Australian Clinical Trials Alliance

2021
2022

ANNUAL REPORT

Better health through best evidence

Acknowledgements

ACTA is grateful to receive grant funding from the Australian Government. This work is supported by the Medical Research Future Fund under grant number MRFTA000001.

We sincerely thank our members and the community for their valuable interactions, insights, inputs and support.

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

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MESSAGE FROM OUR BOARD CHAIR

Prof Steve Webb
MBBS MPH PHD FCICM
FRACP FAHMS

There is no doubt that clinical research and trials remain both a priority and necessity on a global scale, and while the number of people conducting, and participating in research remains stable, there is substantial unmet need for new effective treatments as well as better evidence regarding the comparative effectiveness of existing treatment options. During the year, ACTA continued its role of supporting our 300 members (see pages 8 and 9) and partners who share our optimism for a strong, and stable sector. By working together, we find practical ways to increase collaborations, outcomes, and impact.

It is an interesting time to be involved in clinical trials as the effects of COVID-19 continue to reverberate across the sector. This year, the impacts of the pandemic have continued to effect how clinical research is undertaken, as well as the ongoing desire from consumers to be informed and involved in clinical trials. I believe this is the time for clinical trials to shine, and ACTA are proud to represent and support our members to ensure they are well positioned to capture the exciting opportunities in front of them.

This year proved to be a time of transition for ACTA. In November 2021, we completed our *'Strengthening the capacity, efficiency, and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance'* grant activity, while we simultaneously progressed our *Enhancing Clinical Trials Network Capabilities* grant activities. I am very proud of the solid foundation we have built through these grant activities, and I am enthused and optimistic for the many opportunities we have ahead of us.

We were pleased to again showcase and celebrate those working in the clinical trial sector on International Clinical Trials Day at our annual 2022 Clinical Trials: National Tribute and Awards Ceremony (see page 28), and it was also great to bring more than 400 people from across the sector together in our virtual Annual Scientific Meeting (see page 27). Events like these, as well as our targeted collaboration and education events and activities, help to build real connections and capabilities in the sector.

Thank you to my fellow Board Directors for your unwavering support and leadership this year. I also extend my deepest gratitude, and the thanks of our Board, to our outgoing CEO, Ms Simone Yendle, interim CEO Ms Victoria (Vika) Potarina, and new CEO, Dr Stewart Hay. Simone enthusiastically steered our *'Strengthening the capacity, efficiency, and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance'* grant activity from 2017 to 2021 and I am pleased to provide a summary of some of the achievements from this grant from page 16. I have enjoyed seeing Stewart capably take the reins on our 2020-2024 MRFF *Enhancing Clinical Trials Network Capabilities* grant delivery, and I have highlighted some of the achievements to date from page 20.

I sincerely thank our small, but mighty ACTA central team, as well as our 400+ volunteers who so generously help us to deliver our projects through their work in our advisory committees, working groups and special interest groups. I also gratefully acknowledge and thank the many organisations that we partner with across the sector including fellow trialists, industry, peak bodies and government.

ACTA ultimately exists for our members who, like us, want to make a positive impact for the Australian community. This report showcases some of the ways we have supported our members and worked across, and with, the broader sector during the last year. We acknowledge that any change is only possible with the support of consumers and carers who have been or are currently involved in clinical research. We do our work for, and with you, and we certainly hope that together we can create a better future for you and the wider community.

ABOUT US

The Australian Clinical Trials Alliance (ACTA) is the national peak body for investigator-led clinical trials and Clinical Quality Registries.

We are focused on:

- creating a system that generates and implements high-quality trial evidence
- embedding clinical trials and registries into standard healthcare delivery to make them more efficient and economical
- improving health outcomes for all Australians.

ACTA AT A GLANCE

10,000
CLINICAL RESEARCHERS

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

93
GROUP MEMBERS

In 2021/22, our 93 full members, associate members and affiliate members represented:

+ CTNs
+ CQRs
+ CCs
+ Research institutes
+ Universities
+ Hospitals
+ Professional colleges and societies
+ Regulatory and statutory bodies

207
INDIVIDUAL MEMBERS

In 2021/22, our 207 individual members included clinicians; allied health and nursing professionals; research or health admin/policy professionals; and consumers.

400
VOLUNTEERS

During 2021/22, over 400 volunteers provided invaluable input to our eight Reference Groups, six Project Working Groups (plus subgroups) and five Special Interest Groups.

35+
RESOURCES

Our projects have led to the development of a range of insightful and practical tools, guides, frameworks, consultation reports, environmental scans, discussion papers, and reviews which are available through the ACTA resource library.

30+
EVENTS

To date, we have convened more than 30 project-based events, workshops, webinars, education sessions, round tables, plus our annual flagship events our National Tribute and Awards Ceremony and our Annual Scientific Meeting. These events provided our members and sector colleagues with opportunities to connect and collaborate.

7
PUBLISHED PAPERS

Our projects have led to the publication of seven papers in peer-reviewed journals. This included four published in 2021/22 which are outlined on page 19.

OUR MEMBERS

Australian Clinical Trials Alliance

Alliance for Vascular Access Teaching and Research (AVATAR) Group

Australia and 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

Australian and New Zealand Intensive Care Society

Australian and New Zealand Urogenital & Prostate Cancer Trials Group

Australian Epilepsy Clinical Trials Network

Australian Orthopaedic Association National Joint Replacement Register

Australian Red Cross Lifeblood

Australasian Bone Marrow Transplant Recipient Registry

Australasian Leukemia and Lymphoma Group

Australasian Myeloma Research Consortium

Australasian Radiopharmaceutical Trials Network

Australasian Society for Infectious Diseases Clinical Research Network

Australasian Stroke Trials Network

Australasian College for Emergency Medicine Clinical Trials Group

Breast Cancer Trials

Centre for Eye Research Australia

Clinical Trials Network Australia New Zealand

Consumer and Community Involvement Program

Database Program

Datapharm Australia

GensisCare Site Research Organisation

Hunter Medical Research Institute

Icon Institute of Innovation and Research

JDRF Australia – Juvenile Diabetes Research Foundation

Melbourne Children's Trials Centre

MQ Health

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 – AGCMC)

PRAXIS

Primary Care Collaborative Cancer Clinical Trials Group, University of Melbourne

Pulmonary Fibrosis Australasian Clinical Trials Network

Regional Trials Network – VIC

School of Optometry and Vision Science

School of Public Health and Preventive Medicine, Monash University

St John of God Healthcare Inc

Sydney Local Health District

The George Institute for Global Health

Victorian Ambulance Cardiac Arrest Registry

Victorian State Trauma Registry (VSTR)

THE VALUE OF CTNS, CQRS AND CCS

ACTA believes that healthcare decisions should be supported by high quality evidence derived from clinical trials.

Clinical Trials Networks (CTNs), Clinical Quality Registries (CQRs) and Coordinating Centres (CCs) are playing a critical role in changing how evidence is generated and implemented, however there is even greater potential to truly embed these practices into the healthcare system and ACTA's activities are actively supporting this work. Figure 1 shows the cycle of interaction and collaboration for CTNS, CQRS and CCs in investigator-initiated trials (IITs), and how they play a part in elevating healthcare in Australia.

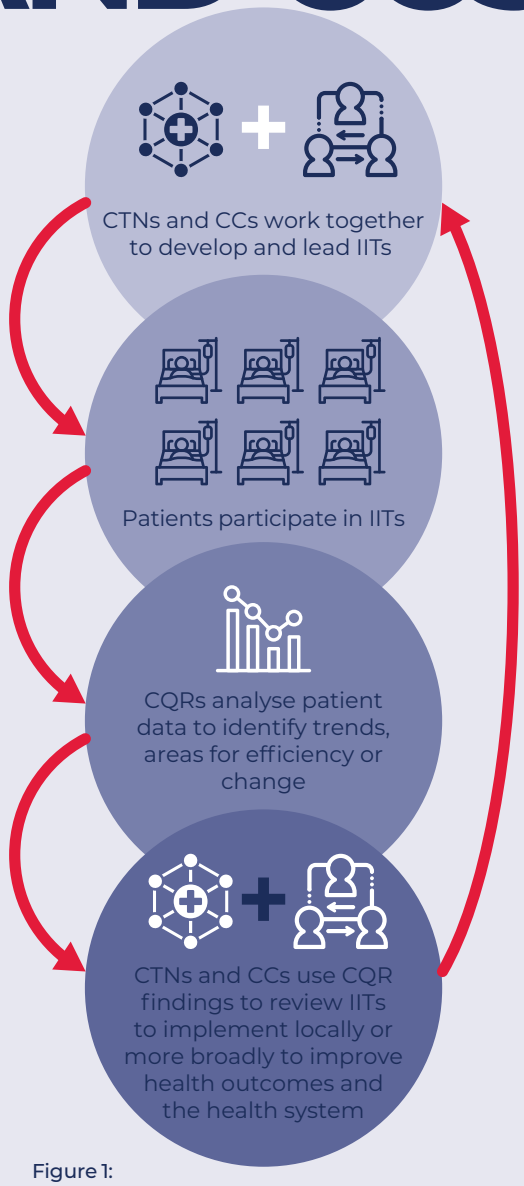


Figure 1:
CYCLE OF INTERACTION AND COLLABORATION FOR CTNS, CQRS AND CCS

CLINICAL TRIALS NETWORKS

Clinical Trials Networks (CTNs) are collaborative groups of practising clinical researchers. These networks bring together hundreds of doctors, nurses, allied health and research professionals working in acute or primary care settings to design and conduct trials that provide definitive evidence about which treatments work, which don't, and which are most cost-effective in the context of clinical practice.

Unlike academic health science centres or other geographically focused academic/health research partnerships, CTNs extend across state borders and into regional and rural Australia. This means:

- results are more likely to be broadly representative of real-world practice
- access for eligible patients is maximised
- increased training and mentoring opportunities for clinical trial sites and the workforce outside major metropolitan teaching hospitals.

It has been reported that Australia's CTNs have initiated more than 1000 clinical studies involving more than 1 million participants and representing at least $1 billion in research funding.[1]

The key benefit of CTNs is the facilitation of more rapid translation of trial results into practice because they have the engagement or buy-in of large and broadly distributed groups of practising clinicians.

CLINICAL QUALITY REGISTRIES

Led by research and health care professionals, Clinical Quality Registries (CQRs) measure and monitor the quality, appropriateness and effectiveness of healthcare by collecting, analysing and reporting on health information. This information is used to set benchmarks, identify trends and significant variations, determine alignment with guidelines and standards, as well as informing healthcare decisions. According to the Australian Commission on Safety and Quality in Health Care (ACSQHC) there are currently 96 CQRs in Australia.[2]

CQRs are mostly independent of the healthcare system and have an independent governance structure that guides data collection and usage. The work of registries provides:

- access to extensive and high-quality data
- improved transparency and sharing of data
- strong links across clinical communities
- a continuous cycle of learning.

The key benefit of CQRs is their great potential for research-driven healthcare improvements at a service and individual patient level. Examples of these improvements are highlighted in the National Clinical Quality Registry and Virtual Registry Strategy including a benefit equivalent to $600m in savings and another registry that realised a return on investment of $2 for every $1 invested.[3]

COORDINATING CENTRES

The role of Coordinating Centres (CCs) is to provide direct project management for trial conduct (regulatory compliance, site liaison and management, protocol development, recruitment, monitoring, data management, statistical analysis, etc). They offer critical expertise in trial methods, biostatistics, health economics, project coordination and data management.

Supporting the facilitation of CTNs, the key benefit of CCs is the central recruitment and monitoring of trial operations and patients leading to improved trial management and consolidated reporting efforts. CCs are often found within some of the 100+ clinical trial sites in Australia.[4]

1 *Reference: https://clinicaltrialsalliance.org.au/wp-content/uploads/2015/12/ACTA_Networks_Report_2004-14_online.pdf*

2 *Reference: https://www.safetyandquality.gov.au/publications-and-resources/australian-register-clinical-registries*

3 *Reference: https://www.health.gov.au/sites/default/files/documents/2021/02/national-clinical-quality-registry-and-virtual-registry-strategy-2020-2030.pdf*

4 *Australian Government. Trial Sites. [Internet]. Available from: https://www.australianclinicaltrials.gov.au/clinical-trial-sites*

OUR WORK

ACTA builds the capacity, capability, efficiency, and effectiveness of CTNs, CQRs and CCs.

We do this through industry engagement, cross-sector collaborations, committee involvement, input into policy, advocacy, resource development and dissemination, and professional development.

Our work is focused on:

- Increasing the number of CTNs across diseases and disciplines
- Removing participation barriers for consumers and improving recruitment equity
- Building on strategic partnerships with stakeholders, to address clinical priorities and facilitate effective sharing of experience, capacity, and resources between CTNs, CCs, CQRs, government, consumers, and industry
- Encouraging innovation, and the translation of research into healthcare.

THE EVOLUTION OF OUR WORK

WHERE WE STARTED

+ 2013-2016

Seed funding was provided by the Victorian Department of Health in 2013, with a second allocation of funding from the Victorian Department of Health and Human Services in 2016. We acknowledge the vision shown by Victoria in helping to establish ACTA as a national resource.

In 2015, the Western Australia Department of Health also announced seed funding to support ACTA's development in collaboration with Victoria as a matched contribution.

WHERE THAT LED US

2017-2021 +

In June 2017, ACTA was awarded funding through the Medical Research Future Fund (MRFF) to coordinate, connect, share, and ultimately improve the clinical trials sector in Australia.

We finalised our *'Strengthening the capacity, efficiency, and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance'* program in November 2021. This program supported coordinated programs of work and activities designed to increase capacity and capability to conduct clinical trials across all diseases and disciplines. Figure 2 highlights the key focus areas and three special interest groups for this grant activity.

The key activity focus areas were:

- Tools and criteria for research prioritisation
- Embedding clinical trials in healthcare
- Innovative trial design
- Impact and implementation of CTN trials
- Leadership and collaboration
- Efficient and effective CTNs
- Innovative outcomes data
- CTN expansion
- Strengthening consumer engagement

and three Special Interest Groups:

- ACTA Registries Special Interest Group
- ACTA Statistics in Trials Interest Group (STInG)
- ACTA Special Interest Group for Network Managers (SIGNet)

Figure 2:
SUMMARY OF ACTA'S MRFF 2017-2021 GRANT ACTIVITY

WHERE WE ARE HEADING

+ 2020-2024

In September 2020, ACTA was awarded an *MRFF 2020 Enhancing Clinical Trials Network Capabilities Grant*.

Through this grant, we are working on projects that will further consolidate and strengthen the clinical trial sector's capability and collaboration, with the aim of embedding evidence-based care into the health system and improving patient outcomes.

Figure 3 highlights the six workstreams that are guiding our projects and activities through this grant, which commenced in November 2020.

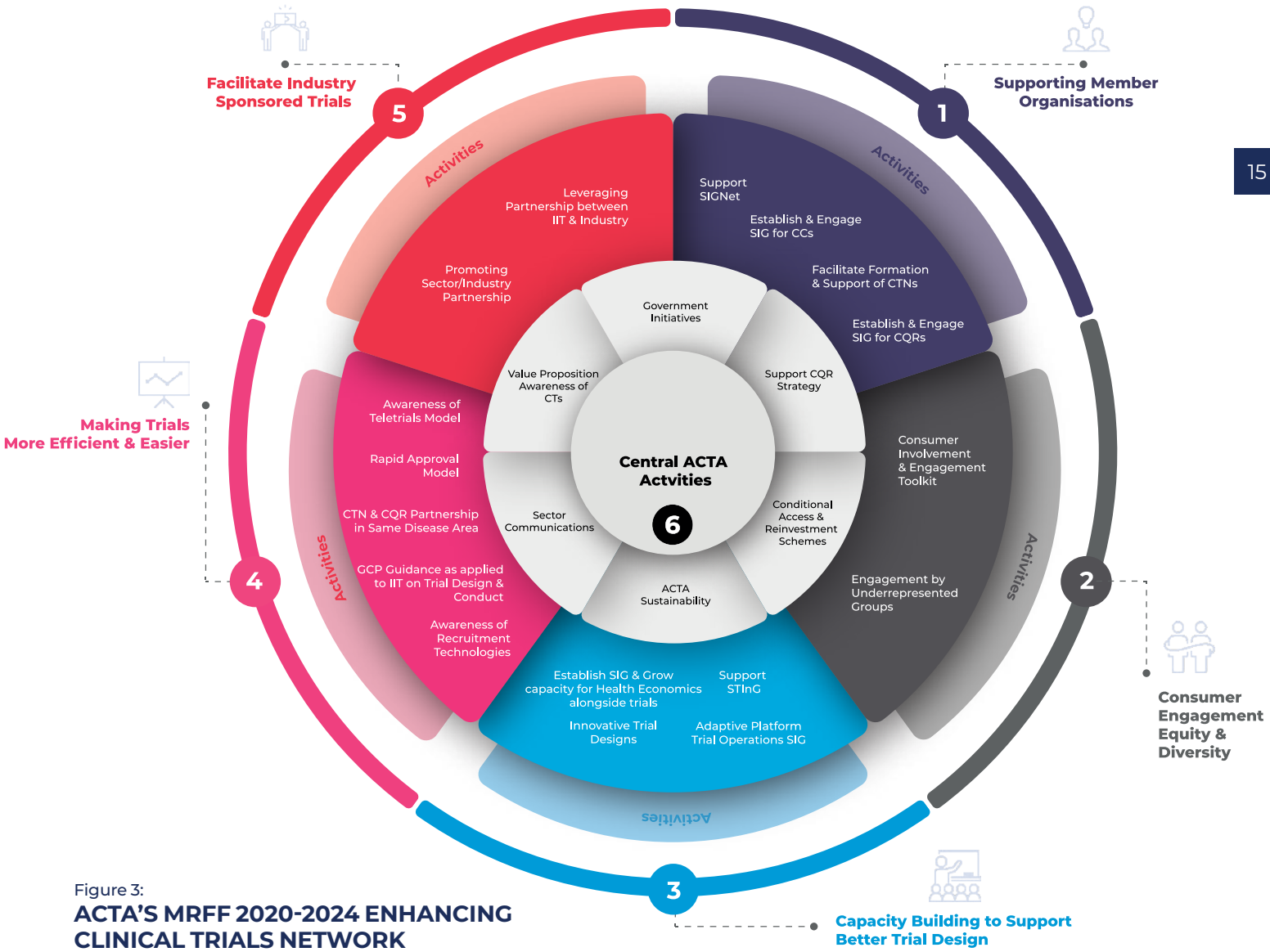


Figure 3:
ACTA'S MRFF 2020-2024 ENHANCING CLINICAL TRIALS NETWORK CAPABILITIES GRANT WORKSTREAMS

2017-2021

WHAT PROMPTED THIS WORK?

In 2017, ACTA and the Australian Commission on Safety and Quality in Health Care published a landmark report detailing a series of case studies used to evaluate the health and economic benefits of trials conducted by Clinical Trial Networks (CTNs).[5]

In this report, investigator-initiated clinical trials that were conducted by established CTNs demonstrated high value for money for funding bodies and the broader health system, with a conservative estimate of the overall consolidated benefit-to-cost ratio for trials conducted by CTNs showing a return of AUD$5.80 for every $1 invested.

A return of **AUD$5.80** for every **$1** invested

the benefit-to-cost ratio for trials conducted by CTNs

The significant findings of this work included the economic evaluation estimates of:

- an additional $1.4b toward better health outcomes for patients
- a $580m reduction in health service costs
- a $2b potential gross benefit to the Australian economy.

WHAT DID WE ACHIEVE?

We recognised that the economic benefits of CTNs could only be fully realised if our grant objectives of strengthening the capacity, efficiency and effectiveness of Networks was achieved. Over the grant period, we actively contributed to a more than a 50% increase in the number of CTNs formed or under establishment in Australia, from 33 in 2017 to 52 in 2021.

Through our work, we also helped to increase understanding of the pivotal work of Coordinating Centres (CCs) and Clinical Quality Registries (CQRs) in investigator-initiated trials.

WHAT HAS BEEN THE IMPACT OF THIS WORK?

- Clinical trials are better coordinated across Australia
- This coordinated approach means that more Australians will have gained access to clinical trials
- CTNs and their investigators have greater access to support, resources and mentoring
- Communities of practice have been established across the Australian research sector as well as links with international sector colleagues
- There has been improved collaboration across the sector through facilitated knowledge sharing
- ACTA cultivated thought leadership to drive contemporary models for research prioritisation and design.

5 *Reference: Australian Clinical Trials Alliance (ACTA), in association with Quantium Health Outcomes. Economic evaluation of investigator-initiated clinical trials conducted by networks [Internet]. NSW; 2017 [cited 2018 Aug 27]. Available from: http://www.clinicaltrialsalliance.org.au/about-acta/majorinitiative)*

OUR END-OF-GRANT ACHIEVEMENTS

- Assessing the impact of clinical trials: a scoping literature review – to identify research impact frameworks and measures as well as approaches and tools that can be used in the prospective (i.e. predictive) assessment of clinical trial impact.
- Implementability guidance document: after the trial – outlining practical considerations, this document can assist CTNs and individual trialists to identify whether clinical implementation of an intervention is appropriate based on the results of a particular trial.
- Applying a simplified consent approach for low-risk clinical trials – ACTA and a panel of experts, including researchers and consumers, shared their work on applying a simplified (integrated) consent approach in the context of low-risk clinical trials. They discussed the challenges of a one-size-fits-all approach to obtaining clinical trial consent, particularly for low-risk, pragmatic comparative effectiveness trials.
- A pilot study to prospectively estimate the health and economic return on research investment – it is essential to ensure that funded trials represent value for money. This study presents the results of a pilot study using the Value of Information (VOI) framework to prospectively estimate the (ROI) of clinical trials.
- Research prioritisation uncovered workshops – showcased key outcomes from the ACTA Research Prioritisation and the Impact and Implementation of Clinical Trial Networks Reference Groups. They supported clinicians, researchers, and funders interested in learning more about research prioritisation.
- Practical tools on fundraising, communications and marketing strategies for new and emerging CTNs.
- Access to 1000minds – to support the prioritisation and selection of research proposals, the ACTA community have access to a licence for 1000minds software, which provides free use of a Multi-Criteria Decision Analysis (MCDA) tool.
- Find a statistician database – search for other statisticians with experience in a particular area to be able to reach out to them for support and collaboration. The database is only accessible to statisticians who are members of ACTA STInG.
- Ongoing, individualised pragmatic advice, support, and workshop facilitation for new and emerging CTNs.

NSW HEALTH LEARN ABOUT CLINICAL RESEARCH PROJECT

Taking part in clinical research studies provides valuable knowledge to help people live healthier and better lives, now and in the future. But not many of us truly understand the study journey or what we need to consider before we take part in a clinical study.

In August 2021, ACTA, in partnership with NSW Health and CT:IQ, worked with consumers and researchers in NSW to develop educational resources including videos and digital brochures, to further enhance community understanding about the role, process, and value of clinical studies.

The learn about clinical research resources explore four themes often considered by participants prior to taking part in a clinical study, including:

- What is a clinical study?
- What is consent?
- Questions to ask about participating in a clinical study?
- What are the risks and benefits of taking part in a clinical study?

OUR SPECIAL INTEREST GROUPS

SPECIAL INTEREST GROUP FOR CLINICAL TRIAL NETWORK MANAGERS (SIGNet)

SIGNet was established to facilitate information sharing and provide support for the Executive Officers and Network Managers from Australian and New Zealand CTNs.

STATISTICS IN TRIALS INTEREST GROUP (STinG)

STInG was established to improve the quality of clinical trials within Australia by strengthening links among trial statisticians, and developing a structured support network for trial statisticians across Australia. Within this, centres provide specialist support for particular trial designs or clinical areas.

CLINICAL QUALITY REGISTRIES SPECIAL INTEREST GROUP (CQR SIG)

CQR SIG was established to provide a forum for registry representatives to share knowledge and expertise, discuss proposals and receive advice and advocate for the support of registries within Australia.

HOW DID THIS WORK HELP OUR MEMBERS?

The Australian Health Research Alliance of NHMRC Research Translation Centres National Women's Health Research, Translation and Impact Network (WHRTN) has applied the 1000minds software and support program to establish priority principles for women as consumers to be applied in research across the Alliance. The results here have guided our $5M research program with Prof Helena Teede as the lead investigator. Our grant program focuses on national policy priorities, and now aligns to research principles and priorities of consumers. A strong focus of the 1000minds results was the implementation of existing evidence and the generation of research directly applicable to healthcare to deliver tangible impacts on health outcomes. Prof Georgina Chambers and Leslie Arnottt (chair of the WHRTN consumer committee) led this work with our WHRTN research committee.

"
- *Clinical trials are better coordinated across Australia*
- *This coordinated approach means that more Australians will have gained access to clinical trials*
- *CTNs and their investigators have greater access to support, resources and mentoring*
- *Communities of practice have been established across the Australian research sector as well as links with international sector colleagues*
- *There has been improved collaboration across the sector through facilitated knowledge sharing*
- *ACTA cultivated thought leadership to drive contemporary models for research prioritisation and design."*

Anonymous ACTA member feedback received during project evaluation

"*[This work is] important and a good starting point to move in the right direction to overcome the barriers limiting the embedding of clinical trials in healthcare."*

"*The method adopted by ACTA to utilise templates and coordinating resources improved efficiencies for CTNs. Efficiencies were also gained in the RG through the adoption of templates."*

"*Resources developed incredibly useful to provide an understanding of the gold standard approach."*

"*ACTA appropriately prioritised the outputs according to the needs of the sector/members."*

OUR 2021/22 PUBLICATIONS

NORMALISING COMPARATIVE EFFECTIVENESS TRIALS AS CLINICAL PRACTICE

Comparative effectiveness trials (CETs) represent a diverse range of research that focuses on optimising health outcomes. Specifically, these trials compare currently approved interventions to generate high-quality evidence and, in turn, better informed decision makers.

While it is acknowledged that CETs produce real-world evidence that addresses the key priorities of patients and health systems, many implementation challenges exist within the healthcare environment. Through the work of ACTA's Embedding Reference Group and sector colleagues, the team identified that there was a lack of high-quality evidence underpinning many contemporary clinical practice guidelines embedded in the healthcare systems. They also recognised that ultimately, this could lead to treatment uncertainty and practice variation in most clinical disciplines.

Published in *Trials*, **'Normalising comparative effectiveness trials as clinical practice'** highlights the common barriers to conducting comparative effectiveness trials (CETs) and the potential solutions to normalising their conduct as clinical practice and part of a learning healthcare system.

Briffa, T., Symons, T., Zeps, N. et al. Normalising comparative effectiveness trials as clinical practice. Trials 22, 620 (2021). https://doi.org/10.1186/s13063-021-05566-1

A SNAPSHOT OF CONSUMER ENGAGEMENT IN CLINICAL TRIALS IN AUSTRALIA

Consumer involvement in clinical trials has increased in Australia, but the scope of involvement varies across different research organisations, and therapeutic areas. ACTA undertook a national study to better understand the activity and perceptions of CTNs, CCs, and their consumers, around consumer involvement.

Published in *Research Involvement and Engagement*, **'A snapshot of consumer engagement in clinical trials in Australia: results of a national survey of clinical trial networks and research organisations'** found that consumer involvement in clinical trials is valued by most that do it, however, there are opportunities to further foster and strengthen ongoing partnerships, for example by providing practical advice for researchers on how to best engage and involve consumers.

McKenzie, A., Bowden, J., Zalcberg, J.R. et al. A snapshot of consumer engagement in clinical trials in Australia: results of a national survey of clinical trial networks and research organisations. Res Involv Engagem 8, 3 (2022). https://doi.org/10.1186/s40900-022-00338-w

DEVELOPMENT OF THE CONSUMER INVOLVEMENT AND ENGAGEMENT TOOLKIT

Developed as a joint project between ACTA and CT:IQ, the Consumer Involvement and Engagement Toolkit aims to support greater consumer involvement in shaping how clinical research is prioritised, designed and conducted.

In a manuscript published in *Public Health Research and Practice*, the '**Development of the Consumer Involvement and Engagement Toolkit: a digital resource to build capacity for undertaking patient-centred clinical trials in Australia'** describes the novel approach to developing a toolkit to support meaningful consumer involvement in clinical trials in Australia to help guide others in considering the development of similar resources.

Symons T, Bowden J, McKenzie A. et al. Development of the Consumer Involvement & Engagement Toolkit: a digital resource to build capacity for undertaking patient-centred clinical trials in Australia. Public Health Res Pract. 2022; Online early publication. https://doi.org/10.17061/phrp32122209

ACTIVITIES SUPPORTING THE GROWTH OF CLINICAL TRIAL NETWORKS IN AUSTRALIA

By working collaboratively and sharing existing infrastructure, CTNs enable the ability to attract funding and undertake more influential studies. In turn, this can lead to the generation of better evidence that can be embedded in the healthcare system. However, barriers to forming a CTN such as cost and perceived threats to independence can increase the difficulty of this process.

Published in *Trials*, **'Activities supporting the growth of Clinical Trial Networks in Australia'** provides a suggested roadmap on how to establish a CTN in Australia.

Nemeh, F., Buchbinder, R., Hawley, C.M. et al. Activities supporting the growth of Clinical Trial Networks in Australia. Trials 23, 81 (2022). https://doi.org/10.1186/s13063-021-05974-3

2020-2024

WHAT IS PROMPTING THIS WORK?

The important groundwork laid in our early project activities is continuing with a $5 million four-year Medical Research Future Fund (MRFF) *'2020 Enhancing Clinical Trials Network Capabilities Grant'*. Under this grant, we will build on our support of Clinical Trial Networks (CTNs), Clinical Quality Registries (CQRs) and Clinical Trial Coordinating Centres (CCs) to facilitate research in emerging health priority areas. The grant aims to make it easier to initiate and govern trials and accelerate the impact of research into clinical practice.

There is an opportunity to strengthen investigator-led sector capability to embed evidence-based care in the health system and an ongoing commitment to increase the number of CTNs across diseases and disciplines and improve consumer involvement across the diverse Australian population.

WHAT WILL BE THE IMPACT OF THIS WORK, AND WHY DOES IT MATTER?

- Improved healthcare for Australians including greater equity of access to trials leading to increased recruitment for underrepresented groups
- Increased visibility and faster recruitment into clinical trials that are available in Australia
- Clinical trials will become a core business of the health system
- More efficient utilisation of budget available to support trials and registries
- More and higher quality trials with enhanced evidence-based healthcare
- Increased industry and IIT sector linkages with more and better-quality industry trials
- Increased cross-sector collaboration in new clinical trials, as well as consolidated and strengthened capacity of the sector
- Productive CTN and CQR engagement with jurisdictional and federal government initiatives
- Better support to the clinical trials community through better availability of biostatistical and health economic input
- Trials with more reproducible results
- Innovate trial designs that lead to greater efficiencies and faster conclusions
- Increased number of Clinical Trial Networks across diseases and disciplines
- Strengthen ACTA's sustainability model to ensure we can continue to provide pivotal support to the sector.

WHAT HAVE WE DONE SO FAR?

Our current work focuses on six workstreams. The following pages outline some of the work we have already undertaken in each of these workstreams, as well as an overview of some of our long-term priorities.

SUPPORTING MEMBER ORGANISATIONS

- Continued support of CTN Executive Officers and Network Managers through the Special Interest Group for Clinical Trial Network Managers (SIGNet), which attempts to facilitate collaborative learning and sharing of knowledge, resources, and expertise among its member base.
- Established a Special Interest Group for CCs, which aims to provide a platform to share common CC challenges and opportunities, explore how to foster growth, as well as international CC models and identify opportunities to adopt best practice approaches.
- Provided ongoing assistance to progress activities within the Communication and Collaboration Hub for CQRs pilot project and the CQR Special Interest Group (CQR SIG).
- Maintained efforts to guide and support new and emerging CTNs across a range of disease areas.

WHAT GOALS ARE WE AIMING TO ACHIEVE?

- Support for SIGNet to facilitate CTN efficiency and effectiveness improvements, which will, in the long run, lead to more, and higher quality clinical trials.
- Continually engage and liaise with CTNs, CCs and CQRs (and other member organisations) and pursue actions that will best support and be a voice for these organisations and the sector.
- An increase in the range and diversity of disease and discipline areas with a CTN.
- Improved cohesion across the CQR sector and jurisdictions.

CONSUMER ENGAGEMENT, EQUITY AND DIVERSITY

- Identified opportunities to update our Consumer Involvement and Engagement Toolkit to provide additional tools and resources for assisting researchers and consumers in trial methodology.
- Established a working group to operationalise the development of strategies to engage and empower consumers, particularly those in CALD communities, to improve equity and ensure the evidence generated will have a higher impact by being more reflective of the diversity within the Australian community.

WHAT GOALS ARE WE AIMING TO ACHIEVE?

- An increase in trials that engage and involve Culturally and Linguistically Diverse (CALD) groups in trial design and conduct.
- Initiate discussions with the Australian Human Research Committee (AHEC) and the Therapeutic Goods Administration (TGA) on the requirement for inclusion of diverse populations in clinical trials as a key factor when looking at clinical trial applications.
- An increase in trials conducted with representation from CALD groups increasing equity of access to trials.

CAPACITY BUILDING TO SUPPORT BETTER TRIAL DESIGN, CONDUCT AND IMPACT

- The Special Interest Group for Health Economists Alongside Trials (HEAT) now has members from each academic institution in Australia as well as health economists working in non-profits and Industry. HEAT is focused on improving methods for economic evaluation using trial data, and connecting clinical trialists with economists for collaborative projects.
- Established a working group focused on raising sector awareness and uptake of innovative trial designs.

WHAT GOALS ARE WE AIMING TO ACHIEVE?

- Create a Find a Health Economist directory by late 2022 to increase the inclusion of economic evaluation in clinical trials.
- Increase of the Data Safety Monitoring Board (DSMB) mentorship program uptake and build trial statistician expertise.
- Increase the number of late phase trials with integrated health economic analysis.
- Combine our working knowledge of current innovative trial designs being utilised nationally, and lessons learnt from international efforts to increase the utilisation of innovative trial designs.
- Influence policy and promote the development of shared infrastructure that can support innovative trial design.

MAKING TRIALS MORE EFFICIENT AND EASIER

We are developing a rapid approval model, called SKYHOOK, to enable better patient access to clinical trials for rare diseases. The overarching purpose of the project is to explore, develop, and obtain endorsement for an innovative model for distributed 'in-principle' approval permitting rapid approval of trials for rare diseases, at locations where new patients present for care. To do this, we have formed an adult and paediatric consortium to test the model. The consortia is represented by two groups forming with up to 12 members in each group including, clinicians, researchers, HREC and RGO members, and other key stakeholders involved in the paediatric and adult space. It is anticipated these two Consortia will be expanded to comprise other sites nationally.

WHAT GOALS ARE WE AIMING TO ACHIEVE?

- Establish a community of practice for interaction between CTNs and CQRs in the same disease or discipline area through the increased awareness of the value of conducting registry randomised trials via educational meetings and/or workshops.
- Facilitate a workshop focused on exploring technologies to improve clinical trial recruitment and develop a scoping review outlining current and upcoming technologies being utilised in Australia for recruitment into clinical trials.
- Support the roll out of a teletrials model that will enable scaling up in rural, remote and regional areas of Australia across different disease and discipline areas for better trial access.

FACILITATE INDUSTRY-FUNDED/ SPONSORED TRIALS

In partnership with Medicines Australia, we held our first Industry Roundtable in April 2022. The event saw over 50 individuals from academia, industry and other sectors come together to explore ways that these sectors can work more closely for mutual benefit. A pre-event survey sought to better understand key benefits, barriers, and enablers of collaboration between industry and investigator-led clinical trials. The findings formed the basis of a background paper for discussion at the roundtable.

The primary outcome of the session was to establish a shared understanding of what stakeholders want from greater collaboration between the sectors and what the key ingredients are to making this happen. The findings from the day will inform a report with recommendations on improving synergies and collaborations between industry, CTNs, CQRs and CCs. An environmental scan on IIT-Industry collaboration in Australia and internationally will also be completed.

WHAT GOALS ARE WE AIMING TO ACHIEVE?

- By better understanding the synergies and differences between CTNs, CQRs, CCs and industry this will allow for targeted promotion for new partnerships including collaborations focused on consumer engagement, co-design of trials and development of clinical trial infrastructure and workforce.
- Continued leverage of expertise within CTNs and CCs by partnering with industry to assist with trial design, site identification and trial conduct for industry trials.
- An increase in the number and quality of industry trials from ACTA's Industry trial stakeholders.

OUR WORK WITH CTNS, CCS AND CQRS

NEW AND EMERGING CTNS, CCS AND CQRS

ACTA plays a vital role in establishing and supporting new and emerging CTNs, CCs and CQRs across various discipline areas.

Specifically, our work includes input into applications for funding, facilitating workshops and meetings where governance structures, terms of reference and establishment of short, medium and long-term goals are considered. We also share relevant sector and ACTA member insights, ACTA and sector resources, and facilitating connections with complimentary or comparable organisations.

In 2019, we undertook a CTN gap analysis which identified disease and discipline areas with no known existing Network. We also estimated the importance to public health of the gap areas that were identified.

Table 1:
TABLE OF DISCIPLINE AREAS WITHOUT A CTN

Discipline-specific area with no known CTN	Estimated impact Based on % of disability adjusted life years (DALY) or similar public health impact
Primary care	>5%
Indigenous healthcare	>5%
Rural and remote healthcare	>5%
Chronic pain	>5%
Rehabilitation	>5%
Surgical specialties	>5%
Geriatrics and aged care	>5%
Diagnostic disciplines	1 to 5%
Nursing and allied health	1 to 5%

During 2021/22, we supported a number of new and emerging Networks including:

- Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN)
- Growing Minds Australia (GMA)
- Mental Health Australia General Clinical Trial Network (MAGNET).

ESTABLISHED CTNS, CCS AND CQRS

ACTA remains focused on strengthening the capabilities of existing CTNs, CCs and CQRs. This support has included the development and dissemination of practical tools and resources across a range of areas of shared focus including improving the impact of clinical trials through implementability, research prioritisation, innovative trial design, understanding the ethical challenges in COVID-19 research, increasing consumer involvement and engagement, and equitable trial recruitment.

CONNECTING NEW AND EMERGING CTNS

Wherever possible, we actively look for opportunities to connect new and emerging organisations with others who are more established. During the year we facilitated meetings between organisations we identified as having similar structures or challenges. These cross-collaboration opportunities often lead to sharing knowledge and resources that can ultimately strengthen both organisations.

During the 2021 ACTA Annual Scientific Meeting, we held a Q&A and networking session for new and emerging Clinical Trial Networks (CTNs). The session was chaired by ACTA Board Director, Prof Chris Reid and panelists included ACTA Chair, Prof Steve Webb, Prof Michael Berk from Mental Health Australia General CTN (MAGNET), Prof Marion Eckert from the Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN), Dr Phyllis Lau from the Primary Health Care Network, and A/Prof Leila Cuttle from the Australian & New Zealand Burn Association (ANZBA).

During the session, Prof Webb spoke about how the Australian and New Zealand Intensive Care Society (ANZICS) was formed. Panelists then shared about their CTN establishment journey and how ACTA resources, and the opportunity to talk to other successful networks, had helped their respective Network. Common themes within the session included governance, funding and peer review of grant applications.

OUR WORK WITH ANMCTN AND MAGNET

"The Australian Clinical Trials Alliance (ACTA) has worked closely with the newly established Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN) to build the first dedicated nursing and midwifery CTN across Australia and New Zealand.

ACTA has been instrumental in connecting the Network with peak bodies, clinician researchers and industry. The foundation documents that ACTA provided also supported the networks administration, governance and policy development. Having ACTA as the national peak body supporting the Network has allowed us to focus on the establishment and growth of the Network, enabling it to be the success it has been today and will be into the future."

Prof Marion Eckert
Chair, Strategic Advisory Committee and Executive Committee
ANMCTN
University of South Australia

"The Mental Health Australia General Clinical Trial Network (MAGNET) is indebted to ACTA for the support and mentorship provided during the establishment of our Clinical Trial Network. ACTA was catalytic in getting the Network up and running and provided wise counsel around the many decisions involved in establishing a new Network."

Prof Michael Berk
MAGNET project lead
Director of the Institute for Mental and Physical Health and Clinical Translation (IMPACT), Deakin University

HOW WE REPRESENT OUR SECTOR

IN 2021/22 WE PROVIDED OPPORTUNITIES FOR COLLABORATION AND ENGAGEMENT, INCLUDING:

- 2021 ACTA Annual Scientific Meeting
- 2022 ACTA Annual Clinical Trials: National Tribute and Award Ceremony
- Twice-yearly ACTA Advisory Council meetings
- Monthly newsletter, social media presence, member email updates, website updates
- One-on-one meetings with members
- Presentations to the broader clinical trials sector at the annual 2021 ARCS Conference
- Participation as a panellist, supporting PRAXIS and the NSW Nurses and Midwives' Association webinar regarding clinical research nurses' role and value in the clinical trial sector.

WE HAD REPRESENTATION ON SECTOR COMMITTEES, INCLUDING:

- Clinical Trials Governance Framework Steering Committee (led by the Australian Commission on Safety and Quality in Health Care)
- Australian Research Data Commons (ARDC) Advisory Committee for Health Studies Australian National Data Asset
- Victorian Clinical Trials Action Plan Steering Committee
- CT:IQ Executive Committee.

WE RESPONDED TO CONSULTATIONS RELEVANT TO CLINICAL TRIALS AND REGISTRIES, INCLUDING:

- 2021 MRFF Australian Medical Research and Innovation Strategy and Priorities consultation
- 2021 Department of Health National One-Stop Shop (and Front Door) consultation
- 2021 Research Australia's consultation Post Pandemic Opportunities for Health and Medical Research and Innovation
- 2021 Department of Education, Skills and Employment – National Research Infrastructure (NRI) Roadmap Consultation
- 2021 Guidance for Good Clinical Trials Collaborative (GCTC) consultation.

2021 ACTA ANNUAL SCIENTIFIC MEETING

Under the theme 'Strengthening the pipeline for clinical research', the 2021 ACTA Annual Scientific Meeting (ASM) provided a great opportunity to highlight, celebrate and discuss key topics across the full clinical research spectrum.

This virtual event brought together a great line-up of experts in the cutting-edge design and conduct of clinical trials and registry custodianship, policy and regulation, healthcare service delivery, health information technology, health economics and consumer engagement.

The event was delivered across five event streams:

STREAM 1:
Translation of clinical registry findings into practice

STREAM 2:
Capacity building to optimise trial design, conduct and impact

STREAM 3:
Facilitating efficient and cost-effective recruitment and completion of clinical trials

STREAM 4:
Accelerating Australian discovery and innovation through trials and well-phenotyped cohorts

STREAM 5:
Australia as the "go-to" partner for global and industry-supported trials

All streams highlighted consumer engagement, equity and diversity

We had over 390 delegates registered across the three days, and we were pleased to see so many people engage in panel discussions and interact with keynote presenters. Our On Demand Library and Poster Gallery also had great engagement during the event.

We sincerely thank our Convenor Prof Gemma Figtree, the Organising Committee, all presenters, and delegates.

We also gratefully acknowledge our event sponsors who made this event possible:

AstraZeneca

Commonwealth Department of Health and Aged Care

Medicines Australia

MTPConnect

Spiral

The George Institute for Global Health

WHAT THE EVENT ATTENDEES TOLD US

"I enjoyed hearing the overall plan to simplify and integrate clinical trials into clinical practice in hospitals."

"A wonderful, diverse group of speakers and organisations represented. I particularly liked the panel discussions - all were enthusiastic and to the point with their answers. All sessions were very well moderated [...], and asked 'probing' questions to some challenging situations. The format was excellent. Being able to view the pre-recorded presentations, even after the conclusion of the program, is valuable. One doesn't always have time to view everything while the meeting is in progress."

"The lively panel discussions were a fantastic addition."

RECOGNISING AUSTRALIA'S OUTSTANDING TRIALS

From a national pool of exceptional collaborative, multicentre, investigator-driven and impactful trial nominations, four major awards were presented for trials demonstrating significant and positive impacts for patients at the Australian Clinical Trials Alliance (ACTA) 2022 Clinical Trials: National Tribute and Awards Ceremony.

The award-winning trials and their subsequent impact on health outcomes successfully highlight the exceptional breadth of trial activity and expertise in Australia.

These awards were established in 2016 to highlight the outstanding Australian achievements that advance clinical practice and save or improve the lives of patients every year.

ACTA CEO, Dr Stewart Hay shared: "The calibre and breadth of our 2022 award winners and nominees illustrate the expertise, experience and enthusiasm for conducting clinical trials in Australia.

"As a peak agency, ACTA is committed to supporting and advocating for trial teams to ensure they can continue their great work in providing the community with access to life-changing trials.

"These awards provide yet another reminder of why our work is so important for the sector and patient care," adds Dr Hay.

Prof Steve Webb, ACTA's Board Chair and the lead Investigator of the ACTA 2022 Trial of The Year award echoed Dr Hay's sentiments, "The quality of nominations for the 2022 ACTA Awards highlights that Australian trials support and align with global trial efforts.

"As an ICU clinician I have seen the lifesaving impact of our REMAP-CAP Trial firsthand, but it was evident that all trial nominees shared ACTA's vision of *Better health outcomes through best evidence*.

"It is such an important time to be involved in clinical trials," added Prof Webb.

ACTA announced the winners at their sixth annual awards ceremony in Sydney that coincided with International Clinical Trials Day. The event included esteemed guests The Hon Brad Hazzard, MP Minister for Health (NSW) and Prof Anne Kelso AO, CEO, NHMRC.

We sincerely thank MC Prof Meg Jardine, the Organising Committee, all presenters, nominees and attendees.

We also gratefully acknowledge our event sponsors who made this event possible:

AusBiotech

Bellberry Ltd

CT:IQ

Medical Technology Association of Australia (MTAA)

MTPConnect

NHMRC Clinical Trials Centre

Research Australia

Congratulations to the 2022 award winners:

ACTA Trial of the Year Award

REMAP-CAP – Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Chief Investigator:
Prof Steve Webb

Network or investigator group:
Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group and School of Public Health and Preventive Medicine, Monash University

(Trial description on page 31)

ACTA STInG Excellence in Trial Statistics Award

This trial presented that dexamethasone can be safely administered to patients to prevent nausea and vomiting when undergoing surgery, without concern about wound infections.

The PADDI Trial:
The Perioperative ADministration of Dexamethasone and Infection

Chief Investigator:
Prof Tomás Corcoran

Network or investigator group:
Australian and New Zealand College of Anaesthetists (ANZCA) Clinical Trials Network

ACTA Consumer Involvement Award

This trial evaluated the reach and usefulness of a lifestyle-focused text message intervention to support women's mental and physical health after breast cancer treatment.

EMPOWER-SMS:
Text messages to improve women's self-efficacy, quality of life and health outcomes after breast cancer treatment: EMPOWER-SMS randomised clinical trial

Chief Investigator:
Dr Anna Singleton

Network or investigator group:
Prof Clara Chow and Prof Julie Redfern, The George Institute for Global Health

ACTA Industry Partnership Award

This partnership, between the University of Melbourne and Medibank, saw the design and evaluation of two new programs for people with knee osteoarthritis, which were highly rated by participants and health professionals for their effectiveness, simplicity and convenience.

Better Knee, Better Me:
Effectiveness of two scalable health care interventions supporting self-management for knee osteoarthritis – a randomised controlled trial

Chief Investigator:
Prof Kim Bennell

Network or investigator group:
University of Melbourne, in collaboration with Medibank

Congratulations to our finalists:

ACTA Trial of the Year
RUNNER-UP:

Quartet Study – Initial treatment with a single pill containing quadruple combination of quarter doses of blood pressure medicines versus standard dose monotherapy in patients with hypertension (QUARTET): a phase 3, randomised, double-blind, active controlled trial

Chief Investigator:
Prof Clara Chow

Network or investigator group:
The George Institute for Global Health

ACTA Trial of the Year
RUNNER-UP:

SSaSS – Salt Substitute and Stroke Study

Chief Investigator:
Prof Bruce Neal

Network or investigator group:
The George Institute for Global Health

ACTA STInG Excellence in Trial Statistics Award
RUNNER-UP:

REMAP-CAP – Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Chief Investigator:
Prof Steve Webb

Network or investigator group:
Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group and School of Public Health and Preventive Medicine, Monash University

(Trial description on page 31)

ACTA Consumer Involvement Award
RUNNER-UP:

Bee Pain Free – A multi-centre, double-blinded, randomised controlled trial to investigate honey use to reduce pain in children post-tonsillectomy

Chief Investigator:
Prof Britta von Ungern-Sternberg

Network or investigator group:
Perth Children's Hospital, Paediatric Trials Network Australia

WHAT THE EVENT ATTENDEES TOLD US

"Promoting the importance of clinical trials and the role that they play in treating patients and setting the next generation of treatment."

"It highlights diversity across the broader health sector, collaboration etc for the betterment of our communities. ACTA has to be proud of its achievements since it was established."

"Allows the community to see the awesome work of amazing researchers."

"Great example of successful trials and implementation science - important benchmark for up and coming researchers."

"The award ceremony is inspiring."

THE 2022 ACTA TRIAL OF THE YEAR
REMAP-CAP

It is likely that the findings produced by REMAP-CAP in 2021 have saved tens of thousands of lives, freed up vital healthcare resources, and saved billions of dollars in healthcare spending.

Scientific name:
Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia (REMAP-CAP)

Chief Investigator:
Prof Steve Webb

Network or investigator group:
Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group and Monash School of Public Health and Preventive Medicine

REMAP-CAP is a randomised, embedded, multifactorial platform trial that was established in 2016 to provide research infrastructure that could adapt quickly in a respiratory pandemic. It was developed and is led by a team of Australian researchers and clinicians, in collaboration with several international partners throughout New Zealand, Europe, Asia, and the Americas.

During the COVID-19 pandemic, REMAP-CAP expanded rapidly to include more than 350 sites in 25 countries, with more than 10,000 patients randomised (and over 17,000 intervention randomisations). It has been recognised as a key global trial by the World Health Organisation during the COVID-19 pandemic, generating vital evidence for the optimal management and treatment of patients who are critically ill with COVID-19.

One of these treatments are drugs known as 'IL-6 inhibitors', which modulate the activity of the immune system. This trial found that patients who were critically ill with COVID-19 were more likely to recover if treated with IL-6 inhibitors, than patients who did not receive these medications. These results have been supported by the findings of other trials, and this treatment has now been adopted as part of standard care for critically ill patients with COVID-19 worldwide.

It is likely that the treatment of critically ill patients with COVID-19 with IL6 inhibitors has saved many lives during the COVID-19 pandemic. To date it is one of the few interventions that has been conclusively demonstrated to reduce mortality from COVID-19.

The REMAP-CAP trial has also found that the use of high-dose anticoagulation may be beneficial for hospitalised patients who are not critically ill. However, it is not effective for patients who are critically ill and receiving treatment in an intensive care unit.

REMAP-CAP also evaluated treatment known as convalescent plasma, which involves administering plasma (a blood product) taken from individuals who have recovered from COVID-19 to individuals who are unwell with COVID-19, to try to boost their immune systems. While this treatment was found to be ineffective, this was a positive result as it allowed the focus of resources on other potentially beneficial interventions.

Finally, the REMAP-CAP trial found that the use of antiviral medications hydroxychloroquine and lopinavir-ritonavir are likely to be harmful to critically ill patients with COVID-19. These medications are widely used to treat other conditions such as arthritis and HIV/AIDS but gained substantial media interest for the treatment of COVID-19. However, several studies, including REMAP-CAP, now show that they should not be administered to patients who are critically unwell with COVID-19.

These findings demonstrate the ability of a large-scale trial like REMAP-CAP, which can evaluate multiple potential treatments simultaneously, to efficiently and rapidly generate evidence that has had an immediate and significant impact on the care of the sickest patients during the COVID-19 pandemic.

OUR OPERATIONS

We can only achieve what we do thanks to the ongoing support of our Board of Directors, members, staff, volunteers and sector colleagues.

OUR BOARD

ACTA is governed by a Board of Directors.
The Directors listed were in office for the entire 2021/22 period.

CHAIR

Prof Steve Webb

MBBS MPH PHD FCICM FRACP FAHMS

Prof Steve Webb is a Senior Staff Specialist in Intensive Care Medicine at Royal Perth Hospital, Director of Clinical Trials at St John of God Hospital Subiaco, and a Prof of Critical Care Research at Monash University.

Prof John Zalcberg OAM

MBBS PHD FRACP FRACMA FAHMS FAICD

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. He holds the inaugural Tony Charlton Chair in Cancer Research at the Alfred Hospital and Monash University, Melbourne, Australia.

Prof Meg Jardine

MBBS PHD FRACP

Prof Meg Jardine is the Director of the NHMRC Clinical Trials Centre and a practicing nephrologist and clinical researcher with an interest in the progression and complications of non-communicable chronic disease.

Ms Margo MacGillivray

LLB (Hons) BA LLM GAICD

Independent Director with expertise in governance and risk management

Ms Margo MacGillivray 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 with expertise in the consumer sector

Ms Anne McKenzie currently serves as a senior consumer representative on key national and state health committees and holds honorary positions at both Telethon Kids Institute and UWA.

Prof Rachael Morton

MSCMED (CLIN EPI)(Hons) PHD

Prof Rachael Morton is Director of Health Economics and Health Technology Assessment at the NHMRC Clinical Trials Centre, and Prof and Principal Research Fellow in the Faculty of Medicine and Health at the University of Sydney.

Prof Christopher Reid

BA DIP ED MSC PHD

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

Mr Kieran Schneemann

Independent Director with expertise in the commercial clinical trials sector

Mr Schneemann is a Special Counsel to AstraZeneca where earlier this year he stepped down from his role as Director of Government Affairs. Mr Schneemann is a current Director on the Board of CanTeen Australia.

Ms Leonie Wilcox

BSC RN

Ms Leonie Wilcox is the manager of the Australasian Bone Marrow Transplant Recipient Registry. Ms Wilcox is a member of the Board of Directors of the Arrow Bone Marrow Transplant Foundation.

Mr Ian Wilson

FCPA ACIS AGIA MAICD

Independent Director with expertise in finance

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.

OUR TEAM

ACTA BOARD
Chair: Prof Steve Webb

- Program Advisory Committee
- Finance Audit and Risk Committee
- Nominations Committee
- Membership Committee

ACTA CENTRAL TEAM
CEO: Dr Stewart Hay

- Projects
- Communications
- Events
- Policy and advocacy

ACTA PROJECTS

- ACTA Working, Reference and Special Interest Groups

ACTA COMMUNITY

- ACTA Advisory Council
- ACTA Members
- Sector partners and stakeholders

OUR THANKS

STANDING COMMITTEE MEMBERS

Finance Audit and Risk Committee

Ms Margo MacGillivray (Chair)
Mr Kieran Schneemann
Prof Steve Webb
Mr Ian Wilson
(Dr Stewart Hay: Participant with standing invitation from 21 April 2022)
(Ms Simone Yendle: participant with standing invitation to 31 Dec 2021)

Membership Committee

Prof Steve Webb (Chair from 1 Jan 2022)
Prof Belinda Gabbe
Prof John Simes
Ms Leonie Wilcox
Ms Simone Yendle (Interim Chair until 31 Dec 2021)
(Dr Stewart Hay: Participant with standing invitation from 21 April 2022)

Nominations Committee

Prof Chris Reid (Chair)
Ms Margo MacGillivray
Mr Kieran Schneemann
Prof Steve Webb
Ms Simone Yendle (until 31 Dec 2021)
(Dr Stewart Hay: Participant with standing invitation from 21 April 2022)

Program Advisory Committee

Ms Sabine Braat
Prof Alan Cass
Prof Geoffrey Donnan
Ms Julia Fallon-Ferguson
A/Prof Katie Groom
A/Prof Ross Haslam
Prof Carmel Hawley
Dr Stewart Hay (from 21 April 2022)
Ms Rebecca James (resigned April 2022)
Prof Meg Jardine
Prof Tony Keech
Prof Stephen McDonald
Ms Anne McKenzie
Prof John McNeil
Prof Rachael Morton
Prof Paul Myles
Prof Vlado Perkovic
Prof Chris Reid
Dr Megan Sanders
Mr Kieran Schneemann
Prof John Simes
Prof Judith Trotman
Prof Steve Webb
Ms Leonie Wilcox
Ms Simone Yendle (until 31 Dec 2021)
Prof John Zalcberg
Prof Nik Zeps

ACTA CENTRAL STAFF

Dr Stewart Hay, CEO (from 21 April 2022)
Ms Vika Potarina, Interim CEO (January – April 2022)
Ms Simone Yendle, CEO and Company Secretary (until 31 December 2021)
Dr Husna Begum (from 20 April 2022)
Ms Courtney Gee (from 20 April 2022)
Ms Jaime Greenup
Ms Kirsty Grove (until 15 February 2022)
Ms Lea Hauchard
Ms Maya Hayes (from 30 May 2022)
Ms Katie Legge
Ms Sharon Lloyd (until 10 December 2021)
Mr Michael Mihatsch
Dr Fiona Nemeh
Ms Nicola Straiton (until 18 February 2022)

REFERENCE GROUP LEADERSHIP

(Note: groups ceased at the conclusion of the 2017-2021 grant)

Clinical Trial Network Sector Expansion Reference Group

Prof Alex Brown
Prof Chris Reid
Dr Jacqui Waterkeyn

Efficient and effective Clinical Trial Networks Reference Group

Dr Ed Oakley
Ms Melanie Gentgall
Ms Donna Goldsmith
Ms Karen Goulding
Dr Kurt Lackovic
Ms Donna Reidlinger

Embedding Clinical Trials in Healthcare Reference Group

Prof Nik Zeps
A/Prof Tom Briffa
Prof Ian Harris
Prof Tony Keech
Prof John Simes
Ms Tanya Symons
Dr Christopher Williams

Impact and implementation of Clinical Trial Networks Reference Group

Prof Alan Cass
Prof Sophia Green
Prof C Levi

Innovative Trial Design Reference Group

Prof Andrew Forbes
Prof Stephane Heritier
A/Prof Katherine Lee
Dr Annie Solterbeck
Prof Steve Webb
Prof Rachel Huxley (resigned)
A/Prof Mustafa Khasraw (resigned)

Innovative Outcome Data Reference Group

Prof Dorota Doherty
Dr Felicity Flack
Prof Steven Tong

Strengthening Consumer Engagement in Clinical Trials Reference Group

Mr Alex Economides
Ms Anne McKenzie
A/Prof Angela Todd
Dr Janelle Bowden
Ms Tanya Symons
Prof John Zalcberg

Tools and Criteria for Research Prioritisation Reference Group

A/Prof Haitham Tuffaha
Prof Rachael Morton
Prof John Simes

WORKING GROUP LEADERSHIP

Adaptive Platform Trials Operations Group
Ms Jocelyn Mora
Mr Arlen Wilcox

Consumer Engagement, Equity and Diversity Working Group
Dr Janelle Bowden
Ms Anne McKenzie

Develop the Rapid Approval Model for Trials of Rare Diseases 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

SPECIAL INTEREST GROUP LEADERSHIP

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 Economist Special Interest Group (HEAT SIG)
Prof Rachael Morton
A/Prof Richard Norman

Special Interest Group for Network Managers (SIGNet)
Ms Julia Fallon-Ferguson (2021)
Ms Jo Fitzsimons (2022 Deputy Chair)
Dr Megan Sanders (2022 Chair)

Statistics in Trials Interest Group (STInG)
Ms Sabine Braat
Prof Andrew Forbes
Prof Katherine Lee

EVENT SPONSORS

2021 ACTA Annual Scientific Meeting
AstraZeneca
Commonwealth Department of Health and Aged Care
Medicines Australia
MTPConnect
Spiral
The George Institute for Global Health

2022 National Tribute and Award Ceremony
AusBiotech
Bellberry Ltd
CT:IQ
Medical Technology Association of Australia (MTAA)
MTPConnect
NHMRC Clinical Trials Centre
Research Australia

IIT-Industry Roundtable
Medicines Australia

EVENT ORGANISING COMMITTEES AND JUDGING PANELS

2021 ACTA Annual Scientific Meeting Organising Committee
Prof Susannah Ahern
Dr Clare Arnott
Ms Sabine Braat
Prof Gemma Figtree (Convener)
Prof Davina Ghersi
Ms Anne McKenzie AM
Prof Chris Reid
Prof Steve Webb
Ms Simone Yendle

Trial of the Year Award Judging Panel
Prof Rachelle Buchbinder
Ms Karen Carey
Prof Dorota Doherty (Chair)
Prof Gemma Figtree
Prof Paul Glasziou
Ms Margo Macgillivray (Board Observer)
A/Prof Peter Mollee

Excellence in Trials Statistics Award Judging Panel
Prof Leonid Churilov
Dr Anneke Grobler
Dr Elizabeth Ryan
Dr Lisa Yelland

Consumer Involvement Award Judging Panel
Dr Janelle Bowden (Chair)
Prof Carmel Hawley
Prof John Myburgh AO
Prof Chris Reid
Prof Toby Richards
Mr John Stubbs
Ms Leonie Wilcox (Board Observer)

Industry Partnership Award Judging Panel
Ms Lorraine Chiroiu (Chair)
A/Prof Lindy Jeffree
Mr Dan Kent
Dr Carlo Maccarrone
Prof Stephen Nicholls
Prof Vlado Perkovic
Mr Kieran Schneemann (Board Observer)
Dr Ana Svensson

OUR MEMBERS AND VOLUNTEERS

We sincerely thank our Full, Affiliate, Associate and individual members for your ongoing support of our work (as showcased on pages 26 and 27).

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 Reference Groups, Working Groups and Special Interest Groups.

FINANCIAL SUMMARY

Abbreviated financial summary as at 30 June 2022

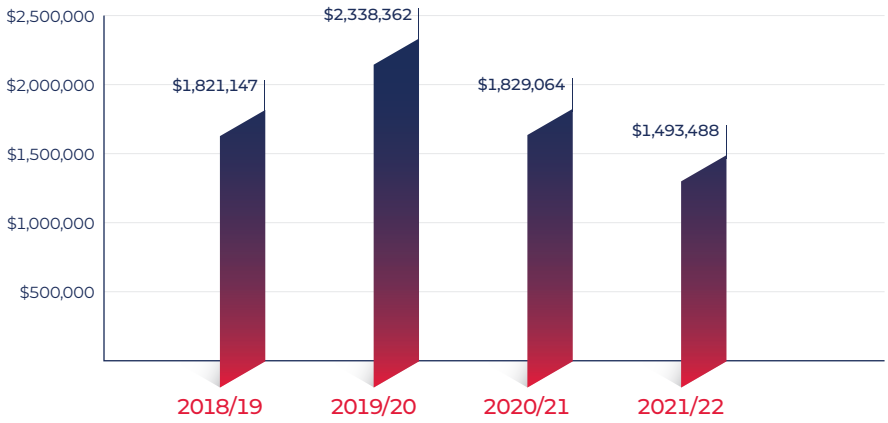
STATEMENT OF SURPLUS OR DEFICIT AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2022

	2022	2021
INCOME	$	$
Total revenue and other income	**1,493,488**	**1,829,064**
EXPENDITURE		
Audit and legal	(8,328)	(23,089)
Consultancy expenses	(346,915)	(299,953)
Depreciation and amortisation expense	(55,943)	(5,923)
Employee benefit expenses	(917,365)	(961,672)
Event and meeting expenses	(45,070)	(65,189)
Operating expenses	(137,761)	(128,012)
Total expenditure	**(1,511,382)**	**(1,483,838)**
Net surplus/(deficit) for the year	**(17,894)**	**345,226**

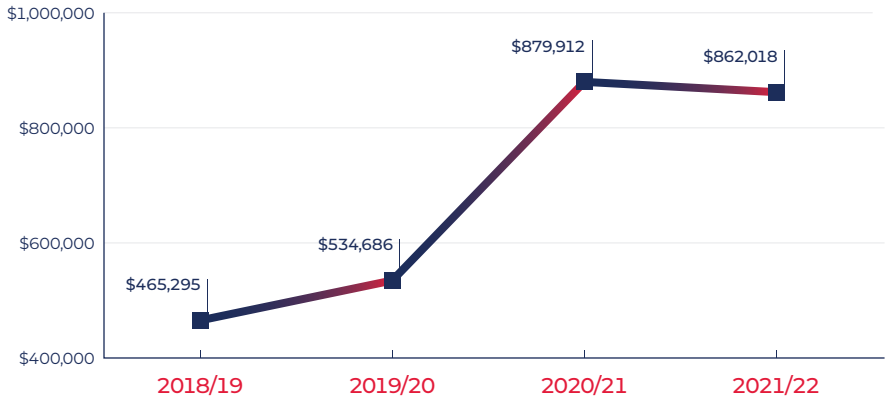
STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2022

	2022	2021
	$	$
TOTAL ASSETS	2,024,691	2,089,794
TOTAL LIABILITIES	1,162,673	1,209,882
NET ASSETS	862,018	879,912

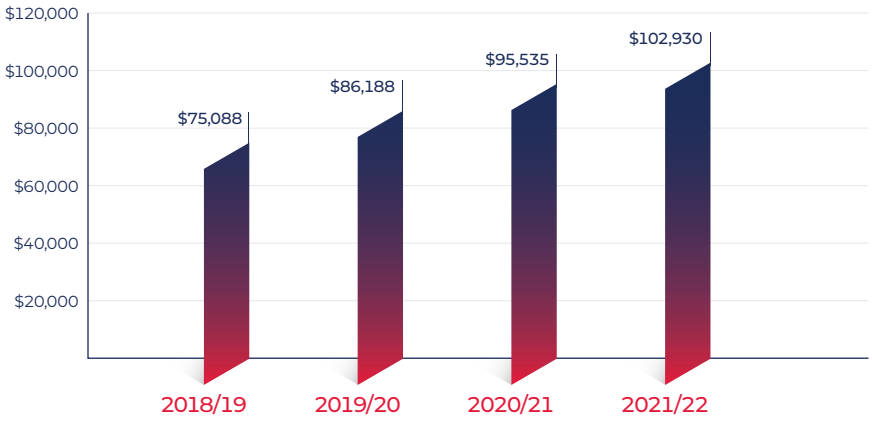
COMPREHENSIVE INCOME SUMMARY



NET ASSET POSITION



MEMBERSHIP FEES



BALANCE SHEET SUMMARY

YEAR	TOTAL ASSETS	TOTAL LIABILITIES	NET ASSETS
2018/19	$2,148,391	$2,148,391	$465,355
2019/20	$1,902,624	$1,367,938	$534,686
2020/21	$2,089,794	$1,209,882	$879,912
2021/22	$2,024,691	$1,162,673	$862,018

Australian
Clinical
Trials
Alliance

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

www.clinicaltrialsalliance.org.au

T | +61 3 8639 0770
E | acta@clinicaltrialsalliance.org.au