



**Australian
Clinical
Trials
Alliance**

Year in Review: Financial Year 2018/2019

TABLE OF CONTENTS

Message from the General Manager	3
An overview of ACTA	4
Our vision	5
Our mission	5
Our strategy	5
ACTA advocacy	6
Clinical Trials Collaborative Forum	6
ACSQHC Clinical Trials Governance Framework Consultation	6
Consultation on the Draft National Clinical Quality Registry Strategy	7
MRFF Priorities and Evaluation Framework Consultations	7
Clinical Trials 2019: National Tribute and Award Ceremony	8
Previous winners	10
ACTA Summit 2018	11
ACTA Summer School	13
Registry-Randomised Trials Colloquium	13
Adaptive Clinical Trial Design Coding Workshops	13
Innovative Trial Design Seminar	13
Webinar Wednesdays with ACTA	14
Data Linkage Webinar Series	14
Studies Within A Trial (Swats): How they can help to make trial process decisions more evidence-based	14
ACTA Hackathon of Novel Trial Designs Webinars	14
Reports and Resources	15
Consumer Involvement in Clinical Trials Consultation Report	15
Efficient and Effective CTNs – Critical Success Factors Focus Groups	15
ACTA Efficient and Effective CTNs Reference Group Toolkit	15
Abbreviated Financial Summary 30 June 2019	16
Thank you	19

MESSAGE FROM THE GENERAL MANAGER

Welcome to our first Year in Review report. We have produced this report as a companion piece to our Annual Financial Report, to illustrate the work we have been doing and the resources and tools created over the 2018–2019 Financial Year.

It has been a privilege to work with the dedicated ACTA Community over the year. We gratefully acknowledge the invaluable support and contributions from our Members, the Australian Government Department of Health and Medical Research Future Fund (MRFF).

It has been a highly productive year with more than 170 members of the ACTA Community, including experts in their fields, donating their time and significant pro bono support to the work of ACTA through eight Reference Groups and three Special Interest Groups. This community of practice, which included consumer groups and industry, met regularly during the year to share their knowledge, and identify, agree and implement best-practice guidance. Together, we worked to promote more effective clinical trials research to deliver optimum patient outcomes and improved clinical practice via the activities of clinical trials networks (CTNs), clinical quality registries and clinical trial coordinating centres.

Across the Reference and Special Interest Groups, and through a series of consultations, ACTA identified current barriers and enablers to effective and efficient investigator-initiated clinical trials and produced guidance, tools and training to support CTNs. Many of the outputs from these groups are highlighted in this report and are available on our website www.clinicaltrialsalliance.org.au.

ACTA fostered a culture of collaboration through the ongoing support of Special Interest Groups for network managers, registries and statistics in trials; mapping of

clinical trials improvement activities across the sector, on behalf of the Clinical Trials Collaborative Forum; organisation of national events to raise awareness of clinical trials, including the Clinical Trials 2019: National Tribute & Awards Ceremony and the ACTA Summit; and partnerships with key stakeholders.

Throughout the year, we held a range of education and training opportunities to facilitate knowledge sharing and professional development and cultivate thought leadership. We participated in public and targeted consultations and provided a voice for the investigator-initiated trial sector through representation on national committees.

Internally, we continued to develop our governance, communication and stakeholder engagement structures. We undertook a governance review and established a plan for the evaluation of the current program. With the team growing to eleven staff early in the year, we moved to larger premises at Suite 1, Level 2, 24 Albert Road, South Melbourne. I would like to sincerely thank the ACTA team, past and present, for their hard work and dedication to our mission.

Finally, I would like to thank and acknowledge our very dedicated Board of Directors, whose passion and support continue to drive our vision of Better health through best evidence.

We look forward to an even bigger 2019-2020 year, and the delivery MRFF program, 'Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks'.



Ms Simone Yendle
General Manager, ACTA



Pictured left to right: Ms Nicola Straiton, Ms Simone Yendle, Ms Lea Hauchard, Ms Anitha Balagurunathan, Dr Megan Sanders, Mr David Barrett, Ms Madeleine Enright, Ms Miranda Cumpston, ACTA Chair Prof John Zalberg at the ACTA Summit

AN OVERVIEW OF ACTA

The Australian Clinical Trials Alliance (ACTA) was incorporated as a company limited by guarantee on 21 March 2014. It was created to provide a national mechanism for supporting high-quality investigator-led clinical trials within the Australian healthcare system. ACTA's formation was driven by individuals who have played key roles in the successful clinical trials networks, and to highlight the importance of clinical trial coordinating centres and clinical quality registries to better health outcomes in Australia. These are the core groups that ACTA is guided by and represents.

In May 2017, the Australian Clinical Trials Alliance (ACTA) was awarded \$5m funding over the 2017–2020 period, through the Medical Research Futures Fund (MRFF). The funding was part of the Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program, to strengthen sector capability and collaboration toward embedding

evidence-based care in the health system. The grant was provided to ACTA to enhance its capacity to provide collaborative and strategic leadership and practical support for Clinical Trials Networks (CTNs), and the coordinating centres (CCs) and clinical quality registries (CQRs) that enable, support, and inform their work.

ACTA has continued to work with its membership to develop and implement a program of strategic activities that strengthen and grow the capacity, capability and effectiveness of the clinical trials sector in Australia with a big picture view to improve health outcomes for all Australians.

At 30 June 2019, ACTA's member profile consisted of 56 full and associate member CTNs, CCs and CQRs, together with 14 affiliate organisation members and 107 individual affiliate members.



The ACTA Summit

OUR VISION

Better health through best evidence.

OUR MISSION

To promote effective and cost-effective healthcare in Australia through investigator-initiated clinical trials and clinical quality registries that generate evidence to support decisions made by health practitioners, policymakers, and consumers.

OUR STRATEGY

ACTA's 2018–2021 Strategy includes three interlocking areas of equal focus and priority (Strategies 1–3), underpinned by a fourth foundational area (Strategy 4), designed to strengthen ACTA and support our mission.

OUR STRATEGY

1 GROWING OUR CAPACITY TO CONDUCT HIGH-QUALITY CLINICAL TRIALS TO IMPROVE EVIDENCE, BY:

- > Supporting the coordinated development of new networks, registries and coordinating centres to fill identified gaps
- > Increasing clinical research capacity through greater education and training opportunities for researchers and consumers
- > Developing frameworks for improved research prioritisation and impact
- > Developing and promote transformational models of a learning health system

2 IMPROVING THE EFFECTIVENESS AND EFFICIENCY OF CLINICAL TRIAL PRACTICE, BY:

- > Creating communities of practice to maximise the impact of ACTA reference groups
- > Identifying and promote best-practice guidelines to achieve optimal CTN operational standards
- > Exploring innovative, value-adding shared services, tools and technologies for CTNs and Registries
- > Enhancing links between ACTA members to enable efficient cross-sector learning
- > Engaging with consumers and other stakeholders to further improve best practice models

3 PROMOTING, ADVOCATING AND COLLABORATING TO STRENGTHEN THE SECTOR, BY:

- > Developing and implement marketing and communications to deliver key messages
- > Focusing advocacy for best practice and evidence-based healthcare
- > Maintaining relationships with all stakeholders based on trust and respect
- > Providing advice as the authoritative point of contact for members and policymakers
- > Collaborating with Industry to advance the sector

4 BUILDING A SUSTAINABLE AND WELL-RUN ORGANISATION, BY:

- > Building the membership base and connect with members to ensure optimal engagement
- > Identifying new ways of engaging with external stakeholders
- > Developing governance systems to ensure responsive and responsible leadership
- > Furthering internal processes and policy to ensure effective and efficient management
- > Diversifying and expand funding sources

Advocacy activity over the period included:

- Representation on national committees
- Participation in the ClinTrial Refer GP Roundtable
- Response to consultations relevant to clinical trials and registries, including:
 - > Australian Commission on Safety and Quality in Health Care Clinical Trials Governance Framework
 - > Co-chaired Clinical Trial Collaborative Forum
 - > Department of Health Consultation on the Draft National Clinical Quality Registry Strategy
 - > Medical Research Future Fund Strategy and Priorities
 - > Medical Research Future Fund Evaluation Framework (Return on Investment)
 - > Australian Research Data Commons and Commonwealth Scientific and Industrial Research Organisation Clinical trial data sharing
 - > Australian Academy of Science and Australian Academy of Health and Medical Sciences Data in Health and Medical Research



Pictured left to right: Prof Steve Webb, Ms Simone Yendle, Prof John Zalcberg OAM, Minister for Health, The Hon. Greg Hunt, MP.

Previous major initiatives undertaken by ACTA include:

- Report on activities and achievements of Clinical Trial Networks in Australia 2004–2014
- Economic evaluation of investigator-initiated clinical trials conducted by networks (2017)
- Clinical Trials: National Tribute and Awards Ceremony including TOTY (2016–)
- Submissions to the MRFF legislation on MRFF strategy and priorities.

CLINICAL TRIALS COLLABORATIVE FORUM

The Clinical Trials Collaborative Forum is a cross-sectoral forum established by the Australian Government Department of Health to identify issues, exchange information and engage in collaborative problem-solving. It consists of a wide range of clinical trials stakeholders, including State and Territory Health Departments, industry, and peak bodies. The Forum is co-chaired by Ms Melissa Hagan, Queensland Health, and ACTA's Deputy Chair, Prof Steve Webb.

A key discussion item at the last Forum, held in Melbourne on 13 November 2018, was clinical trial improvement activities underway across the sector, identified as part of a scoping and analysis activity that was coordinated by ACTA on behalf of the Forum. The purpose of the discussion was to identify opportunities for collaboration or synergy, identify gaps and minimise duplication. Areas discussed at the meeting included targeted workforce development, enhancing capabilities for Phase I trials and digital health.

ACSQHC CLINICAL TRIALS GOVERNANCE FRAMEWORK CONSULTATION

Clinical trials contribute over \$1.1bn annually to the Australian economy. More importantly, they give Australian patients access to potentially life-saving treatments as well

as helping to improve the evidence base underpinning best practice health care. However, ongoing issues of fragmentation and inefficiency impact Australia's attractiveness as a preferred location for clinical trials.

As a first step toward a nationally consistent accreditation approach for health services undertaking clinical trials, the Australian Commission on Safety and Quality in Health Care (ACSQHC) has been contracted by the Australian Government Department of Health on behalf of all jurisdictions to develop the national Clinical Trials Governance Framework (the Governance Framework).

We responded to the draft framework after consulting with our Members. ACTA will continue to participate in the process as the peak body for CTNs.

The Governance Framework and accreditation standard represents a priority area agreed by governments, to strengthen and enhance consistency of governance arrangements for trials, and provide clarity to governments, health services, hospital administrators, clinicians and others responsible for delivering clinical trials. It is due for completion in mid-2019.

CONSULTATION ON THE DRAFT NATIONAL CLINICAL QUALITY REGISTRY STRATEGY

The Australian Department of Health, on behalf of the Australian Health Ministers' Advisory Council (AHMAC), consulted with stakeholders to inform the development of the National Clinical Quality Registry (CQR) Strategy 2019–2029.

The draft National CQR Strategy aims to 'drive continuous improvements in the quality and value of health care to achieve better health outcomes for all Australians'.

We consulted with our Members to inform a response to the Department of Health and we continue to be involved with the consultation process.

MRFF PRIORITIES AND EVALUATION FRAMEWORK CONSULTATIONS

In 2018, the Australian Medical Research Advisory Board undertook a national consultation to inform the development of the second set of MRFF Australian Medical Research and Innovation Priorities for 2018-2020. The Priorities serve to inform future Government decisions on MRFF initiatives and therefore are of high importance to the ACTA Community.

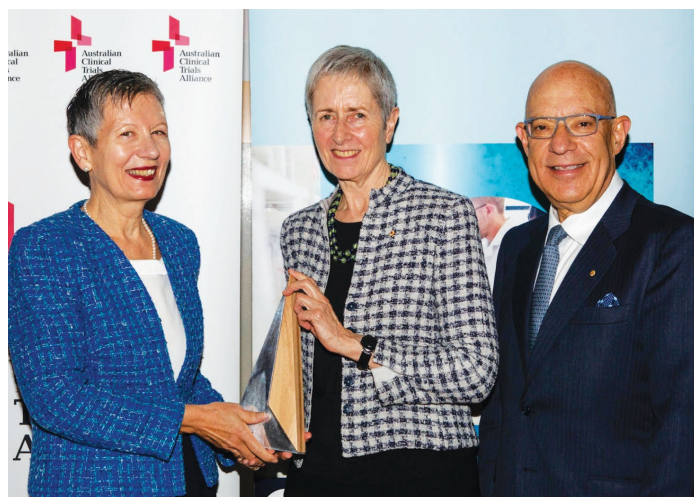
Our submission focused on three ongoing priorities recognised by the MRFF: CTNs, CQRs and investigator-led clinical trials. We also proposed three new priorities to address gaps in the current funding landscape: CCs as hubs for critical research and expertise, Practitioner Fellowships accessible to a broader range of clinical contexts and earlier in clinician-researcher careers, and closer collaboration between funding decision-makers such as the Pharmaceutical Benefits Advisory Committee and the Medical Services Advisory Committee and investigator-driven research. The submission is available on our website in the resources area.

In addition, we provided feedback to Research Australia on the Draft Evaluation Framework for the MRFF, acknowledging the challenges in measuring short-term outcomes for clinical research while highlighting the value of resources like CTNs and the importance of ensuring consumer involvement.



The ACTA Summit

In 2019, we once again celebrated Australian achievements in clinical trials with a breakfast awards ceremony on International Clinical Trials Day at the Royal Children's Hospital Melbourne. ACTA Trial of the Year Winner 2019 was the ASPREE study. The team was well represented at the event, headed by Associate Professor Robyn Woods and with some words of wisdom offered by study participant, Emeritus Professor Bruce Holloway.



The Trial of the Year 2019 Winner – the ASPREE study, Monash University Department of Epidemiology and Preventative Medicine. Pictured left to right: A/Prof Robyn Woods, Prof Anne Kelso AM and ACTA Chair Prof John Zalcberg OAM

THE WINNER OF THIS YEAR'S 2019 TRIAL OF THE YEAR – THE ASPREE STUDY

Led by: Monash University, Department of Epidemiology and Preventative Medicine

Coordinated by: ASPREE Clinical Trial Co-ordinating Centre

The ASPREE (ASpirin in Reducing Events in the Elderly) study was an international, multicentre clinical trial to determine whether daily low-dose aspirin prolonged good health by preventing or delaying age-related illness such as cardiovascular disease, dementia, depression and certain cancers in the healthy elderly. It is the largest primary prevention aspirin study ever undertaken in healthy people aged 70 years or above and the first to weigh the benefits versus the risks.

Associate Professor Robyn Woods, accepting the award said, "I'm proud to have been involved in such a significant study as ASPREE, and to have led such a fine, talented team of researchers and support staff. It was a huge undertaking that is already seeing real impact in the community, with millions of older people around the world without a clinical need to take aspirin, now able to take one less daily medication."



2019 ACTA STInG Excellence in Trial Statistics Winner. ADRENAL Trial – accepted by A/Prof Laurent Billot. Picture: Prof Anne Kelso AM and A/Prof Laurent Bilot

2019 TRIAL OF THE YEAR FINALISTS AND 2019 ACTA STING EXCELLENCE IN TRIAL STATISTICS AWARD WINNER – ADRENAL: Adjunctive CorticosteRoid TrEatment iN CriticAlly iLL patients with septic shock

Led by: ANZICS (Australian and New Zealand Intensive Care Society) Clinical Trials Group

Coordinated by: The George Institute for Global Health.

Steroids have been used for decades by some clinicians to treat patients admitted to an ICU with septic shock, but whether such treatment improved survival was unclear. The ADRENAL study was conducted to determine if hydrocortisone, compared to a placebo, reduces 90-day-all-cause mortality in patients admitted to an ICU with septic shock.

The design of ADRENAL resulted in several firsts for the Australian ICU network. Randomisation was performed using a minimisation algorithm via an encrypted web-based interface, stratified according to participating site and an operative or non-operative diagnosis on admission to the ICU. A detailed analysis plan was pre-published in *Critical Care and Resuscitation*, one of the leading journals in critical care medicine in Australia. The statistical analyses used, including competing risk analysis, multiplicity adjustments. All pre-specified and post-hoc analyses were transparently reported in the NEJM publication.

Associate Professor Laurent Billot said: "We knew that the ADRENAL trial was likely to have substantial impact. Our goal was to make sure the statistical analysis was as 'robust' as possible. In particular, we paid a lot of attention to the statistical analysis plan to ensure a high degree of precision and transparency. We are very pleased to be recognised with the Excellence in Trial Statistics award."



TOTY 2019 Finalist – RELIEF. Pictured: Prof Anne Kelso AM and Prof Paul Myles

2019 TRIAL OF THE YEAR FINALISTS – RELIEF: Restrictive versus Liberal Fluid Therapy for Major Abdominal Surgery

Led by: ANZCA CTN (Australian and New Zealand College of Anaesthetists Clinical Trials Network)

Coordinated by: Department of Anaesthesia and Perioperative Medicine, Alfred Hospital, Melbourne

Every year at least 310 million people undergo major surgery worldwide, and they all receive intravenous fluids – generally receiving up to 7 litres on the day of surgery. The RELIEF team believed existing evidence for how much fluid to administer during and immediately after abdominal surgery was inconclusive. They were concerned that fluid restriction could increase the risk of hypotension and decrease kidney and other vital organ perfusion, leading to serious complications after surgery but too much fluid could cause pulmonary oedema and other complications of fluid overload. The RELIEF study provides high-quality guidance to clinicians about how much fluid therapy is optimal.

2019 CONSUMER INVOLVEMENT AWARD WINNER – TORPIDO 30/60: Targeted Oxygenation in the Respiratory care of Premature Infants at Delivery: effects on Outcome

Led by: IMPACT (Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network for Mothers’ and Babies’ Health)

Coordinated by: NHMRC Clinical Trials Centre, University of Sydney

The TORPIDO 30/60 study wanted to determine which initial concentration of oxygen should be given to preterm babies in the delivery room. Enrolling babies into a study of this nature is complex because it is not always possible or



TOTY 2019 Consumer Involvement Award Winner – TORPIDO 30/60. Pictured left to right: Prof Anne Kelso AM, Ms Melinda Cruz and Prof William Tarnow-Mordi

appropriate to gain parents’ consent during a difficult and sometimes highly stressful situation.

Melinda Cruz – founder of Miracle Babies, acknowledged consumer expert and mother of three babies who were born preterm – was invited to be a member of the Trial Management Committee, eventually gaining a waiver of consent from the ethics committee for TORPIDO 30/60. This meant more preterm babies could enter the study, widening the study pool and enhancing recruitment rates.

Researchers and clinicians had been asking which level of oxygen was better for preterm babies 30 years; and TORPIDO 30/60 managed to answer that question.

Thanks to everyone who joined us for the Clinical Trials 2019: National Tribute and Award Ceremony. A special thanks also to the members of the three independent judging panels, whose substantial contributions made these awards possible. Next year’s Awards will take place in Sydney.

ACTA would also like to thank the many supporters of the Clinical Trials National Tribute and Award Ceremony: Our partners; MTPConnect and Medicines Australia and all those supporting the celebrations; Bellberry, CT:IQ, Consumers Health Forum of Australia, Medical Technology Association of Australia, National Health and Medical Research Council, Research Australia and our Venue Partner Royal Children’s Hospital.

PREVIOUS WINNERS

TRIAL OF THE YEAR 2018 WINNER APTS: The Australian Placental Transfusion Study. Should very pre-term babies receive a placental blood transfusion at birth via deferring cord clamping versus standard cord clamping procedures?

Led by: IMPACT (Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network for Mothers' and Babies' Health). **Coordinated by:** NHMRC Clinical Trials Centre, University of Sydney

ACTA STInG EXCELLENCE IN TRIAL STATISTICS AWARD 2018 WINNER N3RO: Docosahexaenoic acid for the reduction of bronchopulmonary dysplasia in preterm infants born at less than 29 weeks' gestational age: a randomised controlled trial

Led by: IMPACT (Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network for Mothers' and Babies' Health). **Coordinated by:** Healthy Mothers, Babies and Children, The South Australian Health and Medical Research Institute

FINALIST AND HONOURABLE MENTION FOR THE ACTA STInG EXCELLENCE IN TRIAL STATISTICS

AWARD PRECISE: Pregabalin in addition to usual care for sciatica

Led by: ANZMUSC (Australia and New Zealand Musculoskeletal Clinical Trials Group). **Coordinated by:** The George Institute of Global Health, The University of Sydney

FINALIST TRANSFUSE: A randomised controlled trial of standard transfusion versus fresher red blood transfusion in intensive care

Led by: ANZICS (Australian and New Zealand Intensive Care Society) Clinical Trials Group. **Coordinated by:** ANZIC Research Centre

TRIAL OF THE YEAR 2017 WINNER ATACAS: Aspirin and Tranexamic Acid for Coronary Artery Surgery

Led by: ANZCA CTN (Australian and New Zealand College of Anesthetists Clinical Trials Network). **Coordinated by:** Alfred Hospital & Monash University

RUNNER-UP BOOST II Australia: Benefits of Oxygen Saturation Targeting II

Led by: IMPACT (Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network for Mothers' and Babies' Health). **Coordinated by:** NHMRC Clinical Trials Centre

TRIAL OF THE YEAR 2017 FINALIST AND INAUGURAL ACTA STING EXCELLENCE IN TRIAL STATISTICS AWARD WINNER SAVE: The Sleep Apnea Cardiovascular Endpoints Study

Led by: The George Institute for Global Health and Adelaide Institute for Sleep Health. **Coordinated by:** The George Institute for Global Health

TRIAL OF THE YEAR 2017 FINALIST ENCHANTED: The Enhanced Control of Hypertension and Thrombolysis Stroke Study

Led by: ASTN (Australasian Stroke Trials Network) **Coordinated by:** The George Institute for Global Health

TRIAL OF THE YEAR 2016 WINNER THE PPROMT Trial: Immediate delivery versus expectant care in women with Preterm Prelabour Rupture Of Membranes Close to Term

Led by: IMPACT (Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network for Mothers' and Babies' Health). **Coordinated by:** Kolling Institute, University of Sydney

FINALISTS

The EXTEND 1A Trial: EXtending the time for Thrombolysis in Emergency Neurological Deficits with Intra-Arterial therapy

Led by: ASTN (Australasian Stroke Trials Network). **Coordinated by:** Royal Melbourne Hospital

The SOFT Trial: Suppression of Ovarian Function Trial

Led by: Australian and New Zealand Breast Cancer Trials Group. **Coordinated by:** International Breast Cancer Study Group

The AVOID Trial: Air Versus Oxygen in ST-Segment–Elevation Myocardial Infarction Study

Led by: Ambulance Victoria and Monash University **Coordinated by:** Ambulance Victoria Research and Evaluation Department

The EPO-TBI Trial: A randomised placebo-controlled trial of ErythroPOietin in ICU patients with Traumatic Brain Injury

Led by: ANZICS (Australian and New Zealand Intensive Care Society) Clinical Trials Group. **Coordinated by:** ANZIC Research Centre, Monash University

The AVERT Trial A Very Early Rehabilitation Trial after stroke

Led by: Australasian Stroke Trials Network (AVERT Collaboration Group). **Coordinated by:** The Florey Institute of Neuroscience & Mental Health

ACTA SUMMIT 2018

ACTA Summit 2018 presented delegates with a wide variety of speakers and topics, a strong focus on consumer engagement and networking opportunities. Two hundred delegates heard from, questioned and networked with each other and our engaging and eminent speakers.

The key piece of feedback from Summit delegates was the importance of reinforcing consumer involvement in clinical trials from the very beginning. Participants at the Summit saw the engagement of our consumer attendees in question time, as speakers on panels and networking throughout the event.

In addition to members of the Consumer Engagement Reference Group in attendance, ACTA put out a National expression of interest for consumers to receive free tickets to the Summit and received an enthusiastic response! Consumers attended the Reference Group breakfast on Day Two of the Summit to answer the critical question: Where to next for consumer engagement in clinical trials?

In answer to this, the group has gone on to develop guidance and tools for the clinical trials sector to involve consumers and raise awareness about the role and value of clinical trials to the broader community.

ACTA wants to recognise all of our consumer attendees for bringing their passion and valuable experience to the discussions and putting real faces to the work of this group.

A huge thank you to our wonderful Convener, Prof Anthony Keech and his team from the NHMRC Clinical Trial Centre, our engaging and eminent speakers, delegates for your enthusiastic participation, our principle partners Bellberry and CT:IQ, and our sponsors: NSW Health's Office for Health and Medical Research, MTPConnect, ClinTrial Refer, Datapharm, and Research4Me.



Prof Rachele Buchbinder, NHMRC Senior Principal Research Fellow at ACTA Summit 2018



Pictured clockwise from top left: Panel discussion: Network, new and old at ACTA Summit 2018. A/Prof Katie Groom, Prof Judith Trotman, Mr Toby Richards, Prof Alan Cass, Prof Rachelle Buchbinder, Prof Anushka Patel; A/Prof Steven Tong engaging with other delegates during the 2018 Summit networking break; and Ms Melaine Gentgall, CEO, PRAXIS Australia during the Q&A.

ACTA SUMMER SCHOOL

With the change to NHMRC grant deadlines, we invited ACTA Members and Community to make the most of their 'freed-up February' by joining their peers and eminent experts at ACTA Summer School 2019.

More than 90 ACTA Community members attended one and two-day workshops: **Registry-randomised Trials Colloquium**, **Innovative Trial Design Seminar**, and the **Innovative Trial Design Clinic**; and had the option of attending a two-day workshop on **Adaptive clinical trial designs: theory and hands-on skills development** in Melbourne, Sydney or Brisbane.

REGISTRY-RANDOMISED TRIALS COLLOQUIUM

Delegates had the opportunity to hear from trialists who have successfully run trials using clinical quality registries, as well as from policymakers and funders. Delegates left the colloquium better equipped to use these methodologies, with a clear pathway to engage registries to make trials better, cheaper, easier, and quicker.

Representatives from government, the clinical trials sector and consumers shared their knowledge and experience across the day, which closed with a panel discussion. The event was held Monday 11 February 2019 at SAHMRI (South Australian Health and Medical Research Institute).

ADAPTIVE CLINICAL TRIAL DESIGN CODING WORKSHOPS

ACTA held two-day intensive workshops in Melbourne, Brisbane and Sydney, seeing participants take away the knowledge and practical skills fundamental for designing adaptive clinical trials. Hands-on experience was offered in applying cutting edge methods and numerical simulations using R and/or STATA.

International expert presenters from the University of Cambridge: James Wason, Adrian Mander, David Robertson and Newcastle University (UK) Michael Grayling ran the clinics. This event was presented in collaboration with the Victorian Centre for Biostatistics (VicBiostat).

INNOVATIVE TRIAL DESIGN SEMINAR

ACTA hosted a Clinical Trial Adaptation Clinic in Sydney in February 2019 as part of its Summer School. Scott Berry, a global leader in adaptive trial design, along with a panel of local ACTA experts led the clinic at the George Institute to coach attendees through making the most of cutting-edge approaches to trials.

The one-day workshop provided a general introduction to adaptive trials using novel and innovative trial designs that have become increasingly popular with advances in computing and statistical powers.



Pictured clockwise from above left: A/Prof Steven Tong presenting at Adaptive clinical trial designs: theory and hands-on skills development at The George Institute, Sydney; Adaptive clinical trial designs; and Summer School, Melbourne.

WEBINAR WEDNESDAYS WITH ACTA

Webinar Wednesdays with ACTA was a new series of online interactive webinars including opportunities to engage with presenters who are leaders in their field. Topics included 'Studies Within a Trial (SWATs)', a dedicated four-part series exploring 'Data Linkage for Clinical Trialists', and we staged a 'Novel Trial Designs Hackathon'.

The webinars kicked off in March 2019 and ran until mid-May. The presentations are available on our website.

DATA LINKAGE WEBINAR SERIES

The data linkage webinar series was presented in collaboration with Population Health Research Network (PHRN) with support from the Australian Research Data Commons (ARDC).

Australia has a health data linkage network, the PHRN that enables existing health data from around the nation to be brought together and made available for research purposes. To date, the PHRN infrastructure has been infrequently used by clinical trials researchers.

ACTA and the PHRN developed this series of webinars to introduce clinical trial researchers to the PHRN facilities and services available, demonstrate the benefits of using linked data in trials research and assist clinical trial researchers to design clinical trials using linked data and apply for access to linked data

The series consisted of four sessions run weekly across March and April:

- PHRN data linkage webinar 1 – Designing clinical trials using linked data presented by Dr Felicity Flack
- PHRN data linkage webinar 2 – Accessing linked data presented by Dr Felicity Flack
- PHRN data linkage webinar 3 – Ethical considerations presented by Dr Felicity Flack
- Accessing MBS/PBS data presented by Dr Anna Kemp-Casey.

STUDIES WITHIN A TRIAL (SWATS): HOW THEY CAN HELP TO MAKE TRIAL PROCESS DECISIONS MORE EVIDENCE-BASED

Presented by Professor Shaun Treweek, Health Research Unit, University of Aberdeen.

We are all aware that randomised trials are a central component of all evidence-informed health care systems. The evidence coming from them supports health care users, health professionals and others to make more informed decisions about treatment. However, the evidence available



Prof Shaun Treweek, our international Webinar guest presenter

to trialists to support decisions on design, conduct and reporting of randomised trials is sparse.

One way to fill gaps in evidence is to run Studies Within A Trial, or SWATs. This webinar provided a brief definition of SWATs, an explanation of why they are important and some practical 'top tips' from experience of doing SWATs. The guidance was designed for trialists, methodologists, funders, approvals agencies and others with a desire to understand what a SWAT is and how they are done

International guest presenter Professor Shaun Treweek joined ACTA online from the University of Aberdeen on Wednesday 17 April 2019 to present this valuable webinar.

ACTA HACKATHON OF NOVEL TRIAL DESIGNS WEBINARS

ACTA's guest speakers presented proposed new methods for the design, conduct, and/or statistical analysis of trials. The Hackathon focused on novel approaches rather than set research questions, so these strategies could be adapted to address an array of questions across many diseases and disciplines.

We invited attendees to join the webinar live, ask questions, and rate the presentations. The audience choice winner, Dr Jessica Kasza, presented at the ACTA International Clinical Trials Conference.



CONSUMER INVOLVEMENT IN CLINICAL TRIALS CONSULTATION REPORT

Consumer and community involvement in research, particularly clinical trials, is growing in Australia. Increasing numbers of consumers – patients and members of the general public – are working with researchers at organisational and individual trial levels.

Involvement is not limited to participating in a clinical trial, with more consumers choosing to work in active partnership with researchers and research organisations to identify healthcare needs, design research projects and help researchers understand how to change healthcare services to suit patients better.

In 2018, ACTA's Consumer Engagement Reference Group conducted national consultations with CTNs, CCs, triallists and consumers to understand more about consumer involvement across the investigator-led research sector.

A report of our findings, the *ACTA Consumer Involvement in Clinical Trials Consultation Report* provides an overview of how consumers become involved with CTNs or research organisations, and how consumers work with researchers across a wide range of clinical trial and research-based activities. We found that the investigator-led clinical trial sector engages and highly values consumer involvement, but could benefit from more support to foster, strengthen and sustain these important partnerships.

The report is available from the resources area of the ACTA website alongside other resources for CTNs, CCs and CQR.

EFFICIENT AND EFFECTIVE CTNs – CRITICAL SUCCESS FACTORS FOCUS GROUPS

During September and October, ACTA's Efficient and Effective CTNs Reference Group hosted two highly productive focus group sessions with participants drawn from a wide range of clinical trials-interested disease and discipline specialists, including representatives from Queensland, New South Wales, Victoria and New Zealand.

The focus groups' objective was to identify critical success factors affecting CTNs, including unmet needs that get in the way of efficiency and effectiveness. A/Prof Katie Groom, ACTA Director and the Reference Group's Chair, presented initial analysis of findings along with an update on the Reference Group's work on Day One of the ACTA Summit.

ACTA EFFICIENT AND EFFECTIVE CTNs REFERENCE GROUP TOOLKIT

The first three in a series of pivotal tools for CTNs have been released by ACTA's Efficient and Effective Clinical Trial Networks Reference Group.

During the last year, this Reference Group has consulted the sector to prioritise common tools and resources to guide both established and newly establishing CTNs in developing and maintaining effective operational processes. The resources have been developed by drawing from the existing processes of various established CTNs to develop a 'good practice' draft, which then undergoes review by Reference Group members, many of whom are CTN representatives. Where appropriate, resources contain links to exemplar documents.

The first three of these resources encompass CTN Membership structures, CTN Governance structures and CTN Strategic Plan development. Many newly establishing CTNs have already provided feedback that the tools have been extremely valuable, and they are also a useful read for existing CTNs who may want to refine some of their established procedures.

The next resources in the series, to be released at the end of February, include common duties of CTN Executive Officers and a suggested position description, and a suggested template Terms of Reference for governance committees. Following that, groups of approximately three tools will be released every three months over the next year to enhance the efficiency and effectiveness of CTN operational processes.

ACTA would like to thank all CTNs that participated in the sector consultation activities, and all Reference Group members who helped in the development of these tools.

ABBREVIATED FINANCIAL SUMMARY 30 JUNE 2019

PLEASE SEE ACTA'S DIRECTOR'S REPORT FOR FULL FINANCIAL STATEMENT

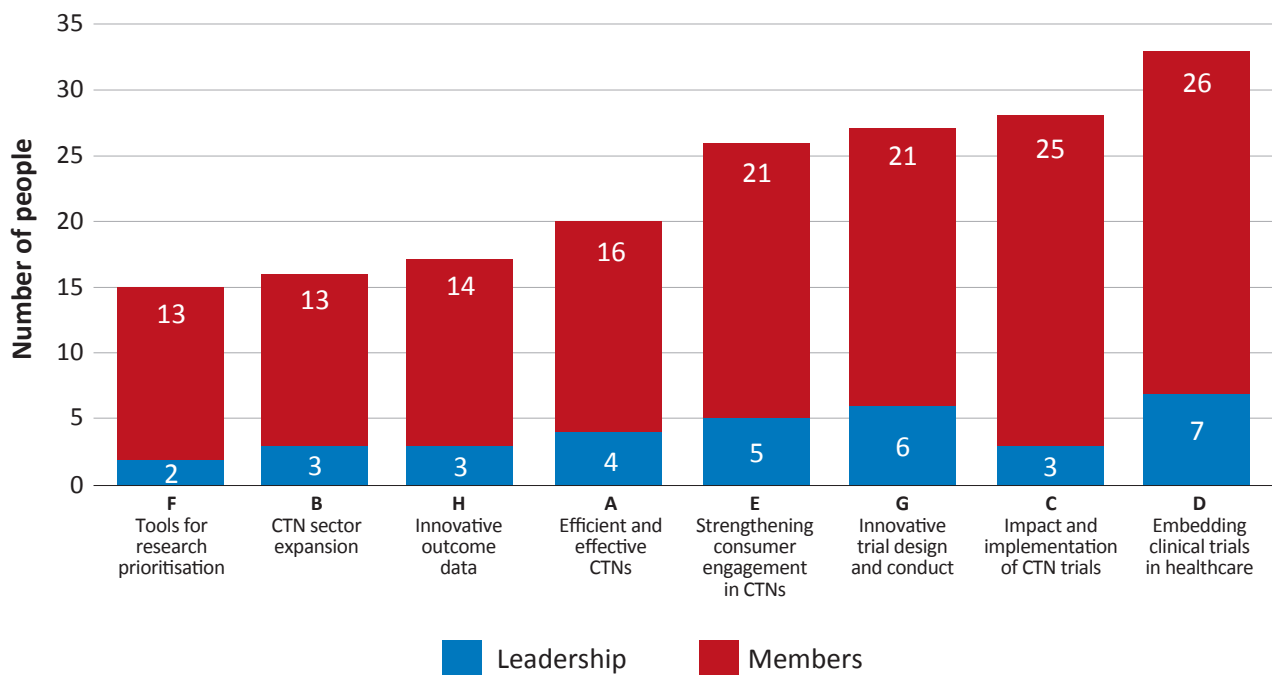
STATEMENT OF SURPLUS OR DEFICIT AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2019

	2019	2018
	\$	\$
INCOME		
Total revenue and other income	1,821,147	736,621
EXPENDITURE		
Audit, legal and consultancy expenses	-214,187	-75,025
Depreciation and amortisation expense	-18,512	-4,766
Employee benefit expenses	-1,092,333	-395,805
Event and meeting expenses	-44,801	-39,121
Operating expenses	-183,021	-119,826
Total expenditure	-1,552,854	-634,543
Net surplus/(deficit) for the year	268,293	102,078

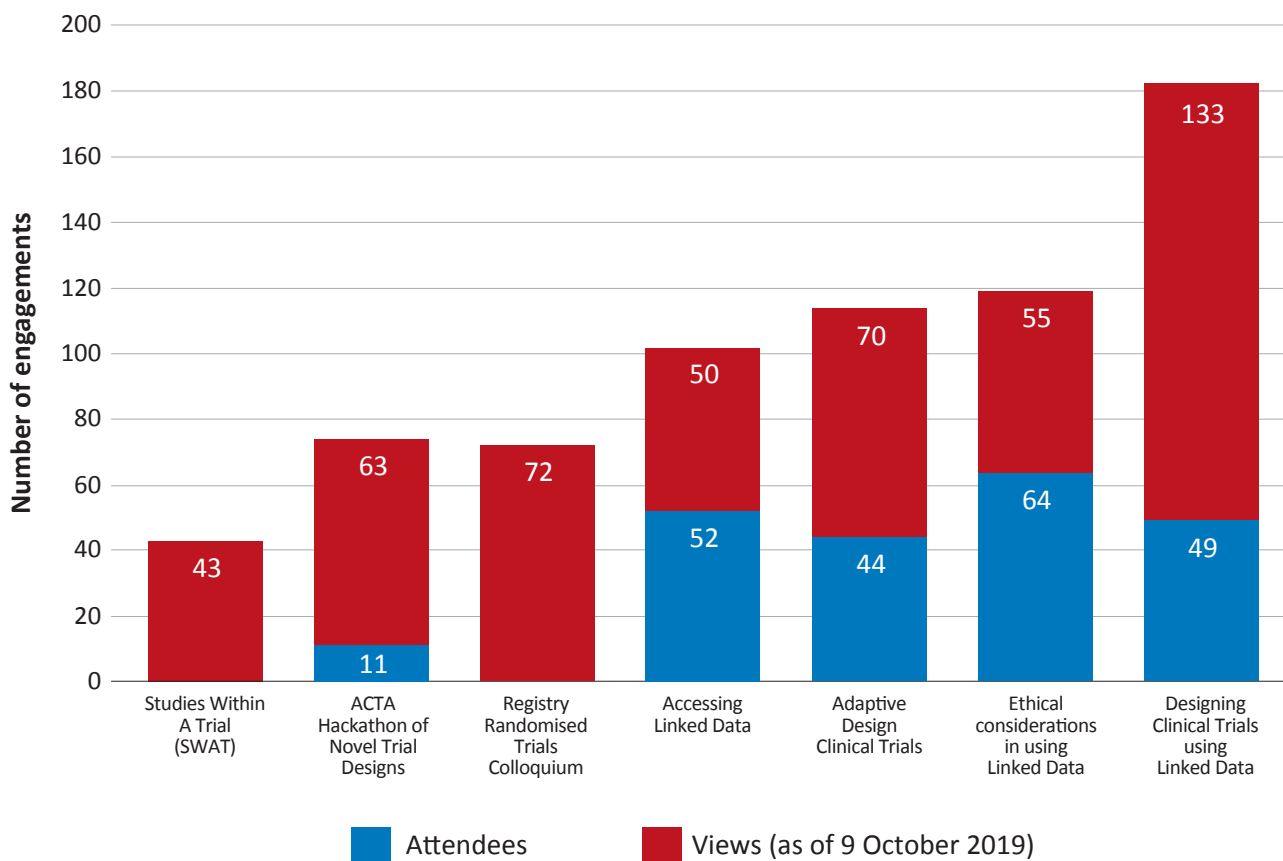
STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2019

	2019	2018
	\$	\$
TOTAL ASSETS	2,613,745	2,242,992
TOTAL LIABILITIES	2,148,391	2,045,930
NET ASSETS	465,355	197,062

Number of Reference/Working Group members



Number of ACTA workshop and webinar participants





At 30 June 2019,
the ACTA Member profile was

56

Full and Associate Member Clinical
Trial Networks, Clinical Trial
Coordinating Centres and Clinical
Quality Registries

14

Affiliate Organisational
Members

107

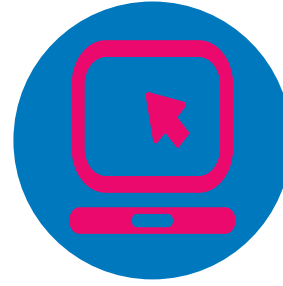
Individual Affiliate
Members

LinkedIn

Over the course of the year

3,207

people connected with the ACTA
LinkedIn account



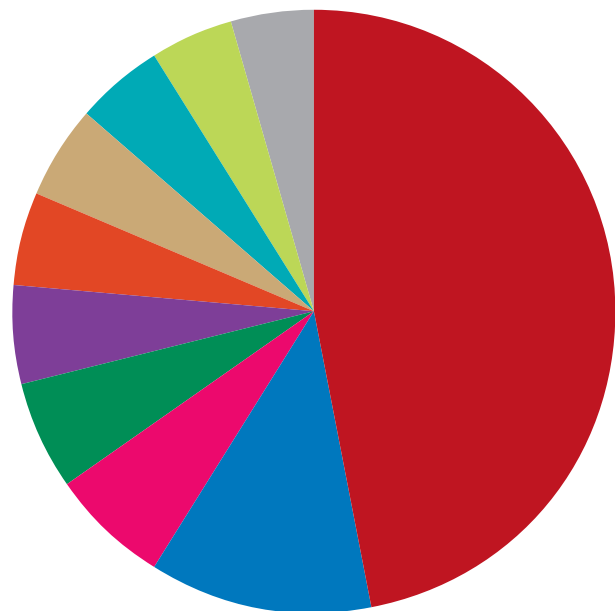
Visits to the ACTA website increased more than

100%

with most popular pages including the ACTA International
Clinical Trials Conference, Clinical Trials 2019: National Tribute
and Award Ceremony and our Resources.

Over the course of the year, the total number of visits
to the ACTA website was

82,892



- Home
- ACTA Summit 2018
- Members
- Forums
- Membership
- Latest news
- Resources
- Data linkage webinar series
- Contact
- Governance

THANK YOU

We gratefully acknowledge the invaluable support and contributions from our Members and operational funding from the Australian Government's Medical Research Future Fund. We thank the following people for their invaluable support and contributions:

ACTA'S BOARD OF DIRECTORS

Professor John Raymond Zalberg

OAM MBBS PhD FRACP FRACMA FAHMS FAICD
Chair

Professor Steven Anthony Rochford Webb

MBBS MPH PhD FCICM FRACP FAHMS
Deputy Chair and Company Secretary

Associate Professor Katie Margaret Allan (Groom)

MBBS BSc PhD FRANZCOG CMFM

Retired 28 November 2018

Ms Rebecca Lynne James

Independent Director with expertise in consumer representation

Ms Margo June MacGillivray

LLB(Hons) BA

Independent Director with expertise in governance and risk management.

Professor Vlado Perkovic

MBBS PhD FASN FRACP FAHMS

Professor Christopher Michael Reid

BA DipEd MSc PHD

Appointed 28 November 2018

Mr Kieran Geoffrey Schneemann

Independent Director with expertise in the commercial clinical trials sector

Professor (Robert) John Simes

BSc(Med) MBBS SM FRACP MD FAHMS

Professor Judith Trotman

MBBS MD FRACP FRCPA

ACTA CENTRAL STAFF

Ms Simone Yendle

General Manager and Company Secretary

Mr Nick Catton

Finance and Operations manager

Ms Miranda Cumpston

Senior Program Manager (until June 2019)

Mr David Barrett

Communications Manager (until December 2018)

Ms Lisa Reid

Communications Manager (from February 2019)

Ms Katie Legge

Office Manager

Dr Megan Sanders

Senior Project Officer (until July 2019)

Ms Nicola Straiton

Senior Project Officer

Ms Madeleine Enright

Project Officer

Ms Anitha Balagurunathan

Project Assistant

Ms Lea Hauchard

Events Coordinator

Ms Eloise Faichney

Communications Coordinator (until March 2019)

Ms Chrystal Moore

Communications Coordinator (from June 2019)

REFERENCE GROUP LEADERSHIP

Efficient and Effective Clinical Trial Networks (Reference Group A)

Ms Melanie Gentgall

Ms Donna Goldsmith

Ms Donna Reidlinger

Ms Karen Goulding

A/Prof Katie Groom

Clinical Trial Network Sector Expansion (Reference Group B)

Prof Alan Cass

Prof Alex Brown

Dr Craig French

Prof Christopher Reid

Dr Jacqui Waterkeyn

A/Prof Katie Groom

Impact and Implementation of Clinical Trial Network Trials (Reference Group C)

Prof Alan Cass

Prof Sally Green

Prof Sophia Zoungas

Embedding Clinical Trials in Healthcare (Reference Group D)

Prof Nik Zeps

Dr Ian Harris

Prof Tony Keech

Ms Tanya Symons

A/Prof Tom Briffa

Prof Ian Harris

Ms Sue Jenkins-Marsh

Dr Christopher Williams

Strengthening Consumer Engagement (Reference Group E)

Dr Janelle Bowden

Ms Anne McKenzie

Ms Tanya Symons

Mr Alex Economides

A/Prof Angela Todd

Tools for Research Prioritisation (Reference Group F)

Dr Haitham Tuffaha
A/Prof Rachael Morton

Innovative Trial Design (Reference Group G)

Prof Andrew Forbes
A/Prof Katherine Lee
Dr Felicity Flack (until July 2018)
Prof Madeleine King
Dr Annie Solterbeck
A/Prof Mustafa Khasraw
Prof Rachel Huxley
A/Prof Stephane Heritier

Innovative Outcome Data (Reference Group H)

Dr Felicity Flack
A/Prof Steven Tong
Prof Dorota Doherty
Prof Christopher Reid (stepped down after election to ACTA Board)

ACTA 2018 SUMMIT AND 2019 INTERNATIONAL CLINICAL TRIALS CONFERENCE CONVENORS

Prof Anthony Keech
Ms Susan Lohan

2019 TRIAL OF THE YEAR AWARDS JUDGES AND BOARD OBSERVERS

Dr Adam Walczak
Prof Mark Nelson
Mr Paul White
Prof Peter Morris (Chair, Consumer Involvement Panel)
Prof Rana Hinman
Prof Toby Richards
Prof Leonard Arnolda
Prof Phil Aylward
Dr Eliza Hawkes
Prof Ian Davis (Chair, TOTY Panel)
Ms Anne McKenzie AM
Prof Stephen Opat
A/Prof Amanda Ullman
Prof Charlie Xue
A/Prof Vasi Naganathan
A/Prof Mark Chatfield (Chair, Statistics Panel)
Dr Anneke Grobler
Dr Qiang Li
Dr Thomas Sullivan
Dr Sabine Braat (ACTA STInG Observer)
Ms Rebecca James (Board Observer)
Prof Judith Trotman (Board Observer for TOTY)

FULL MEMBERS

Australasian Gastro-Intestinal Trials Group
Australasian Kidney Trials Network
Australasian Leukaemia and Lymphoma Group
Australasian Lung Cancer Trials Group
Australasian Radiopharmaceutical Trials Network
Australasian Rehabilitation Outcomes Centre (AROC),
(incorporating Palliative Care Outcomes Collaboration-
PCOC, & Electronic Persistent Pain Outcomes Centre
-ePPOC)
Australasian Society for Infectious Diseases Clinical
Research Network
Australasian Stroke Trials Network
Australasian College for Emergency Medicine Clinical Trials
Group
Australia & New Zealand Gynaecological Oncology Group
Australia and New Zealand Sarcoma Association Limited
Australia and New Zealand Society of Cardiac & Thoracic
Surgeons National Cardiac Surgery Database Program
Australian Genomic Cancer Medicine Centre
Australian & New Zealand Neonatal Network
Australian & New Zealand Urogenital & Prostate Cancer
Trials Group
Australian and New Zealand Children's Haematology/
Oncology Group (ANZCHOG)
Australian and New Zealand College of Anaesthetists
Clinical Trials Network
Australian and New Zealand Dialysis and Transplantation
Registry (ANZDATA)
Australian and New Zealand Intensive Care Society
Australian Orthopaedic Association National Joint
Replacement Register
Breast Cancer Trials
Cooperative Trials Group for Neuro-Oncology
Icon Institute of Innovation and Research
Impact Trials, School of Medicine, Deakin University
Interdisciplinary Maternal Perinatal Australasian
Collaborative Trials Network
Mater Misericordiae Health Services Brisbane Limited
Melanoma and Skin Trials Limited
Melbourne Children's Trials Centre
Menzies School of Health Research
Neuroscience Trials Australia
NHMRC Clinical Trials Centre
NSW Drug and Alcohol Clinical Research and Improvement
Network
Paediatric Research in Emergency Departments
International Collaborative
Palliative Care Clinical Studies Collaborative
Primary Care Collaborative Cancer Clinical Trials Group,
University of Melbourne
Prostate Cancer Outcomes Registry – Australia & New
Zealand

Psycho-oncology Co-operative Research Group
School of Public Health and Preventive Medicine, Monash University
South Australian Health and Medical Research Institute
The George Institute for Global Health
Therapeutic & Vaccine Development Research Group, The Kirby Institute
Trans-Tasman Radiation Oncology Group (TROG Cancer Research)
Victorian Ambulance Cardiac Arrest Registry
Victorian Cardiac Outcomes Registry
Victorian Orthopaedic Trauma Outcomes Registry (VOTOR) and Victorian State Trauma Registry (VSTR)

ASSOCIATE MEMBERS

Alliance for Vascular Access Teaching and Research (AVATAR) Group
ASpirin in Reducing Events in the Elderly – ASPREE Clinical Trial
Australia and New Zealand Musculoskeletal Clinical Trials Group
Australian Epilepsy Clinical Trials Network
BiNational Colorectal Cancer Audit
Cancer Trials Australia
Centre for Biostatistics and Clinical Trials
Lifestyle Medicine and Nutraceuticals Clinical Trials Network: Mental/Cognitive Disorders
Multiple Sclerosis Research Australia Clinical Trials Network
National Endometriosis Clinical and Scientific Trials Network
Paediatric Trials Network Australia
Queensland Centre for Mental Health Research

AFFILIATE ORGANISATION MEMBERS

Australian and New Zealand Falls Prevention Society
Australian Red Cross Blood Service Research & Development
Cancer Council Victoria
Clinical Research Unit (Cancer Services), South East Sydney Local Health District, St George Hospital
Datapharm Australia
Ingham Institute (South Western Sydney Local Health District)
Melbourne Clinical and Translational Sciences Research Platform
Metro North Hospital and Health Services QLD
Research Path Pty Ltd
St John of God Healthcare Inc
The Consumer and Community Health Research Network
T Symons Associates Pty Ltd
Therapeutic Innovation Australia

And a big thank you to our dedicated Affiliate Individual Members.

EVENT SPONSORS

ACTA Summit 2018

Principle partners: Bellberry and CT:IQ; and our sponsors: NSW Health's Office for Health and Medical Research, MTPConnect, ClinTrial Refer, Datapharm, and Research4Me.

Clinical Trials 2019: National Tribute and Award Ceremony

Partners: MTPConnect, Bellberry and Medicines Australia, Supporters: CT:IQ, Consumers Health Forum of Australia, Medical Technology Association of Australia, National Health and Medical Research Council, Research Australia and our Venue Partner Royal Children's Hospital.



Australian Clinical Trials Alliance

www.clinicaltrialsalliance.org.au

ACTA gratefully acknowledges the invaluable support and contributions from its Members and operational funding from the Australian Government's Medical Research Future Fund