Australian Clinical Trials Alliance

2022/23 Annual Report

Better health through best evidence

ACKNOWLEDGEMENTS

ACTA is grateful to receive grant funding from the Australian Government. The work we have conducted during 2022/23 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.

We also acknowledge all consumers, carers and clinical trial participants who continue to inspire and shape our work.

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MESSAGE FROM OUR BOARD CHAIR

The investigator-initiated trials sector is continually evolving and innovating. This is evident in the 2022/23 year which has seen ACTA strengthen and diversify efforts to ensure we remain connected and relevant for our members, and the broader sector in which they serve. Our vision is better health through best evidence, and I believe we are delivering on that vision.

This year we have actively built on some of our longstanding projects including the release of recommendations to advance clinical trial engagement, involvement, and participation for people from culturally and linguistically diverse (CALD) backgrounds (page 17), launch of the Find a Health Economist online directory (page 19), development of the rapid trial approval model checklist as part of our SKYHOOK project (page 22), and our continued efforts to support the HeSANDA project (page 25).

Our member and sector insights also shaped new areas of activity and focus including the Clinical Trial Network masterclass series (page 15), virtual clinics on Adaptive Platform Trials (page 20), and partnership with the Australian Teletrials Program (page 24).

We do our work within a policy and regulatory framework that is set by governments at both Commonwealth and jurisdictional levels. We have increased our advocacy efforts this year and built deeper connections, as well as key sector bodies. We look forward to strengthening these partnerships further in the coming year through our support of new sector-wide initiatives including the National Clinical Trials Governance Framework and the highly anticipated National One Stop Shop. ACTA will also change our membership criteria, adding a category for Health Service Organisations that provide clinical trial services to external sponsors. We're hoping this modification will assist ACTA to achieve the best possible implementation of the Framework and, in time, the One Stop Shop.

I sincerely thank our members for their openness and collaboration during the year, and the unwavering support of our 400+ volunteers.

It is our members, volunteers, and the consumers they work with, who continue to motivate our Board and team, and truly drive our activities.

I extend my thanks to the Australian Government for their continued funding support and to the MRFF for their ongoing grant support of our activities. I also acknowledge the support and valuable interaction ACTA has had with officers of the Department of Health and Aged Care across the year.

I offer my sincere gratitude to our outgoing Board Directors Ms Leonie Wilcox and Ms Margo June MacGillivray, and I welcome Ms Anita van der Meer and Prof Sophia Zoungas to the Board. I also gratefully acknowledge all fellow Board Directors who have continued to offer their expertise and support throughout the year.

I also want to thank a very large number of health consumers who contribute to the work of ACTA and its members. The insights that these volunteers bring makes a very meaningful difference to the effectiveness of the work that is done by the sector to improve patient outcomes.

I also acknowledge the work of Dr Stewart Hay in his capacity as CEO during 2022/23, and I express my enormous appreciation and admiration of the work that is done on behalf of the sector by the ACTA central team.

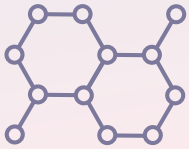
It is an honour to serve as Chair of ACTA and lead a team who are fiercely passionate about representing our diverse member base, and the broader investigator-initiated trial sector. This report offers a snapshot view of our work, and I am pleased to commend it to you.

PROF STEVE WEBB
MBBS MPH PHD FCICM FRACP FAHMS

OUR YEAR AT A GLANCE

10,000+ CLINICAL RESEARCHERS

ACTA represented over 10,000 clinicians and clinical researchers working within the Australian healthcare system.



122
ORGANISATIONAL MEMBERS

Our full members, associate members and affiliate members represented:

- Clinical Trial Networks (CTNs)
- Clinical Quality Registries (CQRs)
- Coordinating Centres (CCs)
- Research institutes
- Universities
- Hospitals
- Professional colleges and societies
- Regulatory and statutory bodies

Find out more on page 10.

208
INDIVIDUAL MEMBERS

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

400+
VOLUNTEERS

Provided invaluable input to our Special Interest Groups, Project Working Groups (plus subgroups) and committees.

6
NEW RESOURCES

Led the development of reports, reviews, environmental scans, discussion papers, a recommendation paper, and an online directory which are available through the ACTA resource library.

21
EVENTS

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

42
SPECIAL INTEREST AND WORKING GROUP MEETINGS

Connected the investigator-initiated trials sector through focused and collaborative meetings for our six Special Interest Groups and six Working Groups.

2
ANNUAL SCIENTIFIC MEETINGS

Hosted the 8th ACTA Annual Scientific Meeting and the inaugural Australian Registry Annual Scientific Meeting.
Find out more on page 29.

OUR MEMBERS HAVE TOLD US THAT ACTA:

- *Is instrumental in establishing new Clinical Trial Networks (CTNs) by providing governance and funding models and assisting with prioritisation*
- *Champions the capability of the investigator-initiated trials in making Australia more attractive to international sponsors*
- *Supports the development of new CTNs*
- *Promotes the importance of embedding clinical trials into healthcare delivery by disseminating information and advocating jurisdictional health departments to enact policies*
- *Contributes to improving the efficiency and effectiveness of Coordinating Centres*
- *Disseminates knowledge and awareness of new, highly efficient clinical trial designs*
- *Increases readiness to design and conduct clinical trials*
- *Builds greater awareness and understanding of the value of involving consumers in clinical trial design*
- *Raises knowledge about innovative clinical trial designs.*

ABOUT ACTA

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.

ACTA is the national peak body supporting and representing more than 10,000 clinician-researchers who conduct investigator-initiated clinical trials through CTNs, maintain CQRs, and operate clinical trial CCs within the Australian healthcare system.

As a member-based body, our activities represent the priorities required to develop, implement and support a national framework to expand the capacity, capability, efficiency and effectiveness of our members across CTNs, CQRs and CCs.

CTNs represent voluntary, generally national, aggregated groups of clinicians and researchers who span a wide range of health states, disease areas and disciplines. CTNs design trials that address clinically important questions. In so doing, they facilitate patient recruitment to important clinical trials and are key to the implementation of these findings, translating research into improved healthcare. The majority of CTNs form close working partnerships with CCs that house a critical mass of expertise in trial methods, biostatistics, health economics, project coordination and data management.

Additionally, high functioning national CQRs monitor the quality, appropriateness, and effectiveness of healthcare, to drive continuous improvement. In combination, these facilities/structures constitute a unique, world-leading effort to drive healthcare improvement for the benefit of patients and the community through the generation of high-quality evidence required to address Australia's health priorities.

Our members are advancing health care by:

- Designing trials that address clinically important questions
- Facilitating wider population trial coverage that enhances clinical practice and improves patient outcomes
- Monitoring and measuring the quality of healthcare through registries
- Facilitating ongoing innovation and the translation of research to improve healthcare.

ACTA are advancing healthcare by:

- Promoting the role of investigator-initiated clinical trials and CQRs to inform decisions made by health practitioners, policymakers and consumers to ensure effective and cost-effective healthcare in Australia
- Increasing Australia's capacity to generate and implement high-quality clinical trial evidence through the development and support of sustainable CTNs, CQRs and CCs, and the provision of mentoring and education opportunities for members
- Supporting communities of practice and providing a forum for the exploration and dissemination of effective and efficient clinical trial practice and policy, to ensure better health outcomes
- Increasing the return on investment in research by providing the essential infrastructure to address key questions efficiently and reducing research waste.

Together, we are embedding evidence-based care into the health system to improve healthcare.

OUR MEMBERS


AVATAR

ANZCA CLINICAL
TRIALS NETWORK

ASPREE

AGITG

AUSTRALASIAN
KIDNEY
TRIALS
NETWORK

ALTG

aroc
Australasian Rehabilitation Outcomes Centre

ANZ
DATA
AUSTRALIA &
NEW ZEALAND

Australia & New Zealand
ANZLITR

ANZSA
Australia and New Zealand
Sarcoma Association

ANZACT

ANZCHOG
Australian and New Zealand
Children's Haematology/Oncology Group

Australian &
New Zealand
Falls Prevention Society

AUSTRALIAN &
NEW ZEALAND
NEONATAL
NETWORK

AVATAR

Cancer
Council
Victoria

Cancer Trials
Australia

canteen

BaCT
Centre for Biostatistics
and Clinical Trials

CHYMAERA

Consumer & Community
Health Research Network

COGNO
COOPERATIVE TRIALS GROUP
FOR NEURO-ONCOLOGY

CSIRO

DACRIN

Australian
CLINICAL TRIALS

EBM ANALYTICS

ePPOC
electronic persistent pain
outcomes collaboration

EPILEPSY SOCIETY OF AUSTRALIA

evrima

Grampians
Health

Growing
Minds
Australia

HealthMatch

HMRI

IMPACT
TRIALS

Ingham Institute

PERINATAL
SOCIETY
PSANZ
IMPACT

Lung
Foundation
Australia
PACT Network

Mackay
Institute of
Research and
Innovation

MAGNET

mater
research

Melanoma and Skin Cancer Trials

MENZIES

menzies
school of health research

Metro North
Health
Queensland
Government

MONASH
University

MS
RESEARCH
AUSTRALIA

Jean Hailes

NECST
Network

neuroscience trials australia

Omico.

ory
gen

PREDICT

PTNA
Paediatric Trials Network Australia

PaCCSC

PROSTATE
CANCER
OUTCOMES

PoCoG

PURECDM

QCMHR

Research Path

Royal Australasian
College of Surgeons

Save Sight Registries

Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)

Australasian Leukemia 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 College for Emergency Medicine Clinical Trials Group

Australia & New Zealand Gynaecological Oncology Group

Australia and New Zealand Musculoskeletal Clinical Trials Group

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

Australian & New Zealand Urogenital & Prostate Cancer Trials Group

Australian and New Zealand College of Anaesthetists Clinical Trials Network

Australian and New Zealand Intensive Care Society

Australian Centre for Health Services Innovation - Queensland University of Technology

Australian Epilepsy Clinical Trials Network

Australian Orthopaedic Association National Joint Replacement Register

Australian Red Cross Lifeblood

Breast Cancer Trials

Centre For Eye Research Australia

Clinical Trials Network Australia New Zealand

Clinical Trials Platform – La Trobe University

Commonwealth Scientific and Industrial Research Organisation (CSIRO)

Consumer and Community Involvement Program

Coronary Angiogram Database of South Australia

CSI Medical Research

Foundation for Angelman Syndrome Therapeutics Australia

Icon Institute of Innovation and Research

InsideOut Institute

JDRF Australia

Kids Cancer Centre, Sydney Children's Hospital

Marilyn Careers

Melbourne Children's Trials Centre

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

Methods and Implementation Support for Clinical and Health Research

MEXEC

MQ Health

National Allergy Centre of Excellence

National Cardiac Registry

National Endometriosis Clinical and Scientific Trials Network

Neurodevelopment Australia

NHMRC Clinical Trials Centre

NHMRC CRE in Wiser Wound Care, Griffith University

NSW Drug and Alcohol Clinical Research and Improvement Network

OMICO (Australian Genomic Cancer Medicine Centre)

PRAXIS Australia

Primary Care Collaborative Cancer Clinical Trials Group, University of Melbourne

Primary Care Medical Clinic Pialba

Pulmonary Fibrosis Australasian Clinical Trials

Ramsay Health Care Australia Pty Limited

Regional Trials Network - Victoria

Resonance Health Analysis Services Pty Ltd

Royal Melbourne Hospital

Save Our Sons Duchenne Foundation

School of Optometry and Vision Science

Sydney Local Health District

The George Institute for Global Health

The University of Sydney

VCCC Alliance

Victorian Ambulance Cardiac Arrest Registry

Walter and Eliza Hall Institute for Medical Research

WeGuide Pty Ltd

OUR WORK

Our work focuses on activities that can consolidate and strengthen the capability and collaboration of the investigator-initiated clinical trials sector.

We do this to:

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

OUR ACTIVITIES

ACTA connects clinical researchers with governments, policy makers and consumers on issues that impact the conduct of investigator-initiated clinical trials across the Australian healthcare system.

We are committed to building the capacity, capability, efficiency, and effectiveness of CTNs, CQRs and CCs.

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

WORKSTREAM 1:
SUPPORTING MEMBER ORGANISATIONS

Workstream purpose:

Improve the efficiency, effectiveness and sustainability of CTNs, CQRs and CCs to ultimately improve health outcomes and productivity of the healthcare system.

What will be the impact of this work?

Broader coverage of disciplines and disease categories leading to a larger number of higher quality trials and registries that will, in turn, result in better health outcomes and a healthcare system with higher productivity.

Our 2022/23 highlights

- The **Special Interest Group for Clinical Trial Network Managers (SIGNet)** brought together Executive Officers and Network Managers from Australian and New Zealand CTNs.

  Through this group, ACTA:

  - Facilitated collaboration and cohesion across CTNs
  - Gained a greater understanding of current capabilities, emerging needs, and issues faced across the sector
  - Collected useful data for reporting activities, specifically on teletrials, consumer engagement, technologies being used for recruitment, and adaptive platform trials
  - Increased awareness of national initiatives.

- The **Coordinating Centre Special Interest Group (CC SIG)** provided a platform for dialogue between CC's to share challenges, explore local and international CC models, plus the sharing and assessing of opportunities for adoption of best practice approaches.

  Through the year, ACTA and the SIG members undertook a deep dive into CC accreditation and potential models. This activity focused on reviewing the Australian and international CC landscapes, seeking insights from CCs on the potential value and impact of accreditation, assessing what it could mean for the Australian research sector, as well as consideration and coordination with key state and national initiatives to ensure no duplication of efforts.

- 70+ Australian Registries are represented on the **Clinical Quality Registries Special Interest Group (CQR SIG).** This considerable representation across the registry landscape, means that the SIG plays a key role in being a national voice of the sector, with the vision of influencing practice, policy and patient outcomes.

  During the year, the CQR SIG facilitated two webinars:

  - The Data Availability and Transparency Act 2020 (Consequential Amendments): Implications for Australian Registries – Presented by Dr Phillip Gould, First Assistant Secretary, Health and Research Division in the Department of Health and Aged Care
  - Health Economic Evaluation of Clinical Quality Registries - Presented by Prof Danny Liew, Head of Adelaide Medical School and Dr Ella Zomer, Senior Research Fellow, Monash University.

  The SIG Co-Chairs and ACTA, co-convened the inaugural Australian Registry Annual Scientific Meeting in November 2022 which brought together 135 delegates from Australian Registries, government departments, not-for-profits and other funders, and clinicians and health services. This event is highlighted on page 29.

  In March 2023, the Group led ACTA's submission to the Australian Commission for Safety and Quality in Health Care (ACSQHC) consultation regarding the revision of the CQR framework.

- During the year we continued to **support new and emerging CTNs** through direct engagement, resource sharing, and tailored advice based on Network needs.

  We also launched our CTN Masterclass Series which created a learning platform for clinicians and researchers who are interested in establishing their own CTN.

  To date, Masterclass topics have included the 'Establishment of a CTN' and 'CTN governance'.

  The sessions have been well attended and participants indicated that they found the sessions beneficial, with significant increases in awareness and understanding of CTNs and their development.

HARNESSING COLLABORATION FOR MENTAL HEALTH RESEARCH

ACTA's Special Interest Group for Network Managers (SIGNet) serves as an important platform to exchange knowledge, expertise, and resources among Clinical Trial Networks (CTNs).

Through SIGNeT, we are able to:

- Empower CTNs to strengthen their operational capacities and strategic planning
- Facilitate peer-based problem-solving
- Promote collective learning.

The Mental Health Australia General Clinical Trial Network (MAGNET) is one of the valued members of SIGNeT, and we have been pleased to see how their involvement in the group is directly assisting MAGNET's development, growth and progress. We believe their involvement in SIGNeT has created a robust foundation for their ongoing contributions to mental health research.

"It is helpful to see issues other CTNs face and be able to discuss them in an open forum."

– Dr Ayla Barutchu, Executive Officer, MAGNET

WORKSTREAM 2:
CONSUMER ENGAGEMENT, EQUITY AND DIVERSITY

Workstream purpose:

Enhance the impact of clinical trials and registries by improved engagement and involvement of consumers in member organisations, the design and conduct of trials and registries, and identification of enablers that reduce inequity.

What will be the impact of this work?

- Increased consumer involvement and improved engagement, equity and diversity in trial design and conduct
- Increased engagement and enhanced awareness of the role of underrepresented groups in Clinical Trial Networks (CTNs) and trials.

Our 2022/23 highlights

- The ACTA and CT:IQ developed, Consumer Involvement and Engagement Toolkit continues to be a well utilised resource however to extend awareness of the Toolkit and support its implantation into clinical trial activities, we undertook a multipronged review during 2022/23.

  This review saw engagement with different user groups across the sector to understand how they use the Toolkit, consider if the content remains relevant to their needs, and identify any content gaps.

- In our ongoing efforts to strengthen the sector's capacity and ability to involve consumers in all activities across the research continuum, we awarded 10 complementary consumer registration passes to the 2022 ACTA Annual Scientific Meeting (ASM).

  We were delighted to be joined by patients, carers and consumers who are working with the sector to improve the design and conduct of clinical trials and quality clinical registries.

  (Find out more about the ASM on page 29)

- This year we also continued our work to increase **clinical trial engagement, involvement and participation of people from Culturally and Linguistically Diverse (CALD) backgrounds.** Key recommendations were developed from this work and the project is highlighted further on page 17.

Consumer representatives at the 2022 ACTA ASM with Co-Chair of the consumer engagement, equity and diversity working group Ms Anne McKenize AM.

PROJECT SPOTLIGHT:

Advancing clinical trial engagement, involvement, and participation for people from CALD backgrounds

In Australia, our CALD populations are significantly underrepresented in health and medical research, including in clinical trials, revealing a gap in equitable access.

Coupled with the growing intensity and focus on CALD inclusion, both internationally and locally, and the desire to further strengthen Australia's reputation as a trial destination of choice, we are at an important junction for change.

Reflecting the diversity of society in clinical research is essential for the generalisability of results. Various demographic factors have been associated with clinically significant differences in risk factors, screening, diagnosis and prognosis, treatment and management related to a range of diseases and conditions. A failure to identify, examine and respond to these differences can ultimately compromise the quality of care and treatments that are available now and into the future.

ACTA is committed to improving clinical trial engagement, involvement, and participation for all, and this is a sentiment shared broadly by the investigator-initiated trial sector. It is widely felt that system level change is needed to achieve sustainable long-term engagement, involvement, and participation of CALD people in clinical trials.

Following extensive consultation with consumers and researchers, including members of ACTA's Consumer Engagement, Equity, and Diversity Working Group, and the broader trials sector, this year ACTA drafted a set of recommendations that provide practical pathways and building blocks to realise a CALD inclusive clinical trial system over time.

A systems approach to improve CALD engagement in clinical trials

The recommendations lay out a systems approach through a set of strategies and pathways that collectively build up a cohesive CALD inclusive clinical trials model from the perspective of the CALD consumer, the investigator/trial team, the funder, and policy maker.

The proposed model also seeks to establish a set of shared resources via a baseline infrastructure service, using either a CALD specific virtual community and/or geographically located communities, that will have a mix of CALD backgrounds but with local needs.

To effectively implement these recommendations, a scaffolded approach that optimises existing resources, pilot programs, and digital environments, will allow for strategy refinement and scale.

In evaluating success as a system, we believe indicators should highlight improvements from the perspectives of CALD people, the clinical trial workforce and their sponsor organisations, and the organisations responsible for policy development, guiding, and funding the clinical trials system.

The potential impact of implementation

Action to implement these recommendations could drive measurable improvement in involvement of CALD people in trial design, and access through their participation in trials, together with enabling changes in the clinical trials system.

We sincerely thank all organisations and individuals who provided insights, experiences, and advice into this project.

WORKSTREAM 3:
CAPACITY BUILDING TO SUPPORT BETTER TRIAL DESIGN, CONDUCT, AND IMPACT

Workstream purpose

Build capacity utilising innovative trial designs, as well as dissemination and implementation of these methods and building capacity in health economic analysis of trials.

What will be the impact of this work?

- Higher-value healthcare
- Better patient care
- Increased use of innovative trial designs by Clinical Trial Networks (CTNs), where appropriate
- Enhanced scope for improved efficiency and impact of trials.

Our 2022/23 highlights

- The **Statistics in Trials Special Interest Group (STInG)** has contributed to improving the quality of clinical trials within Australia through increasing member engagement and various avenues of training and resources.

  Our 2022/23 activity has included a three-part webinar series on data integrity and transparency, which featured both national and international speakers. These webinars were:

  - Effective strategies to manage data integrity risks – Presented by Tracey Meares- Trial Manager from BEAT-CF platform trial, University of Sydney Australia, and Kylie Rogers – Data Management Lead in Adaptive Health Intelligence team
  - Transparency in data analyses – Presented by Prof Laurent Billot – Director of Biostatistics and Data Science Division at the George Institute for Global Health
  - The Data Lifecycle: Ethical use of data – Presented by Dr Ursula Garczarek – Research Principal at Strategic Consulting in Cytel, Germany.

  A two-part webinar series to provide live demonstrations of the use of Stata and R markdown using examples of a clinical trial dataset. These were designed as introductory level workshops to guide graduate research students, early-career researchers and health professionals on how to conduct efficient and reproducible clinical research using both of these statistical packages. Details of the webinars are as follows:

  - Stata Demonstrations webinar – Presented by Dr Anurika De Silva, Biostatistics Research Fellow at the Methods and Implementation Support for Clinical and Health research Hub (MISCH), University of Melbourne
  - R Markdown Demonstrations webinar – Presented by Dr Kristy Robledo, Senior Research Fellow in Biostatistics at the NHMRC Clinical Trials Centre, University of Sydney.

  An additional webinar series on n-of-1 trials was presented by Prof Stephen Senn, Consultant Statistician, on the following topics:

  - Webinar 1: An n-of-1 introduction, using n-of-1 trials to estimate average treatment effects and considering both randomisation approaches and fixed linear models
  - Webinar 2: Estimating individual effects using mixed models with random subject effects and planning of n-of-1 trials.

  The Group also continued to grow the expertise of trial statisticians through ongoing support of the Data Safety Monitoring Board (DSMB) mentoring program. In the reporting period an additional three individuals were trained to participate in DSMBs.

- The **Health Economics Alongside Trials Special Interest Group (HEAT SIG)** provides a community of practice for health economists working with clinical trials data.

  In December 2022, we launched the Find a Health Economist online directory which includes profiles of Australian health economists with experience in economic evaluation alongside trials, or in the use of trial data. This platform endeavours to build capacity and enable collaboration of health economists nationally. It will also enable trialists to locate health economists who have specific relevant experience in applied or methodological areas for the purpose of collaboration.

  During the year we also facilitated four webinars to support the Groups outcomes of establishing and disseminating best practice methods for economic evaluation alongside randomised trials and economic models using trial data. The webinar topics were:

  - Economic evaluation alongside cluster trials – Presented by Dr Manuel Gomes, Associate Professor of Health Economics at University College London
  - Economic evaluation alongside adaptive trials – Presented by Dr Laura Flight, Scientific Adviser in the Science Policy and Research team at the National Institute for Health and Care Excellence (NICE)
  - Use of administrative data for measuring events and healthcare use – Presented by Prof Emily Callander, Health Economist, School of Public Health, Faculty of Health, University of Technology Sydney
  - Flexible survival models and why we (might) need them – Presented by Prof Nicholas Latimer, Professor of Health Economics and Yorkshire Cancer Research Senior Fellow, University of Sheffield.

- We were pleased to commence our **Adaptive Platform Trial Operations Special Interest Group (APTO SIG)** in 2022/23. This Group aims to build capacity to support better trial design through its membership and the broader sector.

  During the year our outputs included:

  - Facilitating an Adaptive Platform Trial Workshop during the 2022 ACTA Annual Scientific Meeting (ACTA ASM) that was co-led with ACTA STInG. This workshop included presentations from two early-stage groups who were working on Adaptive Platform Trials, and allowed them to receive direct feedback from an expert panel
  - Using a similar format as the ACTA ASM workshop, we held an additional two Virtual Clinics on Adaptive Platform Trials. These events saw two presenters receive feedback and questions from an expert panel and event attendees

  With close to 100 attendees per session, 70% of clinic 1 participants and 83% of clinic 2 participants reported that the session had increased their awareness and understanding of innovative trial designs to a great or moderate extent.

  More than 80% of delegates across both clinics reported that they are likely to conduct a trial that utilises an innovative design. See feedback from our Virtual Clinic presenters *on page 20.*

  - Commencing the development of educational resources including Ethical considerations for Adaptive Platform Trials Researchers, Nomenclature/ Linked Glossary for Adaptive Platform Trials, Efficiencies and Complexities of Adaptive Platform Trials web resource, and a consumer resource
  - Developing an adaptive platform resource page which provides trial summaries of each APT involved in the APTO SIG, and work has commenced on a repository of all funded APTs.

PROJECT SPOTLIGHT:
Virtual clinics on adaptive platform trials

During 2022/23 we held three virtual clinics on adaptive platform trials where early-stage groups who were working on adaptive platform trials could present their project to seek feedback from an expert panel. These events were highly engaging and our presenters reported that they took a lot from the sessions.

What our presenters told us...

Dr Jessica Schults, The University of Queensland

Dr Schults presented on IVCare – an adaptive platform trial working towards zero bloodstream infections in IV catheters.

- *"I'm fairly new in this field, but after attending a previous ACTA talk on platform trials, this really piqued my interest."*
- *"The supportive nature of the virtual clinic and ability to get feedback in a safe and collaborative environment through ACTA has been great."*

A/Prof Elliot Long, Royal Children's Hospital

A/Prof Long presented on Paediatric Adaptive Sepsis Platform Trial (PASSPORT) – an adaptive platform trial out of the PREDICT Clinical Trial Network

- *"This session has accelerated our initial journey and exceeded our expectations."*
- *"The network has never done this before, so there is no precedent or roadmap, no steps to date. We were unsure about where to involve the core steering group, participants, sites etc. It has been helpful to have expertise from ACTA in this area."*

Dr Brendan Smyth, NHMRC Clinical Trial Centre

Dr Smyth presented on – SEISMIC – an adaptive platform trial out of The University of Sydney that is investigating symptom therapies in people with kidney failure.

- *"This clinic helped us to focus on a preferred trial design which we intend to develop towards a funding proposal. We got out of it what we had hoped."*
- *"I saw the email from ACTA on the Virtual Clinics and I wanted to use the opportunity to workshop ideas and get independent advice from people who haven't been working in this space...their reactions about our study designs have been useful to help us narrow down some of our options and put aside some thoughts that we had as impractical or statistically not advisable."*

WORKSTREAM 4:
MAKING TRIALS MORE EFFICIENT AND EASIER

Workstream purpose

Improve efficiency and effectiveness of clinical trials to achieve greater equity of access to trials where there are barriers to participation.

What will be the impact of this work?

- Improved efficiency and effectiveness of clinical trials
- Greater equity of access to trials where there are barriers to participation, including for people living significant distances from trial sites, and people with rare diseases.

Our 2022/23 highlights

- To **promote and support the Teletrials model** we facilitated a half-day workshop during the 2022 ACTA Annual Scientific Meeting with attendees from Government, industry, research institutes or coordinating centres, hospitals, universities, and consumers. This workshop raised awareness of challenges in the Teletrials space and opened a dialogue for future discussions to work together on addressing these.

  ACTA has also been working closely with the Australian Teletrial Program (ATP) initiative and we have a separate initiative underway to support learning, development and implementation of Teletrials. Through this activity we have established an expert working group and have appointed a clinical trials specialist who will provide mentorship to the investigator-led clinical trials sector. Find out more about this work on page 24.

- This year we also continued to develop our **rapid trial approval model, SKYHOOK,** to enable better patient access to clinical trials for rare diseases. This saw the development of a Rapid Trial Approval Model Checklist which is featured on page 22.

- Recruitment targets and timelines are often not met by clinical trial sites in Australia, which can cause lengthy research delays, and can impact the validity of trials. Although there are currently many different innovative technologies available to improve recruitment efficiency, there is a need to better implement these technologies into the organisational structure of healthcare systems by addressing systemic issues that may be barriers for successful implementation and utilisation. During the year we launched a number of activities focused on **exploring technologies to improve recruitment.** These activities included:

  - A workshop with panel discussions on ‘Technology implementation and utilisation’ and ‘Evaluating technologies and looking forward’
  - An environmental scan including engagement with 22 technology providers to seek information on their technologies’ capabilities and evidence which they could provide to support their key capabilities
  - Preparation of a short communication manuscript based on the scan findings. This manuscript is being submitted for publication.

PROJECT SPOTLIGHT:
SKYHOOK – A national model for rapid trial approval processes

Rare diseases are an area of medicine where more research is desperately needed.

By virtue of being rare, there are often limited therapeutic options available for patients. In addition, the low number of patients with these rare conditions, along with natural geographic diversity, can potentially result in delayed diagnosis due to less awareness of these diseases.

The current situation

Opening a clinical trial takes a substantial amount of time and resources. If a site can only recruit minimal patient numbers, the costs associated with opening the trial greatly outweigh any perceived net benefit.

This is especially true for trials involving patients with rare diseases, since many sites are only activated by the trial sponsor if they have a strong chance of identifying a suitable potential participant. Many sites may be selected to take part in the trial, but since the disease is rare, may never actually recruit a patient. Paradoxically, unless the patient presents at a site with a suitable study, they may need to travel long distances to access a relevant trial at another site – and in turn, often these patients don't have ready access to clinical trials.

Unfortunately, the alternative option of opening a study locally, that is already open at a site elsewhere in Australia, when the patient presents is next to impossible to achieve in a timeframe that would work based on current ethics and governance processes.

The problem

The current clinical trial governance system makes conducting trials for rare diseases difficult and is creating greater disparities in equitable outcomes for patients with rare diseases.

A potential solution

We propose the development of a policy framework to streamline clinical trial approval processes to facilitate rapid and expanded access to clinical trials to address the limitations of the current systems for people with rare health conditions.

Our SKYHOOK model is a policy initiative that we believe could result in the implementation of a national model for rapid trial approval processes. It aims to address the longstanding delays in trial ethics and governance processes that make trials for rare conditions so challenging.

SKYHOOK may also improve the capacity for clinicians to open trials of rare diseases, and provide increased opportunities for patients with rare diseases to participate in clinical trials, whilst also increasing the number of clinical trials for rare diseases that can be effectively considered 'open' nationally.

In 2022/23, ACTA's Early Trial Approval Working Group developed a Rapid Trial Approval Model Checklist which aims to expedite trial approvals at trial sites through a site-based checklist.

What's next?

The Rapid Trial Approval Model Checklist and the SKYHOOK model will progress to a pilot site where a suitable candidate trial has been identified and there is also potential to expand to a collaboration between other sites. This pilot aims to showcase how trials can be more rapidly initiated through the existing regulatory/legislative environments.

Consecutively we will continue to work closely with the Department of Health and the Australian Commission on Safety and Quality in Healthcare, and specifically monitor any new site approval processes that may be encapsulated in the development of the National One Stop Shop.

ACTA sincerely acknowledges the active support and engagement from all members of the Rapid Trial Approval Working Group/Consortium.

WORKSTREAM 5:
FACILITATE INDUSTRY FUNDED/SPONSORED TRIALS

Workstream purpose

Improve efficiency and effectiveness of clinical trials, improve synergies and partnerships with industry, and overcome barriers to participation in clinical trials.

What will be the impact of this work?

- Improved efficiency and effectiveness of clinical trials
- Improved synergies and partnerships between networks and industry
- Reduced barriers to participation in clinical trials.

Our 2022/23 highlights

- **Environmental Scan: Current environment for industry and academic trial collaboration**

  Following our 2021/22 Industry roundtable event, during the reporting period we used the event outcomes to help inform an environmental scan on 'Exploring greater partnership between CTNs, CQRs and CCs with Industry'.

  The landscape for clinical trials has shifted dramatically over the years and it is recognised that this has been driven by the parallel increase in the industry/commercial sector, and growth of the investigator-initiated sector.

  During the roundtable event there was agreement among participants that greater alignment could lead to benefits for the sector as a whole, and whole. As such, the objective of this scan was to: 'Review existing approaches to building synergies and partnerships between investigator-led and industry clinical trials sectors, and explore ways to improve partnerships and advance activities of mutual interest'.

  The outcome is not a systematic review of literature, but is instead a report on published and 'grey' literature. This report provides contextual information that can be used to inform future activities and build greater collaboration across the sector.

  We acknowledge that the proposed Australian National One Stop Shop (NOSS) could significantly support a national approach to bringing industry and academia together through a single point of contact. In the coming year, we will use the insights from the environmental scan and the roundtable event to inform our advocacy efforts, including working with governments and stakeholders on the anticipated implementation of NOSS.

- **Increased awareness of CTN and CC capabilities**

  This year we have directly engaged with industry peak agencies, and biotechnology and pharmaceutical organisations to promote our member CTNs and CCs to industry, with a view to increased collaboration between industry and academic sectors.

PROJECT COLLABORATION:
Improving access to clinical trials through the Australian Teletrial Program (ATP)

Australian Teletrial Program
Access to clinical trials, closer to home

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 teleheath models of care (see diagram below)
- Identify the critical needs, enablers and barriers to implementation, to increase uptake of the Australasian Teletrial Model.

What will be the impact of this work?

- Increased Teletrial implementation in network-led investigator-initiated clinical trials
- Faster recruitment to trials and the generation of healthcare evidence
- Reduced barriers to participation in clinical trials
- Increased access to clinical trials for rural, regional and remote populations.

According to the Australian Institute of Health and Welfare, at 30 June 2021, 28% of the Australian population resided in rural and remote areas. Data also indicated that these seven million people 'have higher rates of hospitalisations, deaths, injury and also have poorer access to, and use of, primary health care services, than people living in major cities'.[1]

Aligned with our commitment to improving the accessibility of clinical trials for Australians, this year ACTA was pleased to launch a partnership with ATP.

The ATP aims to improve access to, and participation in, clinical trials for rural, regional and remote Australians.

Concluding in 2025, the initial phase of ACTA's project has included three key deliverables:

1. Establishing a Teletrials Project Working Group to provide professional and lived experiences to support and guide the project
2. Recruiting a clinical trials specialist to lead and champion the project
3. Conducting a survey with CTNs and CCs to ascertain a baseline understanding of the Teletrial model and to define likely barriers and enablers for teletrial implementation.

AUSTRALASIAN TELETRIAL MODEL

PRIMARY SITE

- Specialists
- Clinical trial coordinators
- Specialist pharmacy, nursing and allied health clinicians
- Administration support officers

TELEHEALTH

Patients are consented, recruited and managed at satellite sites in partnership between clinicians from satellite and primary sites

SATELLITE SITE

- Patients and families
- Medical officers
- Nursing, pharmacy and allied health clinicians
- With/without trial coordinators

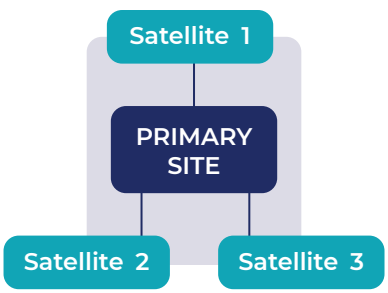
(Larger centres may have specialist doctors, nurses, pharmacies and allied health clinicians)

Ref: Sabesan and Zalcberg, EJCC, 2016

TRIAL CLUSTER

Primary and satellite sites are connected through telehealth models of care.

(Satellite sites can be regional, rural or larger metropolitan centres)



[1]Ref: *https://www.aihw.gov.au/reports/rural-remote-australians/rural-and-remote-health accessed 15/11/23*

PROJECT SPOTLIGHT:
HeSANDA stakeholder engagement

Project purpose

Develop a framework and gather expert advice about stakeholder needs and engagement opportunities for the Health Studies Australian National Data Asset (HeSANDA) program.

Project objectives

- Identify opportunities to promote HeSANDA's purpose, point of difference and benefits with key stakeholders
- Identify where guidance and resources are needed to ensure effective use of the HeSANDA system
- Identify opportunities for HeSANDA to partner with other agencies and organisations to educate and increase awareness of existing policies and guidelines governing issues of consent, ethics and governance associated with secondary use of data.

What will be the impact of this work?

- Increased awareness of the HeSANDA program among key stakeholders
- Stakeholder engagement will be comprehensive and coordinated
- Informed and enhanced implementation of the HeSANDA program.

The sharing and reuse of health data is not currently standard practice in Australia. However, the HeSANDA program, a major initiative led by the Australian Research Data Commons (ARDC), aims to build national infrastructure to facilitate secondary use of data from investigator-initiated clinical trials for new research and research translation.

In 2020/21, ACTA was engaged by the ARDC to consult with the research community to understand their priorities and concerns regarding the secondary use of data from investigator-initiated trials. Insights from this work informed a set of guiding principles which were used by ARDC to refine the design of HeSANDA.

The ARDC now have work underway, through a series of interconnected projects, to develop the infrastructure, operational model and governance arrangements for HeSANDA, with the program launch planned for late 2023.

During 2022/23, we were pleased to again be engaged by the ARDC, to develop a framework and gather expert advice about stakeholder needs and engagement opportunities for the program's implementation.

The HeSANDA Outreach and Engagement Plan—which outlines the breadth of stakeholders, their unique needs, and suggested opportunities for engagement—was a key deliverable for this project.

This was supported by the development of the HeSANDA Best Practice Report which describes the resources and materials needed to effectively implement the Outreach and Engagement Plan.

The outputs from this activity will now be used alongside information from the ARDC's consecutive projects to prioritise further resources and activities, and agree how these will be delivered across the sector as HeSANDA approaches launch.

We look forward to ACTA's continued engagement with this important program and commend the ARDC for their consultative and comprehensive efforts.

OUR IMPACT

As the peak body for the investigator-initiated trial sector, ACTA are proud to represent our members and the broader trials sector by facilitating and coordinating opportunities for connection, advocacy, promotion, and partnership.

A VOICE FOR THE SECTOR

We had representation on sector committees, including:

- Australian Research Data Commons (ARDC) Advisory Committee for Health Studies Australian National Data Asset
- ANZCTR Advisory Council
- Clinical Trials Collaborative Forum (ACTA representation, co-chaired by ACTA Chair, Prof Steve Webb
- Clinical Trials Governance Framework Steering Committee (led by the Australian Commission on Safety and Quality in Health Care)
- Inaugural Isolated Patients Travel and Accommodation Scheme (IPTAAS) Stakeholder Consultative Forum under NSW Regional Health Division
- Victorian Clinical Trials Action Plan Steering Committee
- Victorian Teletrials Collaborative.

We responded to sector consultations, including:

- 2022 TGA consultation on proposed regulatory changes for clinical trials of medical devices
- 2022 WHO consultation on International Clinical Trials Registry Platform guidance for reporting summary results in clinical trial registries
- 2022 Million Minds Mental Health Research Mission consultation led by the Department of Health and Aged Care
- 2023/24 Federal Pre-Budget led by The Treasury
- 2023 Healthcare Identifiers Framework Project Consultation led by the Department of Health and Aged Care
- 2023 Revised National Clinical Quality Registries Framework consultation led by the Australian Commission on Safety and Quality in Health Care.

Opportunities for collaboration and engagement

In 2022/23 we provided our members with opportunities for collaboration and engagement with each other and the broader sector through the following activities:

- 2022 ACTA Annual Scientific Meeting
- 2022 Australian Registries Annual Scientific Meeting
- Twice-yearly ACTA Advisory Council meetings
- Monthly newsletter, social media presence, member email updates and website updates
- One-on-one meetings with members
- Representation and presentation at national conferences including: AusBiotech Conference 2022, the inaugural Australasian Nursing and Midwifery Clinical Trial Network (ANMCTN) Summit, Mental Health Australia General Clinical Trial Network (MAGNET) Annual Scientific Meeting and ANZMUSC Annual Scientific Meeting.

International promotion of the Australian clinical trials sector

During the year, we met with international delegations from CRIS Singapore and KoNECT from South Korea, to share Australian/international clinical trial and sector insights, and discuss opportunities for collaboration.

In November 2022, ACTA also participated in an Australian Trade and Investment Commission (Austrade) biotechnology-initiated delegation to South Korea, at the request of CSIRO.

PROJECT SPOTLIGHT:
The value of investigator-initiated trials

In May 2023, ACTA convened a multi-sectoral workshop to revisit and seek comments on the health outcomes and economic value of investigator-initiated trials (IITs) in Australia.

IITs are an important component of the clinical research activity undertaken in the Australian health system. The benefits that IITs return focus around the quality and cost effectiveness of clinical care. While this has been long understood and recognised by clinicians, and identified by academic research, it remains an aspect of research that struggles for funding and policy recognition.

About the workshop

The workshop format involved brief explanatory papers followed by comment and feedback triggered by questions on the papers. The session was moderated, and participants covered key health sector components, from Government health policy representation, academic policy leaders, consumer advocates, state health service leaders, representatives of clinical trial coordination entities, as well as members of ACTA leadership. This breadth of participation meant that a cross section of voices were heard.

Part 1 – Value proposition

IITs are a loosely defined category of research embracing a range of applied research activities spreading from patient quality research through to large, randomised trials. The category covers: trials designed to validate or test quality of care; its optimal service mix; the functional value of or clinical order of interventions; the quality of care known treatments over time; and treatment innovations. Indeed, one of the complications in assigning value and identifying the beneficiaries of this value is that while patients are the primary beneficiaries, the entity capable of garnering the benefits, and who should pay for the research, is less simply defined.

While the potential benefits arising from trials was not questioned, participants did identify significant qualifications on the benefits being as obvious at a policy or health service level.

The interesting overall theme that emerged from Part 1 of the Workshop was that **“each part of the health system has its own notion of what it values”.**

As such, it is not obvious that the value of clinical trials as seen by trialists has the same priority value from the perspective of Health Departments, hospital CEOs, or other funding entities. This different filter on “value” highlights that entities such as ACTA must frame value, or structure its measurements of success, in a way that makes sense to all stakeholders in the health system.

Part 2 – System models and the size of the value pie

Part 2 of the workshop transitioned from the concept of value into the measurement of potential value that is able to be garnered for the health system.

In the face of evidence of a strong benefit to cost ratio for IITs, and with access to clearer awareness of the need to identify meaningful value measurement and options for value capture, the foundations could be laid for a more integrated clinical trials strategy.

The conclusions of Part 2 of the workshop moved towards bridging the current model into something with better integration.

ACTA understands that it has a role to assist in the leadership of this strategy, and to be successful it will continue to maximise opportunities to partner with key stakeholder entities including, funders, health services, and health policy managers.

Thank you to all participants in the Value of Clinical Trials Workshop for your invaluable insights and contributions.

OUR 2022 ANNUAL SCIENTIFIC MEETINGS

Over 300 delegates joined us on 7-8 November 2022 for the ACTA Annual Scientific Meeting (ASM) and the inaugural Australian Registry ASM which were held at the South Australian Health and Medical Research Institute (SAHMRI).

Under the event themes—*'Implementing Evidence into Practice: how do we plan, engage and act to ensure our trials have the greatest impact and change practice'* and *'The Value of Registries in Challenging Times'*—these events provided a great opportunity to highlight, celebrate and discuss key topics across the full clinical research spectrum.

Across the two days, delegates enjoyed an extensive program including clinical research and registry development keynote presentations, plenary sessions, panel discussions, workshops, and networking events.

During these events we were fortunate to be joined by some of the most innovative and influential minds in healthcare delivery, clinical research and registry development. They represented clinician-researchers, healthcare administrators and health policy experts, along with senior representatives from the Commonwealth and jurisdictions, industry, consumer advocates, allied healthcare professionals and students.

We sincerely thank the ACTA ASM Convenors Prof Rachelle Buchbinder and Prof Andrew Davidson, the Australian Registry ASM Convenors Prof Susannah Ahern and Prof Stephen McDonald, the ASM Organising Committees, all presenters, facilitators, and delegates.

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

ACTA ASM:

- AstraZeneca
- Spiral Software
- South Australian Health and Medical Research Institute (SAHMRI)
- ARCS Australia
- PRAXIS.

Australian Registry ASM:

- Australian Government, Department of Health and Aged Care
- SAHMRI.

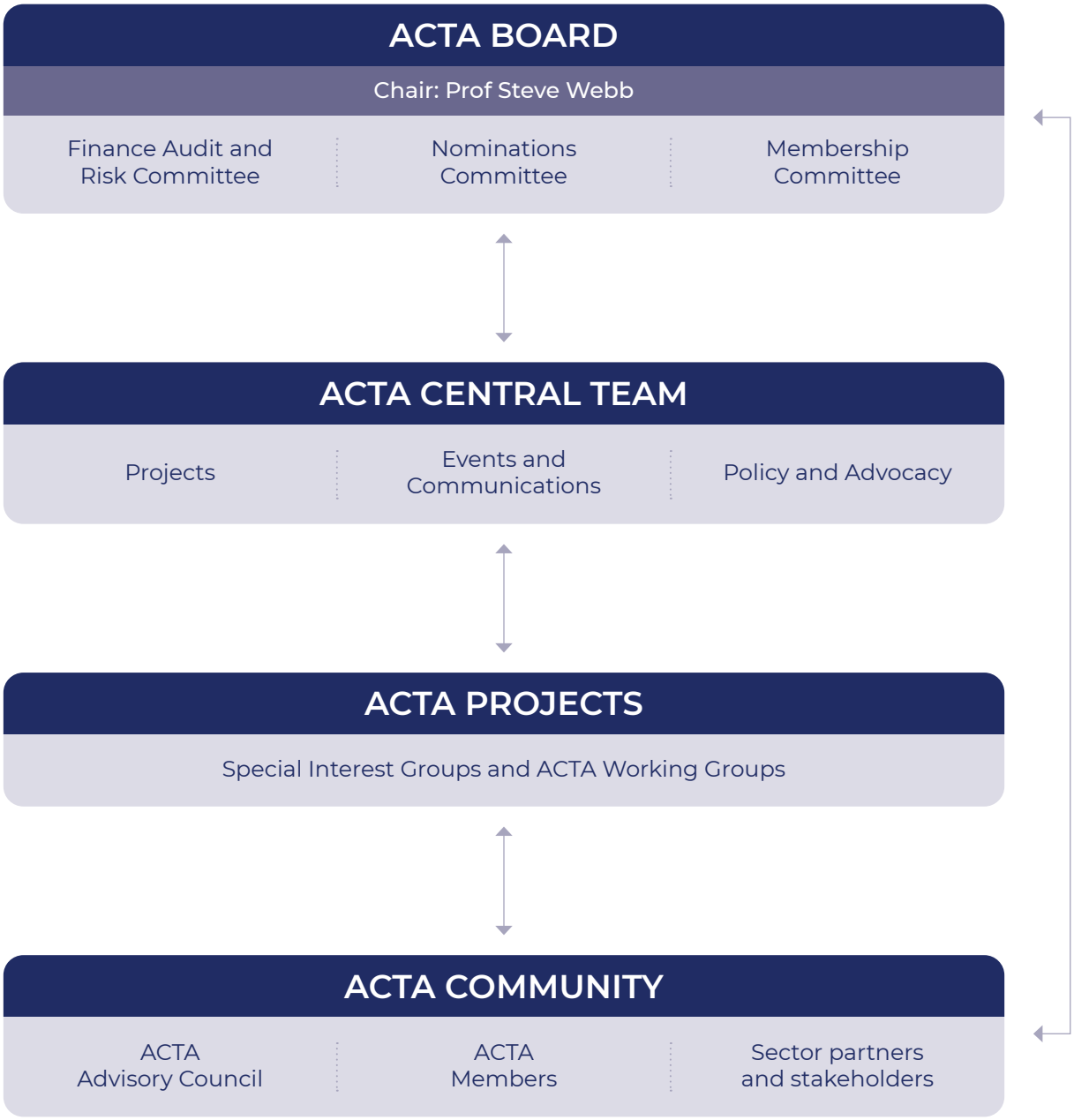
REFLECTIONS FROM OUR DELEGATES

- *"As a relatively new consumer representative I found the conference very insightful in terms of gaining a better understanding of the clinical trial environment and the opportunities for consumers to have more of a voice when it comes to research."*
- *"Obtained some really innovative ideas and was able to see what others are doing in the registry space."*
- *"Implementation science is very new to me and I appreciated the opportunity to understand how different it is from the clinical trials I know. The speakers at both the workshops I attended were very knowledgeable and open to sharing ideas and resources."*
- *"Very useful to see/hear what other registries are doing and how not to reinvent the wheel."*
- *"Practical activities in the research translation workshop were very useful."*

OUR OPERATIONS

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

OUR TEAM


ACTA BOARD
Chair: Prof Steve Webb
Finance Audit and Risk Committee
Nominations Committee
Membership Committee
ACTA CENTRAL TEAM
Projects
Events and Communications
Policy and Advocacy
ACTA PROJECTS
Special Interest Groups and ACTA Working Groups
ACTA COMMUNITY
ACTA Advisory Council
ACTA Members
Sector partners and stakeholders

OUR BOARD

ACTA is governed by a Board of Directors

CHAIR

PROF STEVE WEBB

MBBS MPH PHD FCICM FRACP FAHMS

Elected Director

Prof Steve Webb is a Specialist in Intensive Care Medicine at St John of God Hospital Subiaco and the Mount Hospital, Group Director of Research at St John of God Health Care, and a Professor of Critical Care Research at Monash University. He is a past-Chair of the ANZICS Clinical Trials Group and a member of the Executive of the International Severe Acute Respiratory Illness Consortium. He is a founding Fellow and former member of Council of the Australian Academy of Health and Medical Sciences, and a former member of the National Health and Medical Research Council Health Translation Advisory Committee.

DEPUTY CHAIR (FROM FEB 2023)

PROF CHRIS REID

BA DipEd MSc PhD

Elected Director

Prof Chris Reid is a cardiovascular epidemiologist and clinical trialist with appointments as Research Professor in both the School of Population Health at Curtin University and the School of Public Health and Preventive Medicine, Monash University. He was re-appointed as a John Curtin Distinguished Professor in 2021 and is currently Director of the Monash and Curtin Centre's of Cardiovascular Research and Education (CCRE). His research interests focus on cardiovascular outcome trials and registries and serves on the Executive of the Australia and New Zealand Alliance for Cardiovascular Trials (ANZACT) Network and is a Board Member of the Australian Cardiovascular Alliance (AcvA).

PROF MEG JARDINE

MBBS PHD FRACP

Elected Director

Prof Meg Jardine is the Director of the NHMRC Clinical Trials Centre, the University of Sydney and Lead of the Kidney Health Research Program. Prof Jardine is a member of the Executive Committees of both the International Society of Nephrology (ISN) and the Kidney Disease Improving Global Outcomes (KDIGO) international nephrology guidelines body. She is Chair of the International Society of Nephrology Advancing Clinical Trials (ISN-ACTS) initiative. She serves as a Board Member of the Kidney Health Initiative, a public-private collaboration of the American Society of Nephrology and the United States Food and Drug Administration (US FDA). She is a member of the ANZSN (Australia and New Zealand Society of Nephrology) Research Advisory Committee.

MS MARGO JUNE MACGILLIVRAY

LLB (Hons) BA LLM GAICD

Independent Director – Retired Dec 2022

Ms Margo MacGillivray has more than 25 years' experience as a commercial lawyer and corporate executive. Her track record includes Chief Legal Officer positions across a range of industries, a partnership in a leading international law firm and non-executive directorships in the health and medical research sectors. She is currently a Governance Advisor with the Commonwealth Bank of Australia and a board member of the Prince Charles Hospital Foundation.

MS ANNE MCKENZIE AM

Independent Director

Since 2004, Ms Anne McKenzie has worked as a consumer advocate and manager of Consumer and Community Involvement Programs in universities and research organisations. Most recently, she was the Senior Manager of Community Engagement at Telethon Kids Institute in Western Australia. Ms McKenzie holds honorary positions at both Telethon Kids Institute and UWA.

Ms McKenzie currently serves as a senior consumer representative on key national and state health committees. She is a former Chair and an Honorary Life Member of the Health Consumers Council WA and in 2021 Ms McKenzie received the NHMRC's Biennial Award for Consumer Engagement.

PROF RACHAEL MORTON

MSCMED (CLIN EPI)(Hons) PHD

Elected Director

Prof Rachael Morton is Director of Health Economics and Health Technology Assessment (HTA) at the NHMRC Clinical Trials Centre, and Professor and Principal Research Fellow in the Faculty of Medicine and Health at the University of Sydney. Prof Morton is the President of the Health Services Research Association of Australia and New Zealand, and she oversees a HTA evaluation team for the Australian Government's Medical Services Advisory Committee (MSAC) and Singapore's Agency for Care Effectiveness. Prof Morton is the inaugural Chair of the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) PROMs working group; and founding Executive Board Member of the Melanoma Clinical Outcomes Registry (MelCOR).

MR KIERAN SCHNEEMANN

Independent Director

Mr Schneemann is a highly respected government affairs practitioner with more than 30 years' experience in Canberra. Mr Schneemann has worked for global companies, Australian institutions, and all levels of government, including in federal ministerial offices and parliamentary committees. He has significant experience working with government and Industry and importantly, understands the differences between how government, business and the not-for-profit sectors operate. At present, Mr Schneemann is working part-time as Special Counsel to AstraZeneca. Mr Schneemann is currently a Director on the Board of CanTeen Australia.

MS ANITA VAN DER MEER

MSc MAICD

Independent Director

Ms Anita van der Meer is Chief Innovation Officer at the Ingham Institute for Applied Medical Research, where she is responsible for the Institute's commercialization portfolio, the Centre for Robotics, Medical Devices and Health Technologies, and the Clinical Trials Unit. She is also Principal of Innoveren Pty Ltd, a boutique innovation consultancy, and Resident Director at Acclime Australia. Ms van der Meer is a respected clinical development professional and advocate for the health and medical research sector. Ms van der Meer is also a board member of ARCS Australia Ltd.

MS LEONIE WILCOX

BSC RN

Elected Director – Retired Nov 2022

Ms Leonie Wilcox worked as a registered nurse in midwifery and operating theatres, before earning a degree in Statistics from Macquarie University. She has since worked in clinical trial and research positions in hospitals and universities, and has taught in undergraduate statistics programs at Macquarie University and University of NSW. Since 2006, Ms Wilcox has been the manager of the Australasian Bone Marrow Transplant Recipient Registry. Ms Wilcox has been a member of the Board of Directors of the Arrow Bone Marrow Transplant Foundation since 2007.

MR IAN WILSON

FCPA ACIS AGIA MAICD

Independent Director

Mr Ian Wilson is an experienced Director having held senior finance and corporate governance positions with an early career in the commercial sector and then over 20 years' experience in the not-for-profit sector. Whilst his strength in corporate governance and risk management, he brings a commercial view to not-for-profits, always looking for additional income streams while protecting and growing existing revenue streams.

PROF JOHN ZALCBERG AO

MBBS PHD FRACP FRACMA FAHMS FAICD

Elected Director

Prof John Zalcberg is Head of the Cancer Research Program in the School of Public Health and Preventive Medicine at Monash University, providing academic leadership to a number of clinical quality registries. Prof Zalcberg holds the inaugural Tony Charlton Chair in Cancer Research at the Alfred Hospital and Monash University. A co-founder of the Australasian Gastrointestinal Trials Group (AGITG), he was the prior Chair of the Board of AGITG, a Co-Chair of the Cancer Drugs Alliance, past-President of the Clinical Oncological Society of Australia (COSA), and a previous board member of Cancer Trials Australia, the Cancer Institute of New South Wales, and the Australian Red Cross Blood Service. He is a current Board member of PRAXIS and the ICON Group.

PROF SOPHIA ZOUNGAS

MBBS(Hon) FRACP PhD

Elected Director

Prof Sophia Zoungas is Head of the School of Public Health and Preventive Medicine (SPHPM) at Monash University and Director of the recently established Monash University Clinical Trials Centre. Prof Zoungas established the Australian National Diabetes Audit in 2013 (which gave rise to the Australian Diabetes Clinical Quality Registry in 2022) and oversees the Monash Clinical Registries Unit at SPHPM which coordinates 43 clinical registries operating across Australia, New Zealand and internationally. She has also served on numerous scientific advisory boards, editorial boards, steering committees and data safety monitoring boards, and is regularly called upon to advise governments on research, practice and regulatory issues in diabetes care.

OUR THANKS

Standing committee members

FINANCE AUDIT AND RISK COMMITTEE

Prof Chris Reid (Interim Chair)

Mr Kieran Schneemann

Mr Ian Wilson

Prof John Zalcberg AO

(Dr Stewart Hay: participant with standing invitation)

MEMBERSHIP COMMITTEE

Prof Steve Webb (Chair)

Prof Belinda Gabbe

Prof John Simes

Prof Sophia Zoungas

(Dr Stewart Hay: participant with standing invitation)

NOMINATIONS COMMITTEE

Prof Chris Reid (Chair)

Mr Kieran Schneemann

Prof Steve Webb

Prof Sophia Zoungas

(Dr Stewart Hay: participant with standing invitation)

PROGRAM ADVISORY COMMITTEE (TO DEC 2022)

Prof Steve Webb (Chair)

Ms Sabine Braat

Prof Alan Cass

Prof Geoffrey Donnan

Ms Julia Fallon-Ferguson

Ms Kate Fuller

Prof Katie Groom

A/Prof Ross Haslam

Prof Carmel Hawley

Prof Tony Keech

Ms Margo MacGillivray

Prof Stephen McDonald

Ms Anne McKenzie AM

Prof John McNeil

Prof Rachael Morton

Prof Paul Myles

Mr Ian Pieper

Prof Chris Reid

Dr Megan Sanders

Mr Kieran Schneemann

Prof John Simes

Prof Judith Trotman

Ms Leonie Wilcox (to Nov 2022)

Mr Ian Wilson

Prof John Zalcberg AO

Prof Nik Zeps

Special Interest Group leadership

ADAPTIVE PLATFORM TRIALS OPERATIONS SPECIAL INTEREST GROUP (APTO SIG)

Ms Jocelyn Mora

Mr Arlen Wilcox

CLINICAL QUALITY REGISTRIES SPECIAL INTEREST GROUP (CQR SIG)

Prof Susannah Ahern

Prof Stephen McDonald

COORDINATING CENTRES SPECIAL INTEREST GROUP (CC SIG)

Prof Bruce Neal

Ms Delaine Smith

HEALTH ECONOMICS ALONGSIDE TRIALS SPECIAL INTEREST GROUP (HEAT SIG)

Prof Rachael Morton

A/Prof Richard Norman

SPECIAL INTEREST GROUP FOR NETWORK MANAGERS (SIGNet)

Dr Megan Sanders (Chair)

Ms Jo Fitzsimons (Deputy Chair)

STATISTICS IN TRIALS INTEREST GROUP (STInG)

Prof Katherine Lee

Prof Andrew Forbes

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

TELETRIALS WORKING GROUP

Dr Stewart Hay

Event conveners

2022 ACTA ANNUAL SCIENTIFIC MEETING

Prof Rachelle Buchbinder

Prof Andrew Davidson

2022 AUSTRALIAN REGISTRY ANNUAL SCIENTIFIC MEETING

Prof Susannah Ahern

Prof Stephen McDonald

Event sponsors

2022 ACTA ANNUAL SCIENTIFIC MEETING

- Bellberry Limited
- MTP Connect – Adelaide Intermediary Program in partnership with Adelaide BioMed City (ABMC) and Government of South Australia
- AstraZeneca
- Spiral Software
- South Australian Health and Medical Research Institute (SAHMRI)
- ARCS Australia
- PRAXIS

2022 AUSTRALIAN REGISTRY ANNUAL SCIENTIFIC MEETING

- Australian Government, Department of Health and Aged Care
- South Australian Health and Medical Research Institute (SAHMRI)

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 400 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 surplus or deficit and other comprehensive income for the year ended 30 June 2023

	2023 $	2022 $
TRADING INCOME		
Event sponsorship and registrations	138,338	84,457
Membership fees	109,999	102,930
Project revenue	-	85,000
Revenue from grants	1,474,204	1,219,212
Other income	26,871	1,889
Total trading income	**1,749,412**	**1,493,488**
Gross profit	**1,749,412**	**1,493,488**
OPERATING EXPENSES		
Audit and legal	15,677	8,328
Consultancy expenses	240,429	346,915
Depreciation and amortisation expenses	75,946	55,943
Employee benefit expenses	1,022,789	917,365
Event and meeting expenses	86,258	45,070
Insurance	33,836	28,294
Travel expenses	70,796	17,884
Operating expenses	141,460	91,583
Total operating expenses	**1,687,192**	**1,511,382**
Net profit	**62,220**	**(17,894)**

Statement of financial position as at 30 June 2023

Total assets	2,290,033	2,024,003
Total liabilities	1,365,795	1,161,985
Net assets	**924,238**	**862,018**

Membership fees

Australian Clinical Trials Alliance

Australian Clinical Trials Alliance

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

T +61 3 8639 0770 ✦ **E** acta@acta.au

clinicaltrialsalliance.org.au