Australian Clinical Trials Alliance

Annual Report

2024 – 2025

Better health through best evidence

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ACKNOWLEDGEMENTS

ACTA is grateful to receive grant funding from the Australian Government. The work we have conducted during 2024-2025 has been supported by the Medical Research Future Fund under grant number MRFTA000001.

We sincerely thank our members, consumers, and the investigator-initiated clinical trial sector community for their valuable interactions, insights, inputs, and support during the reporting period.

ACTA acknowledge the Traditional Owners of the lands and waters on which we live and rely. We pay our respects to their Elders past and present.

ACTA acknowledge all consumer advocates and representatives, carers and clinical trial participants who continue to inspire and shape our work.

MESSAGE FROM OUR BOARD CHAIR

Reflecting on another busy year across the clinical trials sector, there are many reasons to feel confident about Australia's position in the global healthcare ecosystem and specifically, the clinical trials discipline.

The Australian clinical trials landscape has thrived in 2024-2025.

This has been supported by a renewed commitment from the Commonwealth in the development of a National Health and Medical Research Strategy, the continued development of the National One Stop Shop program, refinement and further embedding of the National Clinical Trial Governance Framework, ongoing reviews of funding programs, and an ambition to improve alignment across policies and initiatives to ensure equity, access and patient outcomes are front and centre of decision making.

This national approach has been further complemented by Jurisdiction based programs and priorities, which also support the unique communities they operate in.

The clinical trial workforce maintained their momentum to create change, our industry colleagues continued to advocate for innovation through collaboration, and health care providers doubled down on efforts to bring evidence front and centre in patient care, despite challenging financial times.

This year ACTA have continued to facilitate communities of practice, delivered a range of education, collaboration and networking opportunities, advocated for our members, acted as the voice for the clinical trials sector, developed resources, and led initiatives to support the delivery and effectiveness of clinical trials in Australia.

As your national peak body, ACTA are proud of the positive impact our activities have had on the clinical trials sector.

I commend this report to you as it highlights some of our achievements from the year in review, and we stand ready to continue this support again in the year ahead.

I offer my sincere gratitude to our outgoing Board Directors Prof Steve Webb, Prof Sophia Zoungas and Ms Anita Van Der Meer, and I welcome Prof Nadine Foster, Dr Sherman Leung and Prof David Beard to the Board. I also gratefully acknowledge all fellow Board Directors for their unwavering support throughout the year.

I also sincerely thank our COO, Dino Cercarelli and the ACTA central team for their continued hard work this year.

As a nation, we often embrace a culture of humility, but we also recognise and celebrate our achievements and progress. My wish is that we continue to celebrate our individual and collective achievements, the impacts this work is having on the sector, and most importantly, the improvements this can bring to patient care and outcomes.

PROF CHRISTOPHER REID
B.A, Dip Ed, M Sc, PhD

OUR YEAR AT A GLANCE

REPRESENTED 10,000+ INDIVIDUALS

Working within the Australian clinical trials sector.

123 ORGANISATIONAL MEMBERS

Our full members, associate members and affiliate members represented:

- Clinical Trial Networks (CTNs)
- Clinical Quality Registries (CQRs)
- Coordinating Trial Centres (CTCs)
- Site Research Organisations (SROs)
- Hospitals
- Sector based businesses.

Find out more about our members on **page 6.**

171 INDIVIDUAL MEMBERS

Comprised of clinicians; allied health and nursing professionals, consumers, and research or health admin/policy professionals.

500+ VOLUNTEERS

Provided invaluable input to our Special Interest Groups, Project Working Groups and committees.

26 EVENTS

Facilitated workshops, webinars and education sessions. These events provided our members and sector colleagues with opportunities to connect and collaborate.

3 RESOURCES

Developed resources to increase knowledge and share insights with the sector.

- **Innovative trial design glossary**
- **Information and resources on Adaptive and Platform Trials for consumer representatives**
- **Funding Adaptive Platform Trials: A discussion paper.**

7 SPECIAL INTEREST GROUPS AND 6 WORKING GROUPS

Connected the clinical trials sector through focused and collaborative meetings for our seven Special Interest Groups and six Working Groups.

Find out more on **page 23.**

1 PEER REVIEWED PUBLICATION

Platform trials: key features, when to use them and methodological challenges published in MJA.

1 NATIONAL SYMPOSIUM

Hosted the 2024 ACTA Clinical Trials and Registries Symposium.

Find out more on **page 18.**

1 TRIAL OF THE YEAR AWARDS CEREMONY

Announced the recipients of our 2025 Trial of the Year Awards.

Find out more on **page 19.**

ABOUT ACTA

ACTA is the national peak body supporting and representing more than 10,000 individuals who conduct and support the delivery and effectiveness of clinical trials in Australia.

We ensure the voice of our members is included in Government decision making, policy development and sector reforms.

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, policy-makers and consumers.

Australian Clinical Trials Alliance

CLINICAL TRIAL NETWORKS

Clinical Trial Networks (CTNs) are a collaborative network of clinician researchers that identify critical clinical questions and design large trials to answer them.

CLINICAL QUALITY REGISTRIES

Clinical Quality Registries (CQRs) monitor the quality of health care within specific domains by routine collection, analyses and reporting of health-related information for a self-improving health system.

COORDINATING TRIAL CENTRES (CTCS)

Undertake trial design, analysis and methodology research, while providing direct project management for trial conduct.

SITE RESEARCH ORGANISATIONS (SROS) (PRIMARY, SECONDARY AND TERTIARY)

Are embedded in health services and provide direct patient care in both public and private settings across all Australian Jurisdictions.

CONSUMERS

Provide important lived-experience insights into the development of clinical trials and/or participate in trials as part of their health care journey.

GOVERNMENTS AND AGENCIES

Support Australia's position as a destination of choice for clinical trials through effective reforms, funding programs, and safety and quality accreditation.

INDUSTRY

Connect with CTNs, CTCs, and SROs to develop and deliver clinical trials.

WHO WE REPRESENT

ARCS Australia Ltd

Australasian College for Emergency Medicine Clinical Trials Group

Australasian Gastro-Intestinal Trials Group

Australasian Kidney Trials Network

Australasian Leukaemia and Lymphoma Group

Australasian Myeloma Research Consortium

Australasian Nursing and Midwifery Clinical Trials Network

Australasian Radiopharmaceutical Trials Network

Australasian Society for Infectious Diseases Clinical Research Network

Australasian Stroke Trials Network

Australasian Type 1 Diabetes Immunotherapy Collaborative

Australia & New Zealand Gynaecological Oncology Group

Australia and New Zealand Liver and Intestinal Transplant Registry

Australia and New Zealand Musculoskeletal Clinical Trials Group

Australia and New Zealand Sarcoma Association Limited

Australia and New Zealand Society of Cardiac & Thoracic Surgeons National Cardiac Surgery Database Program

Australian & New Zealand Children's Haematology/ Oncology Group (ANZCHOG)

Australian & New Zealand Neonatal Network

Australian & New Zealand Urogenital & Prostate Cancer Trials Group

Australian and New Zealand Alliance for Cardiovascular Trials

Australian and New Zealand College of Anaesthetists Clinical Trials Network

Australian and New Zealand Dialysis and Transplantation Registry (ANZDATA)

Australian and New Zealand Falls Prevention Society

Australian and New Zealand Intensive Care Society

Australian and New Zealand Transplant and Cellular Therapies

Australian Centre for Health Services Innovation - Queensland University of Technology

Australian Orthopaedic Association National Joint Replacement Register

Australian Red Cross Lifeblood

Avatar Brokers Pty Limited

Breast Cancer Trials

Cancer Trials Australia

Canteen - The Australian Organisation for Young People Living with Cancer

Centre for Biostatistics and Clinical Trials

Cerulea Clinical Trials - Centre For Eye Research Australia

Children's Inpatient Research Collaboration of Australia and New Zealand

Clinical Hub for Interventional Research

Clinical Trials Platform – La Trobe University

Collaborative Hyperbaric Medicine and Extreme Environment Research Association Network

Consumer and Community Health Research Network

Cooperative Trials Group for Neuro-Oncology

Curtin Centre for Clinical Research and Education

Datapharm Australia Pty Ltd

Evrima Technologies

GenesisCare Site Research Organisation

Grampians Health

Growing Minds Australia

Hunter Medical Research Institute

Icon Institute of Innovation and Research

IMPACT TRIALS, School of Medicine, Deakin University

Ingham Institute

InsideOut Institute

Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network

Kids Cancer Centre, Sydney Children's Hospital

Lead Lists Data Solutions

Mackay Institute of Research and Innovation

Mater Misericordiae Health Services Brisbane Limited

Melanoma and Skin Cancer Trials Limited

Melanoma Institute Australia

Melbourne Children's Trials Centre

Mental Health Australia Adult General Clinical Trials Network (MAGNET), Deakin University

Menzies School of Health Research

Methods and Implementation Support for Clinical and Health Research

Metro North Hospital And Health Service QLD

MEXEC

Monash University Clinical Trials Centre

MQ Health

MS Australia

National Allergy Centre of Excellence

National Endometriosis Clinical and Scientific Trials Network

NHMRC Clinical Trials Centre

NHMRC CRE in Wiser Wound Care, Griffith University

NHMRC Synergy in Alcohol Treatment

NSW Drug and Alcohol Clinical Research and Improvement Network

Olivia Newton-John Cancer Research Institute

OMICO (Australian Genomic Cancer Medicine Centre)

Oncoshot Australia Pty Ltd

Orygen

Paediatric Research in Emergency Departments International Collaborative

Palliative Care Clinical Studies Collaborative

PRAXIS Australia

Primary Care Collaborative Cancer Clinical Trials Group, University of Melbourne

Prostate Cancer Outcomes Registry - Australia & New Zealand

Psycho-oncology Co-operative Research Group

Pulmonary Fibrosis Australasian Clinical Trials

Queensland Centre for Mental Health Research

Regional Trials Network – Victoria

Research Path Pty Ltd

Save Our Sons Duchenne Foundation

Save Sight Institute

School of Optometry and Vision Science

South Australian Health and Medical Research Institute

Spiral Network

St John of God Healthcare Inc

Sydney Local Health District

Telstra Health

The Australian Frailty Network

The George Institute for Global Health

The PARTNER Network, University of Melbourne

The Thoracic Society of Australia and New Zealand

Therapeutic & Vaccine Development Research Group, The Kirby Institute

Therapeutic Innovation Australia

Thoracic Oncology Group of Australasia

Trans Tasman Radiation Oncology Group (TROG Cancer Research)

Translational Research Institute

TrialScreen Pty Ltd

University of Queensland Clinical Trials Centre

UNSW Medicine and Health, Clinical Research Unit

VCCC Alliance

Victorian Ambulance Cardiac Arrest Registry

Victorian Cardiac Outcomes Registry

Victorian Orthopaedic Trauma Outcomes Registry (VOTOR) and Victorian State Trauma Registry (VSTR)

Walter and Eliza Hall Institute for Medical Research

WeGuide Pty Ltd

Wesley Research Institute Ltd

Westmead Applied Research Centre, The University of Sydney

WriteSource Medical Pty Ltd

360 Biolabs Pty Ltd

OUR WORK

Our work focuses on activities that can consolidate and strengthen the capabilities and connections within the Australian clinical trials sector.

We do this to:

- improve health outcomes
- build an ecosystem based on collaboration
- make it easier to initiate and govern trials
- accelerate the impact of research into clinical practice
- ensure evidence-based care is embedded into the health system.

ACTA connects those involved in developing and delivering clinical trials with consumers, governments, and policy makers on issues that impact the conduct of clinical trials across the Australian healthcare system.

Our work focuses on **six workstreams** and their associated activities (including an ACTA central operational stream).

CASE STUDY

INNOVATIVE TRIAL DESIGN AND THE ADAPTIVE PLATFORM TRIAL OPERATIONS SPECIAL INTEREST GROUP (APTO SIG)

Lauren Barina is a Global Clinical Trial Manager of the Staphylococcus aureus Network Adaptive Platform (SNAP) Trial, which is a large, international, multi-centre Adaptive Platform Trial which aims to improve treatment outcomes for patients with Staphylococcus aureus bloodstream infections.

Lauren has a background in neuroscience, bioethics, research ethics, and research governance and is passionate about supporting researchers to make ethically informed and participant-focused decisions in the ongoing conduct of research studies.

Please provide a short background on your current role and career to date

I am currently one of two Global trial Managers for the SNAP trial. I have worked at the Doherty institute in Adaptive Platform Trials (APTs) for 4 years, and prior to that, I worked at St Vincent's Hospital as an ethics submissions specialist and also in their Research and Governance office doing a variety of things such as ethics review, governance review, quality assurance, etc.

Please tell us about the Adaptive Platform trial you are involved with – Staphylococcus aureus Network Adaptive Platform (SNAP) Trial

How long has this trial been running?

It's been running since 2020, but it's been recruiting since 2022, so running for about 5 years, recruiting for about 3 years.

Why was this trial developed?

This trial aims to improve outcomes for patients with staph aureus bloodstream infections. Optimal management of these infections is uncertain and there are few published studies that compare available treatments that are already used in hospitals. Current evidence is based on less than 3,000 patients enrolled in randomised controlled trials. So, it was felt that there was an unmet need for a large RCT.

How many participants and active sites does this trial have?

There are 4,200 participants in the SNAP platform, which is the randomised aspect that is nested within a clinical quality registry; and there is an additional 4,500 participants just in that data collection clinical quality registry.

The trial is currently active in 9 countries and 131 hospitals, but we continue to open and grow into more countries.

Why was this trial design selected?

The chief investigators had finished and published the CAMERA-2 trial, in which they randomised 350 participants with MRSA bacteraemia, and at the same time were in discussions about Adaptive Platform Trials. So, at this point a larger trial and an adaptive approach was on the forefront of their minds. The attraction of the adaptive structure was that it provided the ability to answer multiple research questions simultaneously within the trial infrastructure and add/drop/change interventions when statistical triggers were reached.

What are the benefits to using this trial design?

Benefits include:

- The ability to answer priority research questions in an efficient manner.
- Be able to drop or change interventions when statistical triggers are met and therefore, be able to answers questions more quickly.
- Be able to borrow data across different populations.

What have been the main challenges with this trial design?

Coming from my perspective as a manager, operational challenges we have faced include:

- **Data management burden** – challenge to keep up with data demands; including frequent analyses associated with statistical design; maintaining a regularly cleaned dataset as the trial aims to run for

many years it is important to keep this as an ongoing process; keeping data from multiple regions harmonised; collating data from various regions in line with their regulatory requirements.

- **Ethics and regulatory approvals** – trial design doesn't fit the mould for most ethics and regulatory document templates. So, trying to explain what you are doing using a form that is not fit for purpose can be difficult.
- **Communication of Results** – Our trial uses Bayesian statistics that is not well understood by people who are not statisticians, including clinicians or lay people. We need to really work hard to clearly explain results and disseminate that information to the wider community in a format that people can then interpret.
- **Collaboration Complexity** – can be difficult because there are so many people involved; in our working groups alone, we have over 230 people, and then another few hundred investigators. We must think about how we can efficiently continue to work together to generate and act upon important ideas, operationalise them, and do this via the correct governance process.

What significant outcomes have come from using this trial design?

We think that even being able to recruit over 4,000 participants into this trial when only 3,000 people had ever been previously randomised to a study about staph aureus bacteraemia is a significant outcome for the study. Not only is it 4,000 patients, but because each patient is randomised to more than one intervention (on average about x1.5), it is over 6,000 randomisations.

Another outcome that has been quite exciting is that this trial design forced us to think of an innovative way to consent people by providing them with information that they need to make a decision and explain to them a really complicated trial design. By having a simplified consent model that SNAP uses has been a great outcome.

We are also working on incorporating smaller sub studies, nested randomised controlled trials, or sample collection studies that can use the existing infrastructure to answer a smaller research question.

Adaptive Platform Trial Operations Special Interest Group (APTO SIG)

How long have you been involved in ACTA and the APTO SIG?

I had heard about ACTA for a long time from my previous work at St Vincent's Hospital and attended a few conferences over the years. I became more involved with ACTA when I joined the APTO SIG, which I have been involved in since its inception 3 years ago.

How did you hear about the APTO SIG and why were you interested in joining?

I heard about it from my manager, who was then co-chair and assisted in the establishment of the working group. I don't usually interact with a lot of clinical trial project managers and people doing the same kind of research, especially in adaptive platform trials.

So, it has been interesting to liaise and share knowledge with others who are more or less experienced than you in a way that we wouldn't otherwise get an opportunity to do.

What has been the most valuable outcome from being involved in the APTO SIG?

Meeting other people working in APTs. Also, the Operational document will be a huge benefit to a lot of people, and I am excited for that to be released and shared.

Does the APTO SIG have value for the broader research community and clinical trial sector?

I think so. Many challenges are not unique to APT, but they can be confounded or exacerbated by the complexity of APT's. Having a space to discuss ethics, regulatory contracts, and other topics we discuss in the SIG helps us to find the best way to do certain things and also challenging the templates that are available to improve the process for everyone. Therefore, I could see how this is beneficial to other people in the clinical trial sector.

Has being part of ACTA influenced or benefited your work, career, or professional confidence?

Yes – it has been great to meet other people, expand the network I can communicate with, and I have learnt a lot from others that I can apply to my own work. Also to know that your knowledge is beneficial to others who are in initial stages in their trial development has been nice to grow my professional confidence.

Would you recommend that others be involved in the APTO SIG or ACTA in general?

Yes absolutely. It's not a burden and I look forward to the meetings and outputs.

CASE STUDY

CERULEA CLINICAL TRIALS

Michelle Gallaher is an award-winning health technology entrepreneur, speaker, and advocate. She has founded four startups, including Trialkey, which uses AI to improve and predict clinical trial outcomes, and Opyl Ltd, an AI health tech company listed on the ASX. With a career spanning clinical, executive, and commercial roles in health, biotech, and pharmaceuticals, Michelle is also a champion for the ethical application of AI in healthcare.

She is a non-executive director on several boards, co-founder of Women in STEMM Australia, and has received numerous accolades, including being inducted into the Victorian Honour Roll for Women. Michelle holds an undergraduate degree in applied science, a postgraduate qualification in business, and a Global Executive MBA.

Please tell us about Cerulea

Cerulea Clinical Trials delivers ophthalmic clinical trials for Australian and international biopharmaceutical and medtech companies – and is the home of investigator-initiated studies for the Centre for Eye Research Australia (CERA).

Cerulea is a fully owned, not-for-profit subsidiary of CERA and share its vision of a world free from vision loss and blindness. Our ambition is for Cerulea to be a world-recognised and trusted partner in clinical trials, playing a pivotal role in translating research discoveries expertly and efficiently from bench to bedside.

Tell us about Cerulea's new state of the art facilities

Our purpose-built ophthalmic trials unit, located in the Royal Victorian Eye and Ear Hospital, was built with the support of a $10million investment from Breakthrough Victoria, an independent organisation that manages an innovation investment fund established by the Victorian Government. Officially opened in May 2024, the unique design of the new unit, our experienced teams, access to participants, and the latest in diagnostic and treatment equipment provide us with highly specialist capabilities in trialling advanced therapeutics such as gene therapies, medical devices and biopharmaceuticals.

Our unit, offering 25 treatment rooms, PC2 bioprocessing lab and secure medication room, is now the largest dedicated ophthalmic clinical trial facility in the world.

Tell us about the type of local and international Sponsors that you work with

Cerulea currently has 30 trials either being initiated or conducted with 10 new trials so far planned to commence early in 2025.

Approximately 80% of our clients are US-based biopharmaceutical companies or small to medium sized enterprises (SMEs) biotech or medtech companies. In working with many sponsors, we also engage with local and international CRO's on a daily basis.

Many of our clients choose Cerulea based on its relationship to CERA and depth of our experience. Our principal investigators are key in attracting sponsors and trials to Cerulea and many of our investigators have long-standing collaborative relationships with sponsors.

Please tell us about the partnership that Cerulea has made with Australian biotech company Opthea

Opthea is an ASX and NASDAQ listed company (ASX: OPT), a member of AusBiotech and has just been a wonderful company to partner with. Opthea's Sozinibercept (OPT-302) is a first-in-class VEGF-C/D 'trap' currently in clinical development to treat wet Age-related Macular Degeneration (wet AMD), has the potential to become the first therapy in more than 15 years to improve visual outcomes in patients with this disease and has received fast track designation from U.S. Food and Drug Administration.

Cerulea is proud to have partnered with Opthea on its global Phase II and pivotal Phase 3 trials — the COAST and SHORe studies — both evaluating sozinibercept in combination with standard-of-care VEGF-A inhibitor, the results of which are scheduled to be published in Q2 2025. It's very satisfying to partner with an Australian biotech, helping them to achieve their goal and providing access to emerging therapies for Australian patients.

The Opthea clinical team are an absolute delight to work with and having such a strong working relationship has ensured the smooth delivery of the trials and many shared learnings between the organisations.

What is Cerulea's involvement with ACTA

While CERA has been a member of ACTA for many years, Cerulea became a member of ACTA in 2024 and looks forward to collaborating with ACTA more in the future to transform and expand the clinical trial sector, grow skills, build capacity, and ultimately improve the lives of people and alleviate suffering.

What advice would you give to other CTNs and ACTA members who are looking to partner with Australian and international biotech companies?

The global clinical trials landscape is a highly competitive one and we need to be clear in understanding and amplifying our competitive advantage, as well as address the elements in which we are less competitive.

Aim to build a long-term relationship, make communication and engagement with them a priority, recognise and support the value drivers for sponsors, acknowledging and mitigating their pain-points and anxieties, creating an experience for them that means they will recommend Australian CTN's and select our sites again.

My advice in preparing to sponsor is to build a quality site capabilities deck and be proficient and polished at delivering the pitch, equip investigators to support the pitch as they are often the first contact, get testimonials, ask for feedback.

Clinical trial is a service industry and we can learn a lot from other service sectors (and each other) in building performance feedback systems, continuous improvement, business development and service promises.

CASE STUDY

REGIONAL TRIALS NETWORK

Donna long is currently the Manager of the Regional Trials Network – Victoria which is a collaborative group of 8 regional oncology clinical research sites working to improve outcomes for regional patients through Government funded projects that are targeted at areas of unmet need in regional centres.

Donna has over 34 years' experience in oncology including 12 years in the gynaecological oncology surgical unit at The Royal Hospital for Women in Sydney. Donna's experience includes palliative care at Sacred Heart Hospice in Sydney, Breast Cancer Peer Support Coordinator at the Cancer Council NSW, 13 years' experience as a Research Nurse/Study Coordinator at Border Medical Oncology Research Unit in Albury and experience as a Service Improvement Facilitator for the Hume Regional Integrated Cancer Service. Donna serves on the Board of the Australian New Zealand Gynaecological Oncology Group (ANZGOG) and has been a member of ANZGOG and the study coordinators committee since 2005/2006.

Tell us about your background and role at RTN

I have over 30 years' experience in oncology, including over a decade at the gynaecological oncology surgical unit at The Royal Hospital for Women in Sydney. I am also a member of ANZGOG, on the Board and the study coordinators committee. I have worked as a Study Coordinator for Border Medical Oncology Research Unit for over a decade.

I am the Manager of the Regional Trials Network – Victoria (RTN-Vic). One of the projects of the RTN-Vic is the flagship ReViTALISE initiative (***R**egional **V**ictorian **T**rials **A**lliance: **L**inkages, **I**nnovation, **S**pecial populations, **E**quity (ReViTALISE)*, an MRFF funded project improving regional, rural and remote Victorians access to clinical trials. This project is a collaboration between the eight regional clinical research sites of the RTN-Vic, University of Melbourne, La Trobe University – Wodonga and the Walter and Eliza Hall Institute. The ReViTALISE project focuses on areas of unmet need in regional Victoria.

Are you a member of SIGNeT, CQR SIG or both?

I am a member of SIGNeT and the RTN-Vic is a member of ACTA.

Do you have links to other groups or networks, and are you a member of any other community of practice meetings outside of the SIGs?

For a small organisation, we have a surprising number of links to other organisations! Listed below:

- RTN-Vic Operational Working Group – managers of member regional clinical trial sites
- **Victorian Teletrial Collaborative** – Alfred TrialHub, VCCC Alliance, RTN-Vic, Safer Care Victoria
- Victorian Rare Cancers Clinical Trials Alliance (VRCCTA)
- VCCC Alliance's Research Managers group

How has ACTA supported RTN?

RTN has had lots of engagement with ACTA over the years, including the SIGs. SIGNeT is a great forum for meeting other CTNs. There is a lot of sharing of lessons learned and knowledge sharing between members of that SIG which is great and the education they provide is fantastic.

There are lots of really great resources on ACTA's website and we have utilised many of these including around topics such as:

- Starting a CTN
- Sustaining a CTN
- Masterclasses

The annual ACTA symposium is a wonderful way to learn different things from a range of speakers and connect and network with peers.

What role do you think ACTA has in the future

ACTA does well in the sector and needs to be supported as a national "backbone" organisation so that things can remain centrally coordinated and knowledge can continue to be shared across networks.

It has a vital role in pushing the clinical trial agenda nationally. It has a pivotal role in providing information to support Networks development, growth and sustainability through masterclasses, resources and communities of practice.

CASE STUDY

HOW ACTA STING PROVIDED VALUABLE NETWORKING OPPORTUNITIES DURING THE PANDEMIC

Francesca Orsini is a senior biostatistician at the Murdoch Children's Research Institute (MCRI) and has been a member of STInG since its inception in 2016. The BRACE trial, for which Francesca is the lead statistician, won the 2024 ACTA STInG Excellence in Trial Statistics Award.

Tell us about your current role and career to date

I graduated in Milan, Italy with a Master of Science in Biostatistics and Experimental Statistics. My career began as a biostatistician and research assistant at a small university, followed by a role at a Contract Research Organization (CRO), where I was introduced to clinical trials.

In 2011, I migrated to Australia and joined MCRI in the Clinical Epidemiology and Biostatistics Unit (CEBU). I am currently a senior biostatistician, and am deeply involved in clinical trials from the grant writing stage, to developing study protocols, conducting statistical analyses, and contributing to publications.

How did you first get involved with ACTA STInG, and what motivated you to join?

I saw the value in connecting with other high-quality biostatisticians outside of CEBU, something that would be particularly valuable for those statisticians that may not have access to a larger network. The opportunity to make connections and share problems was a significant motivator for me to join.

How has being part of the ACTA STInG influenced or benefited your work?

ACTA delivers valuable webinars and workshops that cover both practical topics and emerging concepts, especially in adaptive trial designs, which are becoming increasingly popular.

The resources available on the ACTA website are helpful, and I have used resources beyond statistics, for example the grant application resources to help securing funding. I also find the *Find a Statistician* and *Data Safety Monitoring Board directories* very beneficial.

Tell us your experience winning the ACTA STInG Excellence in Trial Statistics Award

Statisticians often work behind the scenes and rarely receive recognition for their contributions, so this award was particularly meaningful to me. It validated the effort and countless hours and sleepless nights I invested in one of the most challenging trials I've participated in, and it boosted my confidence. The ACTA Trial of the Year Awards provides recognition not only in front of peers, but showcases to the sector the importance of involving a statistician from the very beginning of the trial.

I was also invited to speak at the ACTA 2024 Clinical Trials and Registries Symposium, which provided another opportunity to showcase the importance of high-quality statistics in trials.

What advice would you give to other statisticians or researchers looking to leverage groups like ACTA STInG?

Connecting with other statisticians and peers, particularly if you work autonomously, is invaluable. Go to meetings, webinars, symposium and make connections, as you do not need to be alone. My experience on the BRACE trial is a great example: it was the start of the pandemic, things were moving so quickly, and we were confronted with new challenges that were never encountered before.

Thanks to ACTA STInG we were able to reach out to other experts to discuss and troubleshoot together.

"ACTA delivers valuable webinars and workshops that cover both practical topics and emerging concepts..."

What do you see as the future directions for statistics in trials in Australia, and how is ACTA STInG positioning itself to address these?

The future of statistics in trials in Australia is increasingly moving towards more innovative and flexible methodologies, with adaptive design trials at the forefront.

Adaptive trials allow for modifications to the trial procedures (such as sample size or treatment arms) based on interim data, which can lead to more efficient, faster, and potentially more informative results without compromising the integrity of the study.

ACTA STInG is well-positioned to support this evolution, fostering collaboration between trial statisticians across Australia, focusing on enhancing expertise in adaptive designs, as well as other advanced methodologies like Bayesian approaches and platform trials.

Through ongoing training, mentorship, and networking opportunities, ACTA STInG can help build a strong foundation for these methods to become standard practice, ensuring that Australian clinical trials remain at the cutting edge of global research.

PROJECT COLLABORATION

Australian Teletrial Program
Access to clinical trials, closer to home

IMPROVING ACCESS TO CLINICAL TRIALS THROUGH THE AUSTRALIAN TELETRIAL PROGRAM (ATP)

Project purpose

Engage CTNs and CCs to expand the Teletrial model across broad clinical fields.

Project objectives

- Articulate and promote the benefits and opportunities of the Australasian Teletrial Model, where a trial cluster of primary and satellite sites are connected through telehealth models of care
- Identify the critical needs, enablers and barriers to implementation, to increase uptake of the Australasian Teletrial Model.

Our 2024/25 highlights

ACTA have continued to contribute to national efforts to expand access to high-quality clinical trials beyond metropolitan centres. In 2024/25, these activities have included:

- Establishing the **ACTA Teletrial Raising Equity of Access to Clinical Trials Special Interest Group** and fostering relationships with CTNs. If you would like to be involved in REACT-SIG, please contact us
- Delivering an informative webinar in February 2025 titled ***Avoiding Groundhog Day.*** The presenters discussed a principles-based approach to achieving efficient and effective research governance approvals
- Co-hosting the **ATP & ACTA National Summit** *Driving equitable access to clinical trials for all Australians* in Brisbane in March 2025. Bringing together Australia's leading clinical researchers, healthcare leaders, consumers, policymakers, and industry professionals—the group addressed the challenges of conducting and participating in clinical trials in rural, regional and remote areas. The summit was attended by over 300 people (in person and virtually)
- Launching a **Teletrial web resource** which is housed on the ACTA website. This resource explores how CTNs and CTCs can use the teletrial approach in their trials. It includes examples and aims to promote a community of practice. That is, by sharing experiences we can collectively work toward enhancing access to trials for all Australians.

This project collaboration has provided ACTA with a deep understanding of operational frameworks, and the barriers and opportunities involved in implementing teletrial methodology at scale. We look forward to continuing to support the ATP in the coming year.

OUR 2024 CLINICAL TRIALS AND REGISTRIES SYMPOSIUM

531 delegates came together from 2-4 December 2024 to hear from 85 local and international speakers at the **2024 Clinical Trials and Registries Symposium.**

During the three days, we were inspired by thought-provoking talks from our distinguished speakers and captivated by 43 abstract presentations. Across the three days, delegates enjoyed an extensive program including clinical research and registry development keynote presentations, plenary sessions, panel discussions, workshops, and networking events.

This annual event brings together a broad range of Australian and International experts in the design and conduct of clinical trials, clinical data, consumer engagement, healthcare funding, policy and regulation, healthcare service delivery, and health information technology. It also provides a platform for national and international speakers to share global advances in developing self-improving healthcare systems.

We sincerely thank the ACTA ASM Convenors Prof Katherine Lee and Prof Susannah Ahern, the Organising Committees, all presenters, facilitators, and delegates.

We also acknowledge the generosity and support of our event sponsors:

- **Bristol Myers Squibb** (Silver sponsor)
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- **Australian Teletrial Program** (Lanyard Sponsor)

Thanks also to our event exhibitors:

- Abbot
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CELEBRATING AUSTRALIAN CLINICAL TRIALS AT THE 2025 ACTA TRIAL OF THE YEAR AWARDS

The achievements of Australia's clinical trials sector took centre stage at the **2025 ACTA Trial of the Year Awards** ceremony, commemorated on International Clinical Trials Day, 20 May 2025.

Celebrating a diverse array of collaborative, multicenter trials driven by investigators nationwide, the event celebrated significant progress in healthcare innovation.

Congratulations to our 2025 winners

ACTA TRIAL OF THE YEAR AWARD WINNER

PLUSS
Intratracheal budesonide mixed with surfactant to increase survival free of bronchopulmonary dysplasia in extremely preterm infants

Chief Investigator: Prof Brett Manley
Network or investigator group: Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network

PLUSS investigated whether the administration of intra-tracheal budesonide during the early treatment of respiratory distress syndrome (RDS) in extremely preterm infants increased survival without bronchopulmonary dysplasia (BPD) at 36 weeks' postmenstrual age (PMA). This trial involved over 1,000 extremely premature babies in 21 hospitals across Australia, New Zealand, Singapore, and Canada.

Bronchopulmonary dysplasia (BPD) is a chronic inflammatory lung disease characterised by disordered alveolar and vascular development, most commonly affecting extremely preterm infants exposed to mechanical ventilation and oxygen therapy for RDS. BPD is associated with mortality, and adverse long-term pulmonary and neurodevelopmental outcomes.

RUNNERS-UP

PEAK trial
Telerehabilitation consultations with a physiotherapist for chronic knee pain versus in-person consultations in Australia: the PEAK non-inferiority randomised controlled trial

Chief Investigator: Prof Rana Hinman
Network or investigator group: Australia and New Zealand Musculoskeletal Clinical Trials Group

In this study, nearly 400 people with long-term knee pain, likely caused by osteoarthritis, were treated by physiotherapists in two ways. One group had traditional in-person appointments, while the other used video calls, like Zoom, to receive the same type of care—exercises, activity guidance, and education. This trial was conducted across 27 clinics in Queensland and Victoria. Results found that online physio was just as safe and effective as seeing a physio face to face.

WalkBack
Effectiveness and cost-effectiveness of an individualised, progressive walking and education intervention for the prevention of low back pain recurrence in Australia (WalkBack): a randomised controlled trial

Chief Investigator: Prof Mark Hancock
Network or investigator group: Australia and New Zealand Musculoskeletal Clinical Trials Group

The WalkBack trial tested a personalised, progressive program of walking and education, facilitated by physiotherapists, which was delivered either in person or online. 701 individuals who had recently recovered from an episode of low back pain were randomised to either receive the walking and education program, or to a no-intervention control group. All participants were followed monthly for up to 3 years, to monitor any new episodes of low back pain. The program significantly reduced the pain free period before a new recurrence, from 112 days in the no-intervention control group, to 208 days in the intervention group.

ACTA STING EXCELLENCE IN TRIAL STATISTICS AWARD WINNER

PLUSS
As above

Lead Statistician: Kate Francis
Chief Investigator: Prof Brett Manley

RUNNER-UP

BLING III
A phase III randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients

Lead Statistician: Prof Laurent Billot
Chief Investigator: Professor Jeffrey Lipman
Network or investigator group: The George Institute for Global Health

BLING III was one of the biggest antibiotic studies ever done in ICUs, involving 7,202 patients across 104 ICUs in 7 countries. In total, over 132,000 doses were given. The results showed that giving antibiotics continuously helped more patients survive, improved recovery, and could save one extra life for every 26 patients treated this way.

OUR OPERATIONS

ACTA is supported by our Board of Directors, members, staff, volunteers, and sector colleagues.

OUR BOARD

CHAIR

PROF CHRISTOPHER REID
BA DIP ED MSC PHD

Christopher Reid is a cardiovascular epidemiologist with appointments as John Curtin Distinguished Professor in the School of Population Health at Curtin University and Research Professor at the School of Public Health and Preventive Medicine, Monash University. He is also Director of Monash and Curtin Centre's of Cardiovascular Research and Education (CCRE) and the NHMRC Centre of Research Excellence in Cardiovascular Outcomes Improvement.

PROF DAVID BEARD
GDPhys, MCSP, MA, MSc, DPhil, FBOA (hon), FRCS (hon)

David Beard is a Professor and Surgical & Complex Intervention Trials Program Lead at the NHMRC Clinical Trials Centre, University of Sydney. He is also Professor of Musculoskeletal and Surgical Sciences at the University of Oxford, an NIHR Senior Investigator, and the Director of the Royal College of Surgeons Surgical Intervention Trials Unit.

PROF NADINE FOSTER
DPhil BSc(Hons), FCSP

Nadine Forster is the Academic Director of the University of Queensland's Clinical Trials Centre (UQCTC) and an NHMRC Investigator Fellow. She is also the program lead for the Health Research Accelerator (HERA 2) program focused on innovation in clinical trials (ULTRA - UQ's Clinical Trial Capability) and a theme lead for clinical trials in the Centre of Innovation in Pain and Health Research (CIPHeR).

PROF KATHERINE LEE
BSc Mathematics, MSC, PhD

Katherine Lee is a Professor of Biostatistics at the Murdoch Children's Research Institute (MCRI) and the University of Melbourne, where she is the co-Director of the Clinical Epidemiology and Biostatistics Unit and the Associate Director: Biostatistics of the Melbourne Children's Trials Centre.

DR SHERMAN LEUNG
PhD GDPhys, MCSP, MA, MSc, DPhil, FBOA (hon), FRCS (hon)

Sherman Leung is the Head of Research Operations at Wesley Research Institute. He is also Co-Chair to the Clinical and Consumer Advisory Group of the Australian Teletrials Program and Chair to the Clinical Trials Advocacy Working Group of the Queensland Clinical Trials Consortium.

MS ANNE MCKENZIE AM

Anne McKenzie is a consultant consumer advocate, holds honorary positions at The Kids Research Institute and The University of Western Australia, and currently serves as a senior consumer representative on key national and state health committees.

PROF TRISHA PEEL
MBBS (Hons), GradCertClinRes, FRACP, PhD

Trisha Peel is an Infectious Diseases Physician, and the Deputy Director (Research), Department of Infectious Diseases, Monash University and Alfred Health.

MR KIERAN SCHNEEMANN

Kieran Schneemann is a government affairs practitioner with more than 30 years' experience in global companies, Australian institutions, and all levels of government. He currently works as an independent consultant.

MR IAN WILSON
FCPA ACIS AGIA MAICD

Ian Wilson is an experienced Director having held senior finance and corporate governance professional with an early career in the commercial sector and then over 20 years' experience in the not-for-profit sector.

PROF SOPHIA ZOUNGAS
MBBS(Hons) FRACP PhD FAHMS

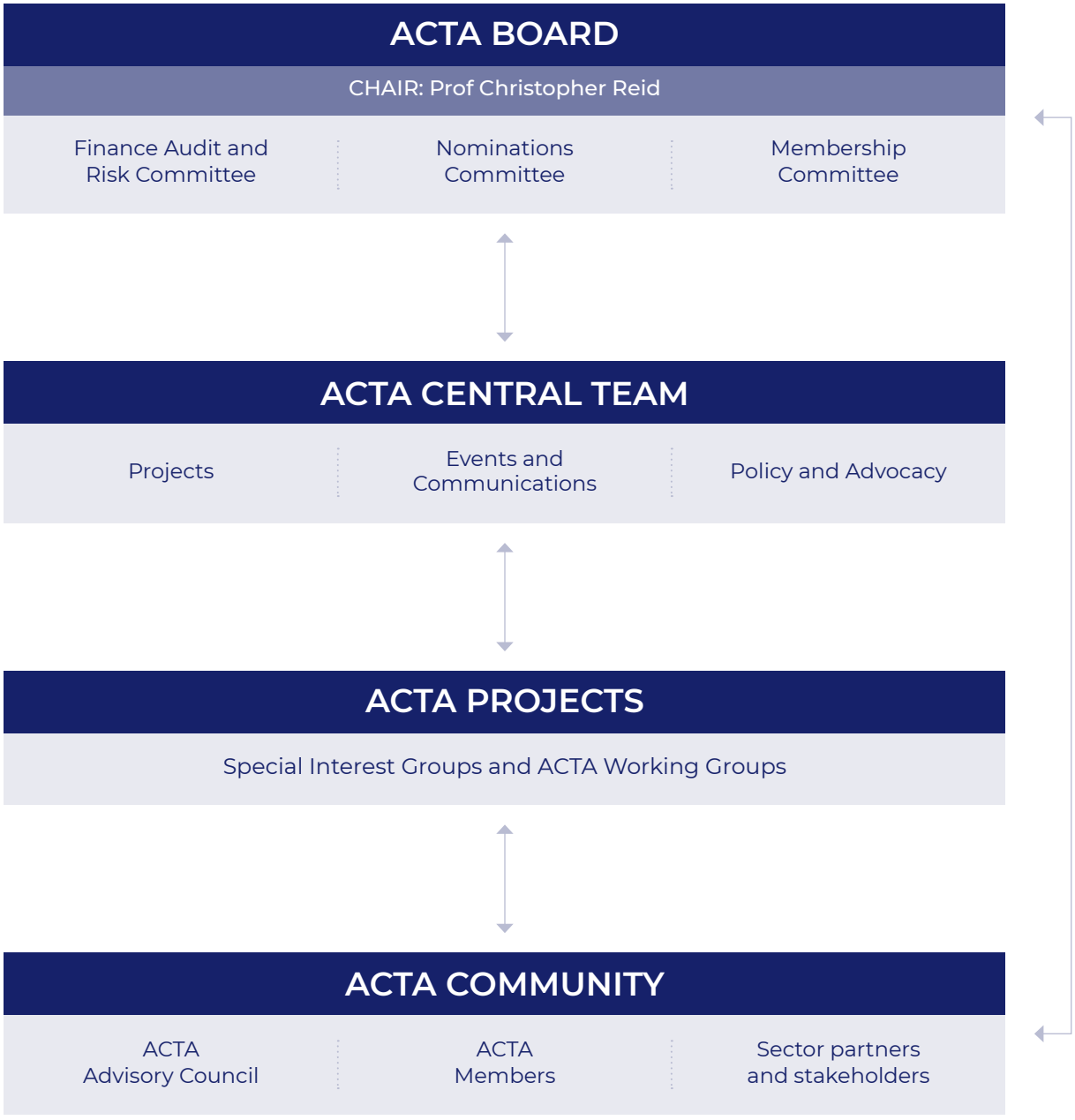
Sophia Zoungas is an endocrinologist and Head of the School of Public Health and Preventive Medicine at Monash University and Academic Director of the Monash University Clinical Trials Centre.

Prof Rachael Morton retired on 12 November 2024

Ms Anita Van Der Meer retired on 23 March 2025

Prof Steven Webb retired on 12 November 2024

OUR TEAM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ACTA Members
Sector partners and stakeholders

OUR THANKS

STANDING COMMITTEE MEMBERS

FINANCE AUDIT AND RISK COMMITTEE

- Prof Christopher Reid (Chair)
- Mr Kieran Schneemann
- Mr Ian Wilson
- Prof Katherine Lee

MEMBERSHIP COMMITTEE

- Prof Trisha Peel
- Prof Sophia Zoungas
- Prof Belinda Gabbe
- Prof John Simes *(until November 2024)*
- Prof Steve Webb *(until November 2024)*

NOMINATIONS COMMITTEE

- Prof Christopher Reid (Chair)
- Mr Kieran Schneemann
- Prof Sophia Zoungas
- Ms Anita van der Meer *(until March 2025)*

SPECIAL INTEREST GROUP LEADERSHIP

ADAPTIVE PLATFORM TRIALS OPERATIONS SPECIAL INTEREST GROUP (APTO SIG)

- Dr Roberta Littleford
- Dr Grace McPhee *(from March 2025)*
- Mr Arlen Wilcox *(until March 2025)*

CLINICAL QUALITY REGISTRIES SPECIAL INTEREST GROUP (CQR SIG)

- Ms Tamara Hooper *(from May 2025)*
- Ms Jade Newman *(from February 2025)*
- Prof Susannah Ahern *(until February 2025)*
- Prof Stephen McDonald *(until October 2024)*

COORDINATING CENTRES SPECIAL INTEREST GROUP (CC SIG)

- Prof Andrew Davidson *(from April 2025)*
- Ms Helen Monaghan *(from August 2024)*
- Prof Bruce Neal *(until August 2024)*
- Ms Delaine Smith *(until February 2025)*

HEALTH ECONOMICS ALONGSIDE TRIALS SPECIAL INTEREST GROUP (HEAT SIG)

- Dr Lisa Higgins *(from July 2024)*
- A/Prof Richard Norman
- Prof Rachael Morton *(until November 2024)*

SPECIAL INTEREST GROUP FOR NETWORK MANAGERS (SIGNet)

- Dr Cecilia Ng
- Mr John Andrews

STATISTICS IN TRIALS INTEREST GROUP (STInG)

- Prof Katherine Lee
- Prof Andrew Forbes

TRANSLATION OF RESEARCH INTO PRACTICE SPECIAL INTEREST GROUP (TRIP SIG)

- A/Prof Ingrid Hickman
- Dr Nicola Straiton

WORKING GROUP LEADERSHIP CONSUMER ENGAGEMENT, EQUITY AND DIVERSITY WORKING GROUP

- Dr Janelle Bowden
- Ms Anne McKenzie AM

EARLY TRIAL APPROVAL MODEL WORKING GROUP

- Prof Nik Zeps

EXPLORING TECHNOLOGIES TO IMPROVE RECRUITMENT WORKING GROUP

- Prof Nik Zeps

FACILITATE INDUSTRY FUNDED/ SPONSORED TRIALS WORKING GROUP

- Prof Steve Webb

INNOVATIVE TRIAL DESIGNS WORKING GROUP

- Prof Katherine Lee
- Prof Ian Marschner

ACTA TELETRIALS RAISING EQUITY OF ACCESS TO CLINICAL TRIALS SPECIAL INTEREST GROUP (REACT-SIG)

- Prof Nik Zeps

EVENT CONVENERS

2024 CLINICAL TRIALS AND REGISTRIES SYMPOSIUM

- Prof Katherine Lee
- Prof Susannah Ahern

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2024 CLINICAL TRIALS AND REGISTRIES SYMPOSIUM

Silver sponsor — Bristol Myers Squibb™

Silver sponsor — Bellberry Limited supporting research and ethics

Lanyard Sponsor — Australian Teletrial Program, Access to clinical trials, closer to home

EVENT EXHIBITORS

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- Syntro
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OUR MEMBERS AND VOLUNTEERS

We sincerely thank all members for your ongoing support of ACTA and the investigator-initiated trials sector. We also share our immense gratitude to our 500 volunteers who so generously give their time to be involved in ACTA activities including participation in our Special Interest and Working Groups.

FINANCIAL SUMMARY

Statement of profit or loss and other comprehensive income for the year ended 30 June 2025

	2024/25 $	2023/24 $
REVENUE		
Revenue	**1,711,283**	1,691,046
Other income	**9,646**	12,392
EXPENSES		
Employee benefits expense	**(792,567)**	(938,760)
Depreciation and amortisation expense	**(71,318)**	(49,105)
Audit, legal and consultancy expenses	**(104,041)**	(170,086)
Event, conference and meeting expenses	**(332,642)**	(254,288)
Project management fees	**(70,182)**	(52,006)
Program expenses	**(185,694)**	(83,296)
Finance costs	**(1,947)**	(3,907)
Administration	**(49,361)**	(127,847)
Other expenses	**(84,723)**	(122,995)
Surplus/(deficit) before income tax expense	**28,454**	(98,852)

STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2025		
Total assets	**1,201,869**	2,026,329
Total liabilities	**348,031**	1,200,945
Net assets	**853,838**	825,384

Membership fees

Australian Clinical Trials Alliance

Australian Clinical Trials Alliance

Suite 1, Level 2, 24 Albert Road
South Melbourne VIC 3205

T 0438 801 011 ▪ **E** acta@acta.au

clinicaltrialsalliance.org.au