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best evidence

ACTA International Clinical Trials Conference

2-5 OCTOBER 2019 | ICC SYDNEY | AUSTRALIA



POCKET PROGRAM

3 - 5 OCTOBER 2019

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INFORMATION

REGISTRATION DESK

If you have any queries or need assistance, please visit us at the registration desk on the ground floor. The desk will be open at the following times:

Wednesday 2 October: 0800 - 1700

Thursday 3 October: 0700 - 1730

Friday 4 October: 0800 - 1700

Saturday 5 October: 0830 - 1530

WI-FI

ICC Sydney provides free Wi-Fi via the network **ICC Sydney Public Wi-Fi**.

CONFERENCE APP

The Conference app is available for free in your iPhone app or Android Google Play stores. Scan the QR code or search for 'EventsAIR' to locate **The Event App by EventsAir**.

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Once installed, enter the event code **acta19**. To access all areas enter your **email address** and the **PIN** that was sent to you in the welcome email.

NAME BADGES

As a security requirement please wear your name badge at all times within the ICC Sydney as this identifies you as eligible for catering and entry into the Conference sessions.

PRESENTATION DOWNLOADS

Presentations will be made available after the Conference where permission has provided by the speaker.

DIETARY RESTRICTIONS

If you have advised any dietary restrictions, please ask the catering staff to direct you to the dietary restrictions buffet. If you are attending the social functions, please advise the wait staff and they will provide you with an appropriate meal as necessary.



INTERNATIONAL SPEAKERS



Prof Derek C. Angus
Distinguished Professor and Mitchell P. Fink Endowed Chair, University of Pittsburgh



Prof Barbara Bierer, M.D.
Professor of Medicine, Harvard Medical School



Mr Simon Denegri OBE
National Director for Patients, Carers and the Public in Research, National Institute for Health Research



Prof Neena Modi
Professor of Neonatal Medicine, Imperial College London



Dr Richard Pazdur
Director, FDA Oncology Center of Excellence







Dr Stuart Spencer
Senior Executive Editor, The Lancet






Dr Pamela Tenaerts
Executive Director, Clinical Trial Transformation Initiative

THURSDAY 3 OCTOBER




0900-1030	The value of clinical trials	
PLENARY 1	<i>Chairs: Prof Anthony Keech and Prof Judith Trotman</i>	Cockle Bay Room
	Welcome to Country	<i>Uncle Allen Madden</i>
	Conference opening	<i>The Hon. Greg Hunt MP, Minister for Health</i>
	A clinician's view	<i>Prof John Zalcberg OAM</i>
	Why and how NHMRC supports clinical trials	<i>Prof Anne Kelso AO</i>
MRFF perspective	<i>Prof Ian Frazer AC FRS</i>	
1030-1100	Morning break <small>SPONSORED BY</small> 	Exhibition Hall - The Gallery
1100-1230	Revolutions in clinical trials <small>SPONSORED BY</small> 	
PLENARY 2	<i>Chairs: Prof Davina Ghersi and Prof Steve Webb</i>	Cockle Bay Room
	Efficiency and quality by design	<i>Dr Pamela Tenaerts</i>
	Embedded adaptive clinical trials: A new standard?	<i>Prof Derek C. Angus</i>
	Evidence-based medicine for rare diseases - a new paradigm	<i>Dr Richard Pazdur</i>
Panel discussion	<i>Faculty</i>	
1230-1330	Lunch and Posters <small>SPONSORED BY</small> 	Exhibition Hall - The Gallery
1245-1315	Lunch session <small>UNRESTRICTED EDUCATIONAL GRANT FROM</small>  <small>*AstraZeneca have contributed no input on content, agenda or the selection of the speaker for this independent educational session</small>	Exhibition Hall - The Gallery
	Late-breaking discoveries: Breakthroughs in heart failure treatment	<i>Prof John Atherton</i>



	Cockle Bay Room	C3.3 Room	C3.4/5 Room
1330-1500	1. Clinical trials governance	2. Improving outcomes in diverse populations	3. Innovative trial design and statistical issues
<i>Chairs:</i>	<i>Dr Teresa Anderson AM and Dr Antonio Penna</i>	<i>Prof Alan Cass and Dr Anne-Marie Eades</i>	<i>Prof Andrew Forbes and Ms Adrienne Kirby</i>
CONCURRENT	<p>RCT approval process - international perspective <i>Dr Pamela Tenaerts</i></p> <p>ACSQHC clinical trials governance framework - implications for clinical trials in Australia <i>Dr Robert Herkes</i></p> <p>The strategy for implementation of the ACSQHC clinical trials governance framework <i>Dr Bernadette Aliprandi-Costa</i></p> <p>Panel discussion <i>Faculty with Prof Chris Brook and Prof John Zalcborg OAM</i></p>	<p>A USA perspective on diversity and inclusion <i>Prof Barbara Bierer</i></p> <p>Conducting clinical trials in partnership with Aboriginal and Torres Strait Islander communities <i>Prof David Peiris</i></p> <p>Clinical research trials achieving equitable health outcomes for Māori <i>Dr Matire Harwood</i></p> <p>Panel discussion <i>Faculty</i></p>	<p>How many times should a cluster crossover trial cross over? <i>Dr Jessica Kasza</i></p> <p>Modern approaches to handling missing data in clinical trials <i>Dr Tom Sullivan</i></p> <p>Aligning the design, conduct, and analysis of clinical trials using the estimand framework <i>Ms Sabine Braat</i></p> <p>Estimating treatment effects following adaptive clinical trials <i>Prof Ian Marschner</i></p> <p>Panel discussion <i>Faculty with lead discussion Prof Derek C. Angus</i></p>
1500-1530	Afternoon break	SPONSORED BY 	Exhibition Hall - The Gallery
1530-1700	Role of clinical trials in health service decisions and policy		SPONSORED BY 
PLENARY 3	<i>Chairs: A/Prof Rachael Morton and Prof John Simes</i>		Cockle Bay Room
	<p>Trial-only item numbers for the MBS?</p> <p>Precision medicine and MSAC - the way forward</p> <p>Value-based health care: A role for clinical trials</p> <p>Panel discussion</p> <p>Business Events Sydney Address</p> <p>Invitation to the Welcome Reception</p>		<p><i>Prof Paul Glasziou</i></p> <p><i>Prof Robyn Ward AM</i></p> <p><i>Mr Paul McBride</i></p> <p><i>Faculty</i></p> <p><i>Kristian Nicholls</i></p> <p><i>Prof Steve Webb</i></p>
1700-1900	Welcome Reception and moderated posters	SPONSORED BY 	Exhibition Hall - The Gallery
1730-1800	Moderated poster themes Engagement in clinical trials Clinical trial results Design issues in clinical trials		Moderators <i>Prof Steve Webb</i> <i>A/Prof Rachael Morton</i> <i>Prof Bruce Neal</i>
1800-1830	Moderated poster themes Integrating trials into clinical practice Methodological approaches in trials		Moderators <i>Dr Laima Brazionis</i> <i>Prof Nik Zeps</i>






FRIDAY 4 OCTOBER

0900-1030	Clinical trials interface with industry partners		SPONSORED BY  The George Institute for Global Health
PLENARY 4	<i>Chairs: Prof Katie Groom and Mr Kieran Schneemann</i>		Cockle Bay Room
	Industry and academia; Opportunities for greater partnerships		<i>Dr Anna Lavelle</i>
	MTP Connect - linking biomedical innovation to clinical trials in Australia		<i>Dr Dan Grant</i>
	New horizons for clinical trials and device registration		<i>Dr John Skerritt</i>
	Panel discussion		<i>Faculty</i>
1030-1100	Morning break	SPONSORED BY Cancer Institute NSW	Exhibition Hall - The Gallery
1100-1230	Cockle Bay Room	C3.3 Room	C3.4/5 Room
	4. Practicalities of consumer engagement	5. Embedding clinical trials in routine healthcare	6. Making YOUR research a priority
<i>Chairs:</i>	<i>Prof Rachelle Buchbinder and Prof William Tarnow-Mordi</i>	<i>Prof Gemma Figtree and Prof Steve Webb</i>	<i>Prof Lisa Askie and Prof Martin Stockler</i>
CONCURRENT	What roles should consumers have and should any limits apply? <i>Simon Denegri OBE</i>	An ABC of embedded trials <i>Prof Neena Modi</i>	Priorities and trials from a patient's perspective <i>Prof Ian Chubb AC</i>
	How to get started and where to look for consumer assistance? <i>Dr Belinda Kiely and Ms Leslie Gilham</i>	Registry-randomised trials: A practical model of embedding <i>Prof Chris Reid</i>	A framework for evaluating research priorities <i>A/Prof Rachael Morton</i>
	Lessons learned from the ANZMUSC experience <i>Ms Ornella Clavisi</i>	Waiver of consent for comparative effectiveness trials <i>Prof Meg Jardine</i>	Value of information analysis in prioritising research <i>Dr Haitham Tuffaha</i>
	ACTA 'Trial of the year Consumer Involvement Award' winner from the TORPIDO 30/60 trial <i>Ms Melinda Cruz</i>	Comparative effectiveness research: The SOCRATES proposal <i>Prof John Simes</i>	Panel discussion <i>Faculty with Dr Stuart Spencer, Dr Pamela Tenaerts and Prof Tom Walley</i>
		Should PROMs and PREMs be standard in clinical care and available for clinical trials? <i>Prof Christobel Saunders AO</i>	
1230-1330	Lunch and posters	SPONSORED BY 	Exhibition Hall - The Gallery
1245-1315	Lunch session	SPONSORED BY 	Exhibition Hall - The Gallery
	Bellberry: Roles and new activities for clinical trials		





	Cockle Bay Room 1	Cockle Bay Room 2	C3.3 Room	C3.4/5 Room
1330-1500	Hot topics in trial methods	Innovations in trial conduct	Novel statistical approaches to RCT design and analysis	Improving participation in trials
<i>Chairs:</i>	<i>Prof Alicia Jenkins</i>	<i>Prof Ian Marschner</i>	<i>Prof Nik Zeps</i>	<i>Prof Terry Campbell</i>
FREE PAPERS	<p>Conducting placebo controlled randomised trials of surgery in Australia <i>A/Prof Manuela Ferreira</i></p> <p>Recruiting for large scale clinical trials in Australian general practice <i>Prof Mark Nelson</i></p> <p>N-of-1 trials in clinical research: Opportunities and challenges <i>Dr Suzanne McDonald</i></p> <p>Linked data for randomised controlled trials: The George Institute for Global Health experience <i>Dr Carinna Hockham</i></p> <p>...continued overleaf</p>	<p>The IMPROVING Evidence-based management and outcomes in community-Acquired Pneumonia (IMPROVE-GAP) trial <i>Ms Melanie Lloyd</i></p> <p>Protocol for ComeBACK: A pragmatic randomised controlled trial of physical activity coaching for adults with mobility limitations <i>Dr Leanne Hassett</i></p> <p>Lights, camera, action: Producing educational materials for adaptive trial designs <i>Ms Grace Currie</i></p> <p>...continued overleaf</p>	<p>Bayesian adaptive trial design to accelerate discovery in regional anaesthesia <i>Dr Robert Gotmaker</i></p> <p>Recurrent time-to-event models with ordinal outcomes <i>Prof Val GebSKI</i></p> <p>"Scientists rise up against statistical significance"[1] but type I error equal to 0.05 is what a regulatory body wanted from me <i>Ms Francesca Orsini</i></p> <p>Changes to aspects of ongoing randomised controlled trials with fixed designs <i>Dr Andrew Martin</i></p> <p>...continued overleaf</p>	<p>The ORVAC trial protocol - a phase IV, double-blind, randomised, Bayesian adaptive, placebo-controlled clinical trial of a third scheduled dose of Rotarix rotavirus vaccine in Australian indigenous infants to improve protection against gastroenteritis <i>Dr Bianca Middleton</i></p> <p>A novel methodology for optimising endpoints for cystic fibrosis pulmonary exacerbation trials <i>A/Prof Tom Snelling</i></p> <p>The Molecular Screening and Therapeutics (MoST) program - A framework platform for multiple, parallel, signal-seeking phase II clinical trials of novel targeted therapies for patients with advanced cancer and unmet clinical need <i>Dr Lucille Sebastian Platinum</i></p> <p>...continued overleaf</p>



1330-1500	Hot topics in trial methods <i>...continued</i>	Innovations in trial conduct... <i>continued</i>	Novel statistical approaches to RCT design and analysis...continued	Improving participation in trials...continued
FREE PAPERS	<p>Can we prospectively estimate the economic returns of clinical trials? <i>Dr Haitham Tuffaha</i></p> <p>A new approach to the design of basket oncology trials in rare tumours <i>Prof Gillian Heller</i></p>	<p>The landscape of clinical trial activity on Indigenous health in Australia: A review using clinical trial registry data from 2008-2018 <i>Dr Ge Xu</i></p> <p>Developing a New Zealand specific framework for research prioritisation in maternal and perinatal health Clara Mossinger process for waiver of consent in pre-hospital trials: The EXACT study as an example <i>Ms Natasha Dodge</i></p>	<p>"Anchoring effect" in random effects meta analysis: A cautionary tale <i>Dr Gian Luca Di Tanna</i></p> <p>In cluster randomised trials with binary outcomes, plausible values of (i) the intra-cluster correlation coefficient and (ii) the standard deviation of true cluster prevalences are bounded by the overall prevalence, its complement, and one third <i>A/Prof Mark Chatfield</i></p>	<p>C: A digital treatment registry for nesting clinical trials of strategies to manage hepatitis C in primary care <i>Ms Jessica Ramsay</i></p> <p>The Australasian Tele-trial model – access to clinical trials closer to home using tele-health <i>Prof Sabe Sabesan</i></p> <p>Marketing and trial recruitment: an evaluation of promotional strategies from the T4DM diabetes prevention trial <i>Ms Karen Bracken</i></p>
1500-1545	Afternoon break		SPONSORED BY 	Exhibition Hall - The Gallery
1545-1715	Consumers front and centre		SPONSORED BY  AND 	
PLENARY 5	<p><i>Chairs: Prof Kirsten McCaffery and Prof John Zalberg OAM</i></p> <p>The UK Model of consumer engagement in clinical trials</p> <p>Consumer prioritisation using the James Lind Alliance method</p> <p>A consumer viewpoint of what consumer engagement means</p> <p>The consumer ACTA and CT:IQ involvement and engagement toolkit</p>		<p>Cockle Bay Room</p> <p><i>Mr Simon Denegri OBE</i></p> <p><i>Prof Jonathan C. Craig</i></p> <p><i>Ms Anne McKenzie AM</i></p> <p><i>Ms Anne McKenzie AM and Ms Tanya Symons</i></p>	
1900-2200	Conference dinner		<p>Doltone House - Darling Island</p> <p><i>Dr Norman Swan</i></p>	



SATURDAY 5 OCTOBER

0900-1030	Data sharing in trials: All trials should share all their data?		
PLENARY 6	<i>Chairs: Prof Fran Boyle AM and Prof John McNeil AM</i>		Cockle Bay Room
	A journal perspective		<i>Dr Stuart Spencer</i>
	The bigger picture; From open access to open scholarship		<i>Prof Virginia Barbour</i>
	An investigator perspective		<i>Prof Barbara Bierer</i>
	Panel discussion		<i>Faculty</i>
1030-1100	Morning break	SPONSORED BY 	Exhibition Hall - The Gallery
1100-1230	Cockle Bay Room	C3.3 Room	C3.4/5 Room
	7. Making data access and data linkage a reality	8. Improving impact and implementation of trials	9. Clinical trials in the community
<i>Chairs:</i>	<i>Prof Virginia Barbour and Ms Allyson Essex</i>	<i>Chairs: Prof Sally Green and Prof Bruce Neal</i>	<i>Prof Barbara Bierer and Prof Mark Nelson</i>
CONCURRENT	Management of linkage variables in clinical trials <i>Dr Felicity Flack</i>	How to design, conduct, and report trials optimised for value to end-users: The ACTA implementability guide <i>Prof Steve Webb</i>	Trials in primary care - lessons from ASPREE <i>Prof Mark Nelson</i>
	Clinical quality registries and registry based trials - data protection issues <i>Prof John McNeil</i>	Promoting impact and implementation: perspective of a funder <i>Prof Davina Ghersi</i>	The REINVEST Study: Challenges in the community <i>Prof Peter Schofield</i>
	Harnessing digital technologies for clinical trial research <i>Dr Charmaine Tam</i>	Working together to promote implementability and impact: The AHRTC perspective <i>Prof Chris Levi</i>	Allied health clinical trials - experience from cerebral palsy <i>Prof Catherine Elliot</i>
	Panel discussion <i>Faculty</i>	What role can journals play? <i>Dr Stuart Spencer</i>	NIHR models for primary care and mental health research <i>Prof Tom Walley CBE</i>
1230-1330	Lunch and Posters		Exhibition Hall - The Gallery
1245-1315	Lunch session	SPONSORED BY 	Exhibition Hall - The Gallery
	Late-breaking discoveries: Cell therapies in Cancer care		
1330-1550	Embedding clinical trials in routine practice		
PLENARY 7	<i>Chairs: Prof Chris Reid and Prof Sally Green</i>		Cockle Bay Room
	Principles of embedding clinical trials in neonatal care		<i>Prof Neena Modi</i>
	The concept and challenges: An Australian perspective		<i>Prof Nik Zeps</i>
	Registry-randomised trials as a pathway to embedding		<i>Prof Stephen McDonald</i>
	Panel discussion		<i>Faculty</i>
	Wrap up and close		<i>Prof Anthony Keech</i>





WITH THANKS

ACTA 2019 INTERNATIONAL CONFERENCE STEERING COMMITTEE AND ORGANISING COMMITTEE*

Prof Anthony Keech (Chair) *

Prof John Zalcberg

Prof Davina Ghersi

Prof Nik Zeps*

Prof John Simes

A/Prof Katie Groom

Prof Steve Webb

Mr Kieran Schneemann*

A/Prof Rachael Morton

Ms Simone Yendle*

Ms Lisa Reid*

Ms Lea Hauchard*

Mr Nick Catton*

Ms Susan Lohan*

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