Australian Clinical Trials Alliance

REPORT ON THE 2014 NATIONAL SUMMIT OF INVESTIGATOR-INITIATED CLINICAL TRIALS NETWORKS

28 – 29 MARCH 2014

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Thank you to all members of the faculty and to everyone who attended and participated in the ACTA Summit.

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Introduction

It gives me great pleasure to present this report on the 2014 National Summit of Investigator-Initiated Clinical Trials Networks. The breadth and depth of expertise in clinical trials in Australia is truly remarkable. We have an outstanding community of clinical researchers that have published trials of international significance across a large range of disciplines. The results of these trials have changed clinical practice and many tens of thousands of lives have been saved or improved as a direct result of these efforts.

Our position as leaders in this field is built on three key elements - a high standard of clinical care, a unique culture of research collaboration within and between clinical disciplines and a critical mass of methodological expertise.

One of the main objectives of the Summit was to bring these highly successful groups together *en masse* to identify ways to increase both the number and impact of clinical trials conducted in Australia. A range of innovative proposals were put forward that will serve as 'first steps' for mapping a pathway towards a self-improving healthcare system in Australia – one capable of systematically identifying what we do and how we can do it better and more efficiently.

The Summit also marked the official launch of the Australian Clinical Trials Alliance (ACTA). The idea to form an umbrella organisation capable of connecting, supporting and representing the investigator-initiated clinical trials sector in Australia was born just under two years ago. In that short time, more than 50 clinical trials networks, trial coordinating centres and clinical quality registries have provided their support to ACTA's development – made possible through an initial seed grant from the Victorian Department of Health.

ACTA's mission is to promote effective and cost-effective healthcare in Australia through investigator-initiated clinical trials that generate evidence to support decision-making by health practitioners, policymakers and consumers.

That such a large proportion of our sector was represented at ACTA's inaugural summit is tremendously encouraging and the interim ACTA Board very much looks forward to working with all of you to improve the health of our community in the future.

Professor John Zalcberg OAM
Chair
Australian Clinical Trials Alliance

Executive Summary

Australia has a long tradition of undertaking world-class clinical trials – led by either clinicians or industry, as well as through partnerships between the two sectors. However, several recent reports have identified threats to the clinical trials sector, both from within Australia and globally[1]. The pharmaceutical and medical devices industry has been vocal about our complex regulatory environment and the impact this is having on Australia's ability to attract local and international investment in clinical trials. As a result, it is the commercial sector that has largely driven the national agenda for clinical trials reform in recent years.

The Australian Clinical Trials Alliance (ACTA) has been established as a national peak advisory body to represent and support clinical trials networks, and related organisations and stakeholders. ACTA's focus is on investigator-initiated trials conducted by collaborative networks of clinician researchers in partnership with trial coordinating centres – so-called 'public-good' trials. These not only lead to better patient outcomes, but a stronger, more productive healthcare system in addition to numerous economic benefits.

ACTA is identifying and engaging with clinical trials networks, as well as trial coordinating centres and clinical quality registries, around the country to seek ways to improve the environment that underpins trials conducted within Australia's healthcare system. This has included a scoping exercise to identify the networks that are currently conducting collaborative, multicentre, investigator-initiated clinical trials.

1 For example, DoHA (Department of Health and Ageing). *Strategic review of health and medical research. Final report February 2013*, 'the McKeon Review', Canberra; and Australian Government (2011). *Clinically competitive: Boosting the business of clinical trials in Australia*, Clinical Trials Action Group Report, Canberra.

The networks identified from around Australia were invited to send senior representatives to the National Summit of Investigator-Initiated Clinical Trials Networks (the ACTA Summit), held at Novotel on Collins, Melbourne, 28–29 March 2014.

The ACTA Summit was made possible with support received from the National Health and Medical Research Council (NHMRC) as part of its broad program of work to improve the clinical trials environment in Australia, and through sponsorship received from Bellberry Limited.

More than 165 senior representatives from 95 organisations involved in clinical trials attended the inaugural ACTA Summit, which incorporated presentations, panel discussions and a workshop-style business meeting over 1.5 days.

It became apparent that there are a range of initiatives currently being coordinated by Australian, and state and territory governments that aim to improve the landscape for conducting clinical trials in Australia. Feedback from the clinical trials community during the summit indicated that there was a high level of support for these initiatives, such as a nationally consistent approach to research ethics and governance. There are, however, still major impediments to conducting 'public-good' trials in Australia that are not currently being addressed. Also, many opportunities – some of them readily implementable – are not being taken.

There was a strong undertone of enthusiasm and commitment to tackling these challenges, and a call for ACTA to provide leadership in promoting innovative, coordinated strategies that will increase the number and impact of public-good clinical trials conducted in Australia. This will, in turn, benefit both patients, and the payers and providers of healthcare.

Executive Summary

Key Summit Outcomes

Proposed strategies for increasing our capacity to conduct high-impact public-good clinical trials within the Australia healthcare system include:

> secure sustainable infrastructure funding for networks to replace wasteful 'project-by-project' funding

> secure sustainable funding for methods centres with strong epidemiology, biostatistics and data-management capabilities that support multiple trials networks and registries

> conduct more innovative clinical trials that address the healthcare system's most important clinical questions

> make research outputs a key performance indicator for hospitals

> improve the quality of routinely collected data and facilitate linkage to research databases

> expand clinical registries to collect risk-adjusted outcomes data across a broad range of high-cost high-significance areas of medicine

> advance local expertise in trial methodology to meet the modern challenges of recruitment in smaller sub-populations of patients or where smaller effect sizes in commonly used interventions have the greatest potential for benefit

> incorporate trials within clinical quality registries

> link networks to conduct more cross-discipline trials

> coordinate and share resources and expertise between clinical trials networks (e.g. outcome measurements, data safety monitoring boards, education for researchers)

> abolish the need to gain approval from multiple ethics and governance committees to conduct multicentre trials

> standardise common trial documentation, such as patient information sheets and case-report forms

> move to a regulatory framework that is proportionate to the additional risk for people participating in public-good clinical trials

> develop an appropriate model of consent for comparative effectiveness studies when these involve widely used and approved therapies

> liaise with the Independent Hospital Pricing Authority to develop an appropriate costing framework for investigator-initiated clinical trials

> work more closely with government, regulators and policy makers – particularly during the trial planning and development phases

> develop models of partnership with international investigators and funding agencies to conduct large-scale pragmatic trials

> develop models of partnership with industry to both conduct trials and improve the competitive environment for conducting trials in Australia

> increase public support through a major public education campaign to inform the community of the purpose and importance of clinical trials

> develop impactful models of consumer engagement in clinical trials

> conduct 'research on research' to demonstrate and understand what it is we currently do, how it can be done better and how it impacts healthcare outcomes

> advocate widely for the health and economic benefits of clinical trials and clinical quality registries to support a self-improving health system.

Based on these proposals, ACTA will provide leadership in the following broad areas:

> advocacy and engagement

> communication, coordination and networking

> education and knowledge exchange

> policy recommendations

> funding and regulatory reform

> public education

> 'research on research'

Panel from left: Professor Warwick Anderson AM, Professor Chris Brook PSM

1 Background

1.1 | Twenty-First Century Healthcare

The health system is a complex, sophisticated, multilayered system through which prevention of ill-health and treatment of people experiencing deterioration in their health status, as well as management of altered health states (such as pregnancy), are coordinated and managed.

Since the latter years of the past century, the breadth and complexity of treatment options to optimise the health of individuals has increased exponentially. As a result, health costs are rising rapidly as clinical systems expand to meet these increasing demands. The overall level of Australian and state government healthcare expenditure, as well as private healthcare contributions, was estimated to be of the order of $140 billion in 2011-12. These costs are predicted to almost double in the next decade[2]. This relates, in part, to an ageing community, as well as overall growth in population. In addition, this increase is due to a shift in the number of people previously experiencing acute conditions – such as cardiovascular and infectious diseases – which are changing in severity and incidence to chronic states of ill-health due to cancer, obesity and diabetes, dementia and other neurodegenerative conditions, and physical disability related to older age.

The United States (US) Congressional Budget Office predicted that the major driver of increasing costs and the greatest threat to the sustainability of the US healthcare system will be the introduction of new technologies[3]. In this context, it is critical that the real value of new therapeutic approaches can be compared to existing modalities in a manner that addresses their clinical value (i.e. how should the new technology be best used in a cost-effective manner to improve outcomes) rather than their commercial value alone (i.e. how does the new technology compare to the old technology).

Given that it's been variously estimated that fewer than 25% of medical interventions are currently based on high-quality evidence[4], it is inevitable that all funders of healthcare, as well as the general community, will ultimately demand that escalating costs only be supported if treatments and interventions are based on proof of their effectiveness. That is, evidence that the procedure, drug, device or treatment has been proven to improve patient outcomes – as well as their relative value compared to other treatment options.

Escalating costs can be tempered (and justified as an appropriate use of the taxpayers' dollars) if used to support interventions known to have a proven value. However, realising these efficiencies will require systems that can provide timely access to reliable evidence and ensure that scarce resources can be redirected to practices, procedures, technologies and interventions that deliver true value for money.

Evidence used to support any clinical intervention can only be derived from clinical trials or other outcomes-based observational data (such as data collected through clinical quality registries). In Australia, the local generation of such evidence depends on the activity of national clinical trials networks that conduct 'public-good' clinical trials, clinical quality registries, and the specialised coordinating centres that manage clinical trials and house registry data.

2 AIHW (2014). *Health expenditure Australia 2011-12: analysis by sector.* Health and welfare expenditure series. Canberra
3 Congress of the United States Congressional Budget Office (2013). *The 2013 Long-term Budget Outlook,* http://www.cbo.gov/sites/default/files/cbofiles/attachments/44521-LTBO2013_0.pdf (accessed September 2014)
4 For example, BMJ Clinical Evidence (2014). *What conclusions has Clinical Evidence drawn about what works, what doesn't based on randomised controlled trial evidence?* http://clinicalevidence.bmj.com/x/set/static/cms/efficacy-categorisations.html (accessed September 2014)

1.2 | Clinical trials in Australia

Australia has a strong clinical trials sector. This includes the typical studies of new pharmaceuticals and medical devices, as well as world-class investigator-initiated clinical trials, or 'public-good' trials. These trials identify current standard practices that can be simply modified, or are not useful or even harmful, or the investigation of treatments that are not the focus of industry (e.g. older drugs no longer under patent).

Public-good trials have the capacity to create better health outcomes and a stronger, more productive healthcare system for Australians. They can also boost the economy by identifying cost-effective healthcare solutions.

Most of the large-scale, multicentre, investigator-initiated clinical trials currently conducted in Australia are funded by the National Health and Medical Research Council (NHMRC) and are led by clinicians and research personnel employed in the public sector. An increasing number are conducted within the private health system. Highly experienced clinician researchers who identify and understand knowledge gaps within in the healthcare system lead these trials.

Though clinical trial research efforts in Australia have historically been relatively strong and globally competitive, the environment for conducting trials in Australia has come under increasing scrutiny in recent years. This is particularly in terms of funding and regulatory constraints, and the complex jurisdictional hurdles that exist in Australia as a consequence of our federated structure.

A number of initiatives at the state/territory and national level are currently under way, with the aim of keeping Australia as a world leader in clinical trials. This includes the forecast establishment of a Clinical Trials Advisory Committee in 2014 to provide advice to the Australian Government departments of Industry and Health on the specifics of the work program required to progress clinical trials reform.

1.2.1 | Clinical Trials Action Group Report

The Clinical Trials Action Group (CTAG) was formed in October 2009 and delivered its report *Clinically competitive: Boosting the business of clinical trials in Australia*[5] in 2011. The report made a series of recommendations to improve the conduct of clinical trials in Australia based around the need to:

> improve the timeliness of ethics and research governance review

> provide for cost recovery of efficient clinical trials

> ensure that clinical trials can take advantage of the developing eHealth system

> improve patient recruitment

> facilitate better national coordination and greater collaboration across clinical trials networks

> progress key clinical trial issues.

Overseen by the CTAG Coordination Group, the NHMRC and the-then Australian Government departments of Health and Ageing (DoHA), and Industry, Innovation, Science, Research and Tertiary Education (DIISCRTE), initiated a series of projects aimed at addressing the CTAG Recommendations. These included a range of reforms to support a single ethical review process for multicentre research, a table of standard cost items associated with trials, a consumer guide to clinical trials, a published list of clinical trials networks and launch of the Australian Clinical Trials website (www.australianclinicaltrials.gov.au).

In February 2013, the Australian Government announced the allocation of $9.9 million to expedite clinical trials reform in Australia and help implement recommendations of the CTAG Report under the *Plan for Australian Jobs*[6] initiative. Specifically, the initiative committed funding to:

> expedite standardisation of the costs of clinical trials

> incorporate clinical research needs into the eHealth system

> develop a national interactive web portal for facilitating clinical trials

> improve clinical trial conduct and timeliness of governance approvals through education and training

> work with the states and territories, and other stakeholders on a nationally consistent approach to clinical trials.

The progress of a number of these projects coordinated by the NHMRC and Department of Industry were presented and discussed at the ACTA Summit.

5 Australian Government (2011). Clinically competitive: *Boosting the business of clinical trials in Australia*, Clinical Trials Action Group report, Canberra.
6 Australian Government (2013). A Plan for Australia jobs: *The Australian Government's industry and innovation statement*, Canberra.

1.2.2 | McKeon Review

The McKeon Review[7] (published in 2013) identified large gaps in Australia's health and medical research capacity, highlighting again that:

> **much of current clinical practice is not based on high-quality evidence**

> **some treatments have not been properly tested**

> **interventions in some areas are random, leading to uncertain health outcomes and poor cost-effectiveness**

> **some treatments that are backed by high-quality evidence take years to implement into routine care, delaying patient and economic benefits.**

The suite of recommendations made by the McKeon Review included accelerating clinical trials reform and increasing funding for non-commercial clinical trials as part of a comprehensive strategy to embed research into the health system.

1.2.3 | Jurisdictional initiatives

In addition to Australian Governments projects focused on boosting the conduct of clinical trials in Australia, most states and territories have dedicated resources towards better supporting clinical trials within their jurisdictions.

The state and territory governments of Australia have signed a memorandum of understanding to introduce National Mutual Acceptance of ethical and scientific review for multicentre clinical trials conducted in public health settings. Under this process, all multicentre clinical trials being conducted at sites within Australia will be ethically and scientifically reviewed only once by a lead human research ethics committee (HREC). Queensland, New South Wales, Victoria and South Australia commenced the first phase of the rollout of National Mutual Acceptance in November 2013.

The following are examples of other state-based initiatives to support clinical trials:

> In November 2013, the New South Wales Office for Health and Medical Research (OHMR) commenced a program of work to reform the pre-approvals process for research governance across NSW[8]. This work forms part of a 10-year Health and Medical Research Plan initiated by the NSW Government in response to the NSW strategic review of health and medical research 2012[9], which included a series of recommendations to support leadership in clinical trials.

> As flagged during the ACTA Summit, the Victorian Government's Coordinating Office for Clinical Trials Research, as part of its Clinical Trial Research Initiative, published a comprehensive guide – *Research governance and site specific assessment: Process and practice*[10] in May 2014.

1.3 | Formation of the Australian Clinical Trials Alliance

The Medical Journal of Australia (MJA) Clinical Trials Research Summit held in 2012 highlighted the need for a new approach to conducting investigator-initiated clinical trials in Australia. Participants recognised that, although there had been numerous publicly funded, high-impact studies published by clinical trials networks around Australia, the sector lacked a national body that could provide leadership to support clinician researchers to generate more high-quality evidence to improve outcomes and efficiencies within the health system.

Key messages from the MJA Summit were that:

> most current routine interventions are not based on high-quality evidence

> some important research areas are not being addressed due to lack of infrastructure, especially in rural and remote Australia, and in Indigenous communities

> some key networks are not sustainable, which means their infrastructure dissipates after each trial and needs to formed again for a new project

> networks need sufficient resources to function more collaboratively, to have the opportunity to share expertise, skills and infrastructure

> extensive regulatory requirements make clinical trials overly expensive and time consuming

> there is a lack of knowledge sharing between researchers, government and policy makers to effect change.

The Australian Clinical Trials Alliance (ACTA) was formed in 2013 to be the national peak body. It will advocate for investigator-led clinical trials in Australia, and provide a unified voice that represents clinical trials networks, clinical trial coordinating centres and clinical quality registries working to improve outcomes for patients, and generate better quality, productivity and efficiency within the Australian healthcare system.

7 Department of Health and Ageing (2013). *Strategic review of health and medical research. Final report* February 2013, 'the McKeon Review', Canberra.
8 NSW Ministry of Health (2013). H*ealth and Medical Research Governance Project: Reform of the research pre-approval process: Discussion paper.* Sydney
9 NSW Ministry of Health (2012). *NSW Government response to the health and medical research strategic review.* Sydney
10 Victorian Department of Health (2014). *Research governance and site specific assessment: Process and practice.* Melbourne

Speaker: Associate Professor Andrew Davidson

2 The ACTA Summit 2014

As part of its role in improving Australia's clinical trials sector, ACTA began a process of identifying and engaging with clinical trials networks around the country in 2013. This included a scoping exercise to identify the networks that are currently conducting collaborative, multicentre, investigator-led trials in Australia (see Appendix A), along with the coordinating centres that facilitate multicentre trials, and national or state-based clinical quality registries capable of supporting the conduct of trials.

These networks were invited to participate in a National Summit of Investigator-Initiated Clinical Trials Networks (held at Novotel on Collins, Melbourne, 28–29 March 2014).

Key opinion leaders from across government, regulatory bodies, funding agencies, consumer groups, research institutes and industry were also invited to participate.

The summit attracted more than 165 participants from around Australia. Representatives from 52 clinical trials networks, coordinating centres and registries representatives were in attendance, as well as representatives from 43 other organisations who are key stakeholders in clinical trials (see Appendix 2).

The ACTA Summit was generously supported by the National Health and Medical Research Council and sponsored by Bellberry Limited.

2.1 | Summit objectives

The first day of the summit involved presentations from leading investigators and senior figures from government and the clinical research community. Open panel discussions provided an opportunity for key themes to be explored and challenged. The following morning, representatives from ACTA's core constituency met to participate in a workshop-style business meeting to discuss the formation of ACTA and agree priorities for its development in the next 12 months. The outcomes of the business meeting will be reported separately for participants.

Box 1 outlines the ACTA Summit 2014 objectives.

Box 1
Objectives of the ACTA Summit 2014

Bring senior representatives from Australia's national and state-based clinical trials networks, clinical trial coordinating centres and clinical quality registries across all of the major disciplines and disease groups together to connect with one another and with key health policymakers and opinion leaders.

Discuss innovative opportunities for increasing the impact of investigator-initiated clinical trials and the capacity of collaborative networks to answer important clinical questions and provide better evidence to support the delivery of high-quality healthcare.

Consider the achievements of existing clinical trials networks in Australia that have made major advances in improving patient outcomes and the cost-effectiveness of treatments, and explore ways to leverage the expertise that has been gained to support new and developing networks.

Be the first step in an ongoing process for the investigator-initiated clinical trials community to have direct input into the development of ACTA, its strategic goals and priorities for supporting the sector.

Speaker: Professor Steve Webb

3

SESSION 1

The landscape for clinical trials in Australia

Introduction and welcome

Professor John Zalcberg OAM, *Chair, Australasian Gastro-Intestinal Trials Group, and Interim Chair, Australian Clinical Trials Alliance*

Session Chair

Professor Tony Keech, *Deputy Director, NHMRC Clinical Trials Centre*

3.1 | Opening address and official launch of ACTA

Speaker

Professor Chris Brook PSM, *Executive Director, Wellbeing, Integrated Care and Ageing, Victorian Department of Health*

Professor Chris Brook officially launched ACTA and provided some reflections on the vital role of clinical trials in improving healthcare delivery. Professor Brook is well qualified to make observations on the healthcare system, having had more than two decades in senior policy and management roles in Victoria, as well as nationally and internationally. He indicated that his new role as Chief Adviser within the Victorian Department of Health will have three major priorities: innovation, quality and clinical trials. He remarked that all three of these priorities are central to ACTA.

Professor Brook made three cardinal observations regarding healthcare delivery:

> Healthcare systems cannot be defined solely by cost signals and access targets.

> It is an accepted act of faith that good research leads to good healthcare delivery, but the part of research that is most crucial is clinical trials – these generate the evidence to actually influence healthcare delivery.

> How healthcare delivery is organised and arranged needs change that is systems based.

> ‘This virtuous cycle is not a novel concept, but it is the most important investment we can make in the future.’

Professor Brook proposed a model in which clinical trials play a crucial role as one component of a virtuous cycle that drives better healthcare delivery. In this model, hospitals or community-delivered healthcare practices are ‘living laboratories’. The activities of the living laboratory provide information to a repository that reports back to the living laboratory, but also provides information that is used to develop research questions. These research questions are answered by the conduct of clinical trials that, in turn, feed back into the living laboratory, guiding and improving healthcare delivery.

Professor Brook concluded by challenging ACTA to make a contribution to improved healthcare delivery within this model.

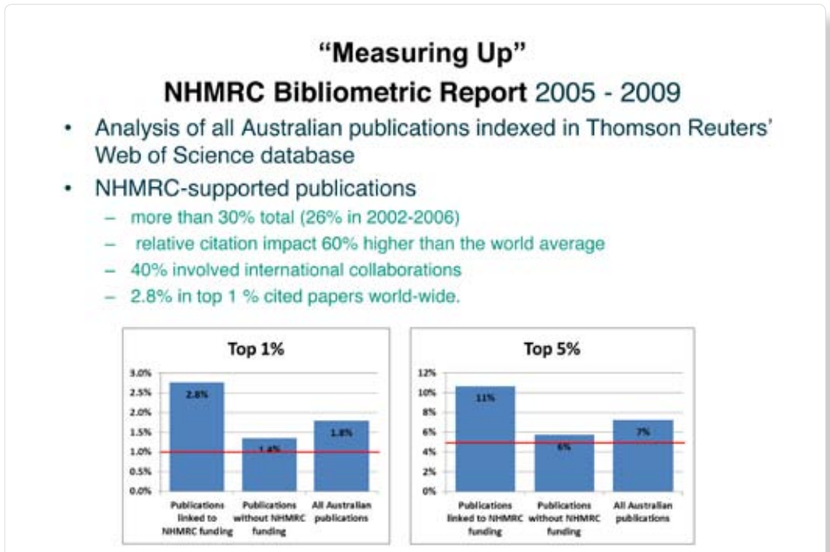
3.2 | Improving the health and wealth of Australians

Speaker
Professor Warwick Anderson AM, *CEO, NHMRC*

> ‘We fund medical research because the tax payer and the government want benefits in terms of healthier people – improved treatments and healthcare – and because we need an economy that grows, increases wealth and creates jobs for Australians.’

Strengthening the bridge between new discovery and frontline clinical practice is a focus for the NHMRC and many of its counterparts around the world. Clinical trials are a very important part of the translation process, but they are not the only part. Policy makers have an equally important role to play.

Outputs from health and medical research conducted in Australia are of an internationally high standard and are increasing. The NHMRC report *Measuring up 2013* [11] analysed Australian publications indexed in the Thomson Reuters’ Web of Science database from 2005 to 2009.



> ‘You can identify a need and do research, but at the end of the day, it’s high-quality research that makes the difference.’

11 NHMRC (2013). *Measuring up 2013*, Canberra.

The McKeon Review[12] reported that health and medical research related companies performed well on the Australian Stock Exchange, growing by 17% in the decade to 2013. This was well above the Australian All Ordinaries index for the same period. The export value of pharmaceuticals and medicinal products in Australia is now higher than wine or car exports[13]. These figures indicate that in terms of creating wealth, Australia has much to benefit from investing in the health and medical research sector.

Economic analyses suggest that, if fully implemented, the results of two trials partly funded by NHMRC – the SAFE TBI (Saline versus Albumin Fluid Evaluation in Traumatic Brain Injury) and the DECRA (Early DEcompressive CRAniectomy in Traumatic Brain Injury) trials conducted by the ANZICS Clinical Trials Group – would roughly save the same amount of money that it costs to provide the total NHMRC funding budget for this year ($100–200 million).

The ASPREE Trial involving 19,000 people in Australia and the US is investigating the effects of aspirin on a healthy lifespan. It has been partly funded by NHMRC across a number of years, and has leveraged a further $70 million in local and international funding. The primary trial has also seeded a number of important additional studies.

> ‘There are huge benefits to Australia from investigator-initiated grants.’

Activities that are currently shaping the future of clinical trials research include:

> Australian Government policies on health and medical research

> the McKeon Review of health and medical research

> the previous CTAG, the CTAG Report and the new Clinical Trials Advisory Committee

> the work of the Independent Hospital Pricing Authority (IHPA) to identify standard costs for clinical trials.

NHMRC’s current activities that are supporting clinical trials reform include:

> streamlining the research governance and ethical review process

> developing training and education for personnel involved in the clinical trial process

> redeveloping the National Ethics Application Form (NEAF)

> working with the Australian Government Department of Industry on the development of a consumer-friendly web portal

> supporting clinical trials networks

12 Department of Health and Ageing (2013). *Strategic review of health and medical research. Final report* February 2013, ‘the McKeon Review’, Canberra.
13 Medicines Australia (2013). *Facing the health of Australians*, Deakin.

3.3 | Clinical trials: The value proposition

Speaker

Professor Steve Webb, *Immediate Past Chair, Australian and New Zealand Intensive Care Society Clinical Trials Group*

‘The purpose of clinical trials is to provide evidence to clinicians who look after patients … and to policy makers who make decisions about how to manage the health system.’

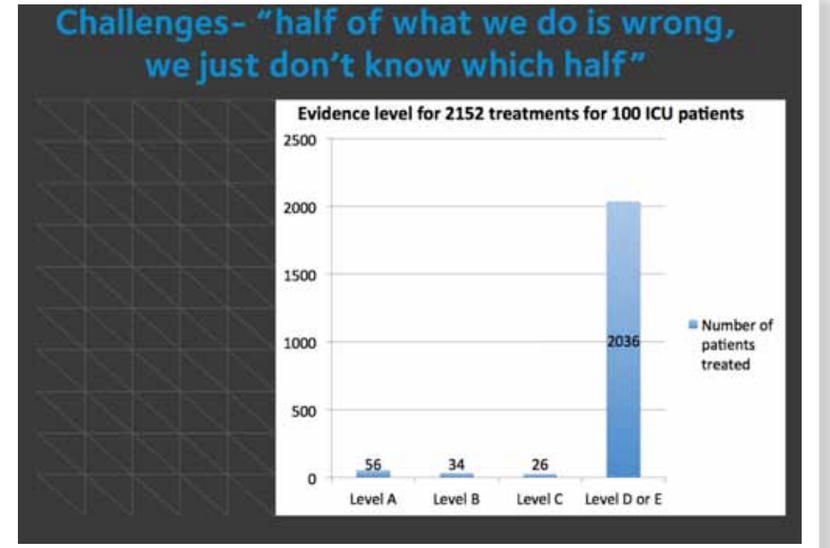
The value of clinical trials is derived from the evidence that they provide that guides decision making by clinicians and policy makers, leading to improved health outcomes or cost savings, or both. Clinical trials are integral to improving the healthcare system. Investigator-led research is not an academic exercise – it is a practical and an applied activity that can and does improved health outcomes. Clinical trials, coupled with registries that measure outcomes and compliance with recommended treatments, should form an integral component of a ‘self-improving’ healthcare system.

‘The clinical trials sector has to be sensitive to the challenges policy makers face in tackling the rising costs of healthcare.’

The healthcare system faces major challenges. Australian Commonwealth healthcare expenditures are projected to rise from $50 billion to $250 billion by 2050[14], mainly due to increased demand, particularly for new and costlier treatments and technologies. Many existing treatments are provided based on a best guess of effectiveness, in the absence of evidence about their effectiveness and cost-effectiveness. There are many variants of standard care, but their relative impact is not known. The aim of comparative effectiveness trials is to compare different approaches to the same clinical problem to clarify the appropriate role of practices that are in widespread use.

More, high-quality ‘public-good’ clinical trials are a logical response to these problems. The characteristics of public-good trials are that they are investigator initiated, scientifically independent and objective, and designed to answer clinically relevant questions that are capable of improving health. They are not designed for marketing or regulatory reasons.

14 Australia Department of the Treasury (2010). *Australia to 2050: future challenges,* Department of the Treasury, Canberra



‘There are many big wins that come from clinical trials but we need to better understand their value proposition in order to determine the “sweet spot” for investment.’

At least $100 million per year, predominantly from the NHMRC, is spent each year on public-good trials in Australia. While the precise value from improved health outcomes and cost savings, from the evidence generated by these trials, is unknown, there is no value if clinical trials:

- **are not completed or not reported**
- **are completed, but the results don’t improve health outcomes**
- **reveal results that can improve health, but are not translated.**

Nevertheless, the results of just a few trials conducted by clinicians in Australia that have been implemented (e.g. SAFE-TBI, DECRA, NICE-SUGAR, ACTOMgSO4, ENIGMA) are saving lives and saving the Australian community several hundred million dollars per year.

While the exact value proposition is unknown and needs to be identified, it is likely that for every dollar invested in clinical trials, there are many dollars of cost savings. Australia needs more research about the real value that is created by the research that we fund and conduct.

3.4 | Current clinical trials activity in Australia

Speaker
Professor John Simes, *Director, NHMRC Clinical Trials Centre*

> ‘Investigator-led networks provide a very effective mechanism for undertaking important public-good research.’

Work undertaken by the NHMRC and, subsequently, by ACTA has thus far identified approximately 38 established investigator-led clinical trials networks (Appendix A) and a further 8 that are in development, across a broad range of clinical and disease-specific areas in Australia, including:

- **anaesthesia**
- **burns**
- **cardiovascular**
- **diabetes**
- **diagnostic imaging**
- **emergency medicine**
- **intensive care**
- **infectious diseases**
- **mental health**
- **musculo-skeletal**
- **neuroscience**
- **oncology**
- **paediatrics**
- **palliative care**
- **perinatal care**
- **primary care**
- **renal**
- **respiratory and sleep**

There are many examples of Australian investigator-initiated, controlled clinical trials that have significantly advanced practice, either by providing evidence for effective new therapies, or demonstrating that therapies in current use were ineffective or harmful. It is important to note that many of the trials that have changed practice in Australia have required large sample sizes to provide definitive evidence (Table 1).

Table 1

Trial	Area	Summary	Sample size
ENIGMA	Anaesthesia	Avoiding NO during surgery reduces complications	7,000
POISE	Anaesthesia	Beta blockers and post-op complications	8,000
IBIS-1	Breast cancer	Tamoxifen reduces breast cancer incidence	7,000
LIPID	Cardiac	Statins save lives for pts with prior CHD and AV cholesterol levels	9,014
FIELD	Diabetes	Fenofibrate prevents microvascular events in diabetes myelitis	9,795
IDEAL	Renal	Compared early vs late start to dialysis	8,28
PROGRESS	Stroke	Demonstrated benefit of BP control to prevent recurrent stroke	6,105
INIS	Neonatal	Gammaglobulin not effective in reducing adverse events from neonatal sepsis	3,493
CO-17	Gastro-intestinal cancer	Longer survival with targeted therapy in pts with KRAS wild-type colorectal cancer	572
NICE-SUGAR	Intensive care	Tight blood sugar control worsens outcomes in critically ill	6,000

Almost 8,000 clinical trials with at least one Australian participating site have been registered on either the Australian and New Zealand Clinical Trials Registry (ANZCTR), or clinicaltrials.gov between 2005 and 2013, and commenced activity. Given the trial registration requirements of journals and the National Statement on Ethical Conduct in Human Research, it is expected that this represents most (but not necessarily all) of the trials conducted in Australia.

There has been a steady increase in the registration of small clinical trials (sample size < 100 patients) in Australia since 2008, but no increase (or a slight decline) in larger phase III clinical trials. This has resulted in a steady decease in the median sample size of new trials commencing in Australia. In the past, investigator-initiated trials that have been practice changing have been larger controlled trials; these data may indicate that large-scale trials are under some threat.

> ‘Further “research about research” is needed to understand the reason for, and potential impact of, the greater number of smaller trials being registered.’

Investigator-initiated trials play a key role in clinical trial activity in Australia; the majority (60%) of trials currently registered were neither sponsored nor funded by industry (non-industry trials), and the proportion of investigator-initiated versus industry trials appears to be increasing. The majority of clinical trials undertaken in Australia are drug trials. However, the ratio between drug trials and other types of interventional trials – for example, those involving prevention, devices, diagnosis and screening – is decreasing.

The top three condition categories for interventional trials under way in Australia are cancer, mental health and cardiovascular disease, which generally reflects the high burden of illness of these conditions. Conditions that are underrepresented in terms of trial activity relative to burden of illness include obesity, injury, dementia and asthma. There is the potential to make much greater use of trial registers (and a register of clinical trials networks) to help plan trials that test new therapies or better define existing treatments for conditions with a high burden of illness.

3.5 |

Investigator-initiated clinical trials networks: The quality agenda

Speaker

Professor John Zalcberg OAM, *Chair, Australasian Gastro-Intestinal Trials Group, and Chair, Australia Clinical Trials Alliance*

> ‘If we’re expecting governments to pay for the rising costs of healthcare, then governments have the right to ask: What are we paying for? What are the outcomes?’

Clinical trials led by clinical trials networks are about improving the quality of healthcare. There are many examples of trials published by networks in Australia that have had a major impact of the quality of healthcare in Australia. The breadth and depth of activity being supported by networks across the country is difficult to fully appreciate as a clinician working in a specialised area. One of ACTA’s roles will be to help promote the work of these networks more broadly, including among the general public.

The Wall Report[15] published in 2002 recommended that the Australian Government improve the capacity of cancer cooperative trials groups. This led to the allocation of $5 million per annum in Australian Government funding for infrastructure support for cancer trials networks. This needs to be duplicated across all trials groups around Australia.

Performing clinical trials in Australia is important for several reasons, to:

- increase the evidence base
- address local patterns of care
- increase access to treatments, technology and devices
- create an academic environment
- improve outcomes for patients in the trial
- change practice outside of the trial.

> ‘When trials are done in Australia, the question is defined, the trial is done, the data are analysed, the results are published and practice is changed in about half the time it takes to implement the findings of a trial conducted overseas.’

15 Oceania Health Consulting (2002). *Cooperative clinical trials in cancer – the need for increased capacity.*

The TOP GEAR trial conducted by the Australasian Gastro-Intestinal Trial Group provides a good example of this. The trial sought to clarify the role of radiotherapy in early gastric cancer. Before the trial could begin, the investigators had to identify and standardise best current practice to be provided in the control arm. This forced clinicians in Australia to examine their practice and ask questions like: How much chemotherapy? What type of surgery is optimal? What scans will we use? What sort of follow-up should we do? These all needed to be defined before the trial intervention could even be considered.

> ‘The process of designing a clinical trial requires clinicians to critically examine current local practice … and practice changes as a result.’

The strength of investigator-led clinical trials networks lies in their unique ability to:

- test interventions with clinical but not necessarily commercial relevance
- help define the standard of care
- engage a multidisciplinary group of stakeholders in that field of medicine/disease state
- identify components of standard care that are ineffective or harmful
- define new uses for old drugs
- evaluate processes of care, strategies of care and parallel versus intersecting interventions
- develop clinical trials capacity and expertise within hospitals and health services
- access sufficient sample sizes
- create infrastructure once (i.e. not for each individual trial)
- create a culture of research
- develop corporate knowledge and expertise in trial design, trial conduct, project management, and data management and analysis
- mentor and train the next generation of clinician researchers
- effectively collaborate with similar international networks
- enhance the translation of evidence into practice through a community of clinicians who are invested in trial results.

> ‘Research isn’t something that you do in your spare time; it isn’t something that you try to pull together from a little bucket of money. Research underpins clinical practice in much the same way that roots underpin a tree.’

4

SESSION 2

Clinical trials and the health system

Session Chair

Professor Steve Webb, *Immediate Past Chair, Australian and New Zealand Intensive Care Society Clinical Trials Group*

4.1 | Pathways to better evidence: Regulatory processes and clinical trials

Speaker

Professor John Skerritt, *National Manager, Therapeutic Goods Administration*

> ‘The TGA is a major user of clinical trials information … ’

As the sole regulator of therapeutic products in Australia, the Therapeutic Goods Administration (TGA) has a responsibility to maintain flexibility and be adaptive to the needs of the Australian community as they arise.

The primary work (99%) of the TGA is the regulation (ipso facto approval) of new therapeutic products, but it also monitors the use of approved products outside of approved indications. The results of clinical trials are heavily relied upon for such approvals, which include the review of trial protocols.

The two schemes under which approvals can be considered are the Clinical Trial Exemption (CTX) and Notification (CTN) schemes. TGA clinicians informally review protocols, particularly for first-in-human studies. TGA data indicate that, in 2012–13, there were 742 medicine trials, 333 devices trials and 13 biologicals trials.

The basic requirements of the TGA are that trials should have an Australian sponsor and all protocol changes are notified. Adverse events are scrutinised, and trials are stopped (albeit rarely) or an audit recommended if required. Guidelines for medicine trials are more developed than for device trials for which there is room for further refinement.

Important current issues for the TGA include ethics, funding models and the involvement of industry, the role of surrogate endpoints, evidence in uncommon groups, and disease prevention compared with treatment. It is recognised that there are problems with risk–benefit assessments, special needs conditions where small numbers in trials has to be accepted and weighting of superiority trials against placebo comparisons.

> ‘Regulators need to recognise that the clinical trial landscape is changing.’

The need for managed entry schemes such as CTX and CTN, and their relationship to reimbursement processes and how risk should be shared, requires further development. In order to prevent delays in approvals, adaptive or provisional licensing may be suitable where there is a high clinical need or where early data suggest positive outcomes. However, concerns with this type of licensing include mandating follow-up studies, how accountability should be managed, efficacy and subjective issues, and minority group concerns. There are also longer-term efficacy issues – for example, if a drug is found to be unsafe, it can be difficult to take it off the market.

One possibility is fast-track licensing. This usually requires phase III trials to be completed, and the treatment must fill an unmet clinical need. This includes off-label use, which is not regulated – only supply is regulated. This happens often, especially in cancer, paediatrics and psychiatry research.

Future treatments and therefore policies will need to address personalised medicine, changing disease types and orphan drugs. There will need to be changes to trial design and policy approaches. In some countries, there are specific, funded schemes to help address smaller and/or specific trials with unique end points. Involvement of global industry has to be recognised.

4.2 | New frontiers: How can clinical trials networks work better with industry?

Speaker

Dr Brendan Shaw, *CEO, Medicines Australia*

There are approximately 50 pharmaceutical companies operating in Australia, and several hundred up-and-coming biotech companies. The pharmaceutical industry employs approximately 40,000 people in this country and invests approximately $1 billion in research and development each year. Around $700 million is directed into clinical trials – roughly half of which are conducted in public hospitals.

> ‘Australia earns more money exporting medicines than it does from exporting cars or wine.’

Collaboration between pharmaceutical companies and the public sector clinical research effort is important for all parties. Companies benefit from the expertise in medical research provided by some of the best clinical researchers and healthcare professionals in the world. Clinical researchers and healthcare professionals benefit because they have the opportunity to be a part of world-class trials and gain access to state-of-the-art technologies. Patients benefit by being able to access new therapies much earlier.

> ‘As we’re sitting here today, there are 634 industry-sponsored clinical trials currently recruiting patients around Australia … ’

The lengthy, high-cost and high-risk nature of bringing new products from discovery through to late phase III development has led to a recent global shift in research and development (R&D) structuring towards alliances between the public and private research industries. As companies seek to develop greater efficiencies in their R&D pipelines, they are increasingly looking to establish partnerships with public institutes and researchers to expand the number and rate of discoveries, and identify non-viable products earlier.

We are not capitalising on this trend in Australia and the pharmaceutical industry remains concerned about the regulatory environment for clinical trials and the decrease in local clinical trials activity. There was a 30% decline in the number of clinical trials undertaken in Australia between 2007 and 2010. While there has been some recovery in recent years, activity is yet to return to pre-2007 levels and competition from other countries is becoming increasingly tough. Australia’s difficult regulatory and cost environment continues to put us at an international disadvantage, despite our reputation for clinical and scientific excellence.

Australia is now the third or fourth most-expensive country in the world in which to conduct clinical trials. We are more expensive than India or China, and a number of emerging markets that are competing for investment in this area, but we are also more expensive than countries like France, Germany and the United Kingdom (UK). These are developed countries with the same level of commitment to quality and safety as Australia.

Global spending on medicines has just topped $1 trillion per year. Approximately 20%, or $200 billion, is re-invested in R&D. Increasingly, this is being spent in the Asia¬–Pacific region, but so far Australia has not managed to attract increased investment here.

The McKeon Review highlighted that achieving regulatory reform was an ‘urgent national priority’ for both the industry and public research sectors. Regularity reform for clinical trials, such as reducing time to ethics and governance approvals, will be critical for ensuring Australia is a competitive place to conduct clinical trials and to capitalise on the shift away from R&D investment in Europe and the US towards the Asia–Pacific region. Fortunately, accelerating clinical trials reform is a priority for the current government and an area of active policy development in Canberra.

> ‘There’s a role for clinical trials networks to work with industry, to help drive reform and to help make this country a more attractive place for investment in clinical trials.’

4.3 | Interaction with policy makers: Connecting clinical trialists with health departments

Speaker

Professor Alan Cass, *Director, Menzies School of Health Research, and Founding Chair, Australasian Kidney Trials Network*

What is evidence-based policy making and how do we get it? How can we as trialists better engage with policy makers? Reflecting on these two questions, there are some key strategies that we need to consider:

The Australasian Kidney Trials Network (AKTN) was established in 2004 with the aid of a NHMRC enabling grant. Kidney disease is an area that has a significant lack of evidence for effective therapies in the context of an increasing demand for dialysis, an increasing burden of illness and comorbid illness associated with end-stage kidney disease, high cost of treatment ($50–100,000 per year to treat a patient on dialysis), and a high variability of practice around the country.

These factors heavily influenced the establishment of the AKTN. However, we must realise that there are many influences on policy, not just research and not just evidence – or a lack of it. Public opinion, the economic climate, expert advice, political ideology and priorities, stakeholder interest and the media all impact on the policy process.

We need to be aware of the whole array of influences that are not about what we do as researchers, or the generation of evidence, that impact and will continue to impact on policy.

> ‘Research shows that policy makers do value research and expect that policies will be informed by research, but they need research that is timely, high quality and helps guide action at the population level.’

The current notion of research ‘translation’ instils a model whereby the interaction with policy makers occurs after we complete the research. There is no engagement with policy makers in formulating the question and no policy ownership of the results. This does not work. We need to develop a better process of exchange and partnership whereby researchers and policy makers come together to develop the question, design and implement the research, and disseminate the findings.

A good example of embedding a trial into the rollout of a new clinical program was seen in the implementation of a UK model of breast screening for woman aged 50 and older. A randomised controlled trial was embedded into the program to evaluate screening starting at 40 years old compared to 50. This meant that a large-scale costly intervention – the effect of earlier screening – could be evaluated as part of funded service delivery. The trial yielded new scientific knowledge and information that was highly relevant to policy makers.

It is also critical for trialists to be thinking of study designs that use existing data collections – such as admitted patient data and outcome data collected through registries – to maximise the efficiency and timeliness of conducting publicly funded clinical trials.

> ‘If policy makers are interested in a question they won’t be willing to wait years to find out the answers.’

Generating evidence about what works in terms of pharmaceutical interventions is crucial, but we need to take on some different questions that are important to policy makers. Some examples from the renal field include the timing of commencement of dialysis (the IDEAL Study), survival versus quality of life for elderly patients with comorbidities choosing between dialysis and supportive care, strategies to improve and sustain rates of home dialysis, and initiatives to improve rates of organ donation.

We need to be advocating in a much more effective way for the role of clinical trials in improving the quality of healthcare. Research Australia addresses this issue in its Strategic Imperative 9, which calls for better recognition, funding, training and evaluation of research within health systems – particularly in the primary care setting[16].

Finally, we all need to do more patient-centred outcomes research.

16 Research Australia (2012). *10 strategic imperatives: 2012–2020.* Sydney.

‘It is incumbent on us to demonstrate that research active services and hospitals deliver better care.’

Professor Alan Cass

Speaker: Professor Alan Cass

4.4 |

Interaction with policy makers: Connecting clinical trialists with Treasury

Speaker

Professor Deborah Schofield, *Chair of Health Economics, NHMRC Clinical Trials Centre, and School of Public Health, University of Sydney*

The Treasury has four policy groups: the Fiscal Group, the Markets Group, the Macroeconomic Group and the Revenue Group. The Social Policy Division sits within the Fiscal Group and provides advice to the Australian Government and Treasurer on social policy issues, the labour market and health. This includes national health reform, aged care and accommodation, public health, hospitals funding, Medicare, private health insurance and the Pharmaceutical Benefits Scheme.

The Intergenerational Report (IGR) is prepared by the Fiscal Group at least once every five years to assess the long-term sustainability of current government policies for the next 40 years, taking into account the financial implications of demographic change. The IGR forecasts population, labour force participation, taxation, revenues and spending on government programs.

So what does the IGR have to do with health? The report indicates how much money will be available for health spending and how much pressure health spending will place on the future budget balance.

Australia's population projections will see a dramatic rise in the number of people aged over 65 in the next 40 years. This will result in a smaller number of people in the labour force that will be supporting a much larger number of people requiring payments and services beyond retirement – particularly healthcare services.

> 'The Intergenerational Report forecasts health spending will almost double as a percentage of GDP by 2050.'

In response, the Treasury has looked at a range of measures at different times to either grow the economy or cut growth in health expenditure, including increasing fertility (birth rate), migration, increasing labour force participation of women and older workers, increasing workforce productivity, and co-payments for pharmaceuticals. However, governments need to always be mindful that healthcare cuts can be counterproductive – good health drives labour force participation.

Measures to increase labour force participation have tended to use fiscal levers such as superannuation tax breaks, increasing aged-pension age and deferred pension incentives. However, the majority of people who retire early do so because they are too sick to work.

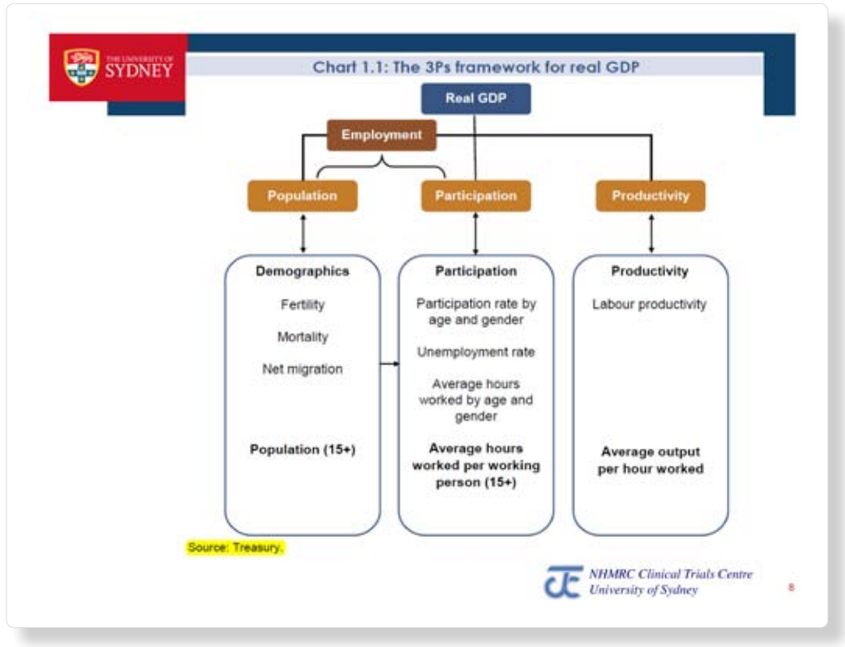
> 'Health itself is one of the economic levers that we can draw on to grow the economy.'

The total number of Australians aged 45–64 years that are not working due to a health conditions is estimated to be around 663,000. This lost workforce reduces Australia's GDP by around $12 billion per annum. The main conditions are back pain, arthritis and mental illness – which don't match the national health priorities.

In terms of reduced consumption possibilities, the cost of retiring early due to illness in Australia results in $18 billion in lost income, $1.5 billion in welfare payments and $2 billion in tax liabilities.

> 'Trialists should be aware that clinical trials and understanding how they impact "the 3 P's" – population, participation (workforce) and productivity – are of great interest to the Treasury.'

A pertinent example of why clinical trials are of such great interest to the Treasury can be seen in work undertaken at the NHMRC Clinical Trials Centre to provide an economic analysis of the drug pregabalin for neuropathic pain. Trial results indicate that just under 1% of patients treated would return to work. Nonetheless, this would result in an additional $75 million in private income and generate $12.5 million in additional tax payments.



4.5 | Streamlining clinical research ethics and governance: What have we achieved?

Speaker

Adjunct Associate Professor Nik Zeps, *Group Research Coordinator, St John of God Healthcare*

HRECs were given increased responsibility and roles in 1992 with the adoption of the CTN/CTX scheme by the TGA; however, the rapid increase in multicentre clinical trial activity overwhelmed the HRECs. A series of steps to address this were taken from the late 1990s, but the ethics approval processes did not improve as a result. More recently, the proposal to separate ethics and governance review was meant to deliver greater efficiency, but this has not yet been achieved and, in many instances, increased governance burden currently exceeds the issues previously identified with HRECs.

A working group of the Australian Health Ministers' Advisory Committee made proposals that did not see mandatory adoption of streamlining as a responsibility of the states and territories, but rather gave the NHMRC the responsibility to reform the sector. The NHMRC has achieved several positive outcomes in reforming HREC processes, but does not have the legislative mandate to enforce this at the jurisdictional level.

> 'Chapter 5.3 of the National Statement published in 2007 states that there is an ethical obligation to minimise duplication of ethical review … and yet seven years on we're still not quite there.'

Multicentre ethics review poses a particular problem – institutions still believe they require their own ethics committees. In contrast, the European Union directive – in effect since 2004 – on reducing duplication of multicentre ethical review has meant that, in some European countries, as few as 30 HRECs are accredited to review multicentre studies (e.g. France). Only one HREC provides the review for any one study for the entire country.

A National Mutual Acceptance of single ethical and scientific review of multicentre clinical trials agreement has been signed by all Australian states and territories, but is still to be fully enacted. In addition to work currently being undertaken by the NHMRC, opportunities to further streamline ethics and governance review being discussed among the sector include:

- **initiating opt-out consent for clinical-effectiveness research**
- **credentialing researchers to streamline ethical and site-specific governance review**
- **developing a sensible patient information consent form (PICF) standard**
- **streamlining reporting for SAEs and CRFs.**

> "Not undertaking clinical research is unethical"
>
> Webb and Zeps, *Medicus*, 4th Feb 2014

4.6 | Streamlining clinical research ethics and governance: Where do opportunities still exist?

Speaker

Ms Imelda Lynch, *Director, Bellberry Limited*

Despite much being achieved, processes for governance and ethical review of clinical trials can still be improved. Timelines for HREC approval are still unacceptably long. Efficiencies could be gained through the use of single national HREC review, which requires cross-jurisidictional and public–private collaboration.

Restrictions on the choice of HREC are unnecessary and inefficient. Using independent national HRECs offers a model that can support a larger pool of committee members, more efficient meeting scheduling and reduced approval times.

HREC efficiencies can also be gained through improvements in the use of opt-out consent and the development of sound procedures for the review of low and negligible risk research.

> 'Only 149 of the 225 ethics committees across the country currently have policies in place for dealing with low and negligible risk research.'

HRECs spend a considerable amount of time liaising with well-intentioned but inexperienced junior investigators who are not skilled at preparing applications. ACTA could provide support through the provision of 'mentors' to assist less-experienced researchers to design trials, and prepare protocols and other documents before submission to HRECs. The development and use of standardised participant information covering matters that pertain to most trials will also assist.

> 'Governance matters could be streamlined by devolving trial sign-off to departmental heads, ensuring insurance cover is appropriate for clinical trials of any type and preventing alterations to standardised contracts.'

5

SESSION 3

The key role and potential of investigator networks and public-good trials

Session Chair

Professor Amanda Thrift, *Head of the Epidemiology and Prevention Division, Stroke and Ageing Research, Monash University*

5.1 | The NHMRC perspective on clinical trials networks

Speaker

Dr Clive Morris, *Head of Strategic Policy Group, NHMRC*

The NHMRC recognises that clinical trials networks represent the vast majority of the clinical research workforce that undertakes both publicly and industry-funded clinical trials in Australia. They provide a wide range of support to investigators and clinicians throughout the whole cycle of a trial, including:

- **trial feasibility, design and protocol development**
- **funding for trials administration and infrastructure – for example, key trial staff, office costs, IT support and travel to collaborative group meetings**
- **education and training for trials personnel**
- **central data management**
- **statistical analysis of data.**

> ‘The NHMRC sees clinical trials networks as critically important for research.’

The 2011 CTAG Report, which was accepted by the government of the day, set the scene for a number of initiatives under way at the NHMRC and across other Australian Government departments to increase support for clinical trials.

> *That greater support for clinical trials networks in priority health areas be provided through the NHMRC by:*
> > *identifying the networks that exist in Australia*
> > *facilitating national coordination and encouraging collaboration across academia, clinical medicine and industry.*
>
> *Recommendation I, CTAG Report 2011*

As outlined by Warwick Anderson (see Section 3.2), the NHMRC is currently undertaking activities to support the implementation of the CTAG recommendations and boost clinical trials activity in Australia. These focus on:

- streamlining research governance and ethical review processes
- developing training and education materials relative to clinical trials
- further developing the Australian Clinical Trials website and web portal
- redeveloping the NEAF.

The NHMRC is also focused on increasing support for clinical trials networks, through initiatives such as the ACTA Summit, and looks forward to working with ACTA to better define the clinical trials networks in Australia, and to understand the different models for establishing and maintaining successful networks.

> ‘There can be a lot of synergises gained from bringing networks together, and defining what they do and the common barriers they have to operating.’

Clinical trials networks can be a very powerful force for change in improving the landscape for conducting clinical trials in this country. Specific opportunities include:

- developing strategies to improve patient recruitment and participation
- supporting early- and mid-career researchers
- coming together to pool resources and knowledge to develop more efficient processes
- supporting the adoption of best-practice processes for site assessment and clinical trial authorisation
- helping to establish standard costs for clinical trials (via IHPA).

For the past decade, it has become increasingly apparent that clinical trials research is a complex environment with multiple layers spanning multiple jurisdictions and agencies. There is work ongoing to try to identify common ‘top-down’ approaches, but ‘bottom-up’ activity is also required to force change.

NHMRC

Next Steps

- Work with ACTA to identify and better understand Australia’s clinical trials networks
- Work with Commonwealth and State/Territory departments and other stakeholders towards a nationally consistent approach to clinical trials.
- Learn from international experience and models for supporting clinical trial networks

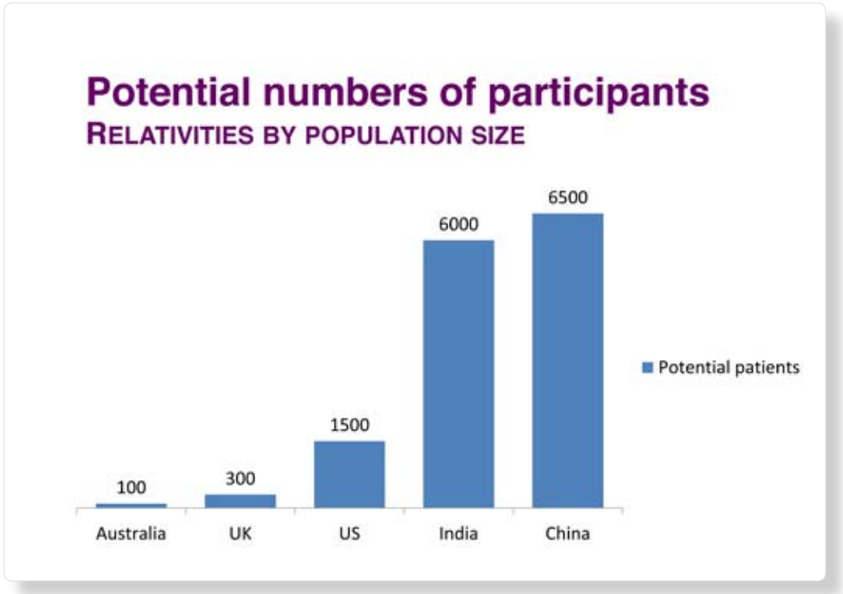
5.2 | Clinical trials networks and international collaboration

Speaker

Professor Vlado Perkovic, *Executive Director, The George Institute for Global Health Australia and George Clinical*

Australia is already viewed internationally as one of the world’s leaders in terms of our capacity to develop and run high-quality investigator-initiated and commercial clinical trials. However, there is a real opportunity for us to increase our regional and global leadership in this area, and for this to directly impact on improved outcomes for patients in Australia.

Australia represents only 0.3% of the world’s population, but there are 3.6 billion people – or around half of the people on the planet – living in our immediate neighbourhood in Asia. Even allowing for the reduced access to healthcare centres for many people living in these countries, the capacity of our neighbours to recruit patients dwarfs our own by some distance. This will become increasingly important as we look to undertake trials in uncommon conditions or conditions that are prevalent in the region.



Large-scale trials, such as the ADVANCE Trial, have shown that adherence to randomised treatment in Asia is excellent, and in many cases superior to other places around the world. Conducting research in Asian countries also increases access to ideas. There is a rapidly growing amount of intellectual property arising from Asia, especially from China, and it is important to consider how we might support and engage with this emerging intellectual leadership to partner in solving some of the key clinical questions that we are all facing.

Our understanding of the risk–benefit ratio of interventions across different populations can also be improved through international trials. For example, the HPS2-Thrive study demonstrated a significantly higher risk of myopathy with high-dose statins in Chinese participants. This has massive implications for our colleagues in China, but with 1 in 16 Australians having an Asian background, it provides important evidence for clinicians treating patients here.

‘Trials that are adequately powered to detect clinically meaningful differences are increasingly requiring budgets in the tens of millions – funding that is simply beyond the capacity of the NHMRC to provide.’

Perhaps one of the most compelling reasons for looking to international collaborations to conduct investigator-initiated trials is the opportunity that opens up in terms of funding. There are a number of successful examples of large international trials that have been led by Australia using different models for collaboration and funding such as the PEXIVAS Trial (large pool of international competitive funding and industry support), the ACTIVE DIALYSIS Trial (NHMRC/industry funding) and the TESTING study (international steering committee with regional coordinating centres and funders).

The challenges related to conducting international trials are rarely about collaboration or the science. The biggest issues are finding a primary funder (once found, leveraging primary funding to increase trial budgets is generally much easier), the regulatory environment, managing sites, dealing with adverse outcomes and insurance, and importing placebos.

‘Many international initiatives are attempting to address the same issues around clinical trial conduct that we face in Australia. It is important that we see ourselves as part of a broader international community, and that we don’t try to solve all of these problems locally in isolation.’

Potential enablers of international collaboration include:

> appropriate and adequate targeted funding schemes like the Global Alliance for Chronic Disease

> appropriate interaction between regulators

> developing formalised ‘networks of networks’ facilitated by a central infrastructure where different networks might take leadership for different parts of the study but work together towards the common outcome.

Speaker: Professor Warwick Anderson AM

5.3 |

How can we maximise the benefit of clinical trials networks?

Speaker

Professor Rinaldo Bellomo, *Founding Chair, Australian and New Zealand Intensive Care Society Clinical Trials Group, and Co-Director, ANZIC Research Centre*

‘The vast majority of healthcare is random and the vast majority of patients are not enrolled into clinical trials. This means that a variety of practices are not routinely questioned, evaluated and refined, and that billions of dollars are spent without asking whether things can be done better.’

For the past 15 years, the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) has adopted an approach to clinical research that seeks to challenge the model of ‘the individual clinician knows best’. This approach is to conduct trials that compare common treatments given randomly on any given day by random doctors, to random patients, to achieve randomly selected goals.

The group has achieved great success in terms of the number of trials completed and published in high-impact journals (nine trials published in the New England Journal of Medicine). It has demonstrated harm in four trials of commonly used therapies in intensive care around the world – tight glucose control, decompressive craniectomy in traumatic brain injury (TBI), albumin fluid resuscitation in TBI and starch fluid resuscitation. Despite saving the Australian economy an independently estimated $1 billion, the group has failed, thus far, to identify a therapy that improves patient outcomes over and above existing standard care.

In evaluating the future of the ANZICS CTG research program, the group has come to recognise the following challenges that lay ahead:

> the need to use innovative statistical methods, such as Bayesian adaptive design, that can more accurately identify complex combined interventions across multiple trial arms with greater efficiency in phase II studies

> the pursuit of new interventions that can make a difference to patient-centred outcomes requires the capacity to conduct trials that are adequately powered to detect a 1–2% absolute risk reduction for mortality

> that surrogate outcomes are a poor predictor of survival in intensive care and have been, at times, spectacularly misleading

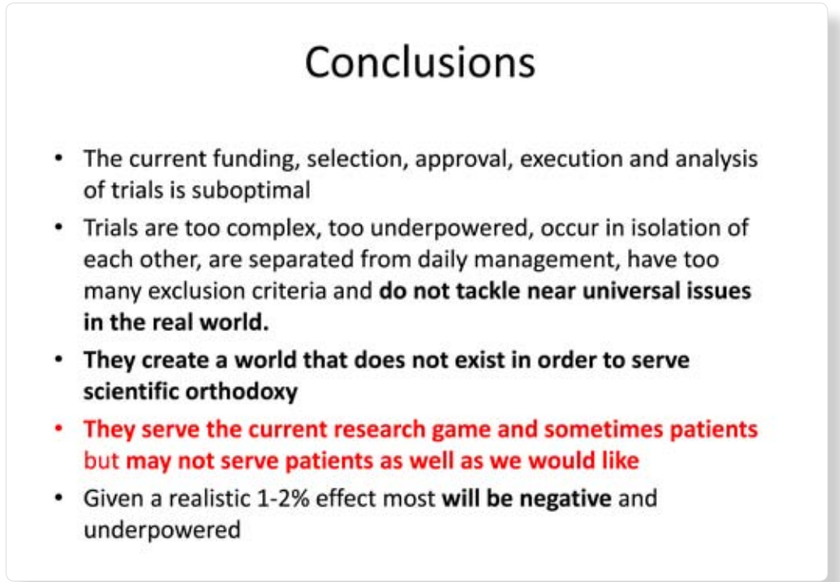
> the need to study near-universal, economically viable interventions so that trials can recruit the large numbers of patients needed to show a difference

> the need to solve the burden of cost such that the cost of randomising and collecting data on tens of thousands of patients into mega trials is not completely prohibitive. This will require simplified data collection, and greater integration and linkage with registries

> the need to explore opt-out consent for comparative effectiveness trials to remove the burden of obtaining individual consent for individually randomised patients

> the need to explore cluster cross-over trials to support large sample sizes with adequate power to detect small but meaningful differences in patient-centred outcomes

> the need to collaborate more to conduct cross-disciplinary trials.



‘In order to maximise their benefit, networks need to:

> **educate the public** that they are better off receiving randomised care than random care

> **educate politicians** that patients are better off receiving randomised care than random care

> **educate funders** that the system is better off with randomised care than random care

> **educate HRECs** that randomised care is more ethical than random care.’

5.4 |

Experiences of a recently established network: Paediatric Trials Network Australia

Speaker

Associate Professor Andrew Davidson, *Chair, Paediatric Trials Network Australia*

The Paediatric Trials Network Australia (PTNA) was formally established in 2013 after several years of gestation. PTNA's mission is to facilitate high-quality research with a focus on collaborative paediatric clinical trials.

'The objectives of the PTNA are to:

> strengthen the evidence base for the treatment of all children and adolescents

> increase the quality and quantity of investigator-driven paediatric clinical studies

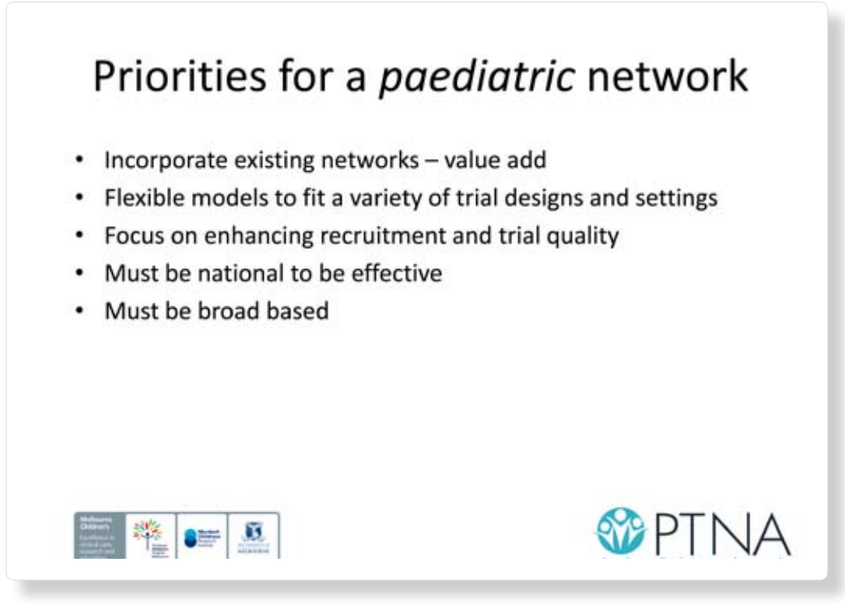
> improve the Australian operating environment for paediatric clinical trials sponsored by industry

> provide a platform for advocacy for collaborative clinical research in paediatrics in Australia.'

Trials in children are difficult for numerous reasons – outcome measures are often not validated in children, the mechanisms of disease in children are often poorly understood, drug doses and pharmacokinetics are often unknown, there are considerable issues in experimenting in young children, and they are a very heterogeneous population.

Paediatrics is also a heterogeneous collection of subspecialties, and there are a number of established clinical trials networks in Australia across areas such as neonatology, oncology, emergency medicine and others.

A major breakthrough in development of the PTNA was the awarding of a major grant from Therapeutic Innovation Australia through its Translating Health Discovery initiative to develop a custom-built clinical trials data management platform (webspirit) to support paediatric trials. This became the central point around which the network grew.



Key lessons for the PTNA from international networks were:

> There is a need to have substantial buy-in and funding from key partners to achieve critical mass.

> Do not rely on industry funding.

> There needs to be ongoing infrastructure funding.

> Be lean rather than overambitious.

> Be flexible and play to your strengths.

> Balance the 'coalition of the willing' with the 'united nations'.

With five trials now under way and a series of others in the pipeline, the PTNA is looking to future challenges, including how to link with other networks in the paediatric space and other trials centres, finding a sustainable funding and membership model, and engaging more with industry.

'How can we use the network to share the educational resources that we have to ensure that paediatric trials across Australia are done to a uniformly high standard?'

5.5 |

Experiences of a recently established network: Type 1 Diabetes Clinical Research Network

Speaker

Dr Dorota Pawlak, *Head of Research Development, Juvenile Diabetes Research Foundation Australia*

The Australian Type 1 Diabetes (T1D) Clinical Research Network (T1DCRN) has been fortunate to receive bi-partisan support from the Australian Government. In 2010, the-then Prime Minister Kevin Rudd announced that $5 million would be provided to support the establishment of an Australian Clinical Trial Network for Type 1 Diabetes. Three years later, the Coalition Government fulfilled a pre-election commitment to provide a further $35 million to fully establish a T1DCRN to deliver a coordinated national approach to diabetes research. The funding was awarded to the Juvenile Diabetes Research Network (JDRF) to administer and manage.

The journey to establishing the T1DCRN began in 2009 with a research strategy meeting that involved all of the broad T1D stakeholder groups. The meeting identified clinical, scientific and research strengths across the country, and chartered research priorities for the next decade.

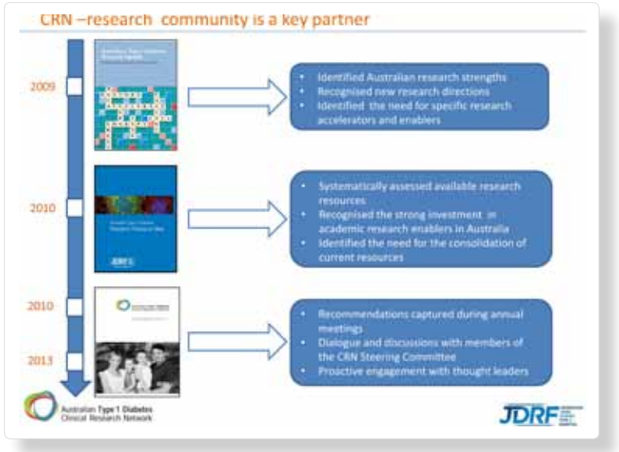
The next step was to identify what research infrastructure and capacity existed to support T1D research in Australia. Although there had been a degree of investment in infrastructure, it was fragmented, and, at that time, not conducive to conducting collaborative clinical trials. A network was desperately needed.

> ‘In 2009, there were only three clinical trials in Type 1 diabetes under way in Australia.’

When the T1D community became aware via JDRF of the need to establish a clinical trials network, they launched a coordinated national advocacy campaign that included more than 135 meetings with members of parliament in more than 85% of federal electorates, and culminated in a visit by 100 children to Parliament House to call on the government to pledge funding to support the network.

> ‘The Australian Type 1 Diabetes Clinical Research Network employs a strategic approach to research: cure, treat, prevent.’

The initial $5 million investment established a strong platform for preclinical and clinical studies, as well as research resources. Now fully funded for the next five years, the T1DCRN can provide assistance with research accelerators; randomised controlled trials; engagement of clinicians, scientists, policy makers and consumers in research; career support for researchers; and pilot and feasibility studies and operations.



5.6 |

The vision for clinical trials in Australia: Networks, registries and beyond ...

Speaker

Professor John McNeil AM, *Head of the School of Public Health and Preventive Medicine, Monash University*

Although clinical trials in Australia have been successful, there is still much to be accomplished, including:

> establishing collaborative trial networks in several key areas of medicine, such as mental health and cardiology

> supporting methodology centres that allow economies of scale and can effectively support multiple trial coordinating centres and clinical registries

> reducing unnecessary red tape, especially that surrounding ethics, governance and insurance

> developing new approaches that will allow trials to be undertaken more rapidly and less expensively.

> ‘We absolutely have to work out how to run clinical trials in a less expensive way.’

Some solutions are relatively straightforward, and include:

> sustainable funding for methods centres (with strong epidemiology, biostatistics and data-management capabilities), which can support multiple trials groups and registries

> infrastructure funding for networks to replace wasteful ‘project-by-project’ funding

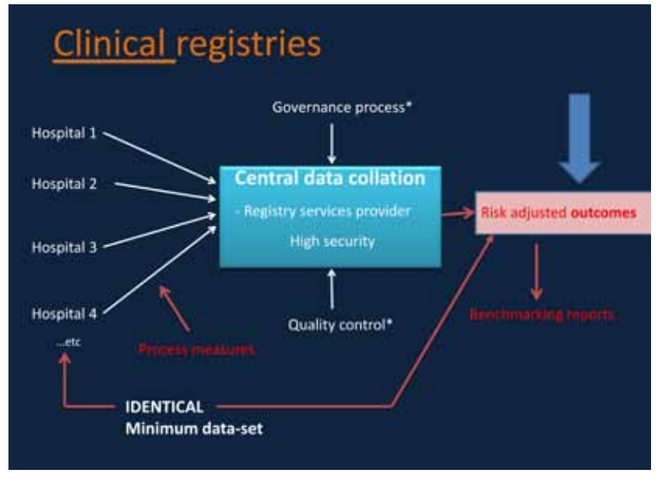
> reduce clinical trial costs through initiatives such as

- developing a model for ‘opt-out consent’ for comparative efficacy studies when these involve widely used and approved therapies
- incorporating trials within clinical registries (as demonstrated by the recent TASTE Trial from Sweden)
- abolishing the need to gain approval from multiple ethics and governance committees

> increase public support through sophisticated marketing that explains the benefits to individuals, their families and their communities

> improve the quality of routinely collected data and facilitate linkage to research databases

> expand clinical registries to collect risk-adjusted outcomes data across a broad range of high-cost high-significance areas of medicine.



‘One of the key goals of medical research is to improve productivity in the healthcare sector. This requires continuous research to identify the most cost-effective and efficacious treatments, and to maximise safety. This goal will be best achieved by the development of an integrated system in Australia that includes:

- clinical trials to establish the efficacy of various interventions
- clinical registries to track appropriateness of interventions, quality of care (via benchmarking) and translation into practice
- biorepositories to allow improved prediction of efficacy and adverse effects.’

Professor John McNeil AM

Speaker: Professor Rinaldo Bellomo

Speaker: Professor John Simes

6

BREAKFAST SESSION 4

Supporting a highly skilled clinical trials workforce

Breakfast Session chair

Adjunct Associate Professor Nik Zeps, *Group Research Coordinator, St John of God Healthcare*

6.1 | Development of OECD Global Core Competencies for Clinical Trials

Speaker

Professor Davina Ghersi, *Senior Principal Research Scientist, NHMRC*

'To successfully run international clinical trials, three main challenges need to be addressed:

- excessive administration complexity
- poor regulation in some countries for some clinical trials, and the desire to implement an risk-based approach to clinical trials management
- uneven national and regional support for education, training and infrastructure, and the lack of patient involvement.'

These issues gave rise to the concept of an Organisation for Economic Co-operation and Development–(OECD-) led global concept forum. Working groups were established to facilitate non-commercial clinical trials and international cooperation.

The result was the publication of OECD recommendations on the governance of clinical trials, which addressed the three main challenges and was to be implemented via several subgroups. It is important that the World Health Organization is involved, especially for low- and middle-income countries.

The membership and mechanisms are yet to be determined but ACTA's work could involve developing core competences to complement the OECD subgroup.

6.2 | Consent training modules project

Speaker

Dr Joanne Shaw, *Research Manager, Psycho-Oncology Cooperative Research Group*

> ‘In oncology, only about 5% of patients participate in research.’

There are several reasons for this low participation rate:

> patients have a preference for a certain treatment

> patients want to avoid the logistics of being in a clinical trial, such as extra travel and testing

> patients are concerned that clinical trials are only for desperate, hopeless cases

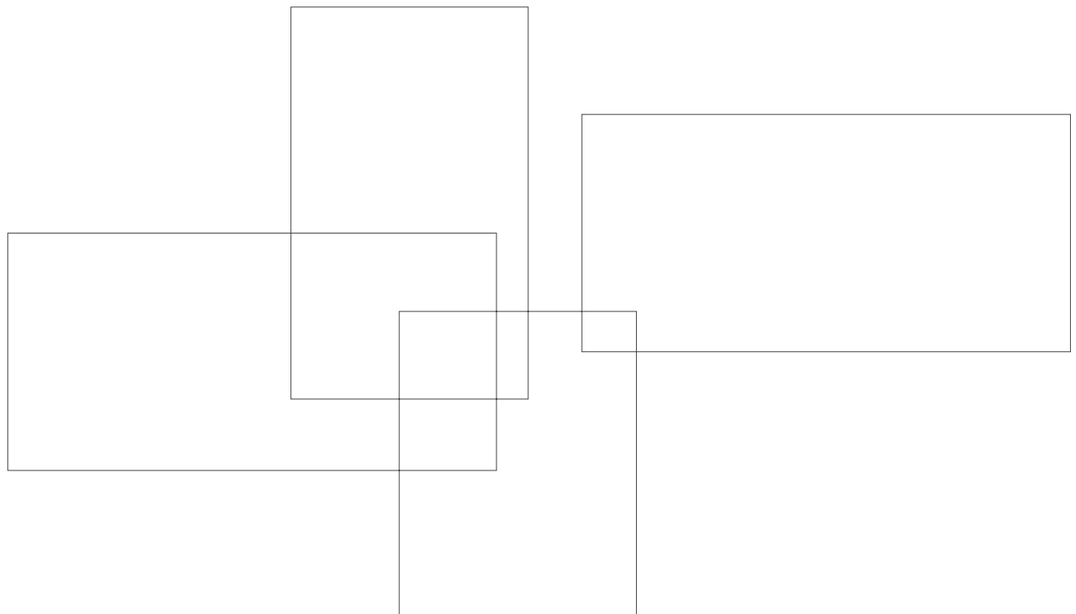
> patients are not asked to participate.

Why are clinicians not asking? One reason is that there is no uniform approach and/or accreditation. Clinicians do find it difficult to communicate to patients the information about trials and all the issues surrounding them. It also takes a lot of time and the paperwork is complex.

Patients have specific needs when learning about clinical trials. They want a collaborative communication, where they can discuss what they already do know, and ask questions about their concerns. They do not want to hear jargon, but do want the conversation backed up with diagrams, lists and written information. Patients need time to process the information, and discuss it with family and others. They also need emotional support.

Patients may need a different communication style when talking about specific aspects of trials, such as tissue analysis (which may affect family members). If researchers are trained to communicate, they will improve.

The consent training modules project uses a consultation pathway and randomised controlled trial to evaluate training methods. The goal is to develop online modules to help train researchers that will be accessible to all potential research groups.



6.3 | Standardised Patient Information Sheet Project

Speaker

Ms Kylie Sproston, *CEO, Bellberry Limited*

In recent years, patient information sheets (PISs) has become a disincentive to recruitment. Investigators and trial participant alike have argued that PISs:

> are too long and complex

> contain language that is confusing

> contain information that is inconsistent and incomplete

> take a substantial amount of time to develop and redevelop.

> ‘Patient information sheets have become an intellectual process that leans more towards the protection of sponsors than the interests of trial participants.’

Bellberry is currently working to develop a generic clinical trials booklet that will be suitable for patients thinking about participating in any clinical trial. The booklet will be supported by short, study-specific information to support the informed consent process.

The focus will be on helping patients understand the clinical trial. The final product is likely to include multimedia tools to meet patient’s needs in accessing information about participating in trials. The aim is to protect and improve the safety of research participants, as well as to improve the quality, effectiveness and efficiency of research.

The progress of this project can be tracked by subscribing to the Bellberry newsletter at www.bellberry.com.au.

6.4 | The TransCelerate Initiative

Speaker: **Mr Adrian Bootes, CEO, ARCS**

TransCelerate BioPharma Inc. is a not-for-profit organisation aiming to advance R&D, identify and solve common R&D challenges, and improve patient safety. The primary objective is to deliver more high-quality medicines to consumers.

'TransCelerate is coordinating a series of projects across five main initiative areas:

- risk-based site monitoring approach and standards
- shared user interface for investigator site portals
- study site qualification and training
- clinical data standards
- comparator drug supply models.'

TransCelerate members are biotechnical and pharmaceutical companies that have active R&D departments. This global initiative offers leadership for R&D and a way to address common practical challenges that impact the conduct of clinical trials in Australia and internationally.

Further information about the TransCelerate Initiative can be found at www.transceleratebiopharmainc.com.

Speaker: Professor Deborah Schofield

7

SUMMARY

Strategies for increasing our capacity to conduct high-impact public-good clinical trials within the Australian healthcare system

ACTA Summit participants had the opportunity to explore key concepts raised during each of the presentations during panel discussions held at the conclusion of each session. A medical writer was engaged to capture discussion on the day, and presentations were recorded and made publicly available via the ACTA website shortly after the summit.

During the 1.5-day meeting, it became apparent that the issues that impact most significantly on clinical trials networks are largely the same – irrespective of their area of clinical specialty or disease process. The perspectives and proposed strategies put forward by speakers were generally supported and reinforced during panel discussions.

Many of the key issues discussed during the summit are not new. However, despite the fact that researchers, governments and policy makers have been struggling to make headway on a number of these fronts for several years, there was a strong undertone of commitment and enthusiasm for reinvigorating efforts to improve the landscape for conducting public-good trials within the Australian health system.

7.1 | Key proposals

> secure sustainable infrastructure funding for networks to replace wasteful ‘project-by-project’ funding

> secure sustainable funding for methods centres with strong epidemiology, biostatistics and data-management capabilities that support multiple trials networks and registries

> conduct more innovative clinical trials that address the healthcare system’s most important clinical questions

> make research outputs a key performance indicator for hospitals

> improve the quality of routinely collected data and facilitate linkage to research databases

> expand clinical registries to collect risk-adjusted outcomes data across a broad range of high-cost high-significance areas of medicine

> advance local expertise in trial methodology to meet the modern challenges of recruitment in smaller sub-populations of patients or where smaller effect sizes in commonly used interventions have the greatest potential for benefit

> incorporate trials within clinical quality registries

> link networks to conduct more cross-discipline trials

> coordinate and share resources and expertise between clinical trials networks (e.g. outcome measurements, data safety monitoring boards, education for researchers)

> abolish the need to gain approval from multiple ethics and governance committees to conduct multicentre trials

> standardise common trial documentation, such as patient information sheets and case-report forms

> move to a regulatory framework that is proportionate to the additional risk for people participating in public-good clinical trials

> develop an appropriate model of consent for comparative effectiveness studies when these involve widely used and approved therapies

> liaise with the Independent Hospital Pricing Authority to develop an appropriate costing framework for investigator-initiated clinical trials

> work more closely with government, regulators and policy makers – particularly during the trial planning and development phases

> develop models of partnership with international investigators and funding agencies to conduct large-scale pragmatic trials

> develop models of partnership with industry to both conduct trials and improve the competitive environment for conducting trials in Australia

> increase public support through a major public education campaign to inform the community of the purpose and importance of clinical trials

> develop impactful models of consumer engagement in clinical trials

> conduct ‘research on research’ to demonstrate and understand what it is we currently do, how it can be done better and how it impacts healthcare outcomes

> advocate widely for the health and economic benefits of clinical trials and clinical quality registries to support a self-improving health system.

7.2 | ACTA’s role

There was a repeated call for ACTA to play a role in bringing together the most experienced investigators in the country to help advocate strongly on behalf of the sector. ACTA could also provide leadership in promoting innovative, coordinated strategies that will increase the number and impact of public-good clinical trials conducted in Australia, to the benefit of both patients, and the payers and providers of healthcare.

Participants in the ACTA Summit articulated a clear leadership role for ACTA across the broad domains of:

> advocacy and engagement

> communication, coordination and networking

> education and knowledge exchange

> policy recommendations

> funding and regulatory reform

> public education

> ‘research on research’.

A business-style meeting of members of the ACTA community (encompassing clinical trials networks, trial coordinating centres and clinical quality registries) was held on the second day of the summit. Participants discussed the formation and development of ACTA, and reviewed the key strategies and opportunities that were proposed during the summit to identify priority initiatives for ACTA to pursue during the next 12 months. The outcomes of the business meeting will be reported separately for participants.

Chair: Professor Amanda Thrift
Panel from left: Professor Rinaldo Bellomo, Associate Professor Andrew Davidson, Professor Vlado Perkovic, Professor John McNeil AM

8 Appendixes

8.1 | Appendix A: Clinical Trials Networks in Australia

The following clinical trials networks had been identified by ACTA at the time of the 2014 Summit.

Established networks
Australasian Child & Adolescent Obesity Research Network
Australasian Consortium of Centres for Clinical Cognitive Research
Australasian Gastro-Intestinal Trials Group
Australasian Kidney Trials Network
Australasian Leukaemia & Lymphoma Group
Australasian Lung Cancer Trials Group
Australasian Neuromuscular Network
Australasian Sarcoma Study Group
Australasian Sleep Trials Network
Australasian Society for Infectious Diseases Clinical Research Network
Australasian Stroke Trials Network
Australia & New Zealand Breast Cancer Trials Group
Australia & New Zealand Gynaecological Oncology Group
Australian & New Zealand Children's Haematology/Oncology Group
Australian & New Zealand College of Anaesthetists Trials Group
Australian & New Zealand Melanoma Trials Group
Australian & New Zealand Neonatal Network
Australian & New Zealand Urogenital & Prostate Cancer Trials Group
Australian & New Zealand Intensive Care Society Clinical Trials Group
Australian College of Emergency Medicines Trials Group
Australian Epilepsy Clinical Trials Network
Australian Paediatric Research Network
Australian Research Centre for Health of Women & Babies, Robinson Institute (WOMBAT Collaboration)
Australian Type 1 Diabetes Clinical Research Network
Better Treatments for Kids Research Network (NSW)
Centre for Youth Mental Health
Cooperative Trials Group for Neuro-Oncology
Multiple Sclerosis Research Australia Clinical Trials Network
National Centre for Asbestos Related Diseases
Neuroscience Trials Australia
Paediatric Research in Emergency Departments International Collaborative
Paediatric Trials Network Australia
Palliative Care Clinical Studies Collaborative
Perinatal Society of Australia & New Zealand Clinical Trials Network
Perinatal Society of Australia & New Zealand IMPACT Network
Primary Care Collaborative Cancer Clinical Trials Group
Psycho-oncology Co-operative Research Group
Trans Tasman Radiation Oncology Group

Developing networks / large single-trial networks
ADVANCE Group (T2DM)
ASPREE Trial (Aspirin in the Elderly)
Australasian Radiopharmaceutical Trials network
Australian & New Zealand Cardiovascular Society Trials Working Group
Australian Musculoskeletal Clinical Trials Group
Australian Primary Care Research Network
Collaboration for Burns Trials
FAME 1 (Retinopathy in T1DM)
Spinal Cord Injury Network

8.2 |

Appendix B: List of participating organisations

The following organisations were represented at the ACTA Summit 2014.

ACT Health
ARCS Australia
Australasian Cochrane Centre
Australasian Consortium of Centres for Clinical Cognitive Research
Australasian Gastro-Intestinal Trials Group
Australasian Kidney Trials Network
Australasian Leukaemia & Lymphoma Group
Australasian Lung Cancer Trials Group
Australasian Radiopharmaceutical Trials Network
Australasian Sarcoma Study Group
Australasian Sleep Trials Network
Australasian Society for Infectious Diseases Clinical Research Network
Australasian Stroke Trials Network
Australia & New Zealand Breast Cancer Trials Group
Australia & New Zealand Neonatal Network
Australian & New Zealand Children's Haematology-Oncology Group
Australian & New Zealand College of Anaesthetists Trials Group
Australian & New Zealand Intensive Care Research Centre
Australian & New Zealand Intensive Care Society Centre for Outcomes & Resource Evaluation
Australian & New Zealand Intensive Care Society Clinical Trials Group
Australian & New Zealand Melanoma Trials Group
Australian & New Zealand Neonatal Network
Australian & New Zealand Society of Cardiac & Thoracic Surgeons National Cardiac Surgery Registry
Australian & New Zealand Urogenital & Prostate Cancer Trials Group
Australian Cardiac Procedures Registry
Australian Epilepsy Clinical Trials Network
Australian Government Department of Health
Australian Government Department of Industry
Australian Institute of Health & Welfare
Australian Medical Association
Australian Melanoma Consumers Alliance
Australian Motor Neuron Disease Registry
Australian Musculoskeletal Clinical Trials Group
Australian Primary Care Research Network
Australian Research Centre for Health of Women & Babies, Robinson Institute
Australian Society for Medical Research
Bellberry Limited
Biomedical Research Victoria
Burns Service of Western Australia
Cancer Australia
Centre for Anaesthesia & Cognitive Function
Centre for Biostatistics & Clinical Trials
Centre for Research in Evidence-Based Practice
Clinical Oncology Society of Australia
Colorectal Surgical Society of Australia & New Zealand
Committee of Presidents of Medical Colleges
Consumer Health Forum of Australia
Cooperative Trials Group for Neuro-Oncology
Epworth HealthCare Clinical Trials & Research Centre
Independent Hospital Pricing Authority
Juvenile Diabetes Research Foundation
Lung Foundation Australia
Medical Services Advisory Committee
Medicines Australia
Melanoma Institute Australia
Miracle Babies Foundation
Monash Centre for Health Research & Implementation, Monash University
Multiple Sclerosis Research Australia Clinical Trials Network
Murdoch Children's Research Institute
National Health & Medical Research Council
Neuroscience Trials Australia
New South Wales Department of Health
New South Wales Office for Health and Medical Research
NHMRC Clinical Trials Centre
NSW Better Treatments 4 Kids
Orygen Youth Health Research Centre
Paediatric Research in Emergency Departments International Collaborative
Paediatric Trials Network Australia
Palliative Care Clinical Studies Collaborative
Perinatal Society of Australia & New Zealand
Pharmaceutical Industry Council Research & Development Task Force
Primary Care Collaborative Cancer Clinical Trials Group
Private Healthcare Australia
Psycho-oncology Co-operative Research Group
Queensland Centre for Mental Health Research
Queensland Clinical Trials & Biostatistics Centre
Queensland Department of Health
Research Australia
School of Public Health & Preventive Medicine, Monash University
South Australian Department of Health & Ageing
South Australian Health & Medical Research Institute
Spinal Cord Injury Network
St John of God Healthcare
Sydney Children's Hospitals Network
Tasmanian Department of Health & Human Services
The ASPREE Study Group
The George Institute for Global Health
Therapeutic Goods Administration
Therapeutic Innovation Australia
Type 1 Diabetes Clinical Research Network
University of Melbourne
Victorian Ambulance Cardiac Arrest Registry
Victorian Cardiac Arrest Registry
Victorian Cervical Cytology Registry
Victorian Department of Health
Victorian Department of State Development, Business & Innovation

Australian Clinical Trials Alliance

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