Australian Clinical Trials Alliance

ACTA Summit 2014

Novotel on Collins, Melbourne
28-29 March

A National Summit of Investigator-Initiated Clinical Trials Networks

Marking the official launch of the Australian Clinical Trials Alliance, the ACTA Summit 2014 will bring together more than 100 of Australia's leading clinician researchers from across the healthcare system to join with key policymakers in reviewing pivotal achievements and opportunities for advancing the conduct of investigator-initiated clinical trials.

Program - Friday 28 March

The landscape for clinical trials in Australia:

Identifying strengths and opportunities

9.00 - 11.00
Chair: Prof Tony Keech

Topic	Speaker	Time
Introduction and Welcome	**Prof John Zalcberg OAM**	**9.00 - 9.10**
Opening address and official launch of ACTA	**Prof Chris Brook PSM**	**9.10 - 9.20**
Improving the Health and Wealth of Australians: The importance of clinical trials	**Prof Warwick Anderson AM**	**9.20 - 9.40**
Clinical Trials: The value proposition	**Prof Steve Webb**	**9.40 - 10.00**
Current Clinical Trials Activity in Australia	**Prof John Simes**	**10.00 - 10.20**
Investigator-Initiated Clinical Trials Networks: The quality agenda	**Prof John Zalcberg OAM**	**10.20 - 10.40**
Panel Discussion		**10.40 - 11.00**
Morning Tea		**11.00 - 11.30**

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Clinical trials and the health system:
Accelerating answers to important clinical questions

11.30 - 1.30
Chair: Prof Steve Webb

Topic	Speaker	Time
Pathways to Better Evidence: Regulatory processes and clinical trials	**Prof John Skerritt**	**11.30 - 11.50**
New Frontiers: How can clinical trials networks work better with industry?	**Dr Brendan Shaw**	**11.50 - 12.10**
Interaction with Policy Makers…		
Connecting clinical trialists with Health Departments	**Prof Alan Cass**	**12.10 - 12.25**
Connecting clinical trialists with Treasury	**Prof Deborah Schofield**	**12.25 - 12.40**
Streamlining clinical research ethics and governance…		
What have we achieved?	**A/Prof Nik Zeps**	**12.40 - 10.55**
Where do opportunities still exist?	**Ms Imelda lynch**	**12.55 - 1.10**
Panel Discussion		**1.10 - 1.30**
Lunch		**1.30 - 2.15**

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

2.15 - 4.30
Chair: Prof Amanda Thrift

Topic	Speaker	Time
The NHMRC Perspective on Clinical Trials Networks	**Dr Clive Morris**	**2.15 - 2.35**
Clinical Trials Networks and International Collaboration	**Prof Vlado Perkovic**	**2.35 - 2.55**
How can we maximise the benefit of clinical trials networks?	**Prof Rinaldo Bellomo**	**2.55 - 3.15**
Experiences of a recently-established network…		
Paediatric Trials Network Australia	**Prof Andrew Davidson**	**3.15 - 3.30**
Type 1 Diabetes Clinical Research Network	**Dr Dorota Pawlak**	**3.30 - 3.45**
The Vision for Clinical Trials in Australia: Networks, registries and beyond…	**Prof John McNeil AM**	**3.45 - 4.05**
Panel Discussion	**Prof Steve Webb**	**4.05 - 4.30**

ACTA Networking Dinner

Keynote speaker: Emeritus Professor Richard Larkins AO
Time: 7:00pm
Venue: Australian Centre for the Moving Image (ACMI), Screen Worlds Exhibition
Federation Square, Flinders St, Melbourne
Dress: Business Casual

Program - Saturday 29 March

Supporting a highly-skilled clinical trials workforce

8.00 - 9.15
Chair: A/Prof Nik Zeps

Topic	Speaker	Time
Summit Breakfast		**8.00 - 8.15**
Development of OECD Global Core Competencies for Clinical Trials	**Prof Davina Ghersi**	**8.15 - 8.30**
Consent Training Modules Project	**Dr Joanne Shaw**	**8.30 - 8.45**
Standarised Patient Information Sheet Project	**Ms Kylie Sproston**	**8.45 - 9.00**
The Transcelerate Initiative	**Mr Adrian Bootes**	**9.00 - 9.15**

ACTA Business Meeting: 9.30 - 1.00

Reviewing progress & agreeing plans for the Australian Clinical Trials Alliance

Participants who have been invited to take part in the Summit representing a clinical trials network, trial coordinating centre or clinical quality registry are encouraged to attend this closed meeting of potential future members of ACTA.

A meeting agenda and documents for pre-reading and discussion will be circulated in the week prior to the Summit. Networks, trial centres and registries that are not able to be represented at the Summit will have the opportunity to provide comments.

Topic	Time
Session 1: The Australian Clinical Trials Alliance (ACTA): Progress and plans Presentation and discussion of the proposed ACTA model Developing a comprehensive profile of Australia's Clinical Trials Networks	**9.30 - 11.00**
Morning Tea	11:00-11:30
Session 2: Prioritising issues and opportunities for the investigator-initiated clinical trials sector. Review of key issues and opportunities for sustaining networks and advancing the conduct of investigator-initiated clinical trials Workshop to prioritise key issues and identify projects and policy initiatives to be developed by ACTA	**11.30 - 1.00**

Invited Speakers

Professor Warwick Anderson AM is Chief Executive Officer of the National Health and Medical Research Council (NHMRC). Previously, he was Head of School of Biomedical Sciences at Monash University and Deputy Director of the Baker Medical Research Institute, following research fellowships at the University of Sydney and Harvard Medical School. Warwick is a member of the Prime Minister's Science Engineering and Innovation Council, a Board member of the Global Alliance for Chronic Disease, a member of Heads of International (Biomedical) Research Organizations and of the National Lead Clinicians Group. He is an Honorary Fellow of the Royal College of Pathologists of Australasia and an International Fellow of the American Heart Foundation. He was made a Member of the Order of Australia in 2005.

Professor Rinaldo Bellomo is Professor of Medicine with the University of Melbourne, Honorary Professor of Medicine with Monash University, and with the University of Sydney, Concurrent Professor with the University of Nanjing, NHRMC Practitioner Fellow, Principal Research Fellow, Howard Florey Institute, University of Melbourne, Director of Intensive Care Research and Staff Specialist at the Austin Hospital, Melbourne. He is the Founding Chairman of the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) and Co-chair of the Australian and New Zealand Intensive Care Research Centre (ANZIC RC).

Mr Adrian Bootes joined the pharmaceutical industry in the early 90s working in drug registration and later clinical research. After having been a volunteer Director and Board member for many years, Adrian joined the not-for-profit professional association, ARCS as Chief Executive Officer in 2010. During his time at ARCS (formally the Association of Regulatory and Clinical Scientists), ARCS has delivered training and development to some thousands of clinical research professionals across Australia with the sole aim of up skilling researchers across Australia and improving efficiencies across the sector.

Prof Chris Brook PSM Chris is the Executive Director, Wellbeing, Integrated Care and Ageing for the Victorian Department of Health. This role focuses on prevention and population health; aboriginal health; integrated care - including the primary, sub acute and hospital diversion programs; aged care; workforce policy and planning in the health sector; and internal departmental human resource functions. He is also the State Health and Medical Commander for Emergency Management.

Professor Andrew Davidson is a Senior Staff Anaesthetist, Royal Children's Hospital and Associate Professor, Department of Paediatrics, University of Melbourne. He is also the Medical Director of the Melbourne Children's Trial Centre (MCTC) at the Murdoch Childrens Research Institute. Andrew is a member of the Australian and New Zealand College of Anaesthetists (ANZCA) Clinical Trials Group, Chair of the Society for Paediatric Anaesthesia in New Zealand and Australia (SPANZA) research subcommittee and Chair of the Paediatric Trials Network Australasia (PTNA). He is Editor-in-Chief elect for the Journal Pediatric Anesthesia.

Professor Davina Ghersi is a Senior Principle Research Scientist providing methodological support on issues relating to the creation and translation of research evidence at the NHMRC. She has lead a program to improve the transparency and governance of clinical trials at the WHO as well as the Systematic Review and Health Care Assessment team at the NHMRC Clinical Trials Centre. Davina is Adjunct Professor at Sydney Medical School and a member of the Nutrition Guidelines Advisory Committee of the WHO, the Editorial Board of PLOS Medicine and the GRADE Working Group, and has a long history of involvement with the Cochrane Collaboration.

Ms Imelda Lynch was the founding Chief Executive Officer of Bellberry Limited, the first provider of independent Human Research Ethics Committees in Australia. Imelda took Bellberry from its beginnings in 2004 to it being recognized as the benchmark for HREC's in Australia. She has recently stepped down as CEO and now holds a non- executive director role with Bellberry. Aside from her 10 years with Bellberry she has an extensive background in nursing and health administration having spent 25 years in the health industry.

Professor John McNeil AM is Head of the School of Public health and Preventative Medicine and a member of the Executive of the Medicine, Nursing and Health Sciences Faculty at Monash University. He is on the Boards of the Colonial Foundation, Orygen Youth Mental Health, the International Society of Cardiovascular Pharmacotherapy, Victorian Managed Insurance Authority and Austin Health. He serves on scientific committees for the Red Cross Blood Transfusion Service, the National Blood Authority, the TGA and the Australian Commission for Safety & Quality in Healthcare. John's research background is in epidemiology & clinical pharmacology and he has a long history in clinical trials addressing preventive options in heart disease, renal disease, anesthesia, stroke and eye disease, including as chief Investigator of the ASPREE Trial. He has been instrumental in the development of large-scale clinical registries to improve the measurement and benchmarking of clinical outcomes.

Dr Clive Morris Heads the Strategic Policy Group, at the National Health and Medical Research Council (NHMRC) responsible for developing and implementing strategies for NHMRC's health and medical research funding schemes; new approaches to research funding; continuous improvement of peer review processes; international engagement; the responsible conduct of research; clinical trials; and developing and implementing NHMRC's policies on significant research issues such as Open Access, DURC, and the measurement of research outcomes and achievements. Prior to joining the Federal Government, Clive was active in biomedical research work in Australia and Europe. He has also worked with the TGA and Food Standards Australia and New Zealand (FSANZ).

Dr Dorota Pawlak is the Head of Research Development at the JDRF in Australia and Executive Director of the Australian Type 1Diabetes Clinical Research Network. She is a graduate of the University of Sydney and received her PhD in 2001. Dorota commenced her postdoctoral fellowship at the Children's Hospital, Boston where she studied metabolic mechanisms linking diabetes and obesity. She later studied nutritional factors in pregnancy at the Harvard Medical School before returning to Australia in 2008 to lead the research team at the JDRF. She has been responsible for the establishment and continued growth of the Clinical Research Network since its conception in 2010.

Professor Vlado Perkovic is Executive Director of The George Institute, Australia and George Clinical, and a Professor of Medicine at The University of Sydney. He is a Staff Specialist in Nephrology at the Royal North Shore Hospital and has led the development of George Clinical, the global clinical trials arm of The George Institute. His research focus is in clinical trials and epidemiology, in particular in understanding both the cardiovascular risk associated with kidney disease and the impact of interventions that might mitigate this risk. He is a member of the National Health and Medical Research Council Academy; is Chair of the Scientific Committee of the Australasian Kidney Trials Network (AKTN); and is a Fellow of the Royal Australasian College of Physicians and of the American Society of Nephrology.

Professor Deborah Schofield is Chair of Health Economics at the NHMRC Clinical Trials Centre and School of Public Health at the University of Sydney. Her career has spanned the Australian Government public service, academia and clinical practice and she has a national and international reputation for her work in economic modelling of the health system. She held senior positions in several Australian Government Departments including Director of Health Policy at The Treasury and Director, Acute Care, Department of Health and Ageing, where she was responsible for $42 billion in public hospital funding. Professor Schofield is now an international authority on the productivity impacts of illness and measurement of the cost effectiveness of interventions that impact across several government portfolios within clinical trials.

Dr Brendan Shaw is Chief Executive of Medicines Australia. Brendan has led the development and management of many key medicines industry issues in Australia including the negotiation of the 2010 Memorandum of Understanding on the Pharmaceutical Benefits Scheme between Medicines Australia and the Australian Government, programs to raise political and community awareness of the Australian medicines industry and its contribution to society, debates on the future of the Pharmaceutical Benefits Scheme and intellectual property policy, and the increasing transparency of the medicines industry's operations. Brendan is a member of the Australian Government's Pharmaceutical Benefits Pricing Authority, the Council of the International Federation of Pharmaceutical Manufacturers and Associations, and the Board of Research Australia.

Dr Joanne Shaw is Research Manager for the Psycho-Oncology Co-operative Research Group (PoCoG) and a psycho-oncology researcher with qualifications in science and psychology. Her research focuses on supportive care, evidence-based intervention research and health professional patient communication. Jo's recent experience includes the development and implementation of intervention research that specifically targets the needs of patients with cancer and their families, including research involving vulnerable cancer groups such as those with poor prognosis cancers and from culturally and linguistically diverse (CALD) backgrounds. Jo's skills include design and coordination of multicentre trials, using both qualitative and quantitative methods, as well as experience and skills in, grant administration, ethics and clinical governance.

Professor John Skerritt is National Manager of the therapeutic goods Administration (TGA) and a member of the Executive of the Australian Department of Health, which oversees Australia's $40 billion annual government health budget. He is leading the implementation of TGA's broad-ranging reforms and is helping drive the formation of a new joint regulator between Australia-New Zealand, planned for commencement in 2016. John has a University Medal and PhD in Pharmacology and is an adjunct Professor at both the Universities of Queensland and Canberra. He is formerly a Deputy Secretary in the Victorian State Government and has extensive experience in medical, agricultural and environmental policy, regulation, research, research management, technology application and commercialisation.

Professor John Simes is Senior Principal Research Fellow and Director of the NHMRC Clinical Trials Centre (CTC), University of Sydney. He is Director of the Sydney Catalyst Translational Research Centre and a founding member of the Australian Clinical Trials Alliance (ACTA). He practices as a medical oncologist at the Royal Prince Alfred Hospital and undertakes clinical trials with particular interest in cancer, cardiovascular disease, diabetes and neonatal medicine. John has been awarded the Cancer Achievement Award by the Medical Oncology Group of Australia and the Distinguished Harvard Alum Award (Biostatistics) from Harvard University. He is a member of several research committees, trials groups and boards, including cancer cooperative groups and safety and data monitoring committees.

Ms Kylie Sproston is CEO of Bellberry, a not for profit organisation providing streamlined scientific and ethical review of Human Research projects across Australia. A Chartered Engineer, Kylie has expertise across the full pharmaceutical product lifecycle, and has held key positions in both technical and management disciplines in the global Pharmaceutical and Biotech industries. Kylie previously led and managed the Australasian operations of the global group BTG PLC (a specialist healthcare company based in London, UK), as General Manager and Company Director. Kylie received an MEng (Hons) in Mechanical Engineering from Loughborough University (UK) and an MSc in Pharmaceutical Engineering Advanced Training from University of Manchester (UK). She is a Graduate of the AICD Company Directors Course.

Professor Steve Webb is a Senior Staff Specialist in Intensive Care Medicine at Royal Perth Hospital and a Clinical Professor in the School of Medicine and Pharmacology and the School of Population Health at the University of Western Australia and in the Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University. Steve is the immediate past-Chair of the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) and current Vice-Chair of the International Forum of Acute Care Trialists - a network of the world's ICU-based investigator-led clinical trials networks. He is a Chair of one of four Working Groups of the International Severe Acute Respiratory Illness Consortium and is a founding member of the executive of the Australian Clinical Trials Alliance (ACTA)

Professor John Zalcberg OAM is the Director, Division of Cancer Medicine, at the Peter MacCallum Cancer Centre in Melbourne, Australia. He served as Director of Medical Oncology at the Heidelberg Repatriation Hospital and as Director of Cancer Services at the Austin and Repatriation Medical Centre. John is a founder and current Chair of the Board of the Australasian Gastrointestinal Trials Group (AGITG) and is a founding member and interim Chair of the Australian Clinical Trials Alliance (ACTA). John is also co-Chair of the Cancer Drugs Alliance and a Board Member of Cancer Trials Australia. A past Board Member of the NSW Cancer Institute, past President of the Clinical Oncological Society of Australia, and a past Member of the Consultative Council of the Victorian Cancer Agency, he has received a Medal of the Order of Australia Award (OAM) and the 2011 Cancer Achievement Award from the Medical Oncology Group of Australia.

Adjunct Associate Professor Nik Zeps is National Research Coordinator for St John of God Healthcare (SJGHC) and Adjunct Associate Professor, School of Surgery University of Western Australia and at Notre Dame Medical School. Nik is a member of the NHMRC Research Committee, member of the steering committee of the Global Summit of National Ethics Committees, the Australian representative on the Ethics and Policy Committee of the International Cancer Genome Consortium and a founding member of the Australasian Biospecimen Network. He is co-chair of the Science Policy Committee of the International Society for Biological and Environmental Repositories and a founding member of the Executive of the Australian Clinical Trials Alliance (ACTA).

ACTA Summit Networking Dinner Keynote Speaker: Emeritus Professor Richard Graeme Larkins AO

"The challenges and rewards of being a clinician researcher"

Professor Richard Larkins is an Emeritus Professor at Monash University where he was previously Vice-Chancellor and University President from September 2003 to July 2009. Prior to his appointment at Monash he was Dean of the Faculty of Medicine, Dentistry and Health Sciences at the University of Melbourne. He has an extensive list of academic and clinical appointments that he has held at Australia's leading universities and hospitals.

Richard has also acted as a Chair and President for a variety of medical colleges and councils, including the National Health and Medical Research Council of Australia and the Royal Australasian College of Physicians. His clinical and research interests are in diabetes, endocrinology and general medicine and he has been awarded numerous honorary fellowships and prizes.

Today he is involved with medical institutions and schools in a number of capacities, including Chair of the Board of the Victorian Comprehensive Cancer Centre, President of the National Stroke Foundation, and Chair of the Council of the European Molecular Biology Laboratory (Australia).

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Bellberry Limited is a national, private not-for-profit organisation providing streamlined scientific and ethical review of human research projects across Australia. Our aim is to promote and improve the welfare of research participants and the quality, efficiency and effectiveness of research. As a not for profit company, Bellberry donates surplus funds back into the research community.

NHMRC certified, and recognised in the McKeon review as a Best Practice example, Bellberry Human Research Ethics Committees (HRECs) are professionally managed and operate 24/7 through a dedicated electronic portal providing a paperless and secure HREC process. Bellberry HRECs provide high quality, independent ethics reviews. With 5 committee meetings every month we are able to offer a guaranteed turnaround time of 20 days from submission of application. Dedicated staff provide support at every stage of the process. See Bellberry.com.au to see more about how we can help you.

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