaecological Oncology Group (ANZGOG), which participates in international trials such as CALYPSO.

CANCER OF THE BILIARY TRACT AND GALLBLADDER

Billiary tract cancers have poor prognosis and short survival because most patients have advanced disease at diagnosis. There is no generally accepted standard treatment, and patients' response to treatment varies according to the main site of the cancer: biliary tree or gallbladder. The AGITG and CTC conducted a phase II trial of chemotherapy to test the feasibility of fixed-dose-rate gemcitabine and cisplatin in 50 Australian and New Zealand patients with biliary tract or gallbladder cancer, which was published in *Cancer Chemotherapy and Pharmacology*. The treatment was well tolerated, and some tumours regressed in response to it, although fixed-dose-rate administration did not appear to be an advantage over regular infusion.

THE INTERNATIONAL ESPAC 3 TRIAL FOR PANCREATIC CANCER

Cancer of the pancreas is a challenging disease, with a poor 5-year survival rate. An international collaborative group involving the CTC and AGITG (with 16% of trial sites and 133 patients in Australia and New Zealand) completed a large study that compared two commonly used treatments with different modes of action—fluorouracil-based chemotherapy and gemcitabine. Survival was similar for patients in both arms of the trial: half of the patients in each arm of the trial survived for at least 2 years, showing that both treatments had benefit. The report, by the European Study Group for Pancreatic Cancer, was published in *JAMA*.

CARE AND QUALITY OF LIFE: INPATIENT VS OUTPATIENT CHEMOTHERAPY

Patients requiring high-dose chemotherapy have traditionally needed at least a night in hospital for therapy to help them cope with side-effects. Many hospitals have gradually shifted to outpatient treatment, but whether this suits the patients or has led to worse side-effects or emergency admissions to hospital has been unclear.

A study by the Sydney Cancer Centre and the CTC compared inpatient and outpatient administration of high-dose cisplatin chemotherapy for lung, stomach, bladder and other cancers. Patients were randomly allocated to one of the two treatment settings for their first cycle and then crossed over to the other for the second cycle.

Outpatient treatment was preferred by most patients and appeared to be safe. After outpatient treatment, patients reported less distress about the thought of chemotherapy, but otherwise their perceived quality of life was not different.

Katrin Sjoquist, AGITG and ANZGOG, clinical research fellow

PREFERENCES STUDIES: WHAT SURVIVAL BENEFITS MAKE CHEMOTHERAPY WORTHWHILE?

Dr Prunella Blinman is undertaking a series of studies of how patients and their doctors trade off the benefits and harms of chemotherapy.

Chemotherapy is underutilised for non-small-cell lung cancer, the most common form of lung cancer, although it can improve 5-year survival rates after operation by about 5% and 1-year survival rates of patients with advanced cancer by 9%. In an observational study, lung cancer clinicians were asked to rate the survival benefits that would make chemotherapy worthwhile. Their responses were widely varied and unrelated to other factors, but they judged very small improvements in survival as justifying chemotherapy.

In another recent study, a questionnaire was used to elicit survival and chemotherapy trade-off preferences from patients after the experience of chemotherapy for colon cancer. Many judged that small survival benefits made therapy worthwhile.

These preferences studies underline the need for cancer clinicians to discuss the pros and cons of chemotherapy and allow patients' views and values to influence decisions about treatment.

Dr Prunella Blinman

CARE AND QUALITY OF LIFE: LEARNING ABOUT PAIN

A randomised trial has shown that people with pain from cancer can benefit from a simple educational intervention. People with advanced cancer are often undertreated for their pain, possibly because of their fears of opoid addiction. Learning more about pain from a booklet or video, or both, improved their pain scores and reduced their addiction fears.

FURTHER ANALYSIS FROM TRIALS FOR GASTROINTESTINAL STROMAL TUMOURS

Data from a published AGITG–EORTC trial comparing high and low-dose imatinib treatment for gastrointestinal stromal tumours has been combined with the results of an American trial in MetaGIST, a meta-analysis showing that overall survival was similar for both dosage schedules (p.14).

THE ART OF ONCOLOGY: COMMUNICATING SURVIVAL EXPECTANCY TO PATIENTS

The critical question, 'How long do I have to live?', which a patient with advanced cancer inevitably asks their doctor, and the prognostic uncertainty that surrounds the answer, is the main topic of **Dr Belinda Kiely**'s doctoral research.

'It is very difficult for oncologists to estimate the survival time for such patients and they invariably don't know how best to communicate bad news—so they avoid it', she says. 'As training oncologists, we learn communication skills in a role-play situation but we are not taught what numbers to use in answer to that vital question'.

Dr Kiely's goal is improving communication of life expectancy to patients in a way that is realistic but maintains hope. The median survival is the measure that most cancer professionals are familiar with, but for patients, the median is unnecessarily discouraging and frequently misinterpreted. Many patients interpret the median as a limit and do not realise that 50% live longer. Dr Kiely and her colleagues have suggested framing information in terms of the chance of surviving rather than the chance of dying as a way of conveying hope. They also suggest using multiples and fractions of the median to present typical, best-case and worst-case scenarios to patients, rather than just a single estimate of the median.

These conversations require data. The researchers sought this information from clinical trials of metastatic breast cancer. They were able to provide simple multiples from trial survival curves for clinicians to use to communicate typical, best-case and worst-case survival information for patients about to start chemotherapy for metastatic breast cancer. The results of this research and an essay to stimulate thought and discussion on this aspect of patient care have both been published in the *Journal of Clinical Oncology*.

The CTC is an ideal environment for a cancer researcher. Belinda has gained expertise and experience in statistics, as well as writing protocols, producing a budget and applying for funding. 'I would not have been able to do it without the support of the biostatistics team and the trial groups at the CTC' says Belinda. 'Doctors who are doing their PhDs in other settings such as hospitals don't have access to specialist expertise in publications, trials and statistics'.

How long do I have to live?
'As training oncologists, we learn communication skills in a role-play situation but we are not taught what numbers to use in answer to that vital question.'

Dr Belinda Kiely

PREDICTING INDIVIDUAL SURVIVAL AND THE BENEFITS OF TREATMENT

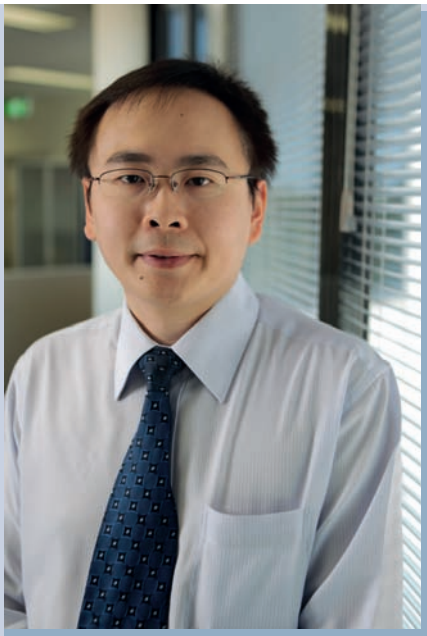
Three years ago, Professor John Simes told a budding researcher, **Dr Chee Lee,** that biomarkers are the research of the future. Chee is now undertaking studies that use biomarkers and other information from clinical trials to predict survival and the benefits of different treatments for cancer patients, particularly women with breast or ovarian cancer.

It is possible to individualise cancer treatment by identifying biological biomarkers that signal that the patient will benefit. This is clearly good for the patient's quality of life, and Chee's quest is to find more treatments that suit each individual cancer patient, replacing the scattershot approach of one chemotherapy regimen for all.

'Having access to patients' tumour tissues donated as part of the clinical trial, we can narrow our research down to finding out where and why the drug worked. In the clinic, when you see a patient you ask: "Is there anything I can do to make it better?" Having access to these data helps me answer that question.'

The laboratory and data collection are done elsewhere, then data are analysed and managed within the CTC.

Chee is passionate about his work. Before starting his PhD at the CTC, he did clinical training in hospitals and participated in distance learning programs in statistics and research methods. In mentoring his registrars, he makes a point that good training in research is important, as it helps to develop useful analytical skills. But research needs to have clinical relevance. 'You can do wonderful analysis and come up with a nice paper, but doctors can tell you the theory doesn't always apply in real life.'



Dr Chee Lee

'I realise that if you don't see patients, you don't understand what is important in real life. '

ACHIEVEMENTS IN CARDIOVASCULAR DISEASE RESEARCH

FENOFIBRATE AND EVENT-LOWERING IN DIABETES (FIELD): FENOFIBRATE PROTECTS AGAINST AMPUTATION, RETINAL DISEASE, AND NOW, KIDNEY DISEASE

The FIELD trial enrolled 9795 patients with type 2 diabetes from Australia, New Zealand and Finland, who were randomly allocated for fenofibrate or placebo.

The trial closed in 2005 and has already resulted in over 20 peer-reviewed research papers, with many substudies under way. These include long-term follow-up of patients and translational studies in which assays of blood samples will help to reveal molecular and genetic biomarkers of diabetes and the pathways of action of fenofibrate, new knowledge that will ultimately benefit people with diabetes in the future.

Substudies of FIELD patients have previously shown that the study drug, fenofibrate, is beneficial for people with diabetes in terms of reducing the need for amputations and for laser treatment of eyes. That is, fenofibrate is good for disease of the small blood vessels. Two recent renal studies completed the microvascular-disease trio, showing, first, that mild renal impairment predicts later cardiovascular events and, second, that fenofibrate treatment may reduce loss of kidney function. These were published in *Diabetologia*.

RECURRENT VENOUS THROMBOEMBOLISM

Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE), a trial that aims to determine whether low-dose aspirin prevents recurrence of venous thromboembolism, is an international trial coordinated by the CTC. The trial currently has 767 patients, from Australia, New Zealand, Singapore, the United Kingdom, India and Argentina. The ASPIRE investigators are collaborating with investigators from Italy (WARFASA trial) in the INSPIRE prospective meta-analysis, led by the Australian investigators.

LONG-TERM INVESTIGATION OF HEART DISEASE PREVENTION

The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) trial has reached 16 years of follow-up of patients treated for prevention of recurrent heart disease. Their outcomes are being analysed. Blood samples collected over the first six years of the trial are being analysed in the laboratories of collaborating scientists from Germany, Sweden and the United States, and are being used in a new round of investigations of how various blood components are related to, first, the risk of disease and, second, the effects of pravastatin.

MICE AND MEN: LABORATORY RESEARCH EXTENDING THE FIELD TRIAL RESULTS

Diabetes is a systemic condition with various destructive effects on blood vessels and nerves. Patients are at risk of leg ulcers because of poor circulation and poor sensation. If the ulcers fail to heal properly, there is risk of infection leading to osteomyelitis (inflammation of the bone) or gangrene of the foot, which may require amputation of the toes or foot.

A substudy of the FIELD trial showed that fenofibrate treatment reduces amputations. **Dr Kushwin Rajamani** is now attempting to find the mechanisms of this effect in laboratory mice with diabetes, as part of his PhD research. He is studying the effects of fenofibrate on various cell functions that may be involved in the effects of fenofibrate.

Kushwin says: 'Since I was an intern I have been passionate about cardiology and wanted to be a cardiologist. I enjoy the physiology, the cardiovascular pharmacology, as well as caring for patients with cardiovascular problems and improving patients' wellbeing in many situations. I also enjoy the research and evidence-based medicine in cardiology.

'At the CTC I have had the opportunity to work with world-class leaders in the field who have taught me the principles behind epidemiological research, and the statisticians have helped me tremendously with the analyses. My supervisors have been very supportive throughout my time here, and have helped me grow my research abilities.'

Dr Kushwin Rajamani

'Since I was an intern I have been passionate about cardiology and wanted to be a cardiologist. I enjoy the physiology, the cardiovascular pharmacology, as well as caring for patients with cardiovascular problems and improving patients' wellbeing in many situations. I also enjoy the research and evidence-based medicine.'

INTERNATIONAL DIFFERENCES AND RISK MODELS FOR ACUTE MYOCARDIAL INFARCTION

Rachel O'Connell began her association with the CTC working as a biostatistician with Professor Malcolm Hudson on a large international trial, HERO-2. A trial substudy raised new questions which led her to study the topic further as a PhD student.

The Hirulog and Early Reperfusion or Occlusion (HERO-2) trial, a VIGOUR collaborative trial, randomised 17 073 patients in 46 countries to treatment for myocardial infarction. In this trial, mortality rates across 5 geographical regions (Western countries, Latin America, Eastern Europe, Russia and Asia) varied considerably, with lower rates in western countries. Rachel attempted to find explanations for these differences in mortality, such as patient case-mix, treatments, and national health and economic statistics. The study was published in 2010 in the *American Heart Journal*.

She also developed a comprehensive, international risk model to identify significant predictors of 30-day mortality after myocardial infarction.

Now reaching the end of her PhD, Rachel says: 'The fact that we had data from so many countries and observed such large variations in outcome rates which weren't explained by differences in patient baseline risk was interesting. This is a public health concern. Another interesting finding was that predictors of survival were very consistent across all regions despite the differences in outcome rates.

'The CTC is an excellent place to do research as there are so many gifted people with varying research backgrounds and strengths who are willing to help when problems arise, share ideas and offer interesting perspectives. The standard of intellectual contribution and creative thinking among the statistics group is exceptional. This environment has fostered a culture of learning and personal development and has cultivated the research and statistical skills that I have today'.

'The CTC is an excellent place to do research as there are so many gifted people with varying research backgrounds and strengths who are willing to help when problems arise, share ideas and offer interesting perspectives. The standard of intellectual contribution and creative thinking among the statistics group is exceptional. '

Rachel O'Connell

CLINICAL AND LABORATORY RESEARCH ON DIABETIC KIDNEY DISEASE

Dr Ru-Dee Ting's PhD project is on the microvascular complications of diabetes. In clinical studies based on the FIELD trial, he is examining various markers that might predict kidney disease. He is also elucidating by laboratory research how fenofibrate benefits the kidneys. This seems to involve multiple pathways and is not as straightforward as was initially thought.

'If we have a greater understanding of how fenofibrate works we can then develop other drugs that can better target those parts and produce better efficacy in preventing renal disease', says Ru-Dee.

The opportunity for Ru-Dee to embark on a PhD presented itself when he worked as an advanced trainee cardiologist at Royal Prince Alfred Hospital on a small project with Professor Tony Keech.

'CTC has excellent facilities, supportive staff and an army of statisticians to help out. Expertise in statistics is not available to every research group; they either have to do their own, or send their data to a part-time statistician. To be able to walk across the floor and have a chat with a statistician at CTC is very useful. It is much more effective than just getting a *P* value.'

Dr Ru-Dee Ting

'If we have a greater understanding of how fenofibrate works we can then develop other drugs that can better target those parts and produce better efficacy in preventing renal disease'

COLLABORATIONS

The CTC works with organisations around the world in collaborations that lead to better health outcomes in Australia and internationally. New collaborations are continually sought and then consolidated in research projects benefiting the health of Australians and others.

GROUP	NATURE OF GROUP	ACTIVITY
A la CART and Z6094 US study meta–analysis	Meta-analysis collaboration: international	Member
AMICABLE collaboration	Meta-analysis collaboration: international	Member
ANZ Breast Cancer Trials Group (ANZ BCTG)	Collaborative group for breast cancer trials: Australia, New Zealand International collaborations: International Breast Cancer Study Group (IBCSG), Breast International Group (BIG), International Breast Cancer Intervention Study (IBIS)	Statistical centre for group, including randomisation
ANZ Germ Cell Tumour Study Group (ANZ GCTG)	Collaborative group for testicular cancer trials: Australia, New Zealand	Coordinating centre
ASPIRE Study Group	Collaborative group for ASPIRE trial: Australia, New Zealand, United Kingdom, India, Argentina	Coordinating centre
Australasian Gastro-Intestinal Trials Group (AGITG)	Collaborative group for gastrointestinal cancer trials: Australia, New Zealand International collaborations: NSABP (USA), ECOG (USA), EORTC (Europe), PETACC (Europe), NCIC CTG (Canada), OCTO (UK)	Coordinating centre
Australian and New Zealand Urogenital and Prostate Clinical Trials Group (ANZUP)	Collaborative group for cancer of the genitourinary system	Coordinating centre
Australasian Society of Thrombosis and Haemostasis	Professional group undertaking thrombosis trials: Australia, New Zealand	Coordinating centre
Australasian Lung Cancer Trials Group (ALTG)	Collaborative group for lung cancer trials International collaborations: NVALT (Netherlands), NCIC CTG (Canada)	Coordinating centre
ANZ Gynaecological Oncology Group (ANZGOG)	Collaborative group for gynaecological cancer trials: Australia, New Zealand International collaborations: Gynecological Cancer Intergroup (GCIG), International Gynaecological Cancer Intergroup (IGCI), Gynecologic Oncology Group (GOG)	Coordinating centre
Australian New Zealand Clinical Trials Registry (ANZCTR)	National register of Australian clinical trials	Coordinating centre
Australian universities	University members of Biostatistics Collaboration of Australia	Coordinating centre
Cochrane Collaboration	Collaborative group undertaking systematic reviews of trial evidence: international	Editorial base of the Cochrane Breast Cancer Group; co-convening centre for Prospective Meta-analysis Methods Group
Cochrane Prospective Meta-Analysis Methods Group	Cochrane group ; international	Coordinating centre
Cholesterol Treatment Trialists' Collaboration (CTTC)	Collaboration of clinical trial groups studying cholesterol treatments: Australia, New Zealand, United Kingdom, United States, Italy	Coordination of meta-analyses in heart disease
Clinical Trial Development Unit	Joint venture with Peter MacCallum Cancer Institute	Statistical support for cancer trials
Cooperative Trials Group for Neuro-Oncology (COGNO)	Collaborative group for brain cancer trials	Coordinating centre
Medical Services Advisory Committee Department of Health and Ageing	Government: Australia	Provide assessments of new technologies and other research services BCA: biostatistics education
EPOCH collaboration	Prospective meta-analysis collaboration: international	Data coordination centre
European Organisation for Research and Treatment of Cancer (EORTC)	International collaborative group	Collaborator through Australian groups

GROUP	NATURE OF GROUP	ACTIVITY
FIELD Study Group	Collaborative group for FIELD diabetes trial: Australia, New Zealand, Finland	Coordinating centre
Gynaecologic Cancer Intergroup (GCIG)	International collaborative group	Collaborator through ANZGOG
Gynecologic Oncology Group (GOG)	International collaborative group	Collaborator through ANZGOG
INIS Study Group	Collaborative group for INIS trial: Australia, New Zealand, United Kingdom	Regional coordinating centre
INSPIRE	Meta-analysis: ASPIRE and WARFASA (Italy)	Member
LIPID Study Group	Collaborative group for follow-up and genetic studies of LIPID cholesterol-lowering trial: Australia, New Zealand, Germany	Coordinating centre
Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPiNO) collaboration	Meta-analysis collaboration: international	Data coordination centre
Medical Research Council (MRC)	Government: international	Collaborator
Menzies Research Institute and Charles Darwin University	Research institution: Australia	Collaborator
National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)	Trials research group: Canada	Collaborator through Australian cancer collaborative groups
National Heart Foundation	Nongovernment organisation: Australia	Coordinator of the LIPID trial
National Perinatal Epidemiology Unit (NPEU), University of Oxford	Research institution: UK	Co-collaborator on the INIS neonatal trial
National Surgical Adjuvant Breast and Bowel Project (NSABP)	Collaborative group	Collaborator through Australian groups
Neonatal Oxygenation Prospective Meta-analysis (NeOProM) collaboration	Prospective meta-analysis collaboration; international	Coordinating centre
NSW Cancer Council	Cancer Epidemiology Research Unit	Collaborator
NSW Cooperative Oncology Group	Collaborative group: NSW	Coordinating centre for the group
Oxford Clinical Trials Office (OCTO)	Trials research group: UK	Cancer trials
Perinatal Antiplatelet Review of International Studies (PARIS) collaboration	Meta-analysis collaboration with representation from many countries	Co-coordinating centre
PRECISE collaboration	Meta-analysis collaboration: international	Member
Prevention of Ventilator Induced Lung Injury collaborative study group (PreVILIG)	Meta-analysis collaboration: international	Data coordination centre
PRECISE collaboration	Meta-analysis collaboration; international	Member
Primary Care Cancer Trials Group	Collaborative group: Australia	Collaborator
Primary Coronary Angioplasty versus Thrombolysis (PCAT)	Meta-analysis collaboration with representation from many countries	Co-coordinating centre
Prospective Pravastatin Pooling project	Collaborative group: Australia, New Zealand, United States, Scotland	Coordinating centre
Royal Australasian College of Surgeons (RACS)	Professional society undertaking trials of surgery: Australia and New Zealand	Coordinating the SNAC trial in breast cancer with the RACS
Star Child Health	International collaboration	Member
VIGOUR group	Collaborative group for trials of heart disease: 40 countries	Data coordinating centre, Asia-Pacific Region; International statistical centre (HERO-2 trial)

CURRENT TRIALS AT THE CTC

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Neonatal disorders			
Current trials			
BOOST II: Benefits of oxygen saturation targeting	Neonates born before 28 weeks' gestation	1200	1135
APTS: Australian placental transfusion study	Neonates born before 30 weeks' gestation	1600	6
Trials in follow-up			
INIS: International neonatal immunotherapy study	Neonates with infection and low birthweight who are taking antibiotics	1500 (ANZ); 3500 (international)	1398 (ANZ); 3493 (international)
Cardiovascular disorders			
Current trials			
ASPIRE: Aspirin to prevent recurrent venous thromboembolism	People who have had 6 months of treatment with warfarin for a venous thromboembolism	1200 (international)	671 (ANZ); 767 (international)
Trials in follow-up			
FIELD: Fenofibrate intervention and event lowering in diabetes	Patients with type 2 diabetes	8000	9795
LIPID: Long-term intervention with pravastatin in ischaemic disease	Patients with a history of coronary heart disease	9000	9014
Breast cancer			
Current trials			
SNAC 2: Multicentre randomised trial of sentinel-node biopsy versus axillary clearance RACS and NHMRC CTC study	Women with operable breast cancer, stratified by various factors, including age and tumour size Women with operable breast tumours up to 3 cm	1012	146
Trials in follow-up			
SNAC 1: Sentinel node biopsy versus axillary clearance RACS and NHMRC CTC study	Women with operable breast cancer, stratified by various factors, including age and tumour size	1000	1088
Gastrointestinal cancer			
Current trials			
A la CART: Australian phase III randomised trial of laparascopy-assisted resection compared with open resection (AG0109CS) *AGITG study*	Patients with primary rectal cancer	470 (ANZ);	13
ATTAX 3: Phase II study of docetaxel, cisplatin and fluoropyrimidine with or without panitumumab for oesophagogastric cancer (AG0607OG) *AGITG study*	Patients with metastatic or locally recurrent oesophagogastric cancer	100	20
LAP07: randomised multicentre phase III study of gemcitabine with or without chemoradiotherapy and with or without erlotinib for adenocarcinoma of the pancreas (AG0208PS) *AGITG and GERCOR study*	Patients with locally advanced adenocarcinoma of the pancreas	60 (ANZ); 900 (international	5 (ANZ)
PETACC 6: addition of capecitabine to preoperative oxaliplatin chemoradiotherapy and postoperative oxaliplatin chemotherapy for rectal cancer (AG0707R) *EORTC study*	Patients with locally advanced rectal cancer	100	60

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
REGISTER: multicentre phase II study of risk evaluation in GIST with selective therapy escalation for response (AG0507GS) *AGITG study*	Patients with gastrointestinal stromal tumour not suitable for curative surgery	80	19
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer (AG0308CR) *AGITG study*	Patients with fully resected stage III colorectal cancer	225 (ANZ); 9500 (international)	11
SUPER: Phase III trial evaluating surgical resection of the primary tumour in metastatic colorectal cancer (AG 0209CRS)	Patients with unresectable metastatic colorectal cancer	30 (stage 1); 400 (full trial)	3
SURGIST: Phase III randomised study of surgery of residual disease (AG0108GS) *EORTC study*	Patients with metastatic gastrointestinal stromal tumour responding to Imatinib mesylate	35 (ANZ); 350 (international)	0
TOP GEAR: randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer (AG0407GR, TROG 08.08) *AGITG study*	Patients with resectable gastric cancer suitable for these treatments	120 (stage 1); 632 (stage 2)	12
Pending trials			
ATTACHE: timing of surgery and adjuvant chemotherapy for hepatic colorectal metastases *AGITG study*	Patients with confirmed resectable liver metastases and no other disease	200	
PAN1: phase II study evaluating potential predictive biomarkers and examining the efficacy and safety of mFOLFOX6 compared to gemcitabine for pancreatic cancer *AGITG study*	Patients with confirmed metastatic pancreatic adenocarcinoma	80	
Trials in follow-up			
C07: 5-fluorouracil plus leucovorin compared with oxaliplatin with 5-fluorouracil + for stages II and III carcinoma of the colon *NSABP study*	Patients with resected stage II or stage III colon carcinoma	150	134
C0.20: phase III study of BMS-582664 with cetuximab versus placebo with cetuximab *NCIC CTG and AGITG study*	Patients with metastatic colorectal carcinoma previously treated with combination chemotherapy	370 (ANZ); 750 (international)	416 (ANZ); 686 (international)
EORTC 62005: Phase III study of two different doses of imatinib mesylate for CD117-expressing metastatic or unresectable gastrointestinal stromal tumour *EORTC study*	Patients with metastatic gastrointestinal stromal tumour	80 (ANZ); 600 (international)	116 (ANZ); 946 (international)
EORTC 62024: Randomised trial of adjuvant imatinib mesylate (Glivec) versus no further therapy after complete surgery *EORTC study*	Patients with fully resected gastrointestinal stromal tumour	8 (ANZ); 80 (international)	6 (ANZ); 81 (international)
Quasar 2: phase III study of capecitabine and bevacizumab as adjuvant treatment of colorectal cancer (AG0107CR) *OCTO study*	Patients with colon cancer treated by surgery	120	219 (ANZ); 1179 (international)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Gynaecological cancer			
Current trials			
PORTEC 3: Phase III trial comparing concurrent chemo¬radiation and adjuvant chemotherapy with pelvic radiation alone in high-risk endometrial carcinoma (TROG 08.04) CGOG and *ANZGOG study*	Women with advanced endometrial carcinoma	200 (ANZ); 500 (international)	50 (ANZ); 300 (international)
Symptom benefit: Palliative chemotherapy for ovarian cancer (ANZGOG0701) *ANZGOG and PoCoG study*	Women with platinum-resistant epithelial ovarian cancer	100	92
Accelerated BEP: Feasibility study of accelerated BEP as first-line chemotherapy for advanced germ cell tumours (ANZGCTG0206, ANZGOG0603) *ANZUP and ANZGOG study*	Patients with intermediate and poor-risk advanced germ cell tumours (and selected good-risk tumours)	25	45
Pending trials			
ICON 6: Placebo-controlled trial of concurrent cediranib and chemotherapy versus chemotherapy alone (stage 2) and of maintenance cediranib versus placebo after concurrent cediranib and chemotherapy (stage 3) *ANZGOG study*	Women with platinum-sensitive relapsed ovarian cancer	100 (stage 2); 400 (stage 3)	
Outback: Phase III trial of addition of adjuvant chemotherapy to standard chemoradiation as primary treatment for cervical cancer *ANZGOG study*	Women with locally advanced cervical cancer	780	
PARAGON: phase II study of anastrozole in gynaecological cancers *GCIC study*	Women with potentially hormone-responsive gynaecological cancers	100 (ANZ)	
Trials in follow-up			
TRIPOD: Phase II trial of intraperitoneal chemotherapy (ANZGOG 0601) *ANZGOG study*	Women with ovarian and related cancers	35–100	39
OVAR 16: Phase III study of pazopanib versus placebo for epithelial ovarian, fallopian tube or primary peritoneal cancer *ANZGOG study*	Women with stage II–IV ovarian fallopian tube or primary peritoneal cancer that has not progressed after first-line treatment	65	50
ICON 7: Randomised, two-arm, multicentre trial of adding bevacizumab to standard chemotherapy for epithelial ovarian cancer *GCIG study*	Women with epithelial ovarian cancer who have not received systemic antitumour therapy	100	76
SCOTROC 4: Multicentre randomised trial of carboplatin flat dosing vs intrapatient dose escalation in first-line chemotherapy	Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum–taxane therapy	150 (ANZ); 1300 (international)	64 (ANZ); 937 (international)
Tarceva: phase III study of erlotinib versus observation (EORTC 55041)	Women with high-risk stage I or stages II–IV ovarian cancer which has not progressed after platinum chemotherapy	80	42
Phase III randomised trial of paclitaxel + carboplatin versus triplet or sequential doublet combinations for epithelial ovarian or primary peritoneal carcinoma (GOG 182)	Women with advanced (stage III or IV) primary ovarian or peritoneal cancer	400	183
Prospective study of risk-reducing salpingo-oophorectomy and longitudinal CA-125 screening among women at increased genetic risk of ovarian cancer (GOG 199)	Women aged >30 at risk of ovarian cancer	250	83

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Genitourinary cancer			
Current trials			
Accelerated BEP: feasibility study of accelerated BEP as first-line chemotherapy for advanced germ cell tumours (ANZGCTG 0206, ANZGOG 0603) *ANZUP and ANZGOG study*	Patients with intermediate and poor-risk advanced germ cell tumours (and selected good-risk tumours)	25	45
Aprepitant for germ cell chemotherapy: phase II multicentre trial of a 7-day aprepitant schedule to prevent chemotherapy-induced nausea and vomiting (ANZGCTG 0801) *ANZUP study*	Patients receiving cisplatin-based chemotherapy for germ cell tumours	50	50
Chemo & cognition: cognitive function and treatment for testicular cancer (ANZGCTG 0106) *ANZUP study*	Patients being treated and followed up for testicular cancer	154	121
Eversun: phase II trial of everolimus alternating with sunitinib for renal cell carcinoma (ANZUP 0901) *ANZUP study*	Patients starting first-line systemic therapy for advanced renal cell carcinoma	55	2
SORCE: Adjuvant sorafenib for renal cell carcinoma (RE 05) *MRC (UK) and ANZUP study*	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	250 (ANZ); 1656 (international)	30 (ANZ)
Lung cancer			
Current trials			
B2P2M2: phase II trial of BNC105P as second-line chemotherapy for pleural mesothelioma (ALTG 09/004)	Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy	60	6
BR.26: phase III trial of PF-804 in patients with incurable, non-small cell lung cancer (ALTG 09/002)	Patients with stage IIIB or IV non-small-cell lung cancer	180	2
BR.29: cediranib versus placebo for patients receiving paclitaxel and carboplatin for non-small-cell lung cancer (ALTG 09/001) *NCIC CTG and ALTG study*	Patients with stage IIIB or IV non-small-cell lung cancer	100	75
NITRO: phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for advanced non-small-cell lung cancer (ALTG 06/003) *ALTG study*	Patients with advanced non-small-cell lung cancer	500	71
PACT in NSCLC: Preferences for adjuvant chemotherapy in non-small-cell lung cancer (04/009) *ALTG study*	Patients with non-small-cell lung cancer, surgeons and oncologists	200	42
Trials in follow-up			
MATES: Maintenance thalidomide in mesothelioma *NVALT, ALTG study*	Patients with malignant pleural mesothelioma, after first-line chemotherapy	100 (ANZ); 200 (international)	14
Brain cancer			
Current trials			
CATNON: Phase III trial of concurrent and adjuvant temozolomide chemotherapy anaplastic glioma (EORTC 26053-22054) *EORTC study*	Patients with non-1p/19q- deleted anaplastic glioma	100 (ANZ); 748 (international)	0
LGG: Phase III study of primary chemotherapy with temozolomide versus radiotherapy for low-grade glioma (TROG 06.01) *COGNO and TROG study*	Patients with low-grade glioma, stratified for genetic 1p loss	100 (ANZ); 466 (international)	36 (ANZ); 466 (international)

TRIAL	PARTICIPANTS	TARGET	ACCRUAL
Phase III study of temozolomide and short-course radiation versus radiation alone for glioblastoma multiforme in elderly patients (TROG 08.02) *COGNO and TROG study*	Elderly patients with new glioblastoma multiforme	100 (ANZ); 500 (international)	41 (ANZ); 251 (International)
Pending trials			
Cabaret: phase II study of carboplatin and bevacizumab in for glioma *COGNO study*	Patients with recurrent grade IV glioblastoma multiforme following radiotherapy and temozolomide chemotherapy	120	
Phase II study of acetazolamide plus dexamethasone versus dexamethasone for cerebral oedema in glioblastoma *COGNO study*	Patients with glioblastoma requiring new dexamethasone or dose increase due to progressive or recurrent disease	86	
Phase II study of psycho-educational intervention in patients with primary brain tumour *PoCoG led, COGNO cobadged study*	Patients with confirmed primary brain tumours	60	

Funding

FUNDER	$
NHMRC	
Program grant	1 604 545
Fellowships	390 275
Project grants for trials	3 306 937
Grants for Infrastructure	553 545
Cancer Australia, Cancer Institute and cancer councils	
Trials	1 582 432
Infrastructure	3 988 745
National Heart Foundation	64 500
Public funding for health economics	118 774
Public funding for systematic reviews	1 257 354
Pharmaceutical companies, primarily for trials*	5 572 170
Consulting and donations	52 478
Other	1 404 657
Total	**19 896 412**

* Amgen, Arcagy-Gineco, Bayer, Bionomics Ltd, Bristol-Myers Squibb, Fournier, Solvay Abbott, GlaxoSmithKline, Merck, Merck Sharp & Dohme, Pfizer Canada, Novartis, Roche

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- Australian New Zealand Clinical Trials Registry (ANZCTR) policy advisory committee
- Cancer Clinical Trials Development Unit (CTDU) advisory committee, management committee and health economics advisory committee
- Cancer Institute NSW board
- Cholesterol Treatment Trialists Collaboration (CTTC) (joint coordinator)
- Cochrane Collaboration prospective meta-analysis methods working group
- Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee (deputy chair)
- Benefits of Oxygen Saturation Targeting (BOOST) II trial management committee
- Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee, executive, and cost-effectiveness subcommittee
- Intensive Blood Pressure Reduction for Acute Cerebral Haemorrhage Trial (INTERACT) safety and data monitoring committee (chair)
- International Breast Cancer Intervention Study (IBIS-II) international steering committee
- International Trials of Aspirin to Prevent Recurrent Venous Thrombo-Embolism (INSPIRE) steering committee (chair)
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Perinatal Antiplatelet Review of International Studies (PARIS) collaboration steering committee, writing committee (chair)

PLoS ONE academic editor

Prenatal Repeat Corticosteroid International IPD Study Group: Assessing the Effects Using the Best Level of Evidence (PRECISE) steering committee

Prevention of Ventilation Induced Lung Injury Collaborative Group (PREVILIG) steering committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Amy Boland

Australian & New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) operations executive committee, scientific advisory committee, and Accelerated BEP, Aprepitant for Germ Cell Chemotherapy, Chemo & Cognition, SORCE and EVERSUN trial management committees

Mark Chatfield

Accelerated BEP trial management committee

Aprepitant trial management committee

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee

Jenny Chow

Cancer Institute NSW Neuro-oncology Group (NSWOG), COGNO operations executive, management committee, COSA executive officers network

Christopher Brown

Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee, operational executive committee; CABARET trial management committee

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee, operational executive committee; NITRO trial management committee, B2P2M2 trial management committee

Xanthi Coskinas

Australasian Lung cancer Trials Group (ALTG) scientific advisory committee, operational executive committee; NITRO trial management committee, B2P2M2 trial management committee, PACT in NSCLC trial management committee

Trevor France

Co-operative Trials Group for Neuro-Oncology (COGNO) operations executive and scientific advisory committees, and CABARET and CATNON trial management committees

Val Gebski

Adjuvant chemotherapy versus surgery alone in patients with stage II AND IIIB gastric adenocarcinoma safety and data monitoring committee

Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and MAX, Da Vinci, ATTAX, ATTAX2, DECO, ABC, Gofurtgo, TOPGEAR, ATTACHE, ATTAX3 trial management committees

Australasian KidneyTrials Network advisory board

Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and TRIPOD, Symptom Benefit, and Outback trial management committees

Australian & New Zealand Urinary and Prostate Trials Group (ANZUP) scientific advisory committee and Accelerated BEP and Eversun trial management committees

Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) scientific advisory committee and LATER, NeoGem and ANZ001 trial management committees

Avastin use in platinum-resistant epithelial ovarian cancer safety and data monitoring committee

Biostatistics Collaboration of Australia steering committee and teaching committee

GCIG/GINECO GCIG intergroup study comparing pegylated liposomal doxorubicin (Caelyx) and carboplatin versus paclitaxel and carboplatin in patients with epithelial ovarian cancer trial management committee

LACC trial management committee

LACE trial management committee

Medical Journal of Australia consultant statistician

Multicentre study of RAD in the treatment of pulmonary fibrosis safety and data monitoring committee

NMRC Singapore Indomethacin study for closure of PDA safety data and monitoring committee

NSW Health Eastern Sydney Area ethics committee clinical trials subcommittee

Oxygen versus air in oxygen-naïve patients with refractory dyspnoea and PaO_2>55 safety and data monitoring committee

SNAC trial management committee

Testosterone undecanoate in obese men as adjuvant therapy for a weight loss program safety and data monitoring committee

Trastuzumab with a fluoropyrimidine and cisplatin versus chemotherapy alone as first-line therapy in patients with HER2 positive advanced gastric cancer safety and data monitoring committee

Westmead Cancer Care Joint Radiation Oncology Centre research committee

Reena Gill

Australasian Gastro-Intestinal Trials Group (AGITG), operations executive committee, and PETACC-6, SURGIST and REGISTER and CO.20 trial management committees

Wendy Hague

Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee

Benefits of Oxygen Saturation Targeting (BOOST II) management committee

International Neonatal Immunotherapy Study (INIS) Australian and New Zealand management committee

Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee

Australian Placental Transfusion Study (APTS) management committee

Australasian Gastro-Intestinal Trials Group (AGITG) trials operations committee

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

Cancer Institute NSW infrastructure grant steering committee and human research ethics committee

Adrienne Kirby

Australian Placental Transfusion Study (APTS) management committee

Benefits of Oxygen Saturation Targeting (BOOST) II trial management committee

Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Erica Jobling

Biostatistics Collaboration of Australia writing group

National Curriculum for Entomology evaluation committee

Ann Livingstone

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

Julie Martyn

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

Cancer Institute NSW infrastructure grant subcommittee

Gynecological Cancer Intergroup (GCIG) harmonisation and statistics committee (chair)

iCON-7, PORTEC-3 and OVAR-16 international steering committees

TRIPOD, Symptom Benefit, PORTEC-3 and Outback trial management committees

Danielle Miller

Cancer Australia Clinical Trials Development Unit (CTDU) program management committee, strategic advisory committee and health economics subcommittee

Primary Care Collaborative Cancer Clinical Trials Group (PC4) operations team and scientific advisory committee

SNAC 1 and SNAC 2 trial management committees

Australasian Gastro-Intestinal Trials Group (AGITG) TOPGEAR trial management committee

Rebecca Mister

Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee

Rhana Pike

Australasian Medical Writers Association executive committee (vice-president)

Deborah Schofield

International Medical Workforce planning committee

School of Public Health research committee, Faculty of Medicine, University of Sydney

Katrin Sjoquist

Australia New Zealand Gynaecological Oncology Group (ANZGOG) research advisory committee and operations executive committee, Symptom Benefit trial management committee, Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and operations executive committee, ATTACHE trial management committee, PAN1 CTC clinical lead

Martin Stockler

Australasian Leukaemia & Lymphoma Group safety and data monitoring committee

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee

Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop steering committee (co-convenor)

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

Australian and New Zealand Breast Cancer Trials Group (ANZ BCTG) scientific advisory committee

Cancer Council Australia national oncology education committee

Cancer Trials NSW steering committee, trial selection committee (chair), centre selection committee

Cochrane Collaboration advanced breast cancer working party

Journal of Clinical Oncology editorial board

National Breast Cancer Centre *eClinical Updates* editorial board

National Breast Cancer Centre clinical updates advisory committee

National Breast Cancer Centre hormone therapy working group (chair) and information advisory group (chair)

National Breast Cancer Foundation Strategic research advisory panel

National Cancer Institute (NCI) Intergroup health related quality-of-life committee

National Health and Medical Research Council grant review panels for oncology and palliative care strategic grants

University of Sydney Faculty of Medicine oncology block committee (chair), EBM in GMP3/4 (chair), evidence-based medicine resource group, integrated clinical attachment committee and usmp cancer planning committee

Burcu Vachan

Australasian Gastro-Intestinal Trials Group (AGITG) operations executive, biological subcommittee

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) scientific advisory committee, operations executive and executive

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

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

Australian New Zealand Breast Cancer Trials Group (ANZ BCTG)

Cancer Institute NSW infrastructure grant subcommittee

Cancer Institute NSW partnership grant operational executive committee

Kate Wilson

Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee, study coordinators subcommittee (chair), annual scientific meeting committee, and MAX, Quasar 2, ATTAX, DECO, and A La CaRT and SUPER trial management committees

Cancer Institute NSW infrastructure grant subcommittee

Nicole Wong

Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee and ATTACHE, LAP07, SCOT and ATTAX 3 trial management committees

Sonia Yip

Australasian Gastro-Intestinal Trials Group (AGITG) operations executive and biological subcommittee

Australian and New Zealand Urogenital and Prostate Group (ANZUP) scientific advisory committee, renal cell subcommittee, germ cell subcommittee, and EVERSUN and SORCE trial management committees

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

Australasian Lung Cancer Trials Group (ALTG) scientific advisory committee and B2P2M2 trial management committee

Cooperative Trials Group for Neuro-Oncology (COGNO) scientific advisory committee.

ACADEMIC TEACHING

John Simes

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

Anthony Keech

Cardiology training, and clinical tutor, Royal Prince Alfred Hospital

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

University of Sydney Graduate Medical Program

Lisa Askie

Advanced clinical data management, Master of Health Information Management, University of Sydney

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

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

Evidence-based medicine in the clinical years, University of Sydney Medical Program

Elizabeth Barnes

Advanced clinical trials, Biostatistics Collaboration of Australia

Basic sciences in oncology, NSW Cancer Council

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

Principles of statistical inference, Biostatistics Collaboration of Australia

Prunella Blinman

Oncology and palliative care, University of Sydney Medical Program

Christopher Brown

Australia Asia-Pacific Clinical Oncology Research Development (ACORD) workshop

Basic sciences in oncology, NSW Cancer Council

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

Mark Chatfield

Advanced clinical trials, Biostatistics Collaboration of Australia

Val Gebski

Advanced clinical trials, Biostatistics Collaboration of Australia (coordinator)

Basic sciences in oncology, NSW Cancer Council

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

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

Adrienne Kirby

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

Sally Lord

Advanced evaluation of diagnostic tests, and Decision analysis, Master of Public Health and Master of Medicine, University of Sydney

Critical appraisal, Basic sciences in oncology, NSW Cancer Council

Evidence-based medicine, University of Sydney Medical Program

Andrew Martin

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

Rebecca Mister

Advanced clinical data management, Master of Health Information Management, University of Sydney

Rachel O'Connell

Principles of statistical inference, Biostatistics Collaboration of Australia

Deborah Schofield

Health workforce policy analysis, School of Public Health, University of Sydney

Katrin Sjoquist

Evidence-based medicine in the clinical years, University of Sydney Medical Program

Lukas Staub

Screening and diagnostic test evaluation, Master of Public Health and Master of Medicine, University of Sydney

Martin Stockler

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

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

Clinical epidemiology for physician trainees, Royal Prince Alfred Hospital

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

Medical oncology clinical training, Royal Prince Alfred Hospital

Patient-based measures, Master of Medicine, University of Sydney (course coordinator)

Quality of life in oncology, Cancer Institute NSW

Sonia Yip

Evidence-based medicine, and Oncology problem-based learning, University of Sydney Medical Program

Diana Zannino

Advanced clinical trials, Biostatistics Collaboration of Australia

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

Basic sciences in oncology, NSW Cancer Council

PUBLICATIONS

JOURNAL ENTRIES

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LETTERS

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BOOKS

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Collaborative groups

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INVITED PRESENTATIONS

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Keech AC. Biomarker and inflammation in atherosclerosis current status. APSAVD and Thai Atherosclerosis Society Annual Scientific Meeting; 23–24 Jan 2010; Cha-am,Thailand.

Keech AC. Bring in the harvest: fibrates from out of the cold—the FIELD study—plus what's hot about statins. Port Douglas Heart Meeting; 9–12 Jun 2010; Port Douglas.

Keech AC. Diabetes and cardiovascular risk: 2010 update on treatment strategies. ARCS Scientific Congress; 28 May 2010; Sydney.

Keech AC. Fenofibrate and diabetes complications. 11th Annual Directions in Diabetes Regional Medical Conference; 21–23 May 2010; Sydney.

Keech AC. Fenofibrate for amputation and the FIELD Study: Garden of Eden or a FIELD of dreams? DF Con Global Diabetic Foot Conference; 18-20 March 2010; Los Angeles.

Keech AC. FIELD study: the fibrate story. Australian Diabetes Council Diabetes and Diabesity Update Day; 20 Nov 2010; Sydney.

Keech AC. How to interpret ACCORD and back to RRR. Taiwan Society of Cardiology Annual Convention and Scientific Session; 15–16 May 2010; Taipei.

Keech AC. Microvascular benefits of lipid-lowering therapy. ASEANZ Cardiovascular and Metabolic Forum; 4–6 Jun 2010; Melbourne.

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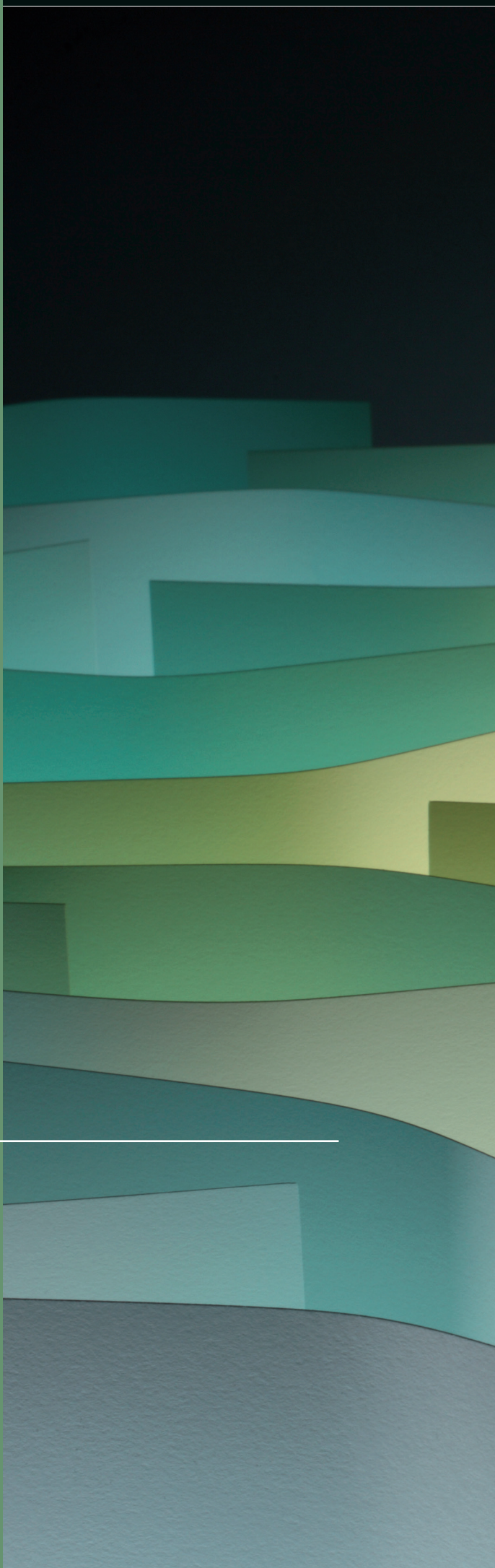

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