New Zealand Association of Clinical Research
13th Annual Conference

NZACRes 2017

Innovation in Research and Clinical Trials

HANDBOOK

17 - 18 August 2017
The Pullman Hotel, Auckland, New Zealand
www.nzacres2017.org.nz

This handbook belongs to .....

Conference Organiser

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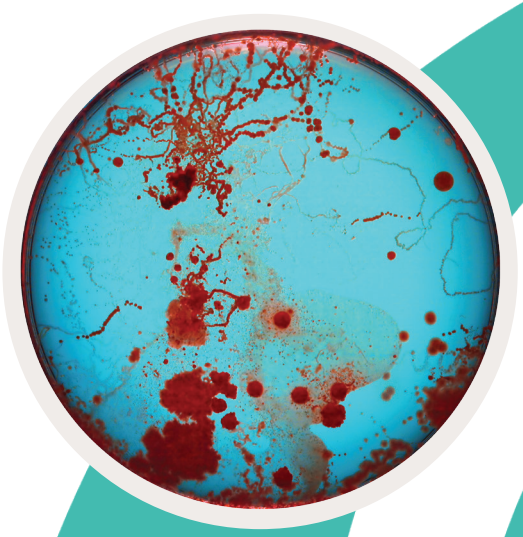

NZACRes

NZACRes is a non-profit scientific educational organisation. It is run by an elected team of volunteer officers from amongst its members.

ORGANISING COMMITTEE

Eileen Bisley
Convenor
Clinical Trials NZ Ltd

Richard Stubbs
President NZACRes
P3 Research Ltd

Philippa Brydon
PPD

Belinda Egan
Canterbury DHB

Ian Griffiths
GSK

Kerin Thompson
ICON Clinical Research

The New Zealand Association of Clinical Research (NZACRes) Executive Committee is delighted to welcome you to our annual conference on 17-18 August 2017.

The theme for our conference this year is "Innovation in Research and Clinical Trials".

The programme is designed to present research, clinical trials and cutting-edge presentations, all of which have issues facing our society.

We have an attractive programme for everyone involved in clinical trials and research, and we have a number of keynote addresses from distinguished national and international speakers.

While building on our strength of conferences over the years, we are this year including clinical trials breakout sessions so that delegates have the opportunity to be a voice and we can bring together the sites and the CROs.

On behalf of the Executive Committee, we welcome you to this very important annual NZACRes event.

Yours sincerely,

Eileen Bisley
Conference Convenor

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Conference Speakers

KEYNOTE SPEAKERS

Mr Chai Chuah

Director-General, Ministry of Health, Wellington, NZ

Chai Chuah has been the Director-General of Health since March 2015. Originally from Malaysia, Chai studied Commerce at the University of Canterbury before commencing a career with PricewaterhouseCoopers in New Zealand and internationally.

He has been a prominent figure in the New Zealand health sector for 25 years, first with Canterbury DHB where he was Chief Financial Officer, Chief Operating Manager and acting Chief Executive, before spending over seven years as Chief Executive of Hutt Valley DHB. He has been in national leadership roles with the Ministry of Health since 2010 when he became National Director of the National Health Board.

He has a passion for working with partners to build a health system that is powered by the needs of the people it serves and that is prepared for rapid changes in technology and demographics.

He is focused on changing the way the health system works with other public services, communities and other non-public service partners to improve health outcomes, increase access to quality care, improve financial and clinical sustainability and develop a unified health system.

Hon Paul Goldsmith

Minister of Science and Innovation, Auckland, NZ

Born in Mt Eden and having attended Auckland Grammar School Paul lives with his wife and their four children in the Epsom electorate.

First elected off the National Party list in 2011, Paul has served as the Chair of the Parliamentary Finance and Expenditure Select Committee. Following the 2014 General Election he was appointed Minister of Commerce and Consumer Affairs, and Associate Minister for ACC.

In 2016 Paul was appointed Minister of Tertiary Education, Skills and Employment, Minister for Science and Innovation, and Minister for Regulatory Reform, and joined the Cabinet.

Before entering Parliament, Paul created his own business as a historian and biographer focusing on New Zealand's history and economic development. His last books were biographies of Alan Gibbs (Serious Fun) and Sir William Gallagher (Legend). Between 2007 and 2010 he served as an Auckland City Councillor.

Paul is an enthusiastic pianist and has a broad interest in the arts; he is a 2nd dan black belt in Tae Kwon Do and plays on the right wing for the Parliamentary Rugby team.

Dr Ronald W. Jones

Retired Obstetrician and Gynaecologist; Former Clinical Professor at The University of Auckland, Auckland, NZ

Ronald W. Jones is a retired obstetrician and gynaecologist and former clinical professor at The University of Auckland. He is a widely published international authority on lower genital tract pre-cancer and cancer. For over 30 years he has served on a range of national and international committees addressing the natural history, prevention and management of these cancers. He is a past president of the International Society for the Study of Vulvovaginal Disease and chair of the Scientific Committee of the International Federation of Cervical Pathology and Colposcopy.

Dr John Moller

Chief Executive Officer, Novotech, Sydney, Australia

Dr John Moller joined Novotech in January 2014 to lead the expansion of Novotech's Asia operations, and became CEO in 2017. Prior to Novotech John was Managing Director of IVF Australia and Queensland Fertility Group and sat on the Board of the parent company Virtus Health. John was previously a management consultant with the Boston Consulting Group specialising in developing growth and operational improvement initiatives with a particular focus on healthcare. John has a Medical Degree from The University of Auckland, a degree in advanced logic from the University of Canterbury and an MBA from the University of Oxford.

WORKSHOP & INVITED SPEAKERS

Dominic Bailey

Chief Executive Officer, Genesis Research Services, Broadmeadow, NSW, Australia

Dom has studied Nursing, Occupational Health and Safety and Clinical Trials Research at university and is a highly experienced healthcare professional having worked extensively in both public hospitals and private companies.

Dom has written and presented international webinars on Social Media in Clinical Trials, presented at both the ARCS (16/17) and the NSANS (17) Annual Scientific Meetings. He has led the development of Genesis Research Services from a small clinical trials practice into a multi-service company that manages trial recruitment services, a research network of investigators, a registry of over 12 thousand trial participants and obtained Quality Management Accreditation for the business.

With a focus on business development, innovation and sustainability, Dom's professional goal is to provide simple plans and modern project management for clinical research business success.

Professor P. Alan Barber

Professor of Clinical Neurology, Neurological Foundation, School of Medicine, Faculty of Medical and Health Sciences, The University of Auckland, Auckland, NZ

Professor Barber is a neurologist and stroke sub-specialist. He graduated from the Otago Medical School and completed his neurology training in Auckland, New Zealand in 1997. He received a PhD from the University of Melbourne in 2000. He returned to New Zealand in 2001 and has established a stroke unit at Auckland City Hospital. He was appointed the Neurological Foundation of New Zealand Professor of Clinical Neurology at The University of Auckland in 2008 and also Deputy Director of the Centre for Brain Research at The University of Auckland in 2009. He is the Honorary Medical Advisor for the Stroke Foundation of New Zealand, Northern Region.

Philippa Bascand

Manager, Ethics Committees, Ministry of Health, Auckland, NZ

Philippa Bascand is Manager for Ethics Committees for the Ministry of Health. The ethics team provide advisory and support services to five ethics committees: four national Health and Disability Ethics Committees and the Ethics Committee on Assisted Reproductive Technology. Prior to this Philippa was an advisor in the Office of then Minister of Health, Hon Tony Ryall and General Manager of Cancer Control NZ. Philippa was previously CEO for the NZ Society of Anaesthetists for eight years and Deputy CEO for the NZ Medical Association. Philippa has a long-standing interest in health policy and has provided advice from a range of perspectives (sector advice, independent ministerial committees, and government view), on health workforce and regulatory functions. Philippa led the joint health sector submission process on the HPCA Bill in 2003, led two successful international bids for world cardiac anaesthesia and world regional anaesthesia meetings in NZ, and has developed a committed expert advisory team in research ethics during a time of transformation in the Ministry of Health.

Zoe Breeze

Vendor Manager/Quality Manager (GCP/GVP), Roche Products (NZ) Limited, Auckland, NZ

From my first role as a clinical trial assistant in 1995, I have been lucky enough to spend the last 22 years in a variety of clinical research roles within the Pharmaceutical and CRO industry. I have lived and worked in UK, Netherlands, Australia and for the past 7 years in New Zealand. My current role as Quality Manager (GCP/GVP) for Roche New Zealand (Auckland), allows me to combine my passion for quality whilst still remaining close to clinical trials.

Philippa Brydon

Principal CRA, Clinical Management, PPD, Wellington, NZ

Philippa Brydon is currently a Principal CRA for PPD in New Zealand and has a Masters of Medical Science in Drug Development from the University of New South Wales. Philippa has over 20 years' experience in clinical research in Australia and New Zealand working within both a CRO and Pharma as a CRA, Regional Trainer and Patient Recruitment specialist.

Elinor Chisholm

Research Fellow, He Kainga Oranga - Housing and Health Research Programme, Department of Public Health, University of Otago, Wellington, NZ

Dr Elinor Chisholm's research speciality is housing and health. She has a particular interest in housing quality assessment, rental housing regulation, and evaluating the effect of housing interventions on health. She is a research fellow at He Kainga Oranga/Housing and Health Research Programme, which was awarded the Prime Minister's Science Prize in 2014.

Donna Fraser

Associate Director, Client Operations, Novotech, Queensland, Australia

Donna graduated with her New Zealand Registered Comprehensive Nurse credentials in 1987 and spent the next 18 years working in NZ and the United States in a variety of clinical roles including Nursing and as a Certified Medical Case Manager. Following a move to Australia in 2005, Donna joined Novotech, Australia's largest privately owned CRO and has spent the past 12 years managing project teams across Australia and New Zealand. Donna's wide-ranging clinical and operational background allows her to provide strategic oversight to Novotech's start-up and business development teams across a variety of therapeutic areas with specialist knowledge.

Jan Gaskin

Director, Site Management Delivery, Country Head, New Zealand, Resourcing Lead Australia & NZ, QuintilesIMS, Auckland, NZ

Jan has over 15 years working in a variety of roles within the industry including experience within CRO, Hospital environment & academic research. Her roles have ranged from study co coordinator, Research Assistant, CRA, Clinical Lead, Project Manager, and Management within Australia & New Zealand.

Jan gained experience within emerging markets in Asia Pacific with a variety of 6-month secondments, including training CRAs & providing project oversight in Vietnam, training managers in China, Acting Country Head in Thailand and providing project oversight and management training in The Philippines.

Currently Jan is Director Site Management and Country Head for Quintiles IMS in New Zealand.

Sophie Goodger

Research Team Leader - Haematology, Cancer and Blood Research, Auckland Regional Cancer and Blood Service, Auckland, NZ

Sophie started her clinical research career eight years ago in the UK working at King's College London. She initially facilitated the setting up of commercial clinical trials for Guy's and St. Thomas' and King's College Hospitals and moved on to negotiating clinical trial budgets and contracts for the same hospitals in many different disciplines.

Sophie has a passionate interest in the fight against cancer and when she moved back to New Zealand she was excited to be offered a position as a Clinical Research Coordinator at Cancer and Blood Research, Auckland Regional Cancer and Blood Service. She became a team leader for the oncology research team in 2013 and is now the team leader for the haematology research team.

Cheryl-Ann Hawkins

Australian Ambassador for Society for Clinical Research Sites (SCRS)
Operations Manager, Oncology Research, Monash Health, Victoria, Australia

Cheryl-Ann Hawkins is the Operations Manager for Oncology Research at Monash Health and is currently The Australian Ambassador for Society for Clinical Research Sites (SCRS). She has worked in various leadership Oncology nursing roles in a career spanning 25 years. Over the past 13 years she has focused her career on early phase/first in human drug trials and has built Monash Oncology early phase trial activity from one to now more than 27 active trials making it one of the largest Oncology early phase units in Australia. Cheryl-Ann completed her post graduate diploma in Oncology/Palliative care nursing in 1996, a Master degree in Health Administration in 2004 and a post graduate certificate in Oncology Research in 2012. Cheryl-Ann holds an affiliate position with Monash University as an educator in GCP.

Dr Christopher Jackson

Consultant Medical Oncologist, Southern Blood and Cancer Service, Southern DHB; Senior Lecturer in Medicine, University of Otago, Dunedin, NZ; and Medical Director, The Cancer Society of New Zealand

After undertaking his initial training in New Zealand, Chris was appointed as a clinical research fellow at the GI Unit at Royal Marsden Hospital in London, later appointed to a locum consultant post.

Since returning to New Zealand he has been active in clinical research and in cancer policy. He was clinical lead for NZ's largest colorectal cancer study, the PIPER project; is deputy director of Cancer Trials NZ, and leads clinical research at Southern DHB. In the policy area he is chair of the colorectal cancer tumour standards group, and serves on the National Bowel Cancer Group and Medical Oncology Work Group.

Currently Chris coordinates undergraduate and postgraduate teaching for oncology at the Dunedin School of Medicine, is Principal Investigator developing an oral form of paclitaxel, and continues with his bowel cancer outcomes work with the PIPER project.

In his spare time he likes watching super hero movies, playing back yard cricket with his kids, and loves cooking.

Professor Joanna Manning

Faculty of Law, The University of Auckland, Auckland, NZ

Joanna Manning is a Professor at the Faculty of Law, the University of Auckland, where she teaches and has published widely on issues of: health law, policy, and ethics; torts, including negligence; and accident compensation, particularly treatment injury. She is a contributing author of the textbook, Skegg and Paterson (eds), Health Law in New Zealand (Thomson Brookers, 2015) and the editor of The Cartwright Papers: Essays on the Cervical Cancer Inquiry 1987-88 (Bridget Williams Books, 2009). She was the consumer representative on the Medical Practitioners Disciplinary Committee for approx 10 years, the lawyer member of the National Ethics Advisory Committee from 2005 to 2011 and the lawyer member of the Scientific Advisory Committee of the Heart Foundation NZ (2011-2014).

Dr Colin McArthur

Intensive Care Specialist and Clinical Advisor - Research, Auckland DHB, Auckland, NZ

Dr Colin McArthur is a senior intensive care specialist in the Department of Critical Care Medicine, Auckland City Hospital. Graduating from Auckland University, he trained in both anaesthesia and intensive care medicine in New Zealand, the UK and Hong Kong. He is the immediate past Chair of the Australia and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group with over 25 years' experience in investigator-led large-scale multicentre intensive care trials. In addition to being an active clinical trialist, Dr. McArthur also leads research governance for New Zealand's largest clinical research facility at Auckland City Hospital, and holds honorary/adjunct appointments at Auckland University and Monash University, Melbourne.

Dr. Richard Milne

Managing Director, Health Outcomes Associates Ltd; Associate Professor, School of Population Health, The University of Auckland, Auckland, NZ

Richard Milne trained in physics/maths, physiology/ pharmacology, neuroscience and health economics in NZ and the USA. He has been researching the epidemiology and economics of healthcare interventions since 1997. Richard has published over 50 peer-reviewed articles in physics, physiology, pharmacology, medical statistics, ethics and health economics and is an Advisory Board member on the leading peer-reviewed Journal PharmacoEconomics, of which he was the founding Editor. He was also the founding President of the NZ chapter of the International Society for Pharmacoeconomics & Outcomes Research.

Stuart Ryan

Medical and Clinical Manager, Roche New Zealand, Auckland, NZ

After receiving his PhD in 1995, Stuart worked briefly as a research scientist at Hort Research in the field of protein biochemistry. Fisher and Paykel Healthcare provided an opportunity to develop skills in applied research within a commercial environment and eventually the chance to lead a clinical research team and managing a global, medical device trial portfolio.

In 2004 he was made General Manager of the Centre for Clinical Research and effective practice (CCRep), an independent research trust established to grow research capability at Middlemore Hospital in South Auckland. Becoming NZ's leading DHB-based research centre, CCRep then led the establishment of the Middlemore Tumour Tissue Bank in 2010, a facility which is now governed by The University of Auckland.

Currently, Medical and Clinical Manager at Roche NZ, Stuart manages the Clinical Operations team while also maintaining oversight and medical responsibility for the Roche cancer immunotherapy products and indications.

Jo Sanders

Operations Manager at Christchurch Clinical Studies Trust (CCST), Christchurch, NZ

Jo Sanders is the Operations Manager at Christchurch Clinical Studies Trust (CCST), an early phase clinical trials unit. Her role is to ensure timely delivery of clinical trials with subject safety, quality and integrity of data being the highest priority.

Jo has worked in clinical research since 1992, she has extensive clinical research experience specialising in haematology/bone marrow transplantation having managed the Haematology Clinical Trials unit at Christchurch Hospital for 15 years.

Saerom Shin

Regulatory Practice and Analysis, Medsafe, Ministry of Health, Wellington, NZ

Saerom Shin is an Assistant Advisor in the Regulatory Practice and Analysis Branch at Medsafe, Ministry of Health. Before joining Medsafe, Saerom worked in the medical devices industry as a regulatory and quality assurance specialist in Seoul, South Korea. She has 6 years of experience in crafting conformity assessment dossiers for product approval as well as assisting GMP audits for overseas manufacturing sites.

Isobel Smith

NZ Country Manager, PPD, Rangiora, NZ

Isobel is currently the NZ Country Manager for PPD, a global CRO. A qualified Pharmacist, she joined the NZ Clinical Research industry after developing a successful career in hospital pharmacy and has worked in New Zealand, Australia and the United Kingdom in a variety of Clinical Research roles.

Kerin Thompson

Senior Study Start-Up Associate, ICON Clinical Research (New Zealand) Ltd, Nelson, NZ

Kerin has worked in Clinical Research for more than 15 years, including study co-ordinator and management roles in a large DHB research department, a term on a NZ Health & Disability Ethics Committee, and as a CRA. She is the current NZACRes Treasurer and was involved in the creation of the NZACRes costing tool. These days Kerin is based in Nelson, working with New Zealand sites to set up commercial clinical trials.

Dr John Wyeth

Medical Director, PHARMAC, Wellington, NZ

John joined PHARMAC in 2012 as a deputy medical director with particular responsibility for secondary care, leading PHARMAC's clinical interactions around hospital medicines and hospital medical devices.

He was appointed Medical Director in 2013, and leads the team that provides clinical input to PHARMAC, including through the Pharmacology and Therapeutics Advisory Committee. The team interacts with clinicians across both the primary and secondary care sectors.

Dr Stewart Jessamine

Director of Protection, Regulation and Assurance; Acting Director of Public Health, Ministry of Health, Wellington, NZ

Born and raised in Scotland, Stewart joined the public service in 1993.

Stewart's career has taken him from rural General Practitioner to Director of Protection Regulation and Assurance. In his 24-year career at the Ministry of Health he has undertaken a number of roles including Group Manager of Medsafe, and Director of Public Health. Stewart completed his Masters in Public Health in 2002 and was admitted as a Fellow of Royal Australasian College of Medical Administration in 2007.

Stewart's experience within the Ministry of Health demonstrates he is an articulate advocate of pragmatic risk management. Stewart has a unique perspective on the cultural, ethical, linguistic and political challenges that face regulators and public health officials when communicating about risk and risk management.

Stewart has been directly involved in dealing with complex public health issues such as the New Zealand response to Ebola, and other major public health and regulatory issues relating to medicines and medical device safety, tobacco control, water fluoridation and rheumatic fever. Internationally Stewart is one of the Western Pacific's representatives on the Executive Board of the World Health Organisation and is Chair of the General Assembly of SNOMED CT International the International Standards Organisation that developed the standardised medicines and medical devices terminology used in New Zealand and over 30 other countries.

THURSDAY 17 AUGUST 2017

0930 - 1030	**Registration & Light Morning Tea**	Regatta Foyer

1030 - 1200

WORKSHOP 1

Regatta D

Developing a Quality Management System

Having a quality management system (QMS) facilitates good quality and efficient working practices, as well as promoting continuous improvement. This workshop aims to provide:

- An overview of the current standards and guidelines for QMS
- An understanding of the practical elements when developing a QMS
- A peek into the future of a possible GCP-specific QMS
- How to leverage the value of a QMS for your clinical research business

Zoe Breeze, Vendor Manager/ Quality Manager (GCP/GVP), Roche Products (NZ) Limited, Auckland, NZ

Dominic Bailey, Chief Executive Officer, Genesis Research Services, Broadmeadow, NSW, Australia

WORKSHOP 2

Regatta B

Interpretation of GCP for Sites & GCP Updates

This workshop is about relating GCP to real life situations. You will have an opportunity to review case studies where GCP was used to guide resolution and to ask any questions you have about interpretation of GCP.

Philippa Brydon, Principal CRA, Clinical Management, PPD, Wellington, NZ

Jan Gaskin, Director, Site Management Delivery, Country Head, New Zealand, Resourcing Lead Australia & NZ, QuintilesIMS, Auckland, NZ

WORKSHOP 3

Regatta C

Budgets, Payments and Fair Market Value

Ideal for those involved with clinical research financial activities, applicable to site, CRO and Pharma. The focus will be on discussing current processes and practices, sharing common challenges & areas for improvement, and identifying potential quick fixes and long term improvements. Attendees will complete and return a questionnaire prior to the meeting, to provide a baseline for discussion.

Stuart Ryan, Medical and Clinical Manager, Roche NZ, Auckland, NZ

Sophie Goodger, Research Team Leader - Haematology, Cancer and Blood Research, Auckland Regional Cancer and Blood Service, Auckland, NZ

Kerin Thompson, Senior Study Start-Up Associate, ICON Clinical Research (New Zealand) Ltd, Nelson, NZ

1200 - 1300	**Registration, Arrival Tea & Coffee and Exhibition Open**	Regatta Foyer

CONFERENCE PROGRAMME

New Zealand Association of Clinical Research

INNOVATION IN RESEARCH AND CLINICAL TRIALS

Thursday 17 - Friday 18 August 2017

The Pullman Hotel, Auckland, New Zealand

www.nzacres2017.org.nz

THURSDAY 17 AUGUST 2017

1300 - 1310	**WELCOME** **Eileen Bisley,** Convenor, NZACRes 2017 Conference **Professor Richard S Stubbs,** President, NZACRes
1310 -1430	**The Importance and Relevance of Clinical Research in Our Public Hospitals** Chair: Richard Stubbs **Mr Chai Chuah,** Director General, Ministry of Health, Wellington, NZ **Dr Colin McArthur,** Intensive Care Specialist and Clinical Advisor - Research, Auckland DHB, Auckland, NZ **Dr Stewart Jessamine,** Director of Protection, Regulation and Assurance; Acting Director of Public Health, Ministry of Health, Wellington, NZ - ***HRC Refreshed Research Strategy*** **Q&A/Discussion**
1430 - 1500	**From Wo to Go, and Beyond - The Role of Economic Evaluation in Product Development, Funding & Outcomes Assessment** **Dr Richard J. Milne,** Managing Director, Health Outcomes Associates Ltd; Associate Professor, School of Population Health, The University of Auckland, Auckland, NZ
1500 -1530	**Afternoon Tea and Industry Exhibition** Regatta A

	CONCURRENT 1	CONCURRENT 2
	Chair: Stewart Jessamine Regatta D	Chair: Ian Griffiths Regatta B/C
1530 -1600	**Innovation in Clinical Trials: Transcelerate Awareness** **Zoe Breeze,** Vendor Manager/Quality Manager (GCP/GVP), Roche Products (NZ) Limited, Auckland, NZ	**Endovascular Clot Retrieval in a New Zealand Setting** **Professor P. Alan Barber,** Professor of Clinical Neurology, Neurological Foundation, School of Medicine, Faculty of Medical and Health Sciences, The University of Auckland, Auckland, NZ
1600 -1630	**Clinical Research Solutions** **Jo Sanders,** Operations Manager, Christchurch Clinical Studies Trust (CCST), Christchurch, NZ	**GCP Updates** **Jan Gaskin,** Director, Site Management Delivery, Country Head, Quintiles, Auckland, NZ
1630 -1700	**The Use of Social Media as a Tool for Recruitment** **Dominic Bailey,** Chief Executive Officer, Genesis Research Services, Broadmeadow, NSW, Australia	**Risk Based Monitoring: Evolution and Change Management** **Isobel Smith,** NZ Country Manager, PPD, Rangiora, NZ
1700-1830	**Welcome Reception in Exhibition Hall** Regatta A	
1900-2300	**Conference Dinner** Top of the Town, The Pullman Hotel	

FRIDAY 18 AUGUST 2017

0730 - 0830	**Registration, Arrival Tea & Coffee and Exhibition Open**	Regatta A

	CONCURRENT 1	CONCURRENT 2
	Chair: Stewart Jessamine — Regatta D	Chair: Pip Brydon — Regatta B/C
0830 - 0900	**Free Paper Presentations** **Setting up a New Tissue Bank in a DHB Environment** **Amber Parry Strong** Centre for Endocrine, Diabetes and Obesity Research, Capital & Coast DHB, Wellington, NZ **Tips on Surviving an FDA Inspection** **Jo Sanders** Christchurch Clinical Studies Trust (CCST), Christchurch, NZ **Online Self-Help Program for Recovery from Chronic Fatigue and Fibromyalgia** **Kim Knight** Director, The Art of Health and Science of Wellbeing, NZ	**Marketing and Growing NZ Research** **Dr John Moller**, Chief Executive Officer, Novotech, Sydney, Australia
0900 - 0930	**Building Health by Building Better Housing** **Dr Elinor Chisholm,** Research Fellow, He Kainga Oranga - Housing and Health Research Programme, Department of Public Health, University of Otago, Wellington, NZ	**PHARMAC: An Evidence Based Organisation** **Dr John Wyeth**, Medical Director, PHARMAC, Wellington, NZ
0930 - 1000	**Colorectal Cancer in NZ and the PIPER Project: Translating Research into Clinical Outcomes** **Dr Christopher Jackson,** Medical Director, The Cancer Society of New Zealand, Dunedin, NZ	**Medsafe – Medical Devices Proposed Legislation** **Saerom Shin**, Regulatory Practice and Analysis, Medsafe, Ministry of Health, Wellington, NZ **Dr Stewart Jessamine**, Director of Protection, Regulation and Assurance; Acting Director of Public Health, Ministry of Health, Wellington, NZ

1000 - 1030	**Morning Tea and Industry Exhibition**	KINDLY PROVIDED BY: QuintilesIMS	Regatta A
1030 - 1130	**A Story of Two Cancers: One Physical and One Moral** **Dr Ronald W. Jones** Former Obstetrician, Gynaecologist and Clinical Professor, The University of Auckland, Auckland, NZ		
1130 - 1200	**NZACRes 2017 AGM**		

FRIDAY 18 AUGUST 2017

1200 - 1310	**Lunch and Industry Exhibition**	Regatta A
1315 - 1330	**Ministerial Address - The Government's Role in Science and Innovation as an Investor, including Health and Clinical Research** **Hon Paul Goldsmith,** Minister of Science and Innovation	Chair: Richard Stubbs Regatta D

	CONCURRENT 1		CONCURRENT 2	
	Chair: Stewart Jessamine	Regatta D	Chair: Belinda Egan	Regatta B/C
1330 - 1400	**Peaks and Pitfalls in HDEC Applications: Tips for those Submitting HDEC Applications** **Philippa Bascand,** Manager Ethics Committees, Ministry of Health, Auckland, NZ		**Unify the Voice of the Global Clinical Research Site Community - Society for Clinical Research Sites (SCRS)** **Cheryl-Ann Hawkins, Australian Ambassador for Society** for Clinical Research Sites (SCRS); Operations Manager, Oncology Research, Monash Health, Victoria, Australia	
1400 - 1430	**Compensation for Research-Related Injury in the UK, Australia and New Zealand: A Legal and Ethical Audit** **Professor Joanna Manning, Faculty of Law,** The University of Auckland, Auckland, NZ		**Setting Up A Clinical Trial... To Ensure We Get The Right Fit** **Donna Fraser, Associate Director, Client Operations,** Novotech, Queensland Australia	

1430 - 1500	**Afternoon Tea and Industry Exhibition**	KINDLY PROVIDED BY: QuintilesIMS	Regatta A
1500 - 1545	**Panel Discussion** Chair: Eileen Bisley **Challenges and Problem Areas for Sites, CROs & Sponsors** **Dominic Bailey,** Chief Executive Officer, Genesis Research Services, Broadmeadow, NSW, Australia **Donna Fraser,** Associate Director, Client Operations, Novotech, Queensland Australia **Stuart Ryan,** Medical and Clinical Manager, Roche NZ, Auckland, NZ **Professor Richard S Stubbs,** Director, P3 Research Ltd, Wellington, NZ		Regatta D
1545 - 1600	**Conference Close** **Dr Stewart Jessamine,** MC **Professor Richard S Stubbs, President, NZACRes**		Regatta A

Social Programme

WELCOME RECEPTION

Date: Thursday 17 August 2017
Time: 5.00 - 6.30 pm
Venue: Exhibition Hall, Regatta A
The Pullman Hotel, Auckland
Dress: Smart Casual

CONFERENCE DINNER

Date: Thursday 17 August 2017
Time: From 7.00 pm
Venue: Top of the Town, The Pullman Hotel, Auckland
Dress: Smart Casual

Dinner Entertainment Features...The Ultimate Music & Science Quiz

Session Abstracts

PLENARY Regatta D

1310 - 1430

Mr Chai Chuah

Director General, Ministry of Health, Wellington, NZ

Dr Colin McArthur

Intensive Care Specialist and Clinical Advisor - Research, Auckland DHB, Auckland, NZ

Dr Stewart Jessamine

Director of Protection, Regulation and Assurance; Acting Director of Public Health, Ministry of Health, Wellington, NZ

The Importance and Relevance of Clinical Research in Our Public Hospitals

1430-1500

Hon. Associate Professor Richard J. Milne

School of Population Health, The University of Auckland, Auckland, NZ

From Wo to Go, and Beyond - The Role of Economic Evaluation in Product Development, Funding & Outcomes Assessment

Economic evaluation is the process of linking costs to outcomes in order to evaluate the cost-effectiveness of interventions compared to other interventions within the same budget. Over the last 30 years, economic evaluation has become a sophisticated industry, especially in Europe and the USA. It is also widely used in Asian countries and in Latin America, and is performed by academics, consultancy groups, health care funding agencies such as PHARMAC, and increasingly by the health insurance industry and healthcare providers including District Health Boards in NZ.

This presentation will outline the role of economic evaluation in informing the development, funding and outcomes assessment of new products including pharmaceuticals, vaccines and medical devices.

CONCURRENT 1 Regatta D

1530 - 1600

Zoe Breeze

Vendor Manager/Quality Manager (GCP/GVP), Roche Products (NZ) Limited, Auckland, NZ

Innovation in Clinical Trials: Transcelerate Awareness

"In the long history of humankind those who learned to collaborate and improvise most effectively have prevailed." - Charles Darwin

Since 2012 Transcelerate Biopharma Inc. has been working to bring innovative solutions to common problems in clinical trials across the globe. Through the collaboration of member companies and across organisations many of their initiatives have now been realised.

As a big fan of the work being done in this area, my presentation is intended to raise awareness of Transcelerate.

1600 - 1630

Jo Sanders

Operations Manager, Christchurch Clinical Studies Trust (CCST), Christchurch, NZ

Clinical Research Solutions

Clinical research is becoming more complex. With this increase in complexity comes a demand for systems that allow processes to be more streamlined. Requests for site information and documents are consistent across all studies regardless if they are from a sponsor, CRO, or a collaborative group.

The amount of work required to action requests for site documentation in a timely manner requires a significant amount of time and resources. There are systems available to help streamline these processes allowing a one stop shop for sponsor, CROs, and collaborative groups. The advantage of these systems is that they ensure the information can be downloaded when they require it and are not waiting for busy sites to respond to their requests.

Site Docs Portal is a commercially

available system. I will discuss this system and the impact it has had in our site's processes.

1630 - 1700

Dominic Bailey

Chief Executive Officer, Genesis Research Services, Broadmeadow, NSW, Australia

The Use of Social Media as a Tool for Recruitment

As consumers become increasingly divided in how they engage with both healthcare and social media, it is apparent clinical research businesses must quickly adapt their presence online to establish and advance new participant communities and connect with them in reliable ways.

From a site management perspective, the benefits of social media in clinical trial recruitment is typified most aptly as a modern means of identification, engagement and enrolment of a previously under-accessed and potentially willing population for trial participation.

If managed conscientiously and ethically, introduction of social media initiatives can be effective across many clinical indications and for research sites, allows for the formation of a business-orientated vehicle for prospective accumulation of not only trial participants, but additional studies and recruitment of additional investigators.

When a digital media initiative such as recruitment via a social media inclusive system is implemented, sites must prepare accordingly and ensure commitment to the development, implementation and ongoing maintenance of an integrated Quality Management System for social media usage.

CONCURRENT 2 Regatta BC

1530 - 1600

Professor P. Alan Barber

Professor of Clinical Neurology, Neurological Foundation, School of Medicine, Faculty of Medical and Health Sciences, The University of Auckland,
Auckland, NZ

Endovascular Clot Retrieval in a New Zealand Setting

In acute ischaemic stroke, endovascular therapy with the Solitaire FR stent retriever has been shown to double recanalisation rates and the numbers of patients who recover to be functionally independent, when compared to standard therapy. At Auckland City Hospital 110 previously independent ischaemic stroke patients have been treated with clot retrieval to the end of June 2017. Just over half of patients are from outside of the Auckland District Health Board region. All patients have had proximal large artery occlusions on CT angiography and many also have CT perfusion scans showing salvageable ischaemic tissue. Patients fall into three groups: anterior circulation occlusion; posterior circulation occlusion; and 'Rescue' clot retrieval, usually with stroke that followed a procedure. We have shown that endovascular clot retrieval can be safely and effectively performed in a New Zealand setting with similar results to recent trials. We suggest that District Health Boards develop clot retrieval services as part of regional hyperacute stroke treatment pathways.

1600 - 1630

Jan Gaskin

Director, Site Management Delivery, Country Head, Quintiles, Auckland, NZ

GCP Updates

1630 - 1700

Isobel Smith

NZ Country Manager, PPD, Rangiora, NZ

Risk Based Monitoring: Evolution and Change Management

Traditionally, clinical monitoring of study data involved 100% SDV – cross-checking each data point against the original data source. This method is undoubtedly time-consuming and expensive - and doesn't guarantee data quality.

Technology changes have allowed methods of Risk-Based Monitoring to develop as an alternative to 100% SDV. Endorsed and encouraged by Regulatory Agencies and the recent revision to ICH GCP E6, the industry believes that Risk-Based Monitoring can lead to both improved data quality and patient safety within clinical trials, with targeted on-site data review in place alongside focused centralised monitoring activities.

This presentation will review current aspects of Risk-Based Monitoring for both CRAs and sites.

CONCURRENT 1 Regatta D

0830-0900 FREE PAPER

Amber Parry Strong

Centre for Endocrine, Diabetes and Obesity Research, Capital & Coast DHB, Wellington, NZ

Setting up a New Tissue Bank in a DHB Environment

Introduction: In 2014 HDEC stopped giving permission for tissue samples to be stored for future research without an HDEC approved Tissue Bank. The Centre for Endocrine, Diabetes and Obesity Research (CEDOR) is a research unit within CCDHB.

Aims and Methods: CEDOR set out to create a tissue bank for sample storage and was the first within CCDHB to do so, thus several hospital departments had to encounter this for the first time. We worked in partnership with the Research Office, Legal and Quality Departments and the Maori Governance Board.

Results: After 18 months of consultation the CEDOR Tissue Bank was granted HDEC approval.

Conclusion: The idea of setting up a Tissue Bank in a DHB can be daunting, but following a process with the relevant departments ensures all relevant legislation and policy is adhered to.

Jo Sanders FREE PAPER

Operations Manager at Christchurch Clinical Studies Trust (CCST), Christchurch, NZ

Tips on Surviving an FDA Inspection

The FDA regularly conducts inspections of clinical trial facilities both domestically and internationally to determine a site's compliance with regulations and protocol adherence. Upon completing the inspection the FDA inspector provides an initial verbal classification of the inspection. This is based on the observations noted during the inspection, the investigator's report, and FDA District Office supervisory personnel review.

If the inspector finds any objectionable conditions the clinical trials unit is presented with an FDA Form 483, which includes the name of the site, dates of inspection, and lists the observations made by the investigator during the inspection.

In May 2017 Christchurch Clinical Studies Trust was inspected by the FDA. This presentation will provide some of the background into the inspection and will cover the following topics in relation to the inspection:

- Preparation required by the clinical trial site prior to the Inspector arriving
- Expectations of the FDA prior to the visit and once on site
- The Sponsor's involvement
- The CRO role in the inspection
- Resource allocation required
- Tips on surviving the inspection

Kim Knight FREE PAPER

Director, The Art of Health and Science of Wellbeing, NZ

Online Self-Help Program for Recovery from Chronic Fatigue and Fibromyalgia

Introduction: In 2015 it was decided to develop an online self-help program to teach patients with chronic fatigue, M.E., PVFS and fibromyalgia how to reduce and clear symptoms through clearing the stress, lifestyle, behavioural and emotional drivers which build up to chronic pain and fatigue. The protocol had been used successfully for nine years prior with consultations held in clinic or via the phone / internet. The program was designed to be accessible online 24/7 anywhere in the world.

Aims and Methods: The goal was to translate the protocol into an online self-help program. Appropriate online delivery software was sourced, tried and tested. A secure password-protected platform was chosen to deliver audio files, video files and pdf documents. The therapy protocol was 'translated' into audio / video / handout formats to be used by the consumer. Program creation took three months and was launched October 2015. Over three months twenty people joined, some electing a 'do-it-yourself' option whilst others enrolled with group support in an online forum. The program could be completed in three months. In June 2016 an anonymous survey was sent out to assess results.

Results: The survey showed symptoms for members as a whole reduced from a mean rating of 7-10/10 to 0-5/10. An 88 year old Australian woman with 55 years of debilitating symptoms rated depression 9-10/10 and fatigue 8/10 before starting the program and six months later rated depression 0/10 and fatigue 2/10. People who participated in the online forum had faster results as a result of the support.

Conclusions: An online self-help program format proved successful for achieving a reduction and clearing of symptoms of chronic illness and this format can be expanded exponentially at an affordable cost to customers.

0900-0930

Dr Elinor Chisholm

Research Fellow, He Kainga Oranga - Housing and Health Research Programme, Department of Public Health, University of Otago, Wellington, NZ

Building Health by Building Better Housing

0930-1000

Dr Christopher Jackson

Consultant Medical Oncologist, Southern Blood and Cancer Service, Southern DHB; Senior Lecturer in Medicine, University of Otago; and Medical Director, The Cancer Society of New Zealand, Dunedin, NZ

Colorectal Cancer in NZ and the PIPER Project: Translating Research into Clinical Outcomes

Colorectal cancer (CRC) is New Zealand's cancer. It is our most common cancer, the second leading cause of cancer death, and we have one of the highest rates in the world. Despite our world-leading rates, our national response in terms of prevention, early diagnosis, and treatment has been sluggish compared to other countries. Several previous researchers had demonstrated that Māori have worse outcomes due to several small but cumulative discrepancies in quality of care, and rural patients were also thought to have worse outcomes.

How can clinical researchers get involved to make a difference?

In 2011 we started the PIPER project, NZ's largest-ever study of CRC. This project involved hand-searching the notes of over 6000 patients, creating a database of over 960,000 data points. We looked to identify key elements of care and key journey times that could be targeted to improve experience and outcomes. This presentation will look at the history of colorectal cancer in NZ, the role of the PIPER project, and how the findings of research have been translated into clinically meaningful differences for patients – or have they?

CONCURRENT 2 Regatta BC

0830-0900

Dr John Moller

Chief Executive Officer, Novotech, Sydney, Australia

Marketing and Growing NZ Research

0900-0930

Dr John Wyeth

Medical Director, PHARMAC, Wellington, NZ

PHARMAC: An Evidence Based Organisation

PHARMAC's statutory objective is to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. PHARMAC can fund and perform research to assist in achieving this objective and it has a long track record of doing this. PHARMAC utilises a network of clinical advisors to give both advice and critical appraisal of evidence in forming recommendations for funding pharmaceuticals.

In mid-2016, PHARMAC entered into a partnership with the Health Research Council of New Zealand (HRC) to fund research looking at questions around pharmaceuticals and their use in New Zealand. Two projects have been funded in 2016/17: "Improving acceptance of generic medicines" by Prof Keith Petrie, and "Improving metformin adherence and persistence in people with type 2 diabetes" by Dr Lianne Parkin.

PHARMAC has published an analysis looking at health gains from cancer medicines funded in Australia and in New Zealand, suggesting more funded medicines may not lead to better health outcomes. A recent summer student project has looked at real world outcomes from funded cancer medicines in New Zealand compared to published clinical trial data and is in the process of being prepared for publication. Funding decisions are based on published clinical trial data and use of drugs in real world situations, once funded, involves different groups of patients with varying co-morbidities which can affect expected health outcomes.

0930-1000

Saerom Shin

Regulatory Practice and Analysis, Medsafe, Ministry of Health, Wellington, NZ

Dr Stewart Jessamine

Director of Protection, Regulation and Assurance; Acting Director of Public Health, Ministry of Health, Wellington, NZ

Medsafe – Medical Devices Proposed Legislation

PLENARY Regatta D

1030-1130

Dr Ronald W. Jones

Former Obstetrician, Gynaecologist and Clinical Professor, The University of Auckland, Auckland, NZ

A Story of Two Cancers: One Physical and One Moral

Ron Jones is a retired National Women's Hospital obstetrician and gynaecologist, and Clinical Professor at the University of Auckland. He co-authored the '1984 paper' which exposed the truth about Associate -Professor Herbert Green's 'unfortunate experiment.' The 'natural history' experiment involved merely observing and not definitively treating a large group of women without their consent. Many women developed cancer and some died.

The presentation will highlight the response of many of Ron's professional colleagues to the '1984 paper' - both before and after the 1987-88 Cervical (Cartwright) Inquiry. The inquiry has had far-reaching consequences for medical research in New Zealand.

1315-1330

Hon Paul Goldsmith

Minister of Science and Innovation

Ministerial Address

The Government's Role in Science and Innovation as an Investor, including Health and Clinical Research.

CONCURRENT 1 Continued

1330-1400

Philippa Bascand

Manager Ethics Committees, Ministry of Health, Auckland, NZ

Peaks and Pitfalls in HDEC Applications: Tips for those Submitting HDEC Applications

The talk will outline tips and pointers on getting your HDEC application validated by the secretariat on submission first time. It will outline the pitfalls some submitters encounter and what things committees look for when reviewing ethics applications. The talk will cover why you need ethics review and when it applies, and how long the process takes.

HDECs only have 25 minutes to review an application at an ethics meeting. What can you as the applicant expect from the process and what happens when the review doesn't go to plan from the applicant's point of view? What steps can you take to make it run effectively and efficiently? Who do you go to for advice? Once approved, what next?

There will be opportunities for questions and answers.

1400-1430

Professor Joanna Manning

Faculty of Law, The University of Auckland, Auckland, NZ

Compensation for Research-Related Injury in the UK, Australia and New Zealand: A Legal and Ethical Audit

Leading bioethicists, national commissions, and leaders of the medical profession around the world have argued that society owes an ethical obligation to compensate for research-related injury, and that no-fault compensation is the best ethical response. In this lecture Professor Jo Manning will assess existing compensation arrangements in place for research-related injury in publicly-funded and commercially-funded clinical research in the UK, Australia and New Zealand (in particular) against this ethical expectation. She will also consider the adequacy of the information about compensation arrangements in place that supervisory ethics agencies in each jurisdiction recommend that potential subjects be given for informed consent purposes, as well as potential alternative options to remedy identified legal and ethical deficiencies

CONCURRENT 2 Continued

1330-1400

Cheryl-Ann Hawkins

Australian Ambassador for Society for Clinical Research Sites (SCRS); Operations Manager, Oncology Research, Monash Health, Victoria, Australia

Unify the Voice of the Global Clinical Research Site Community - Society for Clinical Research Sites (SCRS)

The Society for Clinical Research Sites (SCRS) was founded in 2012 to represent the global clinical research site community, providing sites with a voice and a community focused on greater site sustainability. SCRS has become an active partner in industry wide initiatives and dialogues focused on improving the clinical research enterprise. Learn of the SCRS industry-wide initiatives to support the clinical research site community and how to have your site's voice included as a member of SCRS.

1400-1430

Donna Fraser

Associate Director, Client Operations, Novotech, Queensland Australia

Setting up a Clinical Trial... To Ensure We Get The Right Fit

Identifying sites for the increasingly more complicated studies can be a challenge for any CRO. Navigating the start-up process is vital to ensure Sites meet their obligations and Sponsors achieve their targets.

General Information

Accommodation

Please ensure you settle your accommodation account directly with the hotel in full on departure, including all meals, telephone calls and mini bar charges.

Audio Visual Technician

AV Technicians will be on site throughout the conference. Speakers – please ensure you download your presentations at the technician's desk in each conference room, prior to your presentation time.

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There is a car parking building underneath The Pullman Hotel, it is managed by Wilson Parking.
Alternatively Valet Parking is available from the Pullman Hotel for $40.00 per car per day with unlimited in and outs during 24 hours.
Wilson Parking Website
http://www.wilsonparking.co.nz/park/257_Upper-Shortland-Street_6-Princes-Street-Auckland.

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As a courtesy to speakers, delegates are requested to switch off mobile phones and pagers during sessions. Messages can be left at the registration desk. Delegates will need to check with the registration desk if they are expecting any messages.

Conference Venue

The Pullman Hotel, Auckland
Corner Princes Street and Waterloo Quadrant,
Auckland 1010
t : +64 9 353 1000

Rooms to be used at the Pullman Hotel
Registration Area: Regatta Foyer
Plenary Sessions: Regatta D
Concurrent Sessions & Workshops: Regatta B/C
Exhibition Area: Regatta A
Catering: Regatta A
Welcome Reception: Regatta A
Conference Dinner: Top of the Town, Pullman Hotel

Please ask for directions at the registration desk if you are unsure. Please note, food and drinks are not to be consumed in the conference rooms. Bottled water is acceptable.

Credit Cards & Payment

Accepted cards are Visa, Mastercard and AMEX. Payment may also be made by cheque, payable to "Conference Trust Account - NZACRes". All fees quoted are in New Zealand Dollars and are inclusive of GST.
Payment for registration must be received prior to the end of the Conference.

Exhibition

There will be an industry exhibition in the Regatta A room of the Pullman Hotel. An exhibitor catalogue is printed at the back of this handbook for your convenience. Please make every effort to visit the exhibitors during breaks. The Welcome Reception, morning teas, lunches and afternoon teas as scheduled in the programme, will be held in this area.

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Messages may be left with staff at the registration desk. Please check for messages as no announcements will be made.

Name Badges

Please wear your name badge at **ALL** meeting sessions and social functions.

Refreshments

Morning tea, lunch, afternoon tea and the Welcome Reception as scheduled in the programme, will be served in the Industry Exhibition Area.

Registration and Information Desk

The registration desk is located in the Regatta Foyer of The Pullman Hotel. The registration desk will be open at the following times:

Thursday 17 August 2017 0930 – 1900 hours
Friday 18 August 2017 0730 – 1600 hours

Conference Manager: Donna Clapham, 021 325 133

No Smoking Policy

Delegates should be aware that smoking is banned in public buildings and many hotels and restaurants in New Zealand, including the Conference venue.

Special Diets

Delegates who have registered special dietary requirements are well catered for on a separate table in the catering area. Delegates who have special dietary requirements and have not registered their requirements should advise the staff at the registration desk as soon as possible.

WiFi

WiFi is complimentary for delegates' use over the period of the conference.

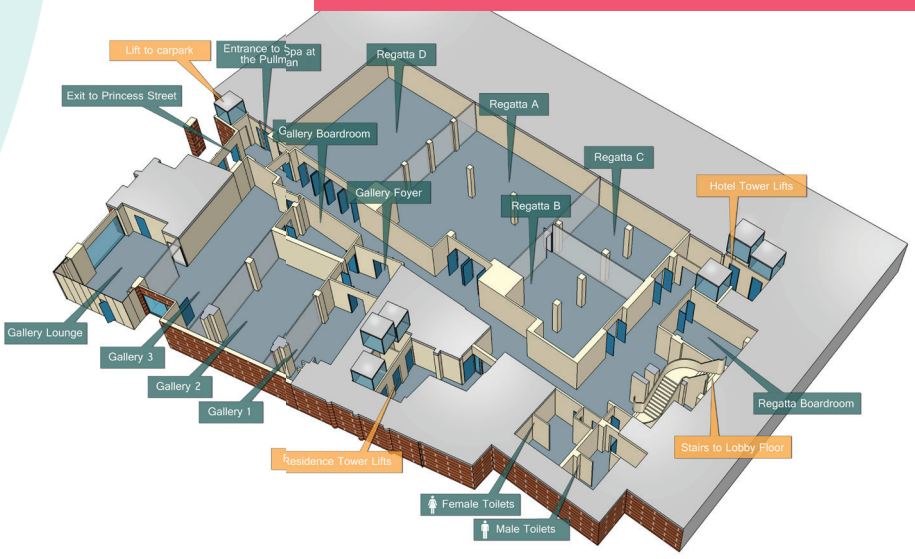
Venue Layout

A floor plan of the venue is provided in the handbook for your convenience.

Regatta D - Main Conference Room & Workshop 1

Regatta A - Exhibition & Catering

Regatta B & C - Concurrent Rooms & Worshops 2 & 3



If you have any questions at all, please don't hesitate to contact our **Conference Organisers:**

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PROCEDURE – Full alarm activated:

Evacuate and Assemble

Upon hearing the Evacuation sound within the Property, this is a loud alarm sound with voice-over sound:

- Please remain calm and make your way to the nearest safe exit, following the exit signs to the exterior of the building and proceeding to the Assembly Point (our Conference fire wardens will assist with escorting you through the exits to the assembly point).
- Do not enter or attempt to use an elevator during an emergency. If stuck in an elevator do not attempt to force open stalled elevator doors, use the emergency phone to contact communication centre.
- Use Emergency Exits
- When using the Emergency Exits please ensure to form one line, and walk down the stairs using the railings as a guide until you reach the assembly point.
- Our staff will be at strategic points to guide you.

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Directly in front of the Pullman.

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Directly opposite the Pullman main entrance, on the Auckland University grounds.

Re-Entry

Staff and guests are only permitted to re-enter the building when the Building Warden in conjunction gives the "All Clear" with the senior emergency services personnel on site.

Delegate List

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Novotech is internationally recognised as Asia Pacific's leading full-service contract research organisation (CRO) operating.

Novotech has been instrumental in the success of hundreds of Phase I - IV clinical trials throughout the region. Novotech provides clinical development services across all clinical trial phases and therapeutic areas including: feasibility assessments; ethics committee and regulatory submissions, data management, statistical analysis, medical monitoring, safety services, central lab services, report write-up to ICH requirements, project and vendor management. Novotech's strong Asia Pacific presence included running clinical trials in all key regional markets. Novotech also has worldwide reach through the company's network of strategic partners.

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IGENZ is an accredited medical testing laboratory located in Auckland, New Zealand.

The laboratory has an interest in targeted cancer testing and supplies services mainly for clinical diagnostics however is also involved in translational (applied) research. Recently IGENZ purchased a genetic profiling laboratory to extend its testing scope.

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P3 Research Ltd is a leading provider of sponsored clinical research in New Zealand. It is a dedicated Clinical Trials Company specialising in phase 2 and 3 clinical trials in common, chronic, relatively stable conditions normally managed in primary care.

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www.pharmac.govt.nz

PHARMAC is the New Zealand Government agency that decides which medicines, medical devices and related products are subsidised, both in the community and public hospitals.

PHARMAC's job is to ensure that New Zealanders get the best possible health outcomes from money the Government spends on pharmaceuticals (this includes medicines, therapeutic medical devices and related products).

The funding for the subsidies comes from District Health Boards. PHARMAC's activity to manage this spend, while at the same time achieving best health outcomes, is important to ensuring the long-term sustainability of the health system.

REALTIME SOFTWARE SOLUTIONS, LLC
BRONZE SPONSOR

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RealTime Software Solutions continues to grow its global footprint with innovative, user-friendly solutions that bring streamlined processes and greater profitability to clinical research sites.

RealTime offers powerful innovations such as leading clinical trial management systems for standalone sites and multi-site organizations (RealTime-CTMS), automated TEXT messaging (RealTime-TEXT), stipend payment portals (RealTime-PAY), eRegulatory solutions (eDOCS), and electronic source (RealTime-eSOURCE).

Further, RealTime is the only software provider that can package these solutions separately or fully-integrated, allowing customers to add on solutions as needed to streamline their organization as they grow. Partnering with RealTime will help your site stand out and lead the pack.

QUINTILES PTY LTD
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At Quintiles we help healthcare and biopharma companies improve their probability of success. We do this by connecting our scientific, therapeutic and analytics expertise with superior delivery.

From advisory through operations, Quintiles and its affiliate companies is the world's largest provider of product development and integrated healthcare services. As one of FORTUNE's 'Most Admired Companies' in 2016, we offer great opportunities for a career in world-leading clinical research. Our global projects, innovative tools and industry leading customers combined with outstanding support from our leadership team and clear career mapping allows you to make a difference in patient health.

CHRISTCHURCH CLINICAL STUDIES TRUST (CCST)
SUPPORTING SPONSOR

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www.ccst.co.nz

Christchurch Clinical Studies Trust (CCST) was establishment in 1999 when it was identified that there was a need for a well-designed dedicated facility to perform Phase I and II pharmacokinetic and pharmacodynamic studies in healthy volunteers and patient populations.

CCST has conducted over 100 clinical trials and we have become known as a centre of excellence for Phase 1 healthy volunteer and renal impairment studies.

The healthy volunteer studies have ranged from entry-in-human, single ascending dose trials to bioequivalence/ food effect studies and more recently biosimilar studies. Many of these studies have been a "critical path" for the sponsors and the development of new novel therapies.

CLINICAL TRIALS NZ LTD
SUPPORTING SPONSOR

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Clinical Trials NZ Ltd (formerly Waikato Clinical Research) is a free standing clinical trials unit which specialises in Phase 1 to Phase 4 clinical trials. CTNZ has credible experience with both in-patient and out-patient trials, and conducts trials in the areas of acute and post-operative pain, Dermatology, Vascular, medical devices and Ophthalmology.

With over 30 years of conducting trials, having leading medical specialists and access to hospitals of world class facilities we can offer efficiently run clinical trials in a first world environment. CTNZ nurses are all dedicated clinical trials co- coordinators trained in ICH/ GCP. Our clinical trials have been presented at International meetings in the USA, Europe and Australasia.

PACIFIC CLINICAL RESEARCH NETWORK
SUPPORTING SPONSOR

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Website Pending

Pacific Clinical Research Network (PCRN) has been formed to achieve faster delivery with consistent quality across multiple clinical trial sites in Australia and New Zealand.

PCRN is a partnership between Southern Clinical Trials Group (NZ), Lakeland Clinical Trials (NZ) and Paratus Clinical Trials (Australia). PCRN will provide a single contact point for sponsors, centralised feasibility and start up processes and a common suite of SOPs, quality systems and processes across the Alliance.

LINK HEALTHCARE
TABLE TOP #5

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www.clinigengroup.com

Link Healthcare are part of the rapidly growing Clinigen Group.

Clinigen Clinical Trial Services (CTS) supply medicines for clinical trials from pre-clinical to phase IV.

Our Clinical Trials Services has unrivalled sourcing capabilities, working directly with a global network of manufacturers, approved distributors and audited suppliers to obtain comparator medicines, analytical samples, rescue medicines, adjuvant drugs and ancillaries.

Right Medicine, Right Patient, Right Time.

ROCHE PRODUCTS (NZ) LTD
TABLE TOP #7

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www.roche.co.nz

Roche NZ is based in Newmarket, Auckland where a team of 30 dedicated people have the goal of facilitating access to our innovative medicines.

With its parent company in Basel, Switzerland, our local company has serviced New Zealand for over 40 years and has supplied over 100 Roche medicines to New Zealanders.

Our clinical research team works closely with New Zealand's clinical research experts. Currently Roche supports or sponsors over 30 clinical trials, making us one of the leading companies investing in medicines research here in New Zealand. Our trials cover diseases such as cancer (solid tumour types and cancers of the blood), multiple sclerosis, haemophilia, and asthma and other diseases of the lung.

SOCIETY FOR CLINICAL RESEARCH SITES (SCRS)
TABLE TOP #6

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SCRS is a global trade organization founded in 2012 which represents almost 9,000 research sites in over 45 countries.

SCRS' mission is to unify the voice of the global clinical research site community for greater site sustainability. SCRS has become an active partner in industry-wide initiatives and dialogues focused on improving the clinical research enterprise.

Sites and the companies that sponsor or support the work conducted at clinical research sites will benefit from membership and partnership. Our Voice. Our Community. Your Success. Join the community and collaborate with the global experts in site sustainability.

THE UNIVERSITY OF QUEENSLAND, AUSTRALASIAN KIDNEY TRIALS NETWORK
TABLE TOP #1

Faculty of Medicine (CHSR), The University of Queensland, Translational Research Institute, Level 5, 37 Kent Street, Woolloongabba, QLD, Australia 4102

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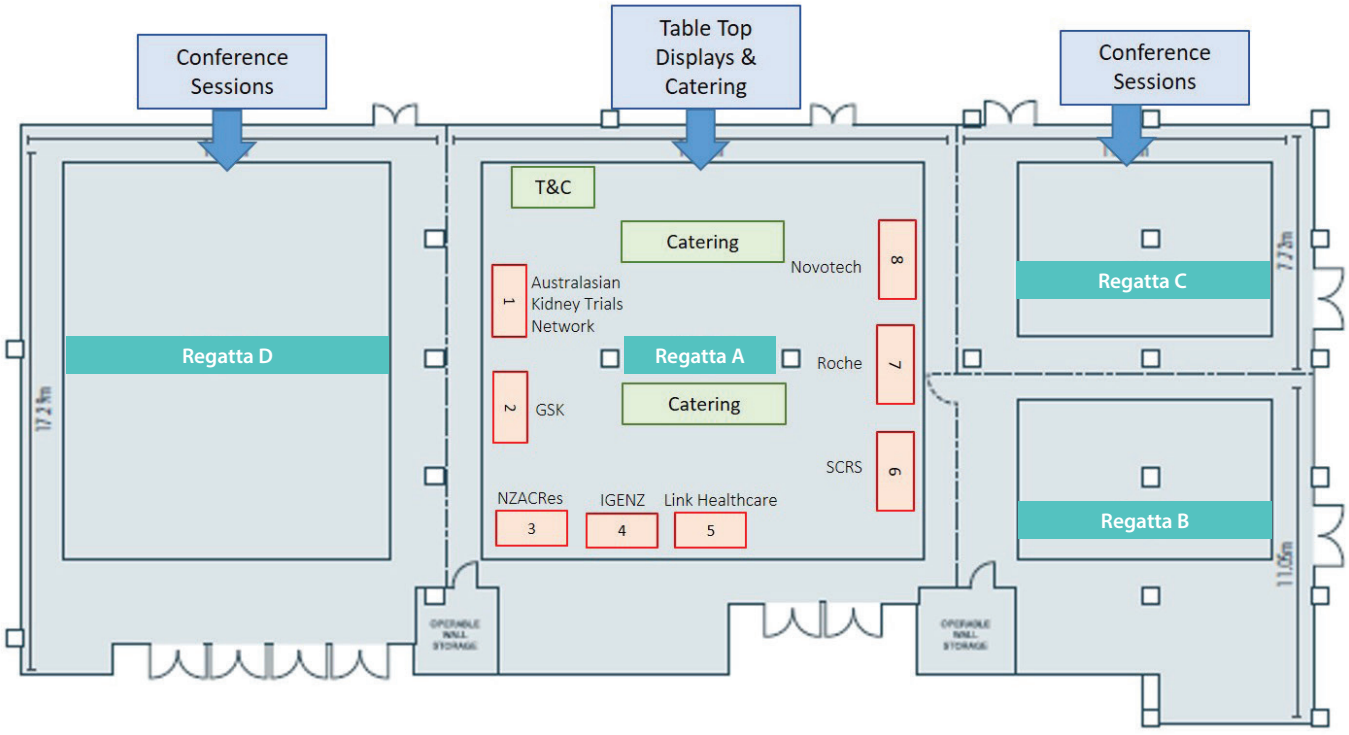
www.aktn.org.au

The Australasian Kidney Trials Network (AKTN) operates under the Centre for Health Services Research at the University of Queensland's Faculty of Medicine.

It is a not-for-profit collaborative research group that designs, conducts and supports investigator-initiated clinical trials with the aim of improving life for people living with Chronic Kidney Disease (CKD).

To date, the AKTN has successfully completed eight trials with a record number expected to be running in 2017. Our research helps bring evidence to medical practice and in doing so improve outcomes for CKD patients.

Exhibition Floor Plan



Australasian Kidney Trial Network	#1
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Novotech	#8
NZACRes	#3
Roche	#7
SCRS	#6

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