



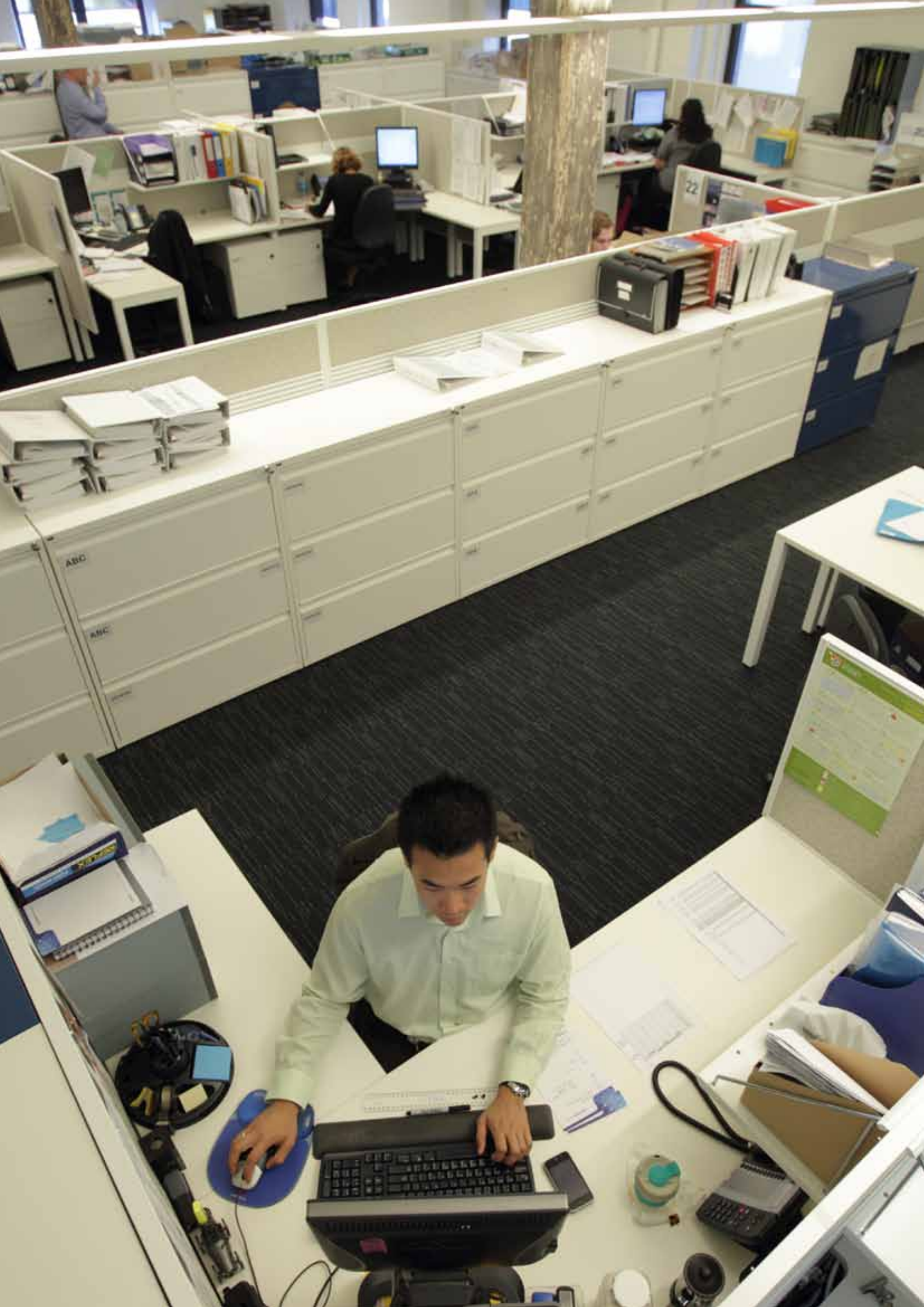
NHMRC CLINICAL TRIALS CENTRE
THE UNIVERSITY OF SYDNEY



RESEARCH REPORT 2008-2009

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The NHMRC Clinical Trials Centre at the University of Sydney runs 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:

- undertakes research into trial methods and is recognised through publications as a leader in trial methodology
- 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, particularly through its Outreach program
- 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
- offers placements for postgraduate students in all of these areas
- 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 the biennium 2008–2009.



20-years on

In 2009 we celebrated our 20 years of research and evidence with a one-day symposium. Leaders from academic and research institutions and government underscored the fundamental role of trials research in clinical practice, policy and health, and explored the likely way ahead. Australia faces rapid aging of the population coupled with increases in the cost and sophistication of both health care and medical research. In addition, biological and genetic clinical research, which can lead to personalised care for patients, will raise new challenges.

The CTC and its collaborators are in a strong position to contribute to Australia's health research over the coming years. From a handful of staff in 1988, the CTC has grown to about 150 in 2009. Government grant funding for the two years, 2008–2009, was over \$24 million, supplemented by substantial funding won from industry for clinical trials. Dedicated research staff and increasing funds have led to success in publication: in 2008–2009, we contributed to over 90 published research articles, most in high-impact journals, and 9 reports for government. CTC staff gave over 80 research presentations at national and international conferences.

We have been at the forefront of research on new treatments and establishing the optimal use of existing treatments.

Central to the success of these activities have been the extensive networks of collaborators we work with and our strong and enduring partnerships with government, nongovernment organisations and industry. We actively work with 7 collaborative groups in oncology on current trials and participate in other projects more broadly. Our research covers cancer types representing about 75% of the cancer disease burden in Australia. A grant from Cancer Australia, together with other grants, has helped us to establish new collaborative groups and to appoint a new chair in health economics, Professor Deborah Schofield.

In collaboration with associated groups we currently have over 50 trials open to recruitment, in follow-up or about to commence. Completed trials have resulted in many exciting discoveries. In FIELD, the finding that fenofibrate can reduce the risk of amputation and damage from small-vessel disease opens up a new treatment option for patients. The SNAC trial showed that sentinel-

CTC Executive: Wendy Hague (clinical trials program director), Kim Russell-Cooper (general manager), Anthony Keech (deputy director) and John Simes (director).



node-biopsy-based management of early breast cancer leads to better quality of life and less arm morbidity than more extensive surgery of the axilla. In advanced colorectal cancer, the *K-ras* gene type can now identify patients who will benefit from cetuximab, a molecular targeted therapy (C0.17 trial). In LIPID, novel biomarkers linked to coronary risk have been identified, and a study differentiating measurement error and true change in cholesterol monitoring revealed that much routine testing could be too frequent.

One of our research strengths is to devise new methods and apply them to trial datasets to strengthen and augment trial findings. A major international prospective meta-analysis of the Cholesterol Treatment Trialists' Collaboration, coordinated by the CTC and the Clinical Trials Service Unit, Oxford, confirmed the benefits of statin therapy in patients with diabetes in an individual-patient-data analysis of a cohort from 14 trials. A neonatal meta-analysis study showed that unrestricted oxygen therapy for premature infants had potential harms without clear benefits. This practice has been abandoned, but more targeted oxygen therapy is being assessed in ongoing trials (BOOST II). Risk models and improved methods for diagnostic test evaluations have allowed better application of new evidence from trial data to individual patients. For example, a study of complex measures of test accuracy combined with available clinical evidence has determined the incremental

accuracy of magnetic resonance imaging and its potential contribution to cancer staging.

All of the research we undertake at the CTC—either by generating relevant evidence through appropriate trials or by developing better methods for integrating trial evidence and other information—is based on ensuring that trial evidence will have optimal impact on future practice. These pages report many examples of clinical trials and related research that should lead to improvements in health outcomes from future changes in clinical practice and health policy.



JOHN SIMES

Director

Professor John Simes is the foundation director of the CTC and represents the CTC on many national and international committees. In 2009, he received the Distinguished Alum Award from the



Department of Biostatistics at the Harvard School of Public Health. Professor Simes is also a specialist medical oncologist at Royal Prince Alfred Hospital.

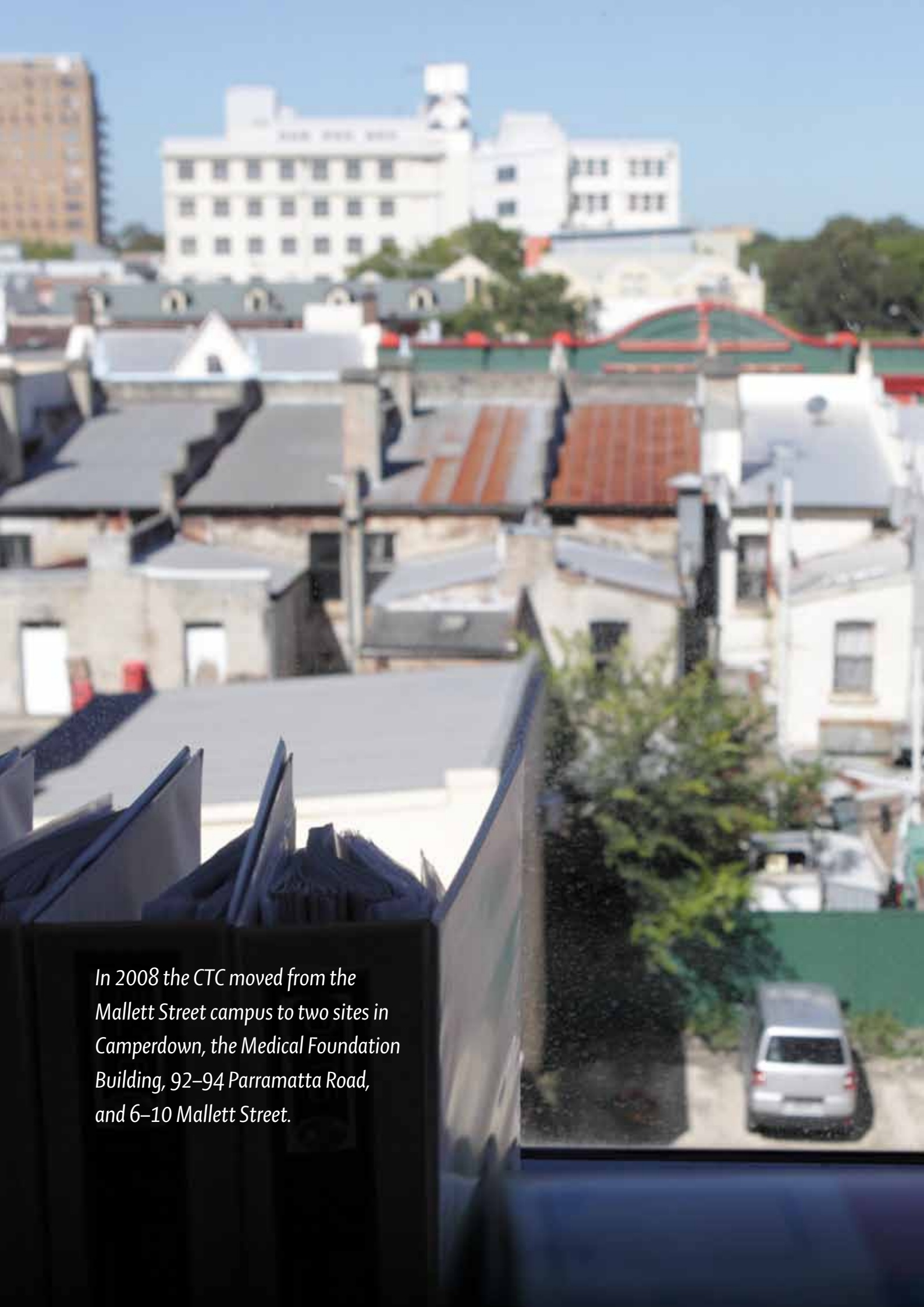
ANTHONY KEECH

Deputy director

Professor Keech, cardiologist and epidemiologist, co-directs the CTC research program. He is chairman of the FIELD study on heart disease and diabetes. As a professor



in the Department of Medicine at the University of Sydney, he initiates, coordinates, develops and teaches courses for medical and other postgraduate students. Professor Keech is also a practising consultant cardiologist at Royal Prince Alfred Hospital.



In 2008 the CTC moved from the Mallett Street campus to two sites in Camperdown, the Medical Foundation Building, 92–94 Parramatta Road, and 6–10 Mallett Street.

20 years of the NHMRC Clinical Trials Centre

THE FIRST DECADE

The CTC was founded in October 1988 in response to a national need for relevant evidence to underpin the individual clinical decisions of Australian doctors. The National Health and Medical Research Council funded the centre at the University of Sydney, on the basis of its international reputation as a centre of excellence in medical research, diverse research infrastructure, and large departments of public health and medicine.

Work began with two staff: Dr John Simes, the director, and his assistant. Within a year, the CTC had acquired biostatisticians, computer systems experts, trial coordinators, research fellows and a deputy director. By the end of 1989, two international cardiovascular trials, LIPID and the TPA/SK mortality trial, and several large cancer trials were up and running, with over 2000 patients recruited.

From the start, the centre's educational role was central to its goals of improving the quality of clinical trials in Australia and being relevant to clinical practice. For the staff, this meant teaching and supervising postgraduate students and turning out short courses in statistics and trial management.

By 1996, trials in germ cell cancer, breast cancer and cardiovascular disease were operational, and several million dollars in annual funding flowed from industry and government. Growing staff numbers prompted the move from the university campus to the Mallett Street campus in December 1996.

Between 1997 and 1998, the CTC began to take on more trials and branched out into trials methodology. It also developed its advising and consulting role.

THE SECOND DECADE

The number and breadth of the trials increased and included important initiatives in neonatal research. Research into trials methodology led to better ways of designing and conducting trials. Data from continuing and completed trials became a rich source for analysis in substudies, secondary studies (such as cost-effectiveness analyses) and meta-analyses. Research activities that added value to trial results became an important focus.

Memorable highlights of this period were the international clinical trial symposiums, in 1999, 2002 and 2007, and the long-awaited Australian New Zealand Clinical Trials Registry, established in 2005.

THE THIRD DECADE

Now, about 150 people work at the CTC. Current trials range from about 50 patients in some of the cancer treatment trials to thousands still being followed up in the international FIELD diabetes trial. The CTC's first major multicentre trial, LIPID, is still following up nearly 7000 patients of the original 9014, 19 years from its first randomisation.

The CTC remains focused on the future. In part because of clinical trials of past years, Australians are living longer, so their health needs may be changing. For example, cancer survivors want better quality of life. In the CTC's third decade, the issues will be: how to conduct more trials in Australia in the face of cost barriers; how to make trials research an integral part of health care; going beyond drug trials to assess other types of therapy; finding out how individual patients respond to treatment, in biotechnology and preference studies; and answering important clinical questions in new areas (such as indigenous health). Future progress will rely on collaboration among many research networks as well as groups in universities, government and industry.

20 years of clinical trials: a symposium

New evidence, better treatment, changed practice

In 2008 the Clinical Trials Centre reached a milestone: 20 years of research generating evidence for high-quality health care. At a celebration symposium, leaders from government, industry, research and the community at large reviewed past and recent trial successes and addressed the following questions and issues concerning the next 20 years.

Research is likely to be shaped by the continued aim of improving practice and health outcomes, but with new challenges and constraints—particularly the need for even larger patient numbers to reliably demonstrate treatment benefits; the ever-increasing costs of new trials and developing new treatments; the growing demands of regulatory and ethical requirements; and the challenges and opportunities associated with new technologies, especially molecular targeted therapies and e-health. Trials need careful planning and conduct to ensure that we get the best evidence and that it can be applied effectively where it is needed. Central to this is answering the right clinical questions in the most efficient and effective ways.

HOW CAN WE MAKE SURE THAT CLINICAL TRIALS ASK THE RIGHT QUESTIONS?

This is a complex issue and involves clinical investigators with relevant trial expertise working with basic scientists (helping to identify potential new treatments), clinicians (with knowledge of current best standard care) and patients or consumers (to ensure questions

relevant to the patients' perspective are addressed). Prioritising potential trials will also depend on the burden of disease (from national morbidity statistics), knowing which studies are already being done (from trial registers), and reviews of current evidence (defining best care and ensuring questions have not already been answered).

WHAT WILL AFFECT DATA AND METHODS IN THE NEXT 20 YEARS?

As clinical research progresses, patients participating in trials are healthier, so trials seek smaller incremental improvements from treatment. This means that larger numbers of participants are needed to show a difference.

Added to this, patients can now be stratified by biological markers into smaller groups to allow more personalised use of therapies according to individual profiles. For example, many new cancer therapies are particularly effective but for only a subgroup of patients, depending on the genetic make-up of the cancer. This means we have the challenge of finding sufficient patients for each new trial as well as less return on cost from the developed therapies (due to the smaller future market).

Triallists are already faced with the quandary that patients are very different: there may be more biological markers and genetic factors in the patients than there are types of event to be measured. This has implications for methods and trial operation. First, methods of incorporating prognostic and predictive biomarkers will be

important. Second, tissue banking and blood sampling should be a routine part of trials (with appropriate ethical and privacy safeguards), so that samples can be tested in, say, 10 years' time, after other treatment discoveries. Synthesising that information requires novel methods.

EFFICIENCY IS A GOAL IN TRIALS RESEARCH

Appropriate trial design can maximise efficiency. The event or disorder being measured in a trial has to be frequent enough to allow valid statistical analysis. Combining various types of clinical event and looking at the total (a composite outcome) leads to more statistical power and more ability to show an effect. Combining several smaller studies can be an alternative to very large trials. Systematic reviews of evidence and prospective meta-analysis are established but evolving methods for obtaining evidence from combined studies. For this to work, all trials must be registered so that none are excluded. Data can also be combined and reanalysed with data from past trials, a method that is particularly useful when augmented by new knowledge, as in studies of new biomarkers.

Strategies to maintain clinical research will require ways of reducing its considerable expense. Regulatory requirements, ethical requirements, contracts, insurance and so on are great administrative burdens for research. We need to ensure that those demands are no more than in routine clinical practice.

The types of trials that obtain pharmaceutical-industry funding are those with a potential commercial return. The private sector model has the advantage that only treatments that work are likely to be developed, but the drawback is that useful treatments without commercial



value can be neglected. Therefore, trials research that improves health presupposes that some of the funding must come from government.

Making clinical trials a routine part of clinical practice would lead to administrative efficiency and thus lower costs. One of the main costs of research is generating and accessing data. Electronic medical records could allow every patient to contribute to research evidence by linking streamlined pragmatic or even virtual trials into health records.

Governments may fund studies because it would be more cost-effective than paying for services without evidence of their effectiveness and value. For other activities, an idea worth exploring is global health research fund that could require investment from government and industry to support questions of major public health importance.

Below: 20-year symposium panellists, Warwick Anderson, chief executive officer of the NHMRC; Sally Crossing (centre), representing health care consumers; and Kevin Lynch, Celgene Australia.

TRIALS IN HARD-TO-RESEARCH AREAS: A CHALLENGE TO CURRENT FUNDING ARRANGEMENTS

Trials that go beyond drugs — such as physical interventions, systems of care, rehabilitation programs, paediatric trials and surgery — often do not fit a commercial model, so governments need to fund them directly or improve the regulatory framework for industry to do so. One example where this has been done is in the United States, where licences for certain drugs have been extended in return for a commitment to use them in paediatric trials.

HOW CAN TRIALS BECOME MORE RELEVANT TO CLINICAL PRACTICE?

Evidence will not be applied if the clinical outcomes do not reflect the full clinical picture: averting clinical events or improving survival may not be enough without quality of life. In addition to this, the trial evidence must be relevant to individuals. Our methods must include exploring the generalisability of results and the individual differences among patients.

Evidence-based management of patients as a criterion of hospital performance would improve the application of evidence to practice generally. One current example is the use of statins, beta-blockers and anticoagulants in protocols of treatment after myocardial infarction.

WILL CLINICAL TRIALS REMAIN VIABLE IN AUSTRALIA?

The growing costs for trials research, whether by the pharmaceutical industry or cooperative trial groups, relate to ethics and governance as well as conduct of trials. Australia will have difficulty competing on costs, but by starting small with a grant from government for capacity building or part of a trial, we can build a framework of expertise and knowledge for major international trials. Australia's advantage is quality. Although local patients may be scarce, we have the opinion leaders, the intellectual resources, and the ability to design and analyse studies and undertake biological substudies. These attest to a capacity to continue to generate new evidence for better treatment and changed practice in the next 20 years.



Funding

Funder	2008	2009
NHMRC		
Program grant	1,543,752	1,574,627
Project grants	2,823,502	4,891,661
Fellowships	283,250	383,000
Public funding for technology assessment and systematic reviews	632,841	1,114,865
Cancer Australia and cancer councils	4,361,427	4,702,732
Cancer Institute NSW	816,694	1,221,872
National Heart Foundation	63,000	64,500
Other public funders	143,727	178,087
Pharmaceutical industry*	4,157,573	4,753,448
Biostatistics Collaboration of Australia and workshops	322,232	316,418
Collaborative projects	1,008,761	227,154
Donations		912,910
Other	268,860	3,644
TOTAL	16,156,760	19,621,275

* Includes Amgen, Abbott Laboratories, Arcagy-Gineco, Aventis Pharma, Bristol-Myers Squibb, Fournier Pharma, Merck Serono, Merck Sharp & Dohme, Novartis, Pfizer, Roche, Sanofi, Schering Plough, Solvay



Pictured (left to right): Mark Chatfield, Angus McDonald and Sandra Healey, and Nina Stromqvist



“Much of our growth and new work has been underpinned by successful infrastructure grants .”

Wendy Hague, clinical trials program director

THE CLINICAL TRIALS PROGRAM

Our capacity to conduct high-quality clinical trials has grown through expansion in our infrastructure and consequent strengthening and streamlining of processes for conducting trials. Consolidation of resources of multiple collaborative clinical groups through the CTC leads to economies and ensures a critical mass in specialised areas of expertise. This has helped our clinical trials program to grow in breadth and depth, particularly in oncology. Two new collaborative groups — COGNO (neuro-oncology) (p. 17) and PC4 (primary care) (p. 19) — have started to work with the support of the CTC.

We are doing more multimodal studies, including trials of chemotherapy with biologicals in addition to radiotherapy and, or, surgery. Recent examples are TOPGEAR, ALaCaRT, and SUPER (p. 44), which have brought additional challenges to the program. Where possible, trials include consent for tissue analysis, so that molecular and genetic studies can be an integral part of the trials (p.41).

Much of this new work has been underpinned by repeated successful infrastructure grants from Cancer Australia and the Cancer Institute of NSW. The CTC, with the oncology collaborative groups, was awarded three Cancer Institute infrastructure grants, one which is supporting central generic processes and systems, specifically in the areas of data systems, biostatistics and quality assurance. Two other grants support infrastructure positions for each of our collaborative groups.

The Clinical Trials Development Unit, supported by a grant from Cancer Australia to the CTC and the Centre for Biostatistics and Clinical Trials at Peter MacCallum Cancer Centre, was an initiative to move towards formally standardising the conduct of oncology studies in Australia and New Zealand.

The neonatal program is also expanding, with the aid of an NHMRC grant for the Australian Placental Transfusion Study (p. 22). In cardiovascular disease, ASPIRE (p. 26) is expanding internationally. The CTC’s two largest and longest trials, LIPID (p. 26) and FIELD (p.24), are still in long-term follow-up. Important clinical and biomarker substudies for both trials are in preparation or publication.

Oncology trials

BREAST CANCER

ANZ BCTG
SNAC

GASTROINTESTINAL CANCER

AGITG

GYNAECOLOGICAL CANCER

ANZGOG

GENITOURINARY CANCER

ANZUP

BRAIN CANCER

COGNO

LUNG CANCER

ALTG

PRIMARY CARE

PC4

The oncology group at the CTC specialises in running phase II and phase III investigator-initiated trials, from concept development to final manuscript preparation and every step in between. The CTC has worked with over 100 clinical sites across Australia and New Zealand as well as in Singapore, Canada, Taiwan and the UK to conduct trials to improve outcomes for cancer patients.

The trials are run in partnership with specialised collaborative groups. Five well-established groups operate through the CTC:

- Australasian Gastro-Intestinal Trials Group (AGITG)
- Australia New Zealand Gynaecological Oncology Group (ANZGOG)
- Australasian Lung Trials Group (ALTG)
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP), formed from a merger in 2008 of the Australian and New Zealand Germ Cell Trials Group and the Australian Prostate and Urogenital Cancer Group
- Cooperative Trials Group for Neuro-Oncology (COGNO).

The CTC also works closely with:

- Australian New Zealand Breast Cancer Trials Group (ANZ BCTG), as the central randomisation and statistical centre
- Primary Care Cooperative Cancer Clinical Trials Group (PC4), a diverse group initiating trials requiring innovative methods of design and operation.

These Australian groups, in turn, are associated with large international cancer collaborations, so the CTC remains at the heart of research initiatives throughout the world.

In 2008–2009, 14 trials were actively recruiting and several trials reached important milestones, including activation, final analysis, presentation and reporting.

The oncology group of 45 staff, led by the program manager and the team of associate program managers, have maintained the CTC's reputation for initiation, concept development, coordination, medical support, timely completion, analysis and reporting of high-quality trials.



At right: Martin Stockler, oncology co-director and oncology managers

Phases of drug development
... for *other* kinds of intervention
... can be tested further
... that warrants further testing
... and harms vs best standard
... and harms in routine practice
... regulatory approval
... regulatory approval

feasibility
activity
effectiveness
application





Karen Bracken, associate oncology program manager for ANZ BCTG

Breast cancer

Australian New Zealand Breast Cancer Trials Group

The CTC is randomisation and statistical centre for the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG).

The group's breast cancer trials are coordinated at the operations office based in Newcastle. The CTC registers and randomises the trial patients and also undertakes statistical and other analyses of trial data. The ANZ BCTG has 13 studies open to recruitment; the CTC randomised 886 patients during 2008–2009.

www.anzbctg.org

SNAC 2: multicentre trial of sentinel node biopsy for early breast cancer

Before the SNAC trial, women with early breast cancer routinely had axillary clearance (removal of armpit lymph nodes) to assess the spread of their disease. The first-year follow-up of SNAC patients published in 2009 showed that in women with tumours smaller than 3 cm, sentinel node biopsy of selected lymph nodes could identify axillary tumours and had fewer side-effects (such as lymphoedema).

In SNAC 2, the investigators are continuing this research by recruiting women with large and multiple tumours as well. The aim is to determine whether the risk of recurrence is greater with the less invasive operation in various subgroups of women. If so, sentinel node biopsy will become standard practice for all women with early breast cancer.

PHD

ADVANCED CANCER STUDIES: 'HOW LONG HAVE I GOT?'

Dr Kiely is a medical oncologist investigating how to estimate survival duration in patients with various types of incurable cancer and how clinicians can communicate this information to patients. In her initial work, she has reviewed data on chemotherapy for metastatic breast cancer that would help clinicians estimate and describe prognosis for their patients in this situation. She and her colleagues have determined a distribution of survival that can be used to show typical, best and worst case scenarios for women starting chemotherapy. One aim of this work is to help clinical oncologists convey realistic hope when discussing life expectancy with patients with advanced cancer.

These studies will extend the value of data obtained from the CTC's oncology trials to provide new information and prognosis tools for practising clinicians.

Belinda Kiely was awarded a National Breast Cancer Foundation doctoral fellowship for her studies in advanced cancer.



Belinda Kiely



Gastrointestinal cancer trials

The CTC coordinates the trials of the Australasian Gastro-Intestinal Trials Group (AGITG), the Australian collaborative group for research into gastrointestinal cancers (which can occur in the oesophagus, stomach, liver, gall bladder, pancreas or bowel).

The CTC works closely with AGITG clinicians and:

- provides project management, trial coordination, quality assurance, trial design, biostatistical analysis and data management
- supports new trials, including multidisciplinary trials in surgery, radiotherapy, chemotherapy, translational research and supportive care
- educates and trains new investigators and research fellows in trial methods and protocol development

Throughout 2009, the CTC managed and coordinated 25 trials in gastrointestinal cancer, some in the final stages of development, some actively recruiting and some in follow-up.

Over 2700 patients have now been recruited to 38 AGITG trials, and the group has 75 sites in Australia, New Zealand, Singapore, Hong Kong and the United Kingdom. In 2008–2009, five trials were open to recruitment —C020, QUASAR2, DECO, REGISTER and PETACC 6. Da Vinci, ESPAC3 and Adjuvant GIST closed during 2009, and another 7 trials were in active follow-up.

www.gicancer.org.au

MAX STUDY—A LOW-TOXICITY REGIMEN FOR COLORECTAL CANCER

Analysis of the MAX study data was completed. The results showed that adding bevacizumab, with or without mitomycin, to capecitabine significantly improves progression-free survival without causing major additional toxicity or impairment of quality of life. This new low-toxicity regimen may be a treatment option for patients with metastatic colorectal cancer, especially older patients.

The results of MAX were presented at the meeting of the American Society of Clinical Oncology and at the European Multidisciplinary Cancer Congress in 2009.



‘For an associate oncology program manager at the CTC, no two days are alike. At one moment I am working with leading Australian researchers developing new studies which could potentially change the standard of care for a particular disease and the next I’m involved in coordinating and managing the talents of our clinical trials team, pointing them towards a common goal. Due to the sheer length of our trials, seeing a project through from its infancy to completion is a rare feat. However, being involved in the daily challenges allows us to use our diverse range of skills and knowledge leading to achievement of our professional goals.’

— **Reena Gill**, associate oncology program manager for the Australasian Gastro-Intestinal Trials Group



**Hani Adhami, Ilka Kolodziej,
Julie Martyn, Ayanthi Salgado
(executive officer of ANZGOG)
and Sarah Chinchin**

Gynaecological cancer

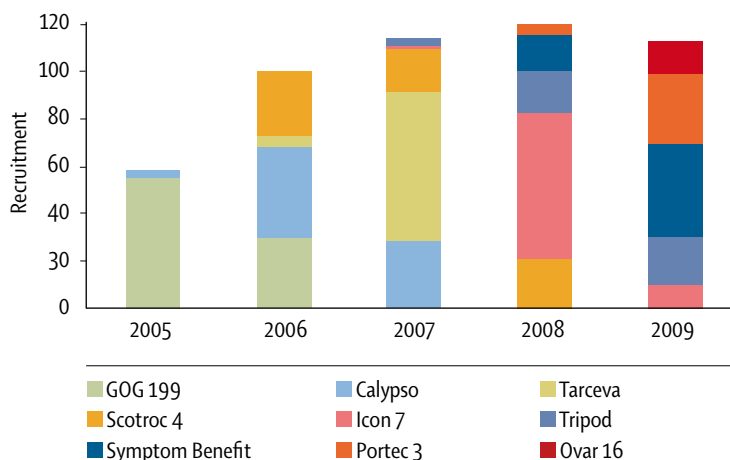
The CTC coordinates all the trials of the Australia New Zealand Gynaecological Oncology Group (ANZGOG), which was established in 2002 and incorporated in 2009. ANZGOG collaborates with international study groups through membership of the Gynecologic Cancer InterGroup (GCIg). The associate oncology program manager for the ANZGOG trials, Julie Martyn, recently became chair of its Harmonisation and Statistics Committee.

ANZGOG has recruited over 500 patients from 47 clinical sites in Australia and New Zealand. Currently, three are open to recruitment:

PORTEC 3, OVAR 16 and Symptom Benefit. ICON 6 (stage 2) and Outback are pending. Another six trials, in ovarian cancer, have closed to recruitment, and their patients are being followed up.

The CTC is statistical centre for the large international Calypso trial. This ovarian cancer trial showed that combination treatment with carboplatin and pegylated liposomal doxorubicin led to longer progression-free survival than standard chemotherapy in patients with platinum-sensitive recurrent ovarian cancer. The results were presented at the meeting of the American Society of Clinical Oncology, the European Society of Gynecological Oncology and the European Society for Medical Oncology in 2009. Patients continue to be followed up, and work on secondary analyses is continuing.

www.anzgog.org.au



Genitourinary cancer trials

In 2008, the Australian and New Zealand Germ Cell Trials Group (ANZGCTG) and Australian Prostate and Urogenital Cancer Group (APUG) amalgamated to form the new collaborative group, the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). ANZUP is supported by funding from Cancer Australia under its Support for Cancer Clinical Trials program.

SORCE, an international trial initiated in the UK and Europe, is the first ANZUP trial in renal cell cancer, and began in Australia in 2009. Australian investigators, Martin Stockler and Prunella Blinman, have also designed and developed a substudy on patient preferences (page 18),

Accelerated BEP, a feasibility study of an accelerated chemotherapy regimen for advanced germ-cell tumours, continues to recruit patients. Encouraging results from this trial and a similar UK trial have provided the rationale for a full-scale randomised trial of the regimen. Chemo & Cognition is a national longitudinal study of learning, memory and attention after chemotherapy for testicular cancer. The study will have implications for informed consent and the way future clinical trials are investigated, and is especially important with cancer survivors living longer. Another trial is seeking to establish the value of an aprepitant-containing anti-emetic regimen in preventing chemotherapy-induced nausea and vomiting for patients receiving 5-day cisplatin-based chemotherapy.

Eligible patients can enrol in all three trials: Accelerated BEP, Aprepitant and Chemo & Cognition.

www.anzup.org.au

Brain cancer trials

The Cooperative trials Group for Neuro-Oncology (COGNO) is a national collaborative trials group formed in late 2007 with funding from Cancer Australia.

The CTC is the coordinating centre for the group and is currently completing data management for a phase II trial of the combination of temozolomide and liposomal doxorubicin for glioblastoma multiforme, a brain cancer.

The group has also joined with the European Organisation for Research and Treatment of Cancer (EORTC) to conduct the CATNON trial in Australia. The trial is investigating chemotherapy treatment added to radiotherapy for glioma. COGNO held its first scientific meeting in 2008 and discussed three new local concepts for trials to add to those already running and two being prepared for start-up.

www.cogno.org.au



ANZUP IS OFF TO A GOOD START

In 2009, ANZUP continued to recruit patients to five trials and activated another — RAVES, in collaboration with the Trans-Tasmanian Oncology Group.

‘The associate oncology program manager’s role for ANZUP at the CTC has provided me with opportunities to mentor more junior staff, liaise with experts in the field, and gain exposure to all aspects of project management from concept development to close-out. The opportunities offered by CTC are diverse, and both personally and professionally rewarding.’

— **Amy Boland**, associate oncology program manager for the Australian and New Zealand Urogenital and Prostate Cancer Trials Group

PHD

INDIVIDUAL PATIENT PREFERENCES IS A MAJOR STRAND OF THE CTC'S ONCOLOGY RESEARCH

Dr Blinman is undertaking studies on the preferences of patients and their doctors for chemotherapy treatment. The studies use the methods of Simes and Coatesto to determine how patients and doctors trade off the benefits and harms of chemotherapy.

In a recently published study, she found that very small survival benefits made adjuvant chemotherapy for early colon cancer worthwhile, but preferences were highly variable and not readily predictable.

Dr Blinman received a Young Investigator Award from the ASCO Cancer Foundation in the United States for her work on preferences for adjuvant chemotherapy in non-small-cell lung cancer. She presented results at national and international meetings in 2009, and this work is continuing.

Other preferences studies include one determining preferences for adjuvant sorafenib in resected renal cell cancer. This is a longitudinal preference study developed, coordinated and led by the CTC as part of the international phase III SORCE trial (page 46).



Prunella Blinman



Lung cancer trials

The CTC coordinates the trials of the Australasian Lung Cancer Trials Group (ALTG), which aims to reduce the incidence and related mortality and morbidity of lung and thoracic cancers and improve the quality of life of patients with lung cancer. The group is supported by infrastructure grants from Cancer Australia.

Four trials have been developed: MATES, NITRO, PACT in non-small-cell lung cancer, and BR.29. MATES, a study of thalidomide for mesothelioma, is a collaboration with a Dutch group, and BR.29 is a collaboration with the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG). A trial using a novel vascular disrupting agent for mesothelioma is being developed.

'Preferences for adjuvant chemotherapy in non-small-cell lung cancer: what makes it worthwhile to patients and their doctors?' is a multicentre observational cohort study of preferences for adjuvant chemotherapy for patients undergoing surgery for lung cancer. Results for patients' preferences were presented at the World Conference on Lung Cancer in 2009 by CTC research fellow, Prunella Blinman.

www.altg.com.au

An initiative to close the evidence gaps in oncology in primary care

In mid-2009 the CTC began collaborating with the Primary Care Cooperative Cancer Clinical Trials Group (PC4), the newest national cooperative oncology group funded by Cancer Australia.

The group focuses on prevention and detection of cancer and care of people with cancer and currently unanswered research questions in these areas. It is actively working to develop and conduct large-scale multisite studies and build research infrastructure in primary care.

The CTC has representation on executive and advisory committees, and its particular roles are trials development support, with advice and expertise in trial operations, statistics and clinical epidemiology. In 2009, the CTC worked with the group to run two concept-development workshops, where participants had an opportunity to workshop their ideas for new clinical trials.

A new approach to trials research in primary care is needed. It has special challenges, including the diversity of general practice patients and the complexity of their care, and the variety of health professionals involved.

www.pc4tg.com.au

rationale

known about the....

epidemiology, causes, effects

mechanisms, benefits and harms

mechanisms, benefits and harms

Neonatal trials

INIS

BOOST II

APTS

“Trials to achieve healthy outcomes for extremely premature babies are challenging. We work with clinicians through global partnerships, aiming to find cost-effective treatments that will reduce death and illness among infants.”

The CTC started its first neonatal trial in 2001 as part of its aim of conducting trials in areas of need. The trial, INIS, now approaches completion after enrolling over 3400 infants internationally.

Other large trials are being conducted or developed — such as BOOST II, which will soon reach full recruitment, and APTS, which began as a pilot study in 2009. These trials also contribute to worldwide meta-analyses of data from many thousands of patients. The CTC has participated or taken a lead in setting up networks of investigators who are making this happen.

What level of oxygen is right for premature babies?

The CTC’s BOOST II trial (Benefits of Oxygen Saturation Targeting) is one of several large trials around the world aiming to ascertain which of two ranges of oxygen saturation within the current clinical range used is better for very premature babies.

Lucille Sebastian, INIS manager, and Alpana Ghadge, BOOST II manager.



Too little oxygen for long periods may harm brain cells and contribute to chronic lung disease or increase the risk of death. Too much oxygen for long periods is known to cause damage to the eyes, may impair brain development or lung development, and may also increase the risk of death.

Infants are randomised to either 85–89% oxygen saturation target or to 91–95% oxygen saturation target. Oxygen saturation is measured with adjusted, masked Masimo Radical SET pulse oximeters. The oxygen saturation monitoring for the study continues until the infant reaches a corrected gestational age of 36 weeks or consistently breathes in room air.

Of the 1036 infants enrolled, 218 have been followed up for their outcomes at 2 years, corrected for gestation.

The abnormalities being measured are rare, so even 1200 infants in the trial will not be enough to determine a clear difference between the two oxygen targets. The data from the trial are being combined with data from five other similar trials in other countries in the international Neonatal Oxygenation Prospective Meta-analysis (NeOProM) (page 32). Eventually, data from 5200 infants will be available for a meta-analysis that was planned before the trials began.





Immunoglobulin for infection

The International Neonatal Immunotherapy Study (INIS) is evaluating polyclonal immunoglobulin (IVIG) added to antibiotic therapy for newborn infants with serious infection. Infants were recruited from Australia, New Zealand, United Kingdom, Europe and Argentina.

Infants with low birth weight and suspected serious infection received infusions of IVIG (Intragam P) or placebo. The main outcome being measured is survival without major disability at 2 years, corrected for gestational age. INIS finished recruitment in May 2007 in Australia and New Zealand. The cohort of 1398 babies from Australia and New Zealand was 40% of the global total of 3493. Locally, the trial successfully followed up 97% of babies eligible to answer the primary study question.

Does placental blood help premature babies?

Researchers led by Professor William Tarnow-Mordi are investigating the value of a simple technique to improve the health and survival of infants born more than 10 weeks early. These infants have a higher rate of death and disability than babies born at term.

Placental transfusion can deliver as much as 30 more millilitres of blood to the baby. It is done by one of three methods: cord milking, delayed cord clamping, or a combination of both. The method leading to the highest haemoglobin levels will be the intervention arm in the main trial. Recruitment began in 2009 for the pilot study.





“Amputation is a real threat for diabetes patients. Fenofibrate treatment appears to substantially reduce this risk”

Anthony Keech, deputy director

PREVENTING CARDIOVASCULAR DISEASE

Cardiovascular trials

FIELD

ASPIRE

LIPID

The international FIELD trial: results continue to reveal benefits of treatment for diabetes

The FIELD (Fenofibrate Intervention and Event Lowering in Diabetes) trial is a study of using fenofibrate to modify blood lipids and therefore reduce cardiovascular disease in people with type 2 diabetes.

The main results were published in 2005, but subsidiary analyses looking at secondary and tertiary endpoints planned in the trial protocol are still continuing. One study showed that fenofibrate reduced the risk of amputation of the toes by almost half. Another explored various features of the metabolic syndrome: people with very high triglyceride levels had the highest risk and also the greatest benefit from fenofibrate treatment.

Many patients in FIELD started using statin drugs during the 5 years of the trial, confounding the main results. The investigators therefore developed a new method for adjusting the effects of a study drug for other treatments taken up during a trial. This was presented at the meeting of the American Heart Association.

PHD



Ru-Dee Ting, cardiology fellow

DIABETIC MICROVASCULAR DISEASE

Dr Ting is looking at the safety of fenofibrate and its effects on diabetic kidney disease. The well-known acute rise in serum creatinine with fenofibrate has been found to be completely reversible even after 5 years of treatment. Hence, the creatinine rise may not indicate structural damage to the kidney; in fact, the preservation of renal function is unmasked on drug withdrawal.

Part of the project examines risk predictors of diabetic microvascular disease, with emphasis on renal pathology. The loss of glomerular filtration and albumin leak appear to represent two separate pathological processes with different sets of risk factors.

Complementary basic science experiments investigate the mechanism of action of fenofibrate. Mesangial, podocyte and proximal tubule cell cultures will be exposed to a diabetic milieu, and the effects of fenofibric acid on the pathological changes of diabetic nephropathy examined: for example, upregulation of collagen. Animal experiments will be conducted to validate these findings, and PPAR-alpha knockout mice will be used to find out whether the renal effects of fenofibrate are solely PPAR-mediated or not.



Over a million Australians have diabetes. The costs of diabetes were estimated by the Diabcost survey in 2002 at \$3 billion a year, and diabetes is implicated in 8% of deaths in Australia. Therefore, the research by the FIELD investigators has important financial implications, especially with the increased cost of health care and the aging population.

The next major phase of the FIELD trial is laboratory analysis of patients' blood samples. This will allow the investigators to determine biological and genetic markers of risk. FIELD is also continuing with long-term follow-up. Of about 8000 patients in Australia and New Zealand, about 16% have died and the rest are being followed up by questionnaire or registry search to ascertain their outcomes.

PHD

LABORATORY AND CLINICAL VASCULAR STUDIES

Dr Rajamani is using cell, molecular, and animal models and human clinical studies to determine the mechanisms of blood vessel damage and repair in patients with type 2 diabetes. These studies are extending the results of the FIELD trial. The objective is to identify novel mechanisms of vascular injury in diabetes and potential pathways through which the clinical benefits of fenofibrate are mediated — at genetic, cellular and molecular levels.

In 2009, Dr Rajamani took a major role in the FIELD amputation study, published in *The Lancet*. Current research includes:

- using clinical and biochemical variables to predict the risk of an amputation
- laboratory studies of the effects of hyperglycaemia on migration, proliferation, tubulogenesis and apoptosis of cultured human vascular endothelial cells
- simulation of limb ischaemia, wound healing and the effects of fenofibrate in mice
- finding specific genetic biomarkers of vascular injury in diabetes patients.



Kushwin Rajamani,
cardiology fellow

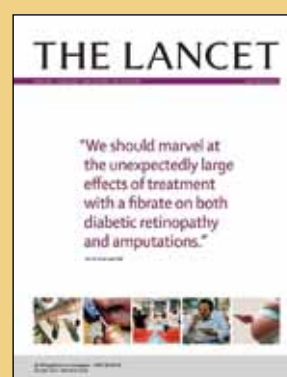
FIELD AMPUTATION STUDY

An amputation due to diabetes occurs around every 30 seconds somewhere in the world.

In FIELD, fenofibrate treatment was found to reduce the risk of a first diabetes-related amputation by 36%. This important finding was reported in *The Lancet* in May 2009. The risk of a minor amputation (toes) without known large-vessel disease was 47% lower in the fenofibrate group.

A patient's height was a major predictor of amputations. The risk of an amputation increased by 60% for every 10 centimetres of a patient's height.

Amputation is a real threat for diabetes patients, even when their blood glucose and blood pressure are kept under control, and is dramatically higher for those who have already had skin ulceration or amputation. Fenofibrate treatment appears to substantially reduce this risk.





Rebecca Mister,
project manager for ASPIRE

A large cost-efficient trial: ASPIRE

Several million patients worldwide who have had a venous thromboembolism are at risk of another.

The aim of ASPIRE is to determine whether low-dose aspirin prevents recurrence of thromboembolism. ASPIRE is also examining the safety of long-term aspirin in these patients, exploring risk factors for recurrent thromboembolism, exploring the link between venous and arterial thrombosis, and assessing the cost-effectiveness of aspirin therapy.

ASPIRE began in Australia and New Zealand in 2004. A larger patient base was sought by expanding into Singapore, the United Kingdom, more recently, India and, in the future, Argentina. Over 650 patients have been recruited.

Italy has a very similar trial (WARFASA). The ASPIRE and WARFASA investigators are cooperating in the INSPIRE prospective meta-analysis, led by the Australian investigators.

Long-term effects of cholesterol-lowering therapy: LIPID

Patients in the Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) trial were recruited between 1990 and 1992 and had clinical follow-up for an average of six years. The results of the trial were published in 1998. Over 90% of surviving patients are still being followed up by letter and telephone, and other data come from searches of registers of morbidity, mortality and cancer. The information is being used to assess the long-term safety and cost-effectiveness of pravastatin treatment, a project funded by the NHMRC.

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 will soon be 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.

Recent publications resulting from LIPID data include: biostatistical studies analysing the risk of a recurrent cardiovascular event; a study showing that two major biomarkers were associated with future coronary heart disease; a study describing differences in Australian and New Zealand cardiovascular mortality according to socioeconomic status; and an investigation of optimal intervals for cholesterol monitoring.



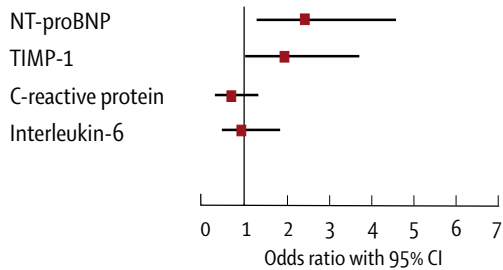


Helen Pater, project manager for LIPID

Coronary heart disease biomarkers

The LIPID study continues to provide information about the ongoing risks of patients who have had coronary heart disease. One study showed that two biomarkers predicted the risk of future cardiovascular events (with odds of more than 1) and two others did not. The analyses were adjusted for confounders (including age, prior myocardial infarction, diabetes, and prior stroke).

Biomarker



Biostatistics

BIostatISTICS

CTC OUTREACH PROGRAM

BIostatISTICS COLLABORATION OF AUSTRALIA

EDUCATION

Biostatistics has a central role in trials from initiation and design through to the final report. CTC biostatisticians have responsibility as the statisticians for national and international trial groups undertaking research into cardiovascular disease, diabetes, neonatal intensive care, and breast, gastrointestinal, gynaecological, urogenital and brain cancers. They also participate in independent safety data monitoring committees, which oversee trial safety at arm's length from the study investigators.

As part of a new collaboration with the Menzies Research Institute in Darwin, in 2008 and 2009 statisticians presented workshops covering material from design of trials to advanced statistical methods for analysis of trial data. Researchers had the opportunity to present a study plan for discussion and development. This activity has paved the way for collaborative trials in Aboriginal health. The first of these, ABRACADABRA, is a multisite trial to assess a web-based early literacy program. School absenteeism has presented special challenges. The success of the intervention will be measured by improvements in students' phonological awareness and word reading. Other outcomes to be assessed include early literacy skills, phoneme-grapheme correspondence and mathematics. Poor literacy underpins many health problems in indigenous groups, so an improvement in early literacy can potentially improve health in the future.

PHD

STATISTICAL METHODS AND ISSUES IN ANALYSIS OF HEALTH-RELATED TRADE-OFFS

Overall summary measures are often needed in clinical trials that evaluate quality of life, in order to encapsulate the balance of positive and negative impacts of conditions and treatments on different quality-of-life dimensions and on other outcomes such as health status and survival.

In this project, Dr Annette Kifley and colleagues are developing joint models for multidimensional, mixed outcomes in quality-of-life trials by applying and extending latent variable modelling methods. The work will be useful for pharmacoeconomic assessments and individual clinical decision making about the overall value of different therapeutic strategies.





“Biostatistics plays a pivotal role in underpinning the science of clinical trial designs as well as ensuring the study results are correctly interpreted.”

Val Gebski, director, Biostatistics.

DEVELOPING A NEW CLINICAL TRIAL: THE STATISTICIAN’S VIEW

‘In the Mel-D study, a phase II pilot trial to assess the effectiveness of vitamin D in preventing melanoma recurrence, the design team has included a biochemist, a surgeon, a clinical researcher, a statistician, a clinical trials manager, a data manager and a clinical trials coordinator.

‘It has taken over 1 year from the concept stage to getting the trial up and running. It will take at least another 2 years before the study can answer its research question.

‘My role in the Mel-D trial as a biostatistician is not just about “doing the stats”. It’s about problem solving, learning how to communicate statistical concepts to the group, and helping design case report forms, among other things. It has been insightful and rewarding experience.’

— **Diana Zannino**, biostatistician



CTC Outreach

CTC Outreach is a research support program designed to promote high-quality clinical trials in currently unsupported clinical areas, including surgery, current clinical practice, new health technologies, clinical management, palliative and supportive care, and complementary medicine. Expertise available to new investigators and groups includes:

- study design and conduct, including statistical considerations, and database and forms design
- concept development, including outlines, trial proposals, protocols and funding applications
- randomisation and drug distribution systems
- development of clinical research skills
- establishing trials support networks in therapeutic areas currently not catered for.

During 2008–2009, Outreach supported over 60 research and education activities. Highlights have included collaboration on several projects funded by the NHMRC and sponsorship of training workshops and short courses in trial concept development and methods. The functionality of the CTC's randomisation and data management systems have been extended, so more trials can be supported. Outreach has contributed to the development and ongoing success of research networks in kidney disease, paediatrics, neonatal disorders and indigenous health.

The program is funded by the National Health and Medical Research Council of Australia.

www.outreachclinicaltrials.org.au



Andrew Martin,
senior biostatistician for Outreach

Biostatistics Collaboration of Australia (BCA)

The BCA has close ties with the NSW Health Biostatistics Training Program, which is also celebrating its 10th anniversary.

The BCA, a collaboration of seven universities administered at the CTC, is meeting the workforce need for biostatisticians in Australia. The BCA offers postgraduate qualifications from each of its member universities and provides courses by distance education. After 10 years of its operation, 182 have graduated (86 master, 33 graduate diploma, 63 graduate certificate) and currently 248 students are enrolled.

This achievement as a model for collaborative education was reported in a paper in *The American Statistician*: 'Biostatistics @ distance: a model for successful multi-institutional delivery'.

www.bca.edu.au

BCA academic staff, left to right:
Professor John Carlin (University of Melbourne), Professor Judy Simpson (University of Sydney), Dr Keith Dear (Australian National University), Professor Philip Ryan (University of Adelaide), Professor Andrew Forbes (Monash University), Professor Annette Dobson (University of Queensland), Professor Cate D'Este (University of Newcastle), Professor Gillian Heller (Macquarie University), and Ms Helen Moore from NSW Department of Health, who supervises the NSW Health Biostatistics Training Program.



Education for clinical trials

The CTC has a program of education activities designed to increase the quality and number of trials undertaken in Australia and improve the interpretation and implementation of their results. New courses are continually being developed:

- Time-to-event analysis is an advanced statistical technique accounting for the observation that the clinical event being measured may occur early in some patients and later in others; others yet may die or drop out of a trial for other medical reasons altogether. The intense 5-day course in time-to-event methods was first offered in 2008. Simple and complex analysis strategies were covered, with an emphasis on interpreting results and the advantages and pitfalls of different approaches.
- Equivalence and noninferiority study designs are becoming increasingly common, but design and analysis methods are still not well understood. A course on equivalence designs and interim analysis was presented for the first time in 2009. The participants came from varied backgrounds, mainly medical, with most having a basic level of knowledge. Participants appreciated the quality and comprehensiveness of the course, saying it was pitched at the right level.
- The CTC with Professor James A Talcott from Harvard conducted a 5-day advanced clinical trials course under the auspices of the NSW Office of Scientific and Medical Research and the NSW Cancer Institute. Participants brought their trial proposals for developing in practical sessions.

CTC biostatisticians and others develop and deliver regular educational programs, including: short courses for clinical researchers and biostatisticians; lectures and workshops for radiation oncology trainees; workshops on study design and data management for paediatrics at the Children's Hospital Westmead; and workshops on developing concepts and protocols for trials.



Combining trial evidence

COMBINING EVIDENCE

SYSTEMATIC REVIEWS
AND META-ANALYSES
COCHRANE COLLABORATION

EVIDENCE FOR DECISION MAKING

ANZCTR
EVALUATING CLINICAL TESTS
MSAC

EVERY PATIENT IS DIFFERENT

RISK MODELS

QUALITY OF LIFE

TRANSLATIONAL RESEARCH

Systematic reviews and meta-analyses

In systematic reviews, information is obtained comprehensively from all possible sources to obtain the best unbiased evidence. The CTC undertakes systematic reviews and meta-analysis to investigate important clinical questions and also to assess new medical devices and technology.

Prospective meta-analysis, in which the data collection and analyses for more than one trial are planned in concert before the trials are conducted, is the gold standard in medical research. It is particularly useful in research areas where large numbers of patients are required for statistical analysis. The CTC is a leader in prospective meta-analysis methods.

Perinatal meta-analyses

OXYGEN THERAPY FOR NEONATES

The Neonatal Oxygenation Prospective Meta-Analysis (NeOProm) is a current collaboration of investigators for the CTC's BOOST II trial (page 21) and trial investigators in the United States, United Kingdom, New Zealand and Canada, who together plan to recruit over 5000 infants born at less than 28 weeks' gestation. This prospective meta-analysis is expected to answer the question of the optimum level of oxygen for very preterm infants.

NITRIC OXIDE IN ASSISTED VENTILATION

Preterm infants often require assisted ventilation, which has a risk of lung and neurological injury. Some trials have shown that inhaled nitric oxide reduces these risks. In MAPPINO, individual-patient data from several trials are being reanalysed to settle this question and to identify any characteristics of the infants that may show benefits of inhaled nitric oxide.

HIGH-FREQUENCY OSCILLATORY ASSISTED VENTILATION

Prevention of Ventilator-Induced Lung injury in Preterm Infants with Respiratory Distress Syndrome (PreVILIG) is a systematic review and individual-patient-data meta-analysis of the value of high-frequency oscillatory ventilation compared with conventional mechanical ventilation in reducing the risk of bronchodysplasia and consequent disability in preterm infants. The dataset includes 3229 participants in 10 trials.





“The CTC undertakes systematic reviews and meta-analysis to investigate important clinical questions and to assess new medical devices and technology.”

Dr Lisa Askie, director of systematic reviews. Lisa also has leading roles in international neonatal collaborations.

ANTIPLATELETS FOR PREVENTING PRE-ECLAMPSIA

The PARIS collaboration was the first individual-patient-data analysis in the perinatal field. It showed that use of antiplatelet drugs, such as aspirin, in pregnancy reduced the risk of pre-eclampsia and other adverse outcomes of pregnancy.

In 2009, Lisa Askie was awarded a research grant from the UK Medical Research Council for further methodological research using the PARIS dataset.

Cardiovascular disease meta-analyses

INTERNATIONAL TRIALS OF CHOLESTEROL-LOWERING DRUGS

The Cholesterol Treatment Trialists' (CTT) Collaboration was the first international prospective meta-analysis group, established in 1994 as a way of pooling individual-patient data from many trials to answer research questions about the effects of the cholesterol-lowering statin drugs. The analysis of data from the subgroup of patients with diabetes (in 14 trials with over 8000 vascular events) was published in 2008. This confirmed that statin therapy reduced the risk of heart disease mortality in people with diabetes at risk of vascular disease.

Data from 25 trials of statins compared with a control or high-dose compared with low-dose statins are now available. These patients had almost 25 000 vascular events, such a large number that analyses of many subgroups can be done with statistical precision.

ASPIRIN TO PREVENT RECURRENT VENOUS THROMBOEMBOLISM?

The investigators of ASPIRE (page 26) are collaborating with the investigators of the WARFASA study (initiated in Italy) in INSPIRE, a prospectively designed meta-analysis of individual patient data. The two groups harmonised their protocols to allow a prospective meta-analysis to be done. The study aims to determine whether aspirin reduces the risk of recurrent thromboembolism.

ACUTE CORONARY HEART DISEASE

An individual-patient-data overview of immediate coronary angioplasty or thrombolysis for the treatment of acute myocardial infarction has shown the benefits of angioplasty and the importance of a comprehensive, unified approach to delivery of cardiac care.

VIGOUR COLLABORATION:

INTERNATIONAL CARDIOVASCULAR RESEARCH SINCE 1990

Data from the 1990s GUSTO trials of acute myocardial infarction continue to be analysed. A study of nearly 50 000 patients comparing the acute mortality and bleeding risks associated with 162 mg versus 325 mg aspirin showed that a lower dose of aspirin is as effective as the higher recommended dose for patients with ST-elevation myocardial infarction.

A collaborative study of 136 247 patients in GUSTO trials and other trials of the VIGOUR collaboration investigated the relationship between the sex of the patient and mortality in the 30 days after they presented at hospital for myocardial infarction or unstable angina. Women had a higher risk of death than men, but were on average older and had more risk factors, which explained most of the differences. The study highlighted the differences between men and women presenting to hospital for acute heart disease.

Reviews of evidence in the Cochrane Library

The Cochrane Library publishes systematic reviews of the evidence in many fields of health care, which is made possible by specialist groups around the world that prepare, maintain and peer-review these studies and protocols for studies.

The CTC is the editorial base of the Cochrane Breast Cancer Group, which has infrastructure support from the Australian Department of Health and Ageing. The group coordinates the Cochrane reviews on breast cancer and maintains a specialised register of over 7000 references. A current project is design of a search portal to broaden public access to breast cancer data. The group has facilitated the publication of 38 reviews and has 15 reviews in progress. CTC members of the group have published reviews themselves, most recently one on radiotherapy for ductal carcinoma and another on single-agent compared with combined chemotherapy regimens for metastatic breast cancer.

CTC authors also write systematic reviews for the Cochrane Library on other topics. In 2009, two systematic reviews of evidence on treatments for preterm infants were published.

Fergus Tai, Cochrane Breast Cancer Review Group trials search coordinator





DIVERSITY IN WORKING FOR THE AUSTRALIAN TRIALS REGISTRY AND CTC SYSTEMATIC REVIEWS

An objective of the Australian New Zealand Clinical Trials Registry (ANZCTR) is to reduce bias in medical evidence.

'In my role as a systematic reviews project officer I promote and implement prospective clinical trial registration through the ANZCTR. By creating a public record of clinical trial information, our registry aims to make health information more accessible and transparent. This will ultimately strengthen the efficacy, validity and value of the medical evidence base used to inform health care decisions.

'I am also involved in various research projects spanning preterm infant health, prospective meta-analysis methods, and obesity in children. The diversity of my role enables me to broaden my knowledge and keep up to date with the latest research being conducted across the full spectrum of health.'

— **Kylie Hunter**,
systematic reviews project officer

Evidence from clinical trials

The Australian New Zealand Clinical Trials Registry

The Australian New Zealand Clinical Trials Registry (ANZCTR) provides public data on trials being conducted in Australia, New Zealand, the neighbouring region, as well as some trials from other countries.

The number of trials registered has grown to 3657 since it started in 2005. An average of 90 new trials are submitted for registration each month, an increase from the 2007 average of 54. About 17% have a commercial sponsor.

The ANZCTR is a primary registry in the World Health Organization's Registry Network, the portal for registered trials throughout the world. The WHO has recently introduced universal trial numbers (UTNs) to enable trials to be tracked more easily. Registry manager Lisa Askie represents the ANZCTR on the WHO platform's Best Practice Group, which is working to further develop minimal acceptable standards for registries throughout the world.

Worldwide trial search through the WHO portal:
<http://apps.who.int/trialsearch>

Lukas Staub and Sally Lord

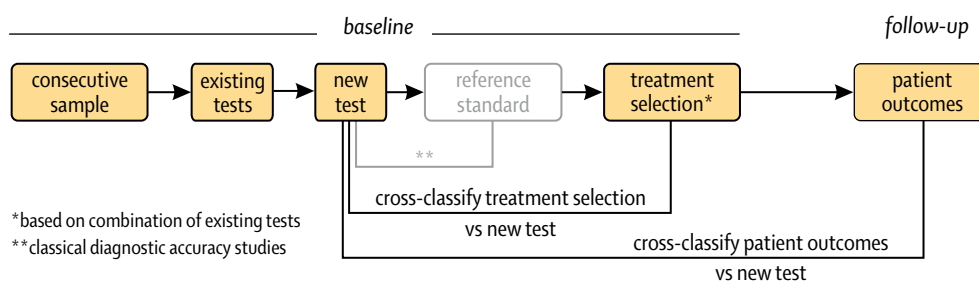


Evaluating clinical tests

In clinical medicine, tests are used for diagnosis and prognosis, and to predict the outcome of treatments. Whether a test is known to be accurate is not enough to recommend its use if there is uncertainty about the effects of treatment. When new tests are introduced, the benefit of detection must be weighed against the risks of overinvestigation and overtreatment due to possible misdiagnosis. Evaluation of tests is a major research strand of the CTC's systematic reviews group.

Knowing whether a test plus treatment will improve outcomes requires evidence. The best evidence comes from clinical trials. However, long-term trials may not always be necessary. Sally Lord and colleagues have been investigating the type of comparative evidence needed for test evaluation. They use a flow diagram of a hypothetical randomised trial and focus on specific populations and outcomes where the new-test pathway differs from the standard-test pathway.

Sally Lord presented an invited white paper for the US Agency for Health Care Research and Quality at the launch of the Diagnostic Test Evaluation Work Group, which is developing guidance for conducting comparative-effectiveness reviews of diagnostic technologies.



PHD

NEW METHODS FOR EVALUATING DIAGNOSTIC TESTS

The clinical value of a new diagnostic test is ideally assessed by randomised controlled trials that measure its effect on health outcomes. This evidence is rarely available, and test accuracy is often used as a surrogate. However, accuracy can only be estimated if a reference standard is available, and improved accuracy does not necessarily lead to better health for the patient.

In the absence of an accepted reference standard, information that goes beyond 'classical' test accuracy can be used in the evaluation of a new test. In collaboration with spine surgeons, Dr Staub and colleagues designed a study to measure the clinical validity of the so-called nerve root sedimentation sign, which uses imaging for diagnosis of lumbar spinal stenosis.

Measuring associations between test results and their downstream consequences may be the best way to judge the clinical validity of this new test. This approach takes into account the diagnostic pathway in which the test will be used, requiring a common understanding between clinicians and epidemiologists of how to apply the principles of test evaluation to addressing clinical questions about tests.



Lukas Staub

Reviews of new technologies and procedures to inform decisions about public funding

The CTC has a contract with the Medical Services Advisory Committee (MSAC), which advises the Australian Minister for Health and Ageing on evidence relating to new medical technologies and procedures. CTC staff, with clinical experts, review the evidence and analyse the findings relating to safety, effectiveness and cost-effectiveness.

Nine of these reviews were completed in 2008–2009. Six of these were on positron emission tomography (PET), which images physiological function and metabolism, complementing anatomical information from computed tomography or magnetic resonance imaging. PET can detect or exclude various cancers and other pathological processes. The other reviews related to ocular coherence tomography (an imaging technique for retinal eye diseases) and tests for cervical cancer.



Samara Lewis, project manager for MSAC reviews

**Luke Marinovich,
Sally Wortley and
Stephanie Schoeppe**



Every patient is different

In clinical trials, usually the benefits and harms of a new treatment are measured as the average for the patient group, but individual patients differ. Trial data are now being used to predict how the course of a disease differs among patients (prognosis) and how patients will respond individually to treatments (prediction). Some prognostic and predictive factors are: risks according to biology; lifestyle risks; and attitudes and values.

Patients may therefore be interviewed about their health or quality of life or asked to allow their blood samples to be analysed. When the data are analysed as part of a trial, the results help clinicians to make appropriate decisions for individual patients.

Risk models in cancer and cardiovascular disease

The data from large numbers of patients in the CTC's clinical trials are used to calculate the risk of various outcomes in comparable populations.

Clinical measures and genetic and biomarker information, individually or together, may be correlated with patient outcomes to define the risk of an individual patient and the degree of benefit an individual patient might have from treatment. Data from trials has been used to build risk models in cancer and cardiovascular disease.

A substudy of FIELD (page 24) showed that self-reported health on a pen-and-paper scale predicted which patients were at higher risk of major complications of diabetes. A 10-point difference in score classified later risk better than a 1-unit change in the the total cholesterol-to-HDL cholesterol ratio or a 10-year longer duration of diabetes. FIELD data have also been used in models that predict of the risk of microvascular disease, such as amputations, kidney disease and diabetic eye disease.

PHD

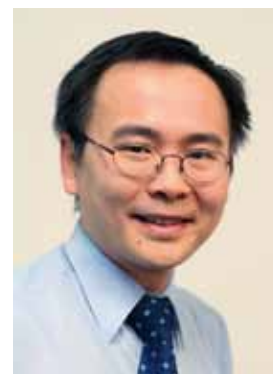
CAN SURVIVAL AND TREATMENT BENEFIT BE PREDICTED FOR INDIVIDUAL PATIENTS?

Dr Lee's objective is to develop and test new methods of analysing data from past trials of breast, colorectal and ovarian cancer to assess how molecular biomarkers and other disease and patient characteristics might predict survival and treatment benefit.

He is also examining the role of quality of life in predicting response, toxicity and treatment benefit in advanced breast cancer patients.

Another study involves constructing a risk model that classifies patients into high-, medium- and low-risk in terms of prognosis. This has value for individualising treatment decisions and for future stratification of patients in randomised studies.

Various hypotheses have arisen from the completed Calypso trial of ovarian cancer. These include considering CA125, a biological marker, as a surrogate for treatment efficacy and for identifying groups of patients with different prognosis.



Chee Lee

Quality of life information is important for clinical decisions

One way that CTC researchers make the most of trial evidence is by incorporating patient-oriented outcome measures, such as quality-of-life, in trials where possible. Recently published studies have focused on novel ways of measuring quality of life and explored relationships between quality of life and survival.

The Patient Disease and Treatment Assessment Form was designed at the CTC to be a simple, pragmatic measure of health-related quality of life in people with advanced cancer. It was validated by Anna Nowak and colleagues in a substudy of a hepatocellular carcinoma treatment trial. In another substudy, Corona Gainford and colleagues adapted and translated it for use in Taiwan.

Individual wellbeing at the start of treatment has also been studied. For example, in a study by Lee and colleagues, a good score on physical wellbeing and appetite at baseline predicted longer survival in women with advanced breast cancer treated with chemotherapy.

PHD

DERIVING PATIENT-VALUED UTILITIES FROM QUALITY OF LIFE QUESTIONNAIRES TO IMPROVE CLINICAL DECISION MAKING

Dr Grimison used data from a simple, self-rated, disease-specific questionnaire in three breast cancer trials to create a utility index based on cancer patients' preferences.

The index can be used to generate utility scores and quality-adjusted life years in clinical trials.

The aim was to facilitate the integration of data about health-related quality of life with traditional trial endpoints (such as survival and tumour response) and ultimately help patients, clinicians and funders make better decisions about cancer treatments, by considering the potential trade-offs between survival and quality of life.



Peter Grimison

Translational research

Translational research, often described as 'from bench to bedside' is the application of laboratory research to patient care. Typically, samples of blood or tumour tissue are collected and analysed for markers that correlate with clinical outcomes. Biomarkers may forecast survival or predict the response of a patient to a treatment — an important part of personalised medicine.

At the CTC, so far about a quarter of trials include an option for patients to consent to biological samples being used in research or being banked for future research. Genetic testing of tissues forms part of the process of screening potential patients for recruitment to some trials. Linking biological and clinical data from a trial creates a powerful data set.

In 2009, Sonia Yip was appointed research fellow and oncology translational research manager. Translational research is also being done in the CTC's large cardiovascular trials, FIELD (page 24) and LIPID (page 26).

The CTC and its collaborative groups aim to build translational research into their trials where possible, with the aim of future applications at the bedside.



Which patients benefit from targeted chemotherapy for colorectal cancer?

A secondary study of C0.17 (a trial of cetuximab therapy in advanced colorectal cancer), published in the *New England Journal of Medicine*, showed that patients with a K-ras gene variant did not benefit from cetuximab.

In identifying the group of patients who would not benefit, the study thus relieves future patients of needless treatment and its side-effects.

Sonia Yip, translational research manager

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	Role or activity
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	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), Gynecologic Oncology Group (GOG)	Coordinating centre
Australian New Zealand Clinical Trials Registry (ANZCTR)	National register of Australian clinical trials	Coordinating centre
Australian universities	Members of the Biostatistics Collaboration of Australia	Coordinating centre
Biostatistics Collaboration of Australia	Collaborative group for biostatistics education: national	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
Cholesterol Treatment Trialists' (CTT) collaboration	Collaboration of clinical trial groups studying cholesterol treatments: Australia, New Zealand, United Kingdom, United States, Italy	Coordination of meta-analyses in heart disease
Clinical Trials 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
Early Prevention of Obesity in Children (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
FIELD Study Group	Collaborative group for field diabetes trial: Australia, New Zealand, Finland	Coordinating centre



Group	Nature of group	Role or activity
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
MAPPINO collaborative group	Meta-analysis collaboration: international	Coordinating 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
NeOProm collaborative group	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
PARIS collaborative group	Meta-analysis collaboration with representation from many countries	Co-coordinating centre
PreVILIG collaborative group	Meta-analysis collaboration; international	Coordinating centre
Primary Care Cooperative Cancer Clinical Trials Group (PC4)	Collaborative group: Australia	Collaborator through the Clinical Trials Development Unit
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

Trial	Participants	Status
Breast cancer		
SNAC 2: Multicentre randomised trial of sentinel-node biopsy versus axillary clearance NHMRC CTC study	Women with operable breast cancer, stratified by various factors, including age and tumour size	Recruitment target: 1012 Recruitment: 131
Gastrointestinal cancer		
Current trials		
CO.20: phase II randomised study of brivanib alaninate + cetuximab versus placebo + cetuximab in metastatic carcinoma (AG0207CR) NCIC CTG and AGITG study	Patients with treated metastatic colorectal cancer of K-ras wild type	Recruitment target: 370 Recruitment: 312
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	Recruitment target: 250 Recruitment: 189
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	Recruitment target: 80 Recruitment: 8
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	Recruitment target: 100 Recruitment: 19
TOP GEAR: randomised phase II–III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for gastric cancer (AG0407GR) AGITG study	Patients with resectable gastric cancer suitable for these treatments	Recruitment target: 120 (stage 1); 632 (stage 2) Recruitment: 3
Pending trials		
A la CART: Australasian laparoscopic cancer of the rectum, phase III randomised trial of laparoscopy-assisted resection with open resection (AG0109CS) AGITG study	Patients with primary rectal cancer	Recruitment target: 470
ATTACHE: Timing of surgery and adjuvant chemotherapy for hepatic metastases from colorectal cancer (AG1209CL) AGITG study	Patients with colorectal cancer and resectable liver metastases and no extrahepatic disease	Recruitment target: 200
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	Recruitment target: 100
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	Recruitment target: 60
SCOT: Short-course oncology therapy, a study of adjuvant chemotherapy in colorectal cancer (AG0308CR) AGITG study	Patients with fully resected stage III colorectal cancer	Recruitment target: 225
SURGIST: Phase III randomised study of surgery of residual disease (AG0108GS) EORTC study	Patients with metastatic gastrointestinal stromal tumor responding to imatinib mesylate	Recruitment target: 35 (ANZ); 350 (international)
SUPER: Phase III trial evaluating surgical resection of the primary tumour in metastatic colorectal cancer (AG 0209CRS)	Patients with unresectable metastatic colorectal cancer	Recruitment target: 400



Trial	Participants	Status
Trials in follow-up		
Da Vinci: Phase III trial of irinotecan versus irinotecan + De Gramont schedule 5-fluorouracil and folinic acid for colorectal cancer (AG0103CR) AGITG study	Patients with treated metastatic colorectal cancer	Recruitment target: 100 Recruitment: 89
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	Recruitment: 81
Gofurtgo: Phase II study of fixed-dose rate gemcitabine–oxaliplatin with 5-fluorouracil and radiotherapy for pancreatic cancer (AG0503P) AGITG study	Patients with localised pancreatic cancer	Recruitment: 48
C06: Oral uracil and fluorouracil + leucovorin compared with 5-fluorouracil + leucovorin for colon carcinoma NSABP study	Patients with stage II or stage III adenocarcinoma, no metastatic disease and a life expectancy (excluding cancer) of at least 10 years	Recruitment: 11
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	Recruitment: 134
EORTC 62005: Phase III study of two different doses of imatinib mesylate for CD117-expressing metastatic or unresectable gastrointestinal stromal tumor EORTC study	Patients with metastatic gastrointestinal stromal tumour	Recruitment: 116
EORTC 40983: Phase III preoperative and postoperative chemotherapy with oxaliplatin + 5-fluorouracil + leucovorin versus surgery alone for liver metastases of colorectal origin EORTC Study	Patients with colon cancer with resectable liver metastases	Recruitment: 35
ESPAC-3: European study of adjuvant chemotherapies in resectable pancreatic cancer ESPAC study	Patients with operated cancer of the pancreas	Recruitment: 133

Gynaecological cancer

Current trials		
PORTEC 3: Phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high-risk endometrial carcinoma CGOG and ANZGOG study	Women with advanced endometrial carcinoma	Recruitment target: 200 (ANZ); 500 (international) Recruitment: 33 (ANZ); 133 (international)
Symptom benefit: Palliative chemotherapy for ovarian cancer (ANZGOG0701) ANZGOG and PoCoG study	Women with platinum-resistant epithelial ovarian cancer	Recruitment target: 100 Recruitment: 56
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	Recruitment target: 50 (ANZ); 900 (international) Recruitment: 14 (ANZ)
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)	Recruitment target: 25 (revised to 45 in 2009) Recruitment: 32
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	Recruitment target: 100 (stage 2); 400 (stage 3)

Trial	Participants	Status
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	Recruitment target: 780
PARAGON: phase II study of anastrozole in gynaecological cancers GCG study	Women with potentially hormone-responsive gynaecological cancers	Recruitment target: 100 (ANZ)
Trials in follow-up		
TRIPOD: Phase II trial of intraperitoneal chemotherapy (ANZGOG0601) ANZGOG study	Women with ovarian and related cancers	Recruitment: 39
ICON 7: Randomised, two-arm, multicentre GCG trial of adding bevacizumab to standard chemotherapy for epithelial ovarian cancer GCG study	Women with epithelial ovarian cancer who have not received systemic antitumour therapy	Recruitment: 76 (ANZ); 1528 (international)
SCOTROC 4: Multicentre randomised trial of carboplatin flat dosing vs inpatient dose escalation in first-line chemotherapy	Women with ovarian, fallopian tube or peritoneal carcinoma who are unsuitable for platinum-taxane therapy	Recruitment: 64
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	Recruitment: 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	Recruitment: 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	Recruitment: 83

Genitourinary cancer

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)	Recruitment target: 25 (revised to 45 in 2009) Recruitment: 32
Aprepitant for germ cell chemotherapy: phase II multicentre trial of a 7-day aprepitant schedule to prevent chemotherapy-induced nausea and vomiting (ANZGCTG0801) ANZUP study	Patients receiving cisplatin-based chemotherapy for germ cell tumours	Recruitment target: 50 Recruitment: 19
Chemo & cognition: cognitive function and treatment for testicular cancer (ANZGCTG0106) ANZUP study	Patients being treated and followed up for testicular cancer	Recruitment target: 154 Recruitment: 75
SORCE: Adjuvant sorafenib for renal cell carcinoma MRC (UK) and ANZUP study	Patients with resected renal cell carcinoma at intermediate or high risk of relapse	Recruitment target: 250 (ANZ); 1656 (international) Recruitment: 17 (ANZ)

Lung cancer

Current trials

NITRO: Phase III multicentre trial of adding nitroglycerine to first-line chemotherapy for advanced non-small-cell lung cancer ALTG study	Patients with advanced non-small-cell lung cancer	Recruitment target: 500 Recruitment: 35
PACT in NSCLC: Preferences for adjuvant chemotherapy in non-small-cell lung cancer ALTG study	Patients with non-small-cell lung cancer, surgeons and oncologists	Recruitment target: 200 Recruitment: 29
BR.29: Phase III randomised trial of adjuvant cediranib vs placebo with paclitaxel-carboplatin chemotherapy for non-small-cell lung cancer NCIC CTG and ALTG study	Patients with advanced or metastatic non-small-cell lung cancer	Recruitment target: 100 (international) Recruitment: 25 (ANZ) 39 (international)

Pending trials

BR.26: Phase III trial of PF-804 in patients with incurable, non-small cell lung cancer	Patients with stage IIIB or IV non-small cell lung cancer	Recruitment target: 720
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Trial	Participants	Status
B2P2M2: Phase II trial of BNC105P as second-line chemotherapy for pleural mesothelioma	Patients with pleural mesothelioma which has progressed after pemetrexed and platinum chemotherapy	Recruitment target: 60
Trials in follow-up		
MATES: Maintenance thalidomide in mesothelioma NVALT, ALTG study	Patients with malignant pleural mesothelioma, after first-line chemotherapy	Recruitment: 14 (ANZ), 200 (international)

Brain cancer

Current trials

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	Recruitment target: 699 (international), 100 (ANZ) Recruitment: 100 (ANZ)
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	Recruitment target: 100 Recruitment: 24

Pending 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	Recruitment target: 100 (ANZ); 748 (international)
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	Recruitment target: 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	Recruitment target: 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	Recruitment target: 60

Trials in follow-up

Temozolomide and caelyx study (P05036) COGNO study	Patients with glioblastoma multiforme treated with radiotherapy and chemotherapy	Recruitment: 40
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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	Recruitment target: 2000 Recruitment: 657
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Trials in follow-up

FIELD: Fenofibrate Intervention and Event Lowering in Diabetes	Patients with type 2 diabetes	Recruitment: 9795
LIPID: Long-Term Intervention with Pravastatin in Ischaemic Disease	Patients with a history of coronary heart disease	Recruitment: 9014

Neonatal disorders

Current trials

BOOST II: Benefits of Oxygen Saturation Targeting	Neonates born before 28 weeks' gestation	Recruitment target: 1200 Recruitment: 846
APTS: Australian Placental Transfusion Study	Neonates born before 30 weeks' gestation	Recruitment target: 1200 Recruitment: 6 (ANZ)

Trials in follow-up

INIS: International Neonatal Immunotherapy Study	Neonates with infection and low birthweight who are taking antibiotics	Recruitment: 1398 (ANZ); 3493 (international)
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 Deborah Schofield, BSpPath, GradDipComp, PhD, professor
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 Martin Stockler, MB BS(hons), MSc, FRACP, associate professor
 Sonia Yip, BSc(hons), PhD, research fellow
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Dr Meera Agar, COGNO
 Dr Sally Baron-Hay, ANZGOG
 Dr David Bernshaw, ANZGOG
 Dr Andrew Biankin, LAP07
 Dr Alex Boussioutas, AGITG
 Dr Alison Brand, ANZGOG
 Dr Timothy Brighton, ASPIRE
 Dr Michael Brown, MTAP
 Dr Ian Campbell, SNAC 2
 Professor Christopher Christophi, AGITG
 Associate Professor Philip Clarke, Health Economics
 Dr Andrew Davidson, NITRO
 Associate Professor Ian Davis, ANZUP
 Dr Jayesh Desai, REGISTER
 Dr Katherine Drummond, COGNO
 Dr Vlatka Duric, Preferences studies
 Dr John Eikelboom, PREDICT
 Dr Jonathan Fawcett, AGITG
 Dr Kathryn Field, CABARET
 Dr Michael Friedlander, ANZGOG
 Professor Alexander Gallus, PREDICT
 Dr Davina Gheris, ANZCTR
 Associate Professor Peter Gill, SNAC
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 Dr Geraldine Goss, ANZGOG
 Dr Michelle Grogan, ANZGOG
 Dr Andrew Haydon, SCOT
 Dr Elizabeth Hovey, ANZ GCTG
 Dr H Malcolm Hudson, Biostatistics
 Dr Monika Janda, COGNO
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 Dr Andrew Kneebone, LAP07
 Dr Eng-Siew Koh, COGNO
 Ms Robyn Leonard, COGNO
 Dr Trevor Leong, AGITG

Ms Karen Livingstone, ANZGOG
 Dr Elizabeth Lobb, COGNO
 Professor G Bruce Mann, AGITG
 Professor Ian Marschner, HERO-2
 Dr Nicole McCarthy, ANZGOG
 Dr Sue-Anne McLachlan, ALTG
 Dr Michael Michael, DECO
 Dr Linda Mileshkin, PORTEC-3
 Professor Michael J Millward, ALTG
 Dr Jeremy Miller, START
 Dr Christopher Milross, ANZGOG
 Professor Anna Nowak, CATNON
 Professor Andreas Obermair, Oncology
 Dr Robert Padbury, AGITG
 Professor Lyle Palmer, COGNO
 Dr Nicholas J Petrelli, AGITG
 Dr Cameron FE Platell, SUPER
 Dr Timothy J Price, AGITG
 Professor Michael Quinn, ANZGOG
 Dr Kushwin Rajamani, FIELD
 Dr David T Ransom, SCOT
 Dr Danny Rischin, ANZGOG
 Dr Mark Rosenthal, COGNO
 Dr Gail Ryan, COGNO
 Dr Eva Segelov, Quasar 2
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 Dr Ben Solomon, BR.24
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 Dr Christopher Steer, EORTC
 Dr Andrew R Stevenson, A la CART
 Mr Denis Strangman, COGNO
 Mr John Stubbs, ANZ GCTG
 Dr Christopher Sweeney, ANZUP
 Professor William Tarnow-Mordi, neonatal trials
 Dr Niall Tebbutt, AGITG
 Professor Damian Thompson, ANZUP
 Dr Ru-Dee Ting, FIELD
 Associate Professor Guy Toner, ANZUP
 Dr Paul Vasey, ANZGOG
 Dr Michell Vaughan, ANZGOG
 Dr David G Walker, COGNO
 Dr Neil Wetzig, SNAC
 Dr Desmond Yip, SCOT
 Professor John Zalcborg, AGITG

EXTERNAL COMMITTEES

John Simes

ANZ Breast Cancer Trials Group scientific advisory committee
 Aspirin to Prevent Recurrent Venous Thrombo-embolism (ASPIRE) trial management committee (chair)

Australasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee, operations executive committee, MAX trial management committee, Quasar 2 trial management committee, Da Vinci trial management committee
 Australian New Zealand Clinical Trials Registry 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 (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-Embolicism (INSPIRE) steering committee (chair)
 Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) management committee, executive, samples subcommittee
 National Health and Medical Research Council large-scale clinical trials committee (chair)
 NHMRC Clinical Trials Centre management review committee and scientific advisory committee
 Percutaneous Coronary Angioplasty versus Thrombolysis (PCAT) collaborative group (co-coordinator)
 Polypill trials safety and data monitoring committee (chair)
 Sentinel Biopsy versus Axillary Clearance (SNAC) trial management committee
Trials associate editor
 Virtual Coordinating Centre for International Collaborative Cardiovascular Research (VIGOUR) statistical group (chair) and a VIGOUR leader

Anthony Keech

Asian-Pacific Society of Atherosclerosis and Vascular Disease Prevention executive

committee (APSAVD) (founding member and treasurer)

Asia-Pacific Study on CHD Risk Factor Intervention (ASPAC) management committee (principal investigator and study chairman)

BLISS study safety and data monitoring committee (chairman)

Cardiac Society of Australia and New Zealand clinical trials working group scientific committee (chairman)

Cholesterol Treatment Trialists' Collaboration (joint coordinator and convenor)

Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) management committee (principal investigator and study chairman), ophthalmology substudy committee, scientific substudies committee, cost-effectiveness substudies committee

Heart Protection Study (HPS) steering committee, executive committee (co-principal investigator)

International Journal of Cardiology clinical trials editor

ISIS Trials Group steering committee

Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) study management committee, executive, and quality assurance subcommittee

NHMRC Clinical Trials Centre management review committee and scientific advisory committee

National Health and Medical Research Council training awards committee

NSW Department of Health shared assessment committee

PLoS Medicine editorial board

Prospective Pravastatin Pooling (PPP) project international steering committee

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

University of Sydney College of Health Sciences board of postgraduate studies

University of Sydney Faculty of Medicine budget advisory committee and faculty awards committee, Department of Public Health research committee

Virtual Coordinating Centre for International Collaborative Cardiovascular Research (VIGOUR)

Lisa Askie

Antenatal Magnesium Sulphate prior to Preterm Birth for Neuroprotection of the Fetus infant and child national clinical practice guidelines, executive panel member

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

Cochrane Collaboration handbook advisory group

Cochrane Collaboration prospective meta-analysis methods working group (coordinator)

Early Prevention of Childhood Obesity (EPOCH) prospective meta-analysis collaboration steering committee, member

International Clinical Trials Registry Platform, World Health Organization, best practice group

International Forum for Standards for Research in Children sample size and data safety monitoring committee subcommittee member

Meta-Analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPINO) Collaboration steering group

Neonatal Oxygen Prospective Meta-analysis (NeOProm) collaboration steering committee (chair)

Perinatal Antiplatelet Review of International Studies (PARIS) collaboration steering committee, writing committee (chair)

PLoS ONE academic editor

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

Royal Prince Alfred Hospital clinical trials (ethics) subcommittee

Amy Boland

Australian and New Zealand Germ Cell Trials Group (ANZ GCTG) operations executive committee

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

Chris Brown

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

Australasian Lung Cancer Trials Group scientific advisory committee, operational executive committee

Xanthi Coskinas

Sentinel Node Biopsy versus Axillary Clearance (SNAC) and SNAC 2 trial management committees

Peta Forder

Australasian Lung Cancer Trials Group scientific advisory committee, operational executive committee

Biostatistics Collaboration of Australia teaching committee

Cancer Institute NSW Partnership operational executive committee

Laparoscopic Approach to Carcinoma of the Endometrium (LACE) management committee

Corona Gainford

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

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

Cancer Institute NSW executive committee, infrastructure grant subcommittee and audit subcommittee

TRIPOD trial management committee (chair)

Val GebSKI

Adjuvant chemotherapy versus surgery alone in patients with stage II AND IIIB gastric adenocarcinoma safety and data monitoring commiAustralasian Gastro-Intestinal Trials Group (AGITG) scientific advisory committee and MAX, Da Vinci, ATTAX, ATTAX2, DECO, ABC, GOFUTGO, 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, 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 acientific advisory committee and LATER NeoGem ANZ001 trial management committee

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 PaO₂>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 CO.20 trial management committee

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

Biostatistics Collaboration of Australia teaching committee

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

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

Erica Jobling

Biostatistics Collaboration of Australia writing group

National Curriculum for Entomology evaluation committee

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

Gynaecological 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

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

Australasian Lung Cancer Trials Group (ALTG) operations executive

Australian and New Zealand Germ Cell Trials Group (ANZ GCTG) operations executive

Australian New Zealand Breast Cancer Trials Group (ANZ BCTG)

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

Rebecca Mister

Aspirin to Prevent Recurrent Venous Thromboembolism (ASPIRE) management committee

Julie Martyn

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

Gynaecological Cancer Intergroup (GCIG) harmonization working group

Rhana Pike

Australasian Medical Writers Association executive committee (vice-president)

Ann Ratcliffe

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

Kathleen Scott

NSW Cancer Institute partnership operations executive committee

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

Martin Stockler

Australasian Leukaemia & Lymphoma Group safety and data monitoring committee

Australasian Lung Cancer Trials Group 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 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 member

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

NHMRC 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 Germ Cell Trials Group (ANZ GCTG) 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

Australasian 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, operations executive committee, study coordinators subcommittee (chair), annual scientific meeting committee; and MAX, Quasar 2, ATTAX, DECO, and Da Vinci trial management committees

Cancer Institute NSW infrastructure grant subcommittee

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Australasian Gastro-Intestinal Trials Group (AGITG) operations executive committee, PETACC 6, SCOT and ATTAX 3 trial management committees

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

Australian and New Zealand Urogenital and Prostate Group (ANZUP) operations 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

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

ACADEMIC TEACHING

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

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

University of Sydney Graduate Medical Program

Cardiology training, Royal Prince Alfred Hospital

Clinical tutor, Royal Prince Alfred Hospital

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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

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Advanced clinical trials, Biostatistics Collaboration of Australia

Basic sciences in oncology, NSW Cancer Council

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Principles of statistical inference, Biostatistics Collaboration of Australia

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Basic sciences in oncology, NSW Cancer Council

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Martin Stockler

Australia & Asia-Pacific Clinical Oncology Research Development (ACORD): convener and chair of international steering committee

Making sense of Cancer Clinical Trials for NSW Medical Oncology Trainees (convener)

Clinical epidemiology for physician trainees, Royal Prince Alfred Hospital

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

Medical oncology clinical training, Royal Prince Alfred Hospital

Oncology and palliative care, University of Sydney Medical Program (block chair)

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

Quality of life in oncology, Cancer Institute NSW

Burcu Vachan

Basic sciences in oncology, NSW Cancer Council

Evidence-based medicine, 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 articles

- Agustin C, Grand M, **Gebski V**, Turner S. Radiation therapists' perspective on barriers to clinical trials research. *Journal of Medical Imaging and Radiation Oncology* 2008; 52(2): 178–182.
- Askie LM**, Henderson-Smart DJ, Ko H. Restricted versus liberal oxygen exposure for preventing morbidity and mortality in preterm or low birth weight infants. *Cochrane Database of Systematic Reviews* 2009; (1): CD001077.
- Atlantis E, **Barnes EH**, Ball K. Weight status and perception barriers to healthy physical activity and diet behavior. *International Journal of Obesity* 2008; 32(2): 343–352.
- Barratt AL, **Stockler MR**. Screening for prostate cancer: explaining new trial results and their implications to patients. *Medical Journal of Australia* 2009; 191(4): 226–229.
- Berger JS, Elliott L, Gallup D, Roe M, Granger CB, Armstrong PW, **Simes RJ**, White HD, Van de Werf F, Topol EJ, Hochman JS, Newby LK, Harrington RA, Califf RM, Becker RC, Douglas PS. Sex differences in mortality following acute coronary syndromes. *JAMA* 2009; 302 (8): 874–882.
- Berger JS, Stebbins A, Granger CB, Ohman EM, Armstrong PW, Van de Werf F, White HD, **Simes RJ**, Harrington RA, Califf RM, Peterson ED. Initial aspirin dose and outcome among ST-elevation myocardial infarction patients treated with fibrinolytic therapy. *Circulation* 2008; 117(2): 192–199.
- Beslija S, Bonnetterre J, Burstein HJ, Cocquyt V, Gnant M, Heinemann V, Jassem J, Köstler WJ, Krainer M, Menard S, Petit T, Petruzelka L, Possinger K, Schmid P, Stadtmauer E, **Stockler M**, Van Belle S, Vogel C, Wilcken N, Wilschke C, Zielinski CC, Zwierzina H; for the Central European Cooperative Oncology Group (CECOG). Third consensus on medical treatment of metastatic breast cancer. *Annals of Oncology* 2009; 20(11): 1771–1785.
- Brennan ME, Houssami N, **Lord S**, Macaskill P, Irwig L, Dixon JM, Warren RML, Ciatto S. Magnetic resonance imaging screening of the contralateral breast in women with newly diagnosed breast cancer: systematic review and meta-analysis of incremental cancer detection and impact on surgical management. *Journal of Clinical Oncology* 2009; 27(33): 5640–5649.
- Brown AM, Atyeo J, Field N, Cox J, Bull C, **Gebski VJ**. Evaluation of patient preferences towards treatment during extended hours for patients receiving radiation therapy for the treatment of cancer: A time trade-off study. *Radiotherapy and Oncology* 2009; 90(2):247–252.
- Burgess D**, Hunt D, **Li LP**, **Zannino D**, **Williamson E**, Davis TME, Laakso M, Kesaniemi YA, Zhang J, Sy RW, Lehto S, Mann S, **Keech AC**. Incidence and predictors of silent myocardial infarction in type 2 diabetes and the effect of fenofibrate: an analysis from the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study. *European Heart Journal*. Published online 29 Sept 2009.
- Carrick S**, **Parker S**, Thornton CE, Ghersi D, **Simes J**, **Wilcken N**. Single agent versus combination chemotherapy for metastatic breast cancer. *Cochrane Database of Systematic Reviews* 2009; (2): CD003372.
- Cholesterol Treatment Trialists' (CTT) Collaborators, Kearney PM, Blackwell L, Collins R, **Keech A**, **Simes J**, Peto R, Armitage J, Baigent C. Efficacy of cholesterol-lowering therapy in 18,686 people with diabetes in 14 randomised trials of statins: a meta-analysis. *Lancet* 2008; 371(9607): 117–125.
- Clarke PM, Hayes AJ, Glasziou PG, Scott R, **Simes J**, **Keech AC**. Using the EQ-5D index score as a predictor of outcomes in patients with type 2 diabetes. *Medical Care* 2009; 47(1): 61–68.
- Cools F, **Askie LM**, Offringa M. Prevention Of Ventilator Induced Lung Injury Study Group PC. Elective high-frequency oscillatory ventilation in preterm infants with respiratory distress syndrome: an individual patient data meta-analysis. *BMC Pediatrics* 2009; 9(1):33.
- Cools F, Henderson-Smart DJ, Offringa M, **Askie LM**. Elective high frequency oscillatory ventilation versus conventional ventilation for acute pulmonary dysfunction in preterm infants. *Cochrane Database of Systematic Reviews* 2009; (3):CD000104.
- Cui J, Forbes A, **Kirby A**, Marschner I, **Simes J**, West M, Tonkin A. Parametric conditional frailty models for recurrent cardiovascular events in the LIPID study. *Clinical Trials* 2008; 5: 565–574.
- Cui J, Forbes A, **Kirby A**, **Simes J**, Tonkin A. Laboratory and non-laboratory-based risk prediction models for secondary prevention of cardiovascular disease: the LIPID study. *European Journal of Cardiovascular Prevention and Rehabilitation* 2009; 16(6): 660–668.
- Dietz HP, **Kirby A**, Shek KL, Bedwell PJ. Does avulsion of the puborectalis muscle affect bladder function? *International Urogynecology Journal* 2009; 20(8): 967–972.
- Duric VM**, Butow PN, Sharpe L, **Heritier S**, Boyle F, Beith J, Wilcken NR, Coates AS, **Simes RJ**, **Stockler MR**. Comparing patients' and their partners' preferences for adjuvant chemotherapy in early breast cancer. *Patient Education and Counseling* 2008; 72: 329–245.
- Dwan K, Altman DG, Arnaiz JA, Bloom J, Chan A-W, Cronin E, Decullier E, Easterbrook PJ, Von Elm E, Gamble C, Ghersi D, Ioannidis JPA, **Simes J**, Williamson PR. Systematic review of the empirical evidence of study publication bias and outcome reporting bias. *PLoS One* 2008; 3 (8) e3081
- Dyer SM**, Levison DB, Chen RY, **Lord SJ**, Blamey S. Systematic review of the impact of endoscopic ultrasound on the management of patients with esophageal cancer. *International Journal Technology Assessment in Health Care* 2008; 24(1): 25–35.
- Friedlander M, Butow P, **Stockler M**, **Gainford C**, **Martyn J**, Oza A, Donovan H, Miller B, King M. Symptom control in patients with recurrent ovarian cancer: measuring the benefit of palliative chemotherapy in women with platinum refractory/resistant ovarian cancer. *International Journal of Gynecological Cancer* 2009; 19: S44–S48.
- Gainford MC**, Yang CH, Liu MY, **Stockler M**. Translation and cultural adaptation of the patient disease and treatment assessment form; a novel quality of life instrument for use in Taiwan. *Asia-Pacific Journal of Clinical Oncology* 2008; 4: 149–156.
- Gill PG, Wetzig N, **Gebski V**, **Stockler M**, Ung O, Campbell I, **Simes J**, and the SNAC Trial Group. Sentinel-lymph-node-based management or routine axillary clearance? One-year outcomes of sentinel node biopsy versus axillary clearance (SNAC): a randomized controlled surgical trial. *Annals of Surgical Oncology* 2009; 16: 266–275.
- Glasziou PP, Irwig L, Heritier S, **Simes RJ**, Tonkin A; LIPID Study Investigators. Monitoring cholesterol levels: measurement error or true change? *Annals of Internal Medicine* 2008;148(9): 656–661.
- Goodwin A, **Parker S**, Ghersi D, **Wilcken N**. Post-operative radiotherapy for ductal carcinoma in situ of the breast — systematic review of the randomised trials. *Breast* 2009; 18(3): 143–149.
- Goodwin A, **Parker S**, Ghersi D, **Wilcken N**. Postoperative radiotherapy for ductal carcinoma in situ of the breast. *Cochrane Database of Systematic Reviews* 2009; (3): CD000563.
- Greaves J, Glare P, Kristjanson LJ, **Stockler M**, Tattersall MH. Undertreatment of nausea and other symptoms in hospitalized cancer patients. *Supportive Care in Cancer* 2009; 17(4): 461–464.

Green MD, Francis PA, **GebSKI V**, Harvey V, Karapetis C, Chan A, Snyder R, Fong A, Basser R, Forbes JF; on behalf of the Australian New Zealand Breast Cancer Trials Group. Gefitinib treatment in hormone-resistant and hormone receptor-negative advanced breast cancer. *Annals of Oncology* 2009; 20 (11): 1813–1817.

Grimison P, Simes RJ, Hudson HM, Stockler MR. Deriving a patient-based utility index from a cancer-specific quality of life questionnaire. *Value in Health* 2009; 12(5): 800–807. **Grimison, PS, Simes RJ, Hudson HM, Stockler MR.** Preliminary validation of an optimally weighted patient-based utility index by application to randomised trials in breast cancer. *Value in Health* 2009; 12(6): 967–976.

Grobler L, Siegfried N, **Askie L**, Hooft L, Tharyan P, Antes G. National and multinational prospective trial registers. *Lancet* 2008 372 (9645): 1201–1202.

Hackett ML, Anderson CS, House A, **Halteh C.** Interventions for preventing depression after stroke. *Cochrane Database of Systematic Reviews* 2008; (3): CD003689.

Hackett ML, Anderson CS, House AO, **Halteh C.** Interventions for preventing depression after stroke. *Stroke* 2009; 40(7): e485–486.

Hayes AJ, Clarke PM, Glasziou PG, **Simes RJ, Drury PL, Keech AC.** Can self-rated health be used for risk prediction in patients with type 2 diabetes? *Diabetes Care* 2008; 31(4): 795–797.

Heller GZ, Forbes AB, Dear KBG, **Jobling E;** for the BCA writing group. Biostatistics @ distance: a model for successful multi-institutional delivery. *American Statistician* 2008; 62(4): 321–329.

Hicks SC, James RE, **Wong N, Tebbutt NC, Wilson K;** on behalf of the Australasian Gastro-Intestinal Trials Group. A case study evaluation of ethics review systems for multicentre clinical trials. *Medical Journal of Australia* 2009; 191(5): 280–282.

Hiukka A, Westerbacka J, Leinonen ES, Watanabe H, Wiklund O, Hulten LM, Salonen JT, Tuomainen TP, Yki-Järvinen H, **Keech AC, Taskinen MR.** Long-term effects of fenofibrate on carotid intima-media thickness and augmentation index in subjects with type 2 diabetes mellitus. *Journal of the American College of Cardiology* 2008; 52(25): 2190–2197.

Houssami N, Ciatto S, Macaskill P, **Lord SJ, Warren R, Dixon JM, Irwig L.** Accuracy and surgical impact of MRI in breast cancer staging: Systematic review and meta-analysis in detection of multifocal and multicentric cancer. *Journal of Clinical Oncology* 2008; 26(19): 3248–3258.

Houssami N, **Lord SJ, Ciatto S.** Breast cancer screening: emerging role of new imaging techniques as adjuncts to mammography. *Medical Journal of Australia* 2009; 190(9): 493–498.

Huang RL, Torzillo PJ, Hammond VA, Coulter ST, **Kirby AC.** Epidemiology of sexually transmitted infections on the Anangu Pitjantjatjara Yankunytjatjara Lands: results of a comprehensive control program. *Medical Journal of Australia* 2008; 189(8): 442–445.

Huang RL, Torzillo PJ, **Kirby AC.** Epidemiology of sexually transmitted infections on the Anangu Pitjantjatjara Yankunytjatjara Lands: results of a comprehensive control program — a postscript. *Medical Journal of Australia* 2008; 189(8): 446.

Karapetis CS, Khambata-Ford S, Jonker DJ, O’Callaghan CJ, Tu D, Tebbutt NC, **Simes RJ, Chalchal H, Shapiro JD, Robitaille S, Price TJ, Shepherd L, Au HJ, Langer C, Moore MJ, Zalcberg JR.** K-ras mutations and benefit from cetuximab in advanced colorectal cancer. *New England Journal of Medicine* 2008; 359(17): 1757–1765.

Keech A, Horowitz JD. Cost-effectiveness considerations of cardiovascular therapeutics. *Heart, Lung and Circulation* 2009; 18(2): 118–122.

Keech AC, Mitchell P. FIELD study revealed fenofibrate reduced need for laser treatment for diabetic retinopathy. *Supplement to Review of Endocrinology* March 2008:1-15.

King MT, **Stockler MR, Cella DF, Osoba D, Eton DT, Thompson J, Eisenstein AR.** Meta-analysis provides evidence-based effect sizes for a cancer-specific quality-of-life questionnaire, the FACT-G. *Journal of Clinical Epidemiology*. Published online 26 Aug 2009.

Lambert G, Ancellin N, Charlton F, Comas Cohn JS, Rye KA, Barter PJ. Plasma PCSK9 concentrations correlate with LDL and total cholesterol in diabetic patients and are decreased by fenofibrate treatment. *Clinical Chemistry* 2008; 54(6):1038–1045.

Lee BB, King MT, Simpson JM, Haran MJ, **Stockler MR, Marial O, Salkeld G.** Validity, responsiveness, and minimal important difference for the SF-6D health utility scale in a spinal cord injured population. *Value in Health* 2008; 11(4) 680–688.

Lee C, **Lord SJ, Coates AS, Simes RJ.** Molecular biomarkers to individualise treatment: assessing the evidence. *Medical Journal of Australia* 2009; 190 (11): 631–636.

Lee CK, Lord SJ, Stockler MR, Coates AS, GebSKI V, Simes RJ. Historical cross-trial comparisons for competing treatments in advanced breast cancer—an empirical analysis of bias. *European Journal of Cancer*. Published online 23 Dec 2009.

Lord SJ, Bernstein L, Johnson KA, Malone KE, McDonald JA, Marchbanks PA, Simon MS, Strom BL, Press MF, Folger SG, Burkman RT, Deapen D, Spirtas R, Ursin G. Breast cancer risk and hormone receptor status in older women by parity, age of first birth, and breastfeeding: a case-control study. *Cancer Epidemiology, Biomarkers & Prevention* 2008; 17(7): 1723–1730.

Lord SJ, Irwig L, Bossuyt PMM. Using the principles of randomized controlled trial design to guide test evaluation. *Medical Decision Making* 29(5): E1–E12.

Mittmann N, Au HJ, Tu D, O’Callaghan CJ, Isogai PK, Karapetis CS, Zalcberg JR, Evans WK, Moore MJ, Siddiqui J, Findlay B, Colwell B, **Simes J, Gibbs P, Links M, Tebbutt NC, Jonker DJ;** Working Group on Economic Analysis of the National Cancer Institute of Canada Clinical Trials Group—Australasian Gastrointestinal Interest Group. Prospective cost-effectiveness analysis of cetuximab in metastatic colorectal cancer: evaluation of National Cancer Institute of Canada Clinical Trials Group CO.17 trial. *Journal of the National Cancer Institute* 2009; 101(17): 1182–1192.

Noushi F, Spillane AJ, Uren RF, **GebSKI V.** Internal mammary node metastasis in breast cancer: Predictive models to determine status and management algorithms. *European Journal of Surgical Oncology*. Published online 19 Oct 2009.

Nowak AK, Cebon J, **Hargreaves C, Dhillon H, Findlay M, GebSKI V, Stockler MR.** Assessment of health-related quality of life and patient benefit as outcome measures for clinical trials in hepatocellular carcinoma. *Asia-Pacific Journal of Clinical Oncology* 2008; 4: 55–67.

O’Connell RI, Hudson HM. Risk of mortality after acute myocardial infarction: performance of model updating methods for application in different geographical regions. *Computational Statistics and Data Analysis* 2009; 53(3): 834–846.

Oddone N, Morgan GJ, Palme CE, Perera L, Shannon J, Wong E, **GebSKI V, Veness MJ.** Metastatic cutaneous squamous cell carcinoma of the head and neck: the immunosuppression, treatment, extranodal spread, and margin status (ITEM) prognostic score to predict outcome and the need to improve survival. *Cancer* 2009; 115(9): 1883–1891.

Rajamani K, Colman PG, Li LP, Best JD, Voysey M, D’Emden MC, Laakso M, Baker JR, Keech AC; on behalf of the FIELD study investigators. Effect of fenofibrate on amputation events in people with type 2 diabetes mellitus (FIELD study): a prespecified analysis of a randomised controlled trial. *Lancet* 2009; 373(9677): 1780–1788.



Scott R, O'Brien R, Fulcher G, **Pardy C**, d'Emden M, **Tse D**, Taskinen MR, Ehnholm C, **Keech A**; on behalf of the FIELD Study Investigators. The effects of fenofibrate treatment on cardiovascular disease risk in 9795 people with type 2 diabetes and various components of the metabolic syndrome: the FIELD study. *Diabetes Care* 2009; 32(3): 493–498.

Shakespeare TP, **Gebski V**, Tang J, Lim K, Lu JJ, Xiaojian Zhang, Guoliang Jiang. Influence of the way results are presented on research interpretation and medical decision making: the PRIMER Collaboration randomized studies. *Medical Decision Making* 2008; 28(1): 127–137.

Smith MJ, Gill PG, Wetzig N, **Sourjina T**, **Gebski V**, Ung O, Campbell I, Kollias J, **Coskinas X**, Macphee A, Young L, **Simes RJ**, **Stockler MR**; Royal Australasian College of Surgeons SNAC Trial Group. Comparing patients' and clinicians' assessment of outcomes in a randomised trial of sentinel node biopsy for breast cancer (the RACS SNAC trial). *Breast Cancer Research and Treatment* 2009; 117: 99–109.

Söderbergh S, Colquhoun D, **Keech A**, Yallop J, **Barnes EH**, **Pollicino C**, **Simes J**, Tonkin AM, Nestel P. Leptin, but not adiponectin, is a predictor of recurrent cardiovascular events in men: results from the LIPID study. *International Journal of Obesity* 2009; 33: 123–130.

Soon YY, **Stockler MR**, **Askie LM**, Boyer MJ. Duration of chemotherapy for advanced non-small-cell lung cancer: a systematic review and meta-analysis of randomized trials. *Journal of Clinical Oncology* 2009; 27: 3277–3283.

Spillane AJ, Noushi F, Cooper RA, **Gebski V**, Uren RF. High-resolution lymphoscintigraphy is essential for recognition of the significance of internal mammary nodes in breast cancer. *Annals of Oncology* 20(6): 977–984.

Stewart RA, North FM, Sharples KJ, **Simes RJ**, Tonkin AM, White HD; for the Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID) study investigators. Differences in cardiovascular mortality between Australia and New Zealand according to socioeconomic status: findings from the Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) study. *New Zealand Medical Journal* 2008; 121(1269): 11–23.

Stockler MR, March L, Lindley RI, Mellis C. ACP Journal Club. Students' PEARLS: successfully incorporating evidence-based medicine in medical students' clinical attachments. *Annals of Internal Medicine ACP Journal Club* 2009; 150(8): JC4-2–JC4-3.

Tai B, De Stavola B, de Gruttola V, **Gebski V**, Machin D. First-event or marginal estimation of cause-specific hazards analysing correlated multivariate failure-time data? *Statistics in Medicine* 2008; 27: 922–936.

Tantipalakorn C, Robertson G, Marsden DE, **Gebski V**, Hacker NF. Outcome and patterns of recurrence for International Federation of Gynecology and Obstetrics (FIGO) stages I and II squamous cell vulvar cancer. *Obstetrics and Gynecology* 2009; 113(4): 895–901.

Taskinen MR, Sullivan DR, Ehnholm C, Whiting M, **Zannino D**, **Simes RJ**, **Keech AC**, Barter PJ; for the FIELD study investigators. Relationships of HDL cholesterol, ApoA-I, and ApoA-II with homocysteine and creatinine in patients with type 2 diabetes treated with fenofibrate. *Arteriosclerosis, Thrombosis and Vascular Biology* 2009; 29(6): 950–955.

Urwiler N, **Staub LP**, Beran D, Deplazes M, **Lord SJ**, Alberio L, Theiler L, Greif R. Is perioperative point-of-care prothrombin time testing accurate compared to the standard laboratory test? *Thrombosis and Haemostasis* 2009; 102(4): 779–786.

Urwiler N, Trell S, Theiler L, Jüni P, **Staub LP**, Luyet C, Alberio L, Stricker K, Greif R. Does point of care prothrombin time measurement reduce the transfusion of fresh frozen plasma in patients undergoing major surgery? The POC-OP randomized-controlled trial. *Trials* 2009; 10: 107.

Veness M, Foote M, **Gebski V**, Poulsen M. The role of radiotherapy alone in patients with Merkel cell carcinoma: reporting the Australian experience of 43 patients. *International Journal of Radiation Oncology Biology Physics*. Published online 23 Nov 2009.

Veness MJ, Chong L, Tiver K, **Gebski V**. Basal cell carcinoma of the nose: an Australian and New Zealand radiation oncology patterns-of-practice study. *Journal of Medical Imaging and Radiation Oncology* 2008; 52(4): 382–393.

Wang W, Do V, Hogg R, Wain G, Brand A, Bull C, Stenlake A, **Gebski V**. Uterine papillary serous carcinoma: patterns of failure and survival. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2009; 49(4): 419–425.

West MJ, Nestel PJ, **Kirby AC**, Schnabel R, Sullivan D, **Simes RJ**, **Pollicino C**, Lubos E, Münzel TF, White HD, Tonkin AM, Bickel C, Tired L, Blankenberg S; for the LIPID Study Investigators. The value of N-terminal fragment of brain natriuretic peptide and tissue inhibitor of metalloproteinase-1 levels as predictors of cardiovascular outcome in the LIPID study. *European Heart Journal* 2008; 29: 923–931.

Letters

Kearney PM, **Keech A**, **Simes J**, Collins R, Baigent C; on behalf of the Cholesterol Treatment Trialists' (CTT) Collaboration. Statins and diabetes — authors' reply. *Lancet* 2008; 371(9626): 1752.

Keech A, Mitchell P, Summanen P, Davis T, Simes R. Fenofibrate and diabetic retinopathy — authors' reply. *Lancet* 2008; 371(9614): 722.

Soon YY, **Stockler MR**, **Askie LM**, Boyer MJ. Reply to A. Sasse et al. *Journal of Clinical Oncology*. Published online 2 Nov 2009: e254.

Reports

Dyer S, **Lord S**, **Wortley S**, Howard K, Canfell K, Smith M, Bin Lew J, Creighton P, Jung Kang Y, Clements M, and the Medical Services Advisory Committee. *Human papillomavirus triage test for women with possible or definite low-grade squamous intra-epithelial lesions*. Canberra: Department of Health and Ageing; 2009.

Dyer S, **Lord S**, **Wortley S**, Howard K, Canfell K, Smith M, Bin Lew J, Creighton P, Jung Kang Y, Clements M, and the Medical Services Advisory Committee. *Automation-assisted and liquid-based cytology for cervical cancer screening*. Canberra: Department of Health and Ageing; 2009.

Dyer S, **Walleser S**, **Lord S**, Howard K, **Lei W**, **Marinovich L**, and the Medical Services Advisory Committee. *Positron emission tomography for recurrent colorectal cancer*. Canberra: Department of Health and Ageing; 2008.

Marinovich L, and the Medical Services Advisory Committee. *Optical coherence tomography*. Canberra: Department of Health and Ageing; 2008.

Marinovich L, **Schoeppe S**, **Wortley S**, and the Medical Services Advisory Committee. *Positron emission tomography for lymphoma*. Canberra: Department of Health and Ageing; 2009.

Marinovich L, **Walleser S**, Howard K, **Lei W**, **Lord S**, **Dyer S**, and the Medical Services Advisory Committee. *Positron emission tomography for recurrent melanoma*. Canberra: Department of Health and Ageing; 2008.

Marinovich L, **Walleser S**, **Lei W**, Howard K, **Lord S**, **Dyer S**, and the Medical Services Advisory Committee. *Positron emission tomography for recurrent ovarian cancer*. Canberra: Department of Health and Ageing; 2008.

Staub L, McIsaac M, Wortley S, Dyer S, Marinovich L, and the Medical Services Advisory Committee. *Positron emission tomography for head and neck cancer*. Canberra: Department of Health and Ageing; 2008.

Walleser S, Dyer S, Lei W, Lord S, Porwal M, Fitzgerald P, Howard K, and the Medical Services Advisory Committee. *Positron emission tomography for oesophageal and gastric cancer*. Canberra: Department of Health and Ageing; 2008.

BOOK CHAPTERS

Hudson HM. Power comparisons of parametric and rank tests: grouped outcomes with zero-spike. In: Proceedings of the 18th World IMACS Congress and MODSIM09 International Congress on *Modelling and Simulation*. Eds. Andersen RS, Braddock RD, Newham LTH. Modelling and Simulation Society of Australia; 2009. pp. 143–149. www.mssanz.org.au/modsim09/A2/hudson_hm.pdf

Gherzi D, Berlin J, **Askie L**. Prospective meta-analysis. In: Higgins JPT, Green S, editors. *Cochrane handbook for systematic reviews of interventions 5.0*. Appendix 11b. Chichester, UK: Wiley; 2008.

Glasziou PP, Irwig L, **Heritier S**. Monitoring cholesterol-modifying interventions. In: Glasziou PP, Irwig L, Aronson JK, editors. *Evidence-based medical monitoring: from principles to practice*. Blackwell BMJ Books, 2008. Chapter 18.

Johnson C, **Scott K**. Chapter 54: Australia. In: Klimaszewski AD, Bacon M, Deiningner HE, Ford BA, Westendorp JG, editors. *Manual for clinical trials nursing*. 2nd ed. Pittsburgh, PA: Oncology Nursing Society; 2008. p. 369–376.

ARTICLES BY COLLABORATIVE GROUPS

Au HJ, Karapetis CS, O'Callaghan CJ, Tu D, Moore MJ, Zalberg J, Kennecke H, Shapiro JD, Koski S, Pavlakis N, Charpentier D, Wyld D, Jefford M, Knight GJ, Magoski NM, Brundage MD, Jonker DJ. Health-related quality of life in advanced colorectal cancer patients treated with cetuximab: overall and Kras-specific results of the NCIC CTG and AGITG CO.17 trial. *Journal of Clinical Oncology* 2009; 27(11): 1822–1828.

Forsbloom M, Hiukka A, Leinonen ES, Sundvall J, Groop PH, Taskinen MR. Effects of long-term fenofibrate treatment on markers of renal function in type 2 diabetes: FIELD Helsinki substudy. *Diabetes Care*. Published online 21 Oct 2009.

Heart Protection Study Collaborative Group. Statin cost-effectiveness in the United States for people at different vascular risk levels. *Circulation: Cardiovascular Quality and Outcomes* 2009; 2(2): 65–72.

INIS Study Collaborative Group. International Neonatal Immunotherapy Study: non-specific intravenous immunoglobulin therapy for suspected or proven neonatal sepsis: an international, placebo controlled, multicentre randomised trial. *BMC Pregnancy Childbirth* 2008; 8: 52.

Le Cesne A, Van Glabbeke M, Verweij J, Casali PG, Findlay M, Reichardt P, Issels R, Judson I, Schoffski P, Leyvraz S, Bui B, Hogendoorn PC, Sciot R, Blay JY. Absence of progression as assessed by response evaluation criteria in solid tumors predicts survival in advanced GI stromal tumors treated with imatinib mesylate: the Intergroup EORTC-ISG-AGITG phase III trial. *Journal of Clinical Oncology* 2009;27(24): 3969–3974. [AGITG]

Michael M, Price T, Ngan SY, Ganju V, Strickland AH, Muller A, Khamly K, Milner AD, Dilulio J, Matera A, Zalberg JR, Leong T. A phase I trial of capecitabine + gemcitabine with radical radiation for locally advanced pancreatic cancer. *British Journal of Cancer* 2009; 100 (1): 37–43. [AGITG]

Neoptolemos JP, Stocken DD, Tudur Smith C, Bassi C, Ghaneh P, Owen E, Moore M, Padbury R, Doi R, Smith D, Büchler MW. Adjuvant 5-fluorouracil and folinic acid vs observation for pancreatic cancer: composite data from the ESPAC-1 and -3(v1) trials. *British Journal of Cancer* 2009; 100(2): 246–250. [AGITG]

Nordlinger B, Sorbye H, Glimelius B, Poston GJ, Schlag PM, Rougier P, Bechstein WO, Primrose JN, Walpole ET, Finch-Jones M, Jaec D, Mirza D, Parks RW, Collette L, Praet M, Bethé U, Van Cutsem E, Scheithauer W, Gruenberger T; EORTC Gastro-Intestinal Tract Cancer Group; Cancer Research UK; Arbeitsgruppe Lebermetastasen und-tumoren in der Chirurgischen Arbeitsgemeinschaft Onkologie (ALM-CAO); Australasian Gastro-Intestinal Trials Group (AGITG); Fédération Francophone de Cancérologie Digestive (FFCD). Perioperative chemotherapy with FOLFOX4 and surgery versus surgery alone for resectable liver metastases from colorectal cancer (EORTC Intergroup trial 40983): a randomised controlled trial. *Lancet* 2008; 371(9617): 1007–1016. [AGITG]

Romeo S, Debiec-Rychter M, Van Glabbeke M, Van Paassen H, Comite P, Van Eijk R, Oosting J, Verweij J, Terrier P, Schneider U, Sciot R, Blay J-Y and Hogendoorn PCW, on behalf of the European Organisation for Research and Treatment of Cancer Soft Tissue and Bone Sarcoma Group. Cell cycle/apoptosis molecule expression correlates with imatinib response in patients with advanced gastrointestinal stromal tumors. *Clinical Cancer Research* 2009; 15: 4191–4198. [AGITG]

Sciot R, Debiec-Rychter M, Daugaard S, Fisher C, Collin F, Van Glabbeke M, Verweij J, Blay J-Y, Hogendoorn, PCW; on behalf of the EORTC Soft Tissue and Bone Sarcoma Group, the Italian Sarcoma Group and the Australian Trials Group. Distribution and prognostic value of histopathologic data and immunohistochemical markers in gastrointestinal stromal tumors. An analysis of the EORTC phase III trial of treatment of metastatic GISTs with imatinib mesylate. *European Journal of Cancer* 2008; 44: 1855–1860. [AGITG]

Simpson J, Ryan P, Carlin JB, Gurrin L, Marschner I; for the BCA writing group. Training a new generation of biostatisticians: a successful consortium model. *Journal of Statistics Education* 2009; 17(2). Available at www.amstat.org/publications/jse/v17n2/simpson.html. [BCA]

Tewari N, Gill PG, Bochner MA, Kollias J. Comparison of volume displacement versus circumferential arm measurements for lymphoedema: implications for the SNAC trial. *ANZ Journal of Surgery* 2008; 78(10): 889–893. [SNAC]

Van Cutsem E, Dicato M, Haustermans K, Arber N, Bosset JF, Cunningham D, De Gramont A, Diaz-Rubio E, Ducreux M, Goldberg R, Glynn-Jones R, Haller D, Kang YK, Kerr D, Labianca R, Minsky BD, Moore M, Nordlinger B, Rougier P, Scheithauer W, Schmoll HJ, Sobrero A, Tabernero J, Tempero M, Van de Velde C, Zalberg J. The diagnosis and management of rectal cancer: expert discussion and recommendations derived from the 9th World Congress on Gastrointestinal Cancer, Barcelona, 2007. *Annals of Oncology* 2008; 19(Suppl 6): vi1–vi8. [AGITG]

Abstracts

Alam M, Blinman P, Stockler M. Useful estimates of life expectancy for patients starting first line chemotherapy for advanced non-small-cell lung cancer based on a systematic review of recent randomized trials. Clinical Oncological Society of Australia 35th Annual Scientific Meeting; 18–20 Nov 2008, Sydney

Alam M, Blinman P, Stockler M. Useful estimates of life expectancy for patients starting first line chemotherapy for advanced non-small-cell lung cancer based on a systematic review of recent randomized trials. MOGA/ FRO/NZSO /NZACS Joint Scientific Meeting; 6–9 Aug 2008; Christchurch.



Alam M, Blinman P, Stockler MR. Useful estimates of survival for patients starting first line chemotherapy for advanced non-small-cell lung cancer based on a systematic review of recent randomized trials. 13th World Congress on Lung Cancer; 31 Jul–4 Aug; San Francisco. *Journal of Thoracic Oncology* 2009; 4(9, suppl. 1): S663–S664.

Australasian Gastrointestinal Trials Group; Shannon JA, Goldstein D, **Brown C**, Tebbutt N, Ackland S, Van Hazel G, Abdi E, Jefford M, **Gainford MC**, Jones-Murphy M. A phase II trial of gemcitabine in fixed dose rate infusion combined with low dose cisplatin in patients with inoperable biliary tract carcinomas. *Gastrointestinal Cancers Symposium*; 25–27 Jan 2008; Orlando. Abstract 243.

Åvall-Lundqvist E, Wimberger P, Gladieff L, **GebSKI V**, Huober JB, Floquet A, Fitzharris B, Zeimet AG, Heywood M, Schmalfeldt B. Pegylated liposomal doxorubicin-carboplatin vs paclitaxel-carboplatin in relapsing sensitive ovarian cancer: a 500-patient interim safety analysis of the Calypso GClG Intergroup phase III study. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 5565.

Berger JS, Gallup D, Roe M, Armstrong PW, **Simes RJ**, White HD, Van de Werf F, Topol EJ, Granger CB, Harrington RA, Califf RM, Becker RC, Douglas PS. Sex-based differences in mortality following acute coronary syndromes. Meeting of the Society for Cardiovascular Angiography and Interventions and the American College of Cardiology; 29 Mar–1 Apr 2008; Chicago. *Journal of the American College of Cardiology* 2008; 51(10): A194.

Berger JS, Gallup D, Roe M, Granger CB, Armstrong PW, **Simes RJ**, White HD, Van de Werf F, Topol EJ, Harrington RA, Califf RM, Becker RC, Douglas PS. Sex differences in clinical presentation and angiographic data in acute coronary syndromes. Meeting of the Society for Cardiovascular Angiography and Interventions and the American College of Cardiology; 29 Mar–1 Apr 2008; Chicago. *Journal of the American College of Cardiology* 2008; 51(10): B55–B56.

Best J, Drury P, Kesäniemi YA, Colman P, Scott R, Taskinen MR, **Pardy C, Keech A.** Maintenance of glycemic control in over 4000 people with type 2 diabetes in 3 countries for 5 years with metformin, sulphonylurea and insulin therapy. 68th Scientific Sessions of the American Diabetes Association; 6–10 Jun 2008; San Francisco. *Diabetes* 2008; 57 (suppl 1): A114.

Best JD, Drury P, Davis T, Taskinen MR, Kesäniemi A, **Keech A.** Metformin, sulphonylurea and insulin therapies maintain glycaemic control over five years in 4900 people with type 2 diabetes. 45th General Assembly of the European Association for the Study of Diabetes; 30 Sep–2 Oct 2009; Vienna. *Diabetologia* 2009; 52 (suppl. 1). S93. Abstract 211.

Best JD, Drury P, Davis T, Taskinen MR, Kesäniemi A, **Keech A;** on behalf of the FIELD study investigators. Metformin, sulphonylurea and insulin therapies maintain glycaemic control over five years in 4900 people with type 2 diabetes: the FIELD study. Australian Diabetes Society and Australian Diabetes Educators Association Annual Scientific Meeting; 26–28 Aug 2009; Adelaide.

Blinman P, Alam M, McLachlan S, Duric V, Stockler M. Patients' preferences for chemotherapy in non-small-cell lung cancer: a systematic review. *Clinical Oncological Society of Australia 36th Annual Scientific Meeting*; 17–19 Nov 2009; Gold Coast.

Blinman P, Duric V, Nowak A, Beale P, Clarke S, Briscoe K, Boyce A, Goldstein D, Hudson M, Stockler M. Patients' preferences for adjuvant chemotherapy in early colon cancer: what makes it worthwhile? 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 4050.

Blinman P, Duric V, Nowak A, Beale P, Clarke S, Briscoe K, Boyce A, Goldstein D, Hudson M, Stockler M. Patients' preferences for adjuvant chemotherapy in early colon cancer: what makes it worthwhile? MOGA/FRO/NZSO /NZACS Joint Scientific Meeting; 6–9 Aug 2008; Christchurch.

Blinman P, McLachlan S, Alam M, Duric V, Stockler M. Preferences for adjuvant chemotherapy after surgery for non-small-cell lung cancer: what makes it worthwhile? 2nd Australian Lung Cancer Conference; 21–24 Aug 2008; Gold Coast.

Blinman P, McLachlan SA, Nowak A, Duric V, Wright G, Millward M, Brown C, Coskinas X, Fong K, Stockler M. Clinicians' preferences for adjuvant chemotherapy in non-small-cell lung cancer: what makes it worthwhile? 13th World Conference on Lung Cancer; 31 Jul–4 Aug; San Francisco. *Journal of Thoracic Oncology* 2009; 4(9, Suppl 1): S581–S581

Blinman P, McLachlan SA, Nowak A, Duric V, Wright G, Millward M, Brown C, Coskinas X, Fong K, Stockler M. Clinicians' preferences for adjuvant chemotherapy in non-small-cell lung cancer: what makes it worthwhile? Medical Oncology Group of Australia Annual Scientific Meeting; 12–14 Aug 2009; Canberra.

Blinman P, Stockler M. Phase II trial of a decision aid for adjuvant chemotherapy in early non-small-cell lung cancer. Australia and Asia-Pacific Clinical Oncology Research Development (ACORD) Workshop, 31 Aug–6 Sep 2008; Sunshine Coast.

Chionh F, Handolias D, Poon A, **GebSKI V**, Dayan S, Aly A, Tebbutt N. The difference in standardized uptake value on 18F-FDG-PET before and after pre-operative chemotherapy is a prognostic factor for recurrence and survival in patients with gastroesophageal cancer. ECCO 15–34th ESMO Multidisciplinary Congress; 20–24 Sep 2009; Berlin. *EJC Supplements* 2009; 7(2) 373.

Clarke SJ, **Brown C, Simes J**, Van Hazel G, Jeffery M, Tebbutt N, Ransom D, Buck M, **Boland A**, Zalberg J; Australasian Gastro-Intestinal Trials Group. AGITG DaVINCI Trial: Randomised phase II trial of De Gramont schedule 5-fluorouracil and leucovorin plus irinotecan versus single agent irinotecan in patients with previously treated metastatic colorectal cancer. *Gastrointestinal Cancers Symposium*; 15–17 Jan 2009; San Francisco.

Colman P, **Rajamani K, Li LP, D'Emden M, Voysey M, Keech A;** on behalf of the FIELD study investigators. Benefits of long-term fenofibrate therapy on amputations in type 2 diabetes mellitus in the FIELD trial. 44th Annual Meeting of the European Association for the Study of Diabetes; 7–11 Sep 2008; Rome. *Diabetologia* 2008; 51 (suppl 1): S549–S550. Abstract 1358.

D'Emden M, **Li LP, Zannino D, Best J, Keech AC;** on behalf of the FIELD Study Investigators. Effect of fenofibrate on cardiovascular events and mortality in women with type 2 diabetes: results from the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study. American Diabetes Association 68th Scientific Sessions; 5–9 Jun 2009; New Orleans. [Winner of ADA Michaela Modan Memorial Award]

Drury P, Davis TM, Sullivan D, Best JD, **Donoghoe M, Keech AC;** on behalf of the FIELD study investigators: revention of nephropathy in type 2 diabetes mellitus using fenofibrate: the FIELD study. Australian Diabetes Society and Australian Diabetes Educators Association Annual Scientific Meeting; 26–28 Aug 2009; Adelaide.

Drury PL, **Pardy C, Davis TME, Zannino D, Laakso M, Keech AC;** on behalf of the FIELD study investigators. Reduced renal function and albuminuria in type 2 diabetes independently predict cardiovascular events and mortality even in a low-risk cohort: the FIELD study. American Heart Association Scientific Sessions 2008; 8–12 Nov 2008; New Orleans. *Circulation* 2008; 118 (18, suppl. 2): S1088.

Franco AV, Shek K, **Kirby A**, Fynes MM, Dietz HP. Avulsion injury and levator hiatal ballooning: two independent risk factors for prolapse? 34th Annual IUGA Meeting; 16–20 Jun 2009; Lago di Como, Italy. *International Urogynecology Journal* 2009; 20 (suppl. 2): S178–S179. Abstract 120.

Gainford MC, Stockler MR, Butow P, Boyle F, Sullivan A, Beale P, Pendlebury S, Nowak AK, **Duric VM**. What caused your cancer? A survey of patients with early breast and bowel cancer. MOGA Joint Scientific Meeting; 6–9 Aug 2008; Christchurch.

Gainford MC, Stockler MR, Butow P, Boyle F, Sullivan A, Beale P, Pendlebury S, Nowak AK, **Duric VM**. What caused your cancer? A survey of patients with early breast and bowel cancer. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 9563.

Gao B, Tiley SM, **Gebski V**, Mann G, Kefford R. Correlates of outcome in patients with metastatic melanoma treated with dacarbazine. 33rd Congress of the European Society of Medical Oncology; 12–16 Sep 2008; Stockholm. *Annals of Oncology* 2008; 19 (suppl. 8): 246.

Gill G, **Gebski V**, Wetzig N, Ung O, Campbell I, Collins J, **Sourjina T, Coskinas X, Stockler M, Simes J**. Sentinel node based management causes less arm swelling and better quality of life than routine axillary clearance: 1 year outcomes of the SNAC trial. *Annals of Surgical Oncology* 2008; 15 (suppl. 1): 46.

Goel S, **Simes RJ**, Beith JM. An exploratory analysis of cardiac biomarkers in women receiving trastuzumab. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 20557.

Goldstein D, van Hazel G, Selva-Nayagam S, Ackland S, Shapiro J, Carroll S, **Cummins M, Brown C, Simes RJ**, Spry N. GOFURTO trial: an AGITG multicentre phase II study of fixed dose rate gemcitabine–oxaliplatin integrated with concomitant 5FU and 3D conformal radiotherapy for the treatment of locally advanced pancreatic cancer. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 4616.

Grimison PS, Coates AS, Forbes JF, Cuzick J, Furnival C, Craft PS, Snyder RD, Thornton RM, Lindsay DF, **Simes RJ**; Australian New Zealand Breast Cancer Trials Group. Tamoxifen for the prevention of breast cancer: Importance of specific aspects of health-related quality of life to global health status in the ANZ BCTG substudy of IBIS-1 (ANZ 92P1). 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 1516.

Grimison PS, Coates AS, Forbes JF, Cuzick J, Furnival C, Craft S, Snyder D, Thornton R, Lindsay DF, **Simes RJ**. Tamoxifen for the prevention of breast cancer: importance of specific aspects of health-related quality of life to global health status in the ANZ BCTG substudy of IBIS-1 (ANZ 92P1). COSA-IACR 2008 Joint Scientific Meeting; 18–20 Nov 2008; Sydney.

Grimison PS, Stockler MR, Thomson DB, Olver IN, Harvey VJ, Gurney H, Lewis CR, **Gebski VJ, Boland AL**, Toner GC; Australia and New Zealand Germ Cell Trials Group. Comparison of two standard chemotherapy regimens for good-prognosis germ-cell tumours: updated analysis of a randomised trial with 8 years follow-up. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 5016.

Grimison PS, Tebbutt N, Price T, van Hazel G, **Wilson K**, Tunney V, **Stockler M**. Comparing utilities for advanced colorectal cancer valued from societal and cancer-patients' perspectives using baseline data from the MAX study of the Australasian Gastro-Intestinal Trials Group (AGITG). Gastrointestinal Cancers Symposium; 25–27 Jan 2008; Orlando. Abstract 449.

Hyams DM, Leichman GC, Klein P, Rietchel P, Levine EG, **Gebski VJ**, Kelley MA. Phase II trial of neoadjuvant pegylated liposomal doxorubicin with paclitaxel and trastuzumab in patients with operable Her2-positive breast cancer. CTRC-AACR San Antonio Breast Cancer Symposium; 9–13 Dec 2009; San Antonio. *Cancer Research* 2009; 69(24): 570S.

Jenkins A, Best J, Otvos J, **Forder P**, Whiting M, Ehnholm C, **Zannino D**, Barter P, Sullivan D, **Keech A**, for the FIELD Study Investigators. Favourable effects of fenofibrate on NMR-determined lipoprotein subclasses in type 2 diabetes patients from the FIELD study. European Atherosclerosis Society Scientific Meeting; 26–29 Apr 2008; Istanbul.

Jonker D, Karapetis C, Harbison C, O'Callaghan C, Tu D, **Simes J**, Xu LA, Moore M, Zalberg J, Khambata-Ford S. High epiregulin gene expression plus K-ras wild-type status predict for cetuximab benefit in the treatment of advanced colorectal cancer: results from NCIC CTG CO.17: a phase III trial of cetuximab versus best supportive care. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 4016.

Karapetis C, Khambata-Ford S, Jonker D, O'Callaghan C, Tu D, **Vachan B, Simes J**, Langer C, Moore M, Zalberg J. K-ras mutation status is a predictive biomarker for cetuximab benefit in the treatment of advanced colorectal cancer — results from NCIC CTG CO.17: a phase III trial of cetuximab versus best supportive care. 2008 Congress of the European Society of Medical Oncology; 12–16 Sep 2008; Stockholm. *Annals of Oncology* 2008; 19: viii2. Abstract LBA6.

Keech A, Drury P, **Ting R**, Davis T, **Donoghoe M**, Laakso M, Whiting M, **Rajamani K**, Scott R, D'Emden M; on behalf of the FIELD study investigators. Effects of fenofibrate on measures of renal function in type 2 diabetes mellitus: the FIELD study. American Society of Nephrology Renal Week; 27 Oct–1 Nov 2009; San Diego.

Keech AC, Drury P, Davis TM, **Donoghoe M**, Laakso M, Whiting M, Scott R, D'Emden M; on behalf of the FIELD study investigators. Protection against nephropathy with fenofibrate in type 2 diabetes mellitus: the FIELD study. American Heart Association Scientific Sessions; 14–18 Nov 2009; Orlando. *Circulation* 2009; 120 (18, suppl. 2): S419–S420.

Lee C. Breast cancer with triple-negative phenotype confers poorer pathological characteristics and survival outcomes. Clinical Oncological Society of Australia 35th Annual Scientific Meeting; 18–20 Nov 2008, Sydney.

Lee C. Clinico-pathologic characteristics and survival outcomes in triple-negative breast cancer — a retrospective analysis of a single centre experience. Medical Oncology Group Australia Annual Scientific Meeting; 6–9 Aug 2008; Christchurch.

Lee CK, Lord SJ, Stockler MR, Gebski V, Coates AS, **Simes RJ**; on behalf of Australian and New Zealand Breast Cancer Trials Group (ANZBCTG). Historical cross-trial comparisons for competing treatments in advanced breast cancer—an empirical analysis of bias. Australasian Society for Breast Disease Seventh Scientific Conference; 1–3 Oct 2009; Gold Coast.



- Lee CK, Stockler M, GebSKI V**, Coates A, **Simes RJ**; Australian New Zealand Breast Cancer Trials Group. Outcomes of first-line chemotherapy for advanced breast cancer in women with good versus poor quality of life at baseline. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 1036.
- Lee CK, Stockler MR, Hudson M**, Coates AS, **GebSKI V**, **Lord S**, Richard SJ. Predicting survival time in women starting first line chemotherapy for advanced breast cancer. CTRC-AACR San Antonio Breast Cancer Symposium; 9–13 Dec 2009; San Antonio. *Cancer Research* 2009; 69(24):7285–7295.
- Marinovich L**. Optical coherence tomography for macular oedema: assessment of a proposed new gold standard. 6th Annual Meeting of Health Technology Assessment International; 21–24 Jun 2009; Singapore.
- Mister R, Scott K, Smith P, Vachan B, Hague W**. Streamlining ethics applications since 2007: the CTC experience. *Clinical Research Excellence* 08; 7–9 Aug 2008; Brisbane.
- Mittmann N, Au HJ, Tu D, O'Callaghan CJ, Karapetis CS, Moore MJ, Zalberg J, **Simes J**, Evans WK, Jonker DJ. A prospective economic analysis of cost-effectiveness of cetuximab for metastatic colorectal cancer patients from the NCIC CTG and AGITG CO.17 trial. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 6528.
- Noushi F, **GebSKI V**, Spillane A, Uren R. Internal mammary sentinel lymph nodes in breast cancer: evaluation of a single institution experience and predictive analysis of survival outcomes. 6th Biennial International Sentinel Node Society Meeting; 18–20 Feb 2008; Sydney. *Annals of Surgical Oncology* 2008; 15 (suppl. 1): 13–14.
- Noushi F, **GebSKI V**, Uren R, Spillane A. Internal mammary lymph node metastasis in breast cancer: predictive modeling on the frequency and survival outcomes. 14th Congress of the European Society of Surgical Oncology; 10–12 Sep 2008; the Hague.
- O'Brien R, Scott R, Best J, Taskinen M-R, **Pardy C**, Ehnholm C, **Keach A**; on behalf of the FIELD study investigators. The clinical value of metabolic syndrome and its components in established type 2 diabetes mellitus: the FIELD trial. 44th Annual Meeting of the European Association for the Study of Diabetes; 7–11 Sep 2008; Rome. *Diabetologia* 2008; 51 (suppl 1): S549–S550. Abstract 1358.
- O'Callaghan CJ, Tu D, Karapetis CS, Au HJ, Moore MJ, Zalberg JR, Trudeau M, **Yip D**, **Vachan B**, Jonker DJ. The relationship between the development of rash and clinical and quality of life outcomes in colorectal cancer patients treated with cetuximab in NCIC–CTC CO.17. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 4130.
- Price T, **GebSKI V**, van Hazel G, Robinson B, Broad A, Ganju V, Chua Y, **Wilson K**, **Tunney V**, Tebbutt N. International multicentre randomised phase II–III study of capecitabine, bevacizumab and mitomycin C in metastatic colorectal cancer: final safety analysis of the AGITG MAX trial. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 4029.
- Price TJ, **GebSKI V**, van Hazel G, Robinson B, Broad A, Ganju V, Chua Y, **Wilson K**, **Tunney V**, Tebbutt N. AGITG MAX trial—capecitabine, bevacizumab, and mitomycin C in metastatic colorectal cancer: safety analysis of 400 patients in an international multi-centre randomised phase II–III study. *Gastrointestinal Cancers Symposium*; 25–27 Jan 2008; Orlando. Abstract 449.
- Price TJ, **GebSKI V**, van Hazel G, Robinson B, Broad A, Ganju V, Chua Y, **Wilson K**, **Tunney V**, Tebbutt N. Safety analysis of an international multi-centre randomised phase II–III study of capecitabine, bevacizumab and mitomycin C in metastatic colorectal cancer: AGITG MAX trial. 33rd Congress of the European Society for Medical Oncology; 12–16 Sep 2008; Stockholm. *Annals of Oncology* 2008; 19 (suppl. 8): viii127. Abstract 365P.
- Pujade-Lauraine E, Mahner S, Kaern J, **GebSKI V**, Heywood M, Vasey P, Reinthaller A, Vergote I, Pignata S, Ferrero A. A randomized, phase III study of carboplatin and pegylated liposomal doxorubicin versus carboplatin and paclitaxel in relapsed platinum-sensitive ovarian cancer: CALYPSO study of the Gynecologic Cancer Intergroup (GCIg). Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 18s. Abstract LBA5509.
- Rajamani K, Li LP**, Best JD, **Voysey M**, D'Emden M, Laakso M, Baker J, **Ting R**, **Keach K**; on behalf of the FIELD study investigators. Predictors of lower limb amputation in patients with type 2 diabetes mellitus: the FIELD study. Australian Diabetes Society and Australian Diabetes Educators Association Annual Scientific Meeting; 26–28 Aug 2009; Adelaide.
- Rajamani K, Li LP**, Kesäniemi YA, **Voysey M**, Hunt D, Drury P, D'Emden MC, Colman PG, Taskinen MR, **Keach AC**; on behalf of the FIELD study investigators. Lower-limb amputation in patients with type 2 diabetes mellitus: factors predicting risk in the FIELD study. American Heart Association Scientific Sessions; 14–18 Nov 2009; Orlando. *Circulation* 2009; 120 (18, suppl. 2): S431.
- Shannon JA, Goldstein D, **Brown C**, Tebbutt N, Ackland S, van Hazel G, Abdi E, Jefford M, **Gainford MC**, **Jones-Murphy M**. A phase II trial of gemcitabine in fixed dose rate infusion combined with low dose cisplatin in patients with inoperable biliary tract carcinomas. *Gastrointestinal Cancers Symposium*; 25–27 Jan 2008; Orlando.
- Simes RJ, Voysey M, O'Connell R**, Glasziou PP, Best JD, Scott R, Sullivan DR, Ehnholm C, **Keach AC**; on behalf of the FIELD study investigators. Larger effects of fenofibrate on CVD in marked diabetic dyslipidemia are not explained by higher use of statin. American Heart Association Scientific Sessions; 14–18 Nov 2009; Orlando. *Circulation* 2009; 120 (18, suppl. 2): S419.
- Staub LP, Dyer SM, Lord SJ**. Assembling the evidence for new cancer staging tests: a systematic review of positron emission tomography (PET) in patients with colorectal liver metastases. *Methods for Evaluating Medical Tests Symposium*; 25 July 2008; Birmingham, UK.
- Staub LP, Lord SJ**, Houssami N. Including evidence about the impact of tests on patient management in systematic reviews of diagnostic test accuracy. 17th Cochrane Colloquium; 11–14 October; Singapore. [Thomas C Chalmers MD Award for best poster presentation]
- Staub LP, Lord SJ**, Melloh M, Barz T. Designing clinically relevant test accuracy studies when the perfect reference standard does not exist and blinding is not possible. 18th Australasian Epidemiological Association Annual Scientific Meeting; 30 Aug–1 Sep 2009; Dunedin. [Received AEA travel award]
- Staub LP, Wortley S, Mclsaac M, Dyer S**. Beyond test accuracy: data collection helps address some uncertainties in positron emission tomography (PET). 6th Annual Meeting of Health Technology Assessment International; 21–24 Jun 2009; Singapore.
- Stockler M, Grimison P**, Price T, van Hazel G, **Wilson K, Tunney V**, Tebbutt N. Comparing utilities for advanced colorectal cancer valued from societal and cancer-patients' perspectives using baseline data from the MAX study of the Australasian Gastro-Intestinal Trials Group. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago.

Sullivan DR, **Donoghoe M**, Bosnjak D, **Li LP**, **Simes J**, George J, **Keech A**. Long-term fenofibrate use is associated with reduced prevalence of liver enzyme elevation in the FIELD study. XV International Symposium on Atherosclerosis; 14–18 Jun 2009; Boston.

Taskinen MR, Ehnholm C, Sullivan D, Best JD, Mann K, **Simes RJ**, Barter P, **Keech AC**; on behalf of the FIELD study investigators. Apo B/apo A-I ratio does not override the traditional lipid ratios as determinants of CVD risk in patients with type 2 diabetes in the FIELD study. American Heart Association Scientific Sessions; 14–18 Nov 2009; Orlando. *Circulation* 2009; 120 (18, suppl. 2): S547.

Tebbutt NC, **Gebski V**, **Wilson K**, **Cummins M**, Chua Y, Robinson B, Broad A, Cunningham D, **Simes J**, Price T. International randomised phase III study of capecitabine, bevacizumab and mitomycin C in first-line metastatic colorectal cancer: final results of the AGITG MAX trial. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 4023.

Tebbutt NC, **Gebski V**, **Wilson K**, **Cummins M**, Chua Y, Robinson B, Broad A, Cunningham D, **Simes J**, Price T. International randomised phase III study of capecitabine, bevacizumab and mitomycin C in first line treatment of metastatic colorectal cancer: final results of the AGITG MAX trial. ECCO 15–ESMO 34 Multidisciplinary Congress; 20–24 Sep 2009; Berlin.

Tebbutt NC, **Sourjina T**, Strickland AH, Van Hazel G, Pavlakis N, Ganju V, Murone C, MacGregor D, **Gebski V**, **Cummins M**. ATTAX2—docetaxel plus cetuximab as second-line treatment for docetaxel refractory oesophago-gastric cancer: final results of a multi-center phase II trial by the AGITG. Gastrointestinal Cancers Symposium; 25–27 Jan 2008; Orlando. Abstract 87.

Tebbutt NC, **Sourjina T**, Strickland AH, Van Hazel G, Pavlakis N, Ganju V, Murone C, MacGregor D, **Gebski V**, **Cummins M**. ATTAX2—docetaxel plus cetuximab as second-line treatment for docetaxel refractory oesophago-gastric cancer: final results of a multi-center phase II trial by the AGITG. 44th Annual Meeting of the American Society of Clinical Oncology; 30 May–3 Jun 2008; Chicago. *Journal of Clinical Oncology* 2008; 26 (May 20). Abstract 15554.

Ting R, **Li LP**, Davis TM, **Donoghoe M**, Best J, **Gebski V**, **Rajamani K**, **Keech AC**; on behalf of the FIELD study investigators. Clinical and biochemical indicators of microvascular complications of type 2 diabetes mellitus: the FIELD study. Australian Diabetes Society and Australian Diabetes Educators Association Annual Scientific Meeting; 26–28 Aug 2009; Adelaide.

Ting R, **Li LP**, Davis TM, **O'Connell R**, **Gebski V**, Best JD, Kesäniemi A, Laakso M, **Keech AC**; on behalf of the FIELD study investigators. Risk predictors of first microvascular complications in type 2 diabetes mellitus: the FIELD study. American Heart Association Scientific Sessions; 14–18 Nov 2009; Orlando. *Circulation* 2009; 120 (18, suppl. 2): S496.

Vasey P, Largillier R, Gropp M, **Gebski V**, Sandvei R, Elit L, Angleitner-Boubezine L, Reed N, Pignata S, Ferrero AM. A GCGI randomized phase III study of carboplatin and pegylated liposomal doxorubicin (C-D) vs carboplatin and paclitaxel (C-P): CALYPSO results in partially platinum-sensitive ovarian cancer patients. ECCO 15–34th ESMO Multidisciplinary Congress; 20–24 Sep 2009; Berlin. *EJC Supplements* 2009; 7(3): 11. Abstract 18LBA.

Wetzig N, **Brown C**, **Gebski V**, Gill P, **Stockler M**. Relationship between clinicians' measurements of arm volume and patients' ratings of arm-swelling in the RACS SNAC trial of sentinel node based management for early breast cancer. 6th Biennial International Sentinel Node Society Meeting; 18–20 Feb 2008; Sydney.

Wilson K, **Munro SC**, **James R**, Tebbutt N, Price TJ, Shapiro J, **Wong N**. Comparison of ethical and regulatory processes in two multicentre, multiregional oncology clinical trials: an Australian perspective. *Clinical Research Excellence* 08; 7–9 Aug 2008; Brisbane.

ABSTRACTS BY COLLABORATIVE GROUPS

Ngan SY, McLachlan SA, Fisher R, Burmeister B, Joseph D, Hruby G, Ackland S, Ganju V, Mackay J, Solomon M. A comparison of quality of life in patients with rectal cancer receiving short course versus long course preoperative radiation. A Trans-Tasman Radiation Oncology Group, Australasian Gastrointestinal Trials Group, Colorectal Surgical Society of Australia and New Zealand, and Royal Australasian College of Surgeons trial. Royal Australian and New Zealand College of Radiologists 59th Annual Scientific Meeting; 16–19 Oct 2008; Adelaide. [AGITG]

Kaye SB, Vasey P, Rustin G, Pledge S, Williams C, Gabra H, Skailes G, Lamont A, Lewsley L, Paulj; Scottish Gynaecological Cancer Trials Group. Randomized trial of inpatient dose escalation of single agent carboplatin as first-line treatment for advanced ovarian cancer: An SGCTG study (SCOTROC 4). Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 5537. [AGITG]

Neoptolemos J, Büchler M, Stocken DD, Ghaneh P, Smith D, Bassi C, Moore M, Cunningham D, Dervenis C, Goldstein D. ESPAC-3(v2): a multicentre, international, open label, randomised controlled phase III trial of adjuvant 5-fluorouracil/folinic acid versus gemcitabine in patients with resected pancreatic ductal adenocarcinoma. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 18s. Abstract LBA4505. [AGITG]

Powell ED, Asmis T, Jonker D, Tu C, Karapetis C, Jeffery M, O'Callaghan C. Comorbidity and overall survival in cetuximab-treated patients with advanced colorectal cancer—results from NCIC CTG CO.17: a phase III trial of cetuximab versus best supportive care. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 4074. [AGITG]

Romeo S, Debiec-Rychter M, Van Glabbeke M, Van Paassen H, Comite P, Van Eijk R, Oosting J, Verweij J, Terrier P, Schneider U, Sciot R, Blay J-Y and Hogendoorn PCW, on behalf of the European Organisation for Research and Treatment of Cancer Soft Tissue and Bone Sarcoma Group. Cell cycle/apoptosis molecule expression correlates with imatinib response in patients with advanced gastrointestinal stromal tumors. *Clinical Cancer Research* 2009; 15: 4191–4198. [AGITG]

Van Glabbeke MM, Verweij J, Casali P, Zalcberg J, Le Cesne A, Reichardt P, Issels R, Judson I, Debiec-Rychter, Blay J. Type of progression in patients treated with imatinib for advanced gastrointestinal stromal tumor: a study based on the EORTC-ESG-AGITG trial 62005. Annual Meeting of the American Society of Clinical Oncology; 29 May–2 Jun 2009; Orlando. *Journal of Clinical Oncology* 2009; 27: 15s. Abstract 10536. [AGITG]

Selected invited presentations

Askie L. Combining trial evidence to improve practice: reviews and individual-patient-data and prospective meta-analyses. Changing Practice and Policy and Improving Health through Clinical Trials Research: a Celebration of 20 Years of Research at the Clinical Trials Centre; University of Sydney; 26 Jun 2009; Sydney.

Askie L. Individual patient data and prospective meta-analysis: the what, why and how. Hot Topics in Neonatology Conference; 6–8 Dec 2009; Washington DC.



- Askie L.** Pediatric trials, individual patient data and prospective meta-analysis. International Forum for Standards for Research in Children International Summit; 26–28 Oct 2009; Amsterdam.
- Blinman P.** Getting patients' preferences in practice. Australia and New Zealand Joint Oncology Scientific Meeting; 6–9 Aug 2008; Christchurch.
- GebSKI V.** Advances in clinical research methods: risk models, trials design and multiple outcomes. Changing Practice and Policy and Improving Health through Clinical Trials Research: a Celebration of 20 Years of Research at the Clinical Trials Centre. University of Sydney; 26 Jun 2009; Sydney.
- Hudson M.** Applications in medical statistics —meta-analysis, nonparametric testing, and power calculations AMSI/SSAI ASC2008 Satellite Workshop: Computing With R; 27–29 Jun 2008; Melbourne.
- Keech AC.** Benefits of long-term fenofibrate therapy on amputations in type 2 diabetes mellitus in the FIELD Trial. 44th Annual Meeting of the European Association for the Study of Diabetes; 7–11 Sep 2008; Rome.
- Keech AC.** Effects of fenofibrate on measures of renal function in type 2 diabetes mellitus: the FIELD study. American Society of Nephrology Renal Week, Oct 30–Nov 4: San Diego.
- Keech AC.** Fenofibrate slows eye disease: the FIELD Study. Metabolic Syndrome, type II Diabetes and Atherosclerosis Congress; 7–11 May 2008; Marrakesh.
- Keech AC.** FIELD macro- and microvascular results. 12th Annual Scientific Meeting of the Lebanese Society Of Endocrinology, Diabetes and Lipids; 2–5 Jul 2009; Brumanna, Lebanon.
- Keech AC.** FIELD study: An update. Cardiac Society of Australia and New Zealand 56th Annual Scientific Meeting; 7–10 Aug 2008; Adelaide.
- Keech AC.** FIELD; macro- and micro-vascular benefits and the metabolic syndrome profile. World Cardiology Congress; 18–21 May 2008; Buenos Aires.
- Keech AC.** Lipid lowering in diabetes. India-Australia Diabetes Symposium; Nov 2008; Hyderabad.
- Keech AC.** Macrovascular and microvascular residual risk reduction: current limitations and insights into the future. Metabolic Syndrome, Type II Diabetes and Atherosclerosis Congress; 19–26 May 2009; Berlin.
- Keech AC.** Moving towards global protection against complications of type 2 diabetes. XVI International Cardiovascular & Diabetes Continuum; 10–12 Oct 2008; Prague.
- Keech AC.** Prevention of macrovascular and microvascular complications of type II diabetes mellitus using fenofibrate: the FIELD study. Metabolic Syndrome, Type II Diabetes and Atherosclerosis Congress; 19–26 May 2009; Berlin.
- Keech AC.** The clash between value and expectation: cost effectiveness of therapeutics. Cardiac Society of Australia and New Zealand 56th Annual Scientific Meeting; 7–10 Aug 2008; Adelaide.
- Keech AC.** The clinical value of metabolic syndrome and its components in established type 2 diabetes mellitus: the FIELD trial. 44th Annual Meeting of the European Association for the Study of Diabetes; 7–11 Sep 2008; Rome.
- Keech AC.** Total myocardial infarction, MS profiles: latest results from the FIELD study. European Society of Cardiology Congress; 30 Aug–3 Sep 2008; Munich.
- Keech AC.** Use of PPAR agonists in the management and prevention of vascular disease in diabetes. XV International Symposium on Atherosclerosis; 14–18 Jun 2009; Boston.
- Keech AC.** Value of clinical trials to change practice: costs of undertaking vs not undertaking trials research. Changing Practice and Policy and Improving Health through Clinical Trials Research: a Celebration of 20 Years of Research at the Clinical Trials Centre. University of Sydney; 26 Jun 2009; Sydney.
- Lord SJ, Irwig L, Bossuyt PPM.** Using comparative evidence of test accuracy and other intermediate outcomes as an alternative to RCTs. American Healthcare Research and Quality; 28 May 2008; Rockville, MD, USA.
- Lord SJ, Irwig L, Bossuyt PPM.** The role of randomised controlled trials in the evaluation of the impact of tests on patient outcomes. Methods for Evaluating Medical Tests : First International Symposium; 24–25 July 2008; Birmingham, UK.
- Simes J.** Cholesterol lowering with statins: the LIPID trial and the Cholesterol Treatment Trialists' Collaboration. Changing Practice and Policy and Improving Health through Clinical Trials Research: a Celebration of 20 Years of Research at the Clinical Trials Centre; 26 June 2009.
- Simes J.** Confronting the costs of cancer. The role of clinical trials. Clinical Oncological Society of Australia Annual Scientific Meeting; Nov 2009; Gold Coast.
- Simes J.** Ezetimibe and cancer. Issues in evaluating the evidence. Cholesterol Treatment Trialists Collaboration Annual Meeting; Nov 2008; New Orleans.
- Simes J.** Ezetimibe and cancer: false alarm or cause for concern? Cardiac Society of Australia and New Zealand 57th Annual Scientific Meeting; 13–16 Aug 2009; Sydney.
- Simes J.** Future directions in lipid lowering. Cardiac Society of Australia and New Zealand 57th Annual Scientific Meeting; 13–16 Aug 2009; Sydney.
- Simes J.** Multinational clinical trials in cancer. Lessons from the NHMRC Clinical Trials Centre and opportunities for future trials research. Sino-Australian Symposium, University of Sydney; Aug 2009; Sydney.
- Simes J.** Patient and community-relevant outcomes from clinical trials: quality of life and cost-effectiveness. Changing Practice and Policy and Improving Health through Clinical Trials Research: a Celebration of 20 Years of Research at the Clinical Trials Centre. University of Sydney; 26 Jun 2009; Sydney.
- Simes J.** Translating evidence into practice. Sydney Institutes for Health and Medical Research; Nov 2008; Sydney.
- Simes RJ.** A career in clinical trials: from beginnings at Harvard. Harvard Biostatistics Alum Award Presentation; Jun 2009; Boston.
- Stockler M.** Prognosticating in advanced cancer. Australia and New Zealand Joint Oncology Scientific Meeting; 6–9 Aug 2008; Christchurch.
- Stockler M.** Adjuvant systemic therapy: what makes it worthwhile to patients? Toronto Breast Cancer Symposium, 12–13 Jun 2008; Toronto.

Notes

