Australian Clinical Trials Alliance

Annual Report 2019-2020

November 2020

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

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MESSAGE FROM THE CHIEF EXECUTIVE OFFICER

Welcome to our annual Year in Review report. I am honoured to be part of the incredibly dedicated ACTA Community. We gratefully acknowledge the invaluable support and contributions from our Members, the Australian Government Department of Health, and the Medical Research Future Fund (MRFF).

This report highlights the achievements of the Australian Clinical Trials Alliance (ACTA) throughout an incredibly disruptive and challenging year. The 2019-2020 financial year was highly productive for our team, despite the unique challenges we faced with remote working, and learning to stay connected while being apart. Throughout the year, ACTA has remained focussed on promoting the role of investigator-initiated clinical trials and clinical quality registries, and strengthening the capacity, efficiency and effectiveness of Clinical Trial Networks (CTNs), at a time when sharing knowledge has never been more important.

In response to the COVID-19 pandemic, we rapidly developed an online forum – 'Beyond COVID-19: A Solution-Focussed Forum' – in partnership with Praxis, ARCS and CT:IQ to provide an opportunity for industry leaders to come together to discuss solutions together. We also released a dedicated COVID-19 newsletter that featured new information as it became available.

In late April, members of ACTA's Special Interest Group for Network Managers (SIGNet) met to discuss COVID-19 related challenges for networks and to share learnings and exchange solutions. Members shared a range of experiences with COVID-19's effect on clinical trials in their networks; from some trials being put on hold, through to others not experiencing any disruptions. ACTA Special Interest Group of Statisticians (ACTA STInG) set up weekly meetings to discuss COVID-19 related statistical issues, challenges and best practice for existing trials and new COVID-19 trials. This community of practice continues to meet on a regular basis.

We continued advocating for evidence-based medicine through ACTA STInG, who were signatories to open letters expressing concerns about the quality of the statistical analysis and data integrity for two COVID-19 publications in the Lancet and the NEJM, which have since been retracted.

This year, we marked an International Clinical Trials Day like no other. Now, more than ever, we – and the broader community – are all aware of the role and importance of clinical trials in researching treatments, cures and guarding our safety as we try to find a way to reduce the enormous toll of COVID-19.

With the 'Clinical Trials 2020: National Tribute and Award Ceremony' postponed, ACTA began a campaign to profile our community through our newsletter, social media channels and website, to highlight and celebrate the hard work of the investigator-initiated clinical trials community.

In November 2019, our new website was launched, where our Members can find key activities, resources and news from ACTA and the broader sector. We also launched an online, interactive 'Consumer Involvement and Engagement in Clinical Trials Toolkit, in collaboration with Clinical Trials: Impact and Quality' (CT:IQ). The Toolkit is based on international best practice and locally developed resources – providing tools and guidance on consumer involvement and engagement in clinical trials in Australia.

Throughout the 2019-2020 financial year, ACTA continued to run several events, workshops and online webinars. In October 2019, the ACTA International Clinical Trials Conference brought together the ACTA Community, together with policymakers, industry and consumers.
The Conference was opened by the Hon. Greg Hunt MP, Minister for Health, and supported by the Australian Department of Health, who were Principal Partners. The Conference and accompanying workshops highlighted the importance of clinical trials in delivering quality care and treatment, innovation and economic value to the health care system throughout Australia and was attended by over 400 delegates.

In November 2019, we also welcomed three new Directors; Prof Rachael Morton, Director of Health Economics at NHMRC Clinical Trial Centre; Ms Leonie Wilcox, Manager of the Australasian Bone Marrow Transplant Recipient Registry; and consumer advocate Ms Anne McKenzie AM.

I would like to sincerely thank our Board of Directors for their passion and support throughout the year, and our ACTA Central staff for their continued dedication and hard work. Our vision of 'better health through best evidence' remains our focus as we look to the future, and a bigger and better 2020–21.

Simone Yendle
ACTA CEO

VISION AND MISSION

OUR VISION

Better health through best evidence.

OUR MISSION

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

AIMS AND OBJECTIVES

- Promote the benefits of investigator-initiated clinical trials and clinical quality registries
- Raise awareness of the valuable contributions of clinical trial networks (CTNs), coordinating centres (CCs) and clinical quality registries (CQRs)
- Bring focus to common issues impacting the conduct of clinical trials and clinical quality registries
- Facilitate collaboration among CTNs, CCs and CQRs
- Coordinate communication and consultation with clinician researchers
- Provide expert advice on investigator-initiated clinical trials and CQRs to governments, policymakers and others
- Develop policy recommendations for improving the quality and impact of investigator-initiated clinical trials and CQRs
- Support the development of new CTNs, CQRs and CCs that conduct, or support the conduct of investigator- initiated clinical trials
- Encourage capacity building, promote education and training and coordinate projects with the aim of improving all aspects of for the clinical research workforce
- Foster effective partnerships between clinician researchers and governments, policymakers, health care providers, industry and consumers.

OUR STRATEGY

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

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

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

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

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

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

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

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

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

AN OVERVIEW OF ACTA

The Australian Clinical Trials Alliance (ACTA) was incorporated as a company limited by guarantee on 21 March 2014. It was created to provide a national mechanism for supporting high-quality investigator-led clinical trials within the Australian healthcare system.

ACTA's formation was driven by individuals who have played key roles in the successful clinical trials networks, and to highlight the importance of clinical trial coordinating centres and clinical quality registries to better health outcomes in Australia. These are the core groups that ACTA is guided by and represents.

In May 2017, ACTA was awarded $5m funding over the 2017–2020 period, through the Medical Research Futures Fund (MRFF). The funding was part of the Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program, to strengthen sector capability and collaboration toward embedding evidence-based care in the health system. The grant was provided to ACTA to enhance its capacity to provide collaborative and strategic leadership and practical support for Clinical Trials Networks (CTNs), and the coordinating centres (CCs) and clinical quality registries (CQRs) that enable, support, and inform their work.

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

At 30 June 20, ACTA's Member profile consisted of 65 Full and Associate CTN, CC and CQR Members, together with 16 Affiliate Organisation Members and 168 Affiliate Individual Members.

PROGRAMS OF WORK

During the 2019–2020 financial year, ACTA remained focussed on strengthening the capacity, efficiency and effectiveness of CTNs through our Activity Plan, eight key program areas, and three special interest groups. We also continued to provide support for Registries holding a number of workshops on Registry Randomised Trials.

Alongside the ACTA Central team, more than 170 members of the ACTA Community, including experts in their fields, donated their time and significant pro bono support to the work of ACTA through Reference Groups dedicated to the eight key program areas along with three Special Interest Groups.

ACTA's work to date includes establishing Reference Groups and communities of practice; setting up programs of direct support to existing and emerging CTNs and training in clinical trials methodology. In addition, we conducted extensive groundwork through consultation with the sector, identifying barriers and good practices and accordingly curated guidance for our Members.

The purpose of the key program areas is to deliver substantive and lasting impacts, with a sector that is stronger, more efficient and effective, and ready to meet the critical challenges awaiting us. The eight Reference Groups and three Special Interest Groups are detailed in the tables (below).

REFERENCE GROUPS

Creating Efficient and Effective Clinical Trial Networks **Goal:** Enable CTNs to operate in an effective and efficient manner.	**Clinical Trial Network Sector Expansion** **Goal:** The establishment of efficient, effective, and sustainable CTNs in areas of major importance to public health and the healthcare system.
Impact and Implementation of Clinical Network trials **Goal:** Maximise and measure the value of clinical trials to the community and the healthcare system, including the consideration of the implementation of trial results into standard care.	**Embedding Clinical Trials in Healthcare** **Goal:** Reduce the cost and shorten the duration of clinical trials by integrating clinical trial processes as a routine and integrated component of the healthcare system.
Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials **Goal:** Strengthen the CTN sectors' capacity and ability to involve consumers in all activities across the research continuum.	**Research Prioritisation: Tools and Criteria** **Goal:** To ensure that trials conducted by networks identify research questions with the greatest possible impact on health outcomes.
Innovative Trial Design **Goal:** Transition CTNs from conventional trial designs to the use of innovative trial designs, where appropriate.	**Innovative Outcome Data** **Goal:** Widespread uptake of the use of linked data, automated patient-reported outcome measures, and registry datasets by CTN trials.

SPECIAL INTEREST GROUPS

ACTA Statistics in Trials Interest Groups (STinG) **Goal:** To improve the quality of clinical trials within Australia by strengthening links among trial statisticians, and develop a structured support network for trial statisticians across Australia, within which different centres provide specialist support for particular trial designs or clinical areas.	**ACTA Registries Special Interest Group** **Goal:** To provide support and advocacy for registries and the broader clinical trials community, by undertaking projects in areas of need identified by the group.
ACTA Special Interest for Network Managers (SIGNet) **Goal:** To link network Executive Officers, facilitate information sharing and mentoring of new Executive Officers, provide an opportunity to share insights on activities done well and to identify solutions to problems.	

RESPONSE TO COVID-19

Solving problems is at the heart of clinical trials, and the COVID-19 pandemic has seen the sector become more agile; adapting existing trials, finding new ways to commence planned trials, or moving quickly to help test treatments and solve the riddles of coronavirus. ACTA too was nimble in our response.

Early in the pandemic, ACTA identified the need to have one central repository to house the latest COVID-19 information relevant to clinical trials. This repository is on our website and has become our most visited webpage. In addition, we created a forum called Beyond COVID-19 in partnership with Praxis, ARCS and CT:IQ, which we launched on Clinical Trials Day. It is a place for the sector to come together and discuss solutions for the future, and has nearly 200 registered users. Clinical trialists can instantly share their knowledge, assist with responses and point each other to useful resources or contacts – from ethics to telehealth, pharmaceutical supply to remote monitoring.

Continuing with the theme of bringing experts together, ACTA has supported the opening up of communication channels between statisticians involved in COVID trials through the Community of Practice initiative. It provides an opportunity for members to meet regularly and share their professional experiences.

As the pandemic evolved, we also recognised that our community needed access to regular, reliable information, so we began a succinct COVID-19 newsletter, focussing on keys guidance and grant updates, releasing new information on the pandemic as it became available.

With COVID-19 putting research to the fore, the ACTA STInG Special Interest Group of Statisticians were signatories to open letters expressing concerns about the quality of the statistical analysis and data integrity for two COVID-19 publications in the Lancet and the NEJM. As a result, these pieces were retracted.

At the height of COVID-19 in Australia, it was heavily reported in the news that concerns about the pandemic had significantly impacted the number of general practitioner consultations. We were proud to support the launch of the 'Don't Wait Mate' campaign highlighting the importance of addressing health issues or concerns early and continuing with any ongoing monitoring and treatment.

As part of the Commonwealth Government's response to COVID-19, the National Medical Stockpile (NMS) secured the supply of a number of experimental medicines for use in clinical trials, in the event those medicines cannot be obtained through usual sources. ACTA has have been assisting the NMS with determining whether supply of a stockpiled medicine should be released to a specific trial.

The world has changed in the face of the COVID-19 pandemic. We are proud to have played a part in helping increase appreciation for the role and importance of clinical trials in researching treatments, cures and guarding our safety, as our community tries to find a way to reduce the enormous toll of the coronavirus.

ACTA ADVOCACY

Collaborations and engagement with ACTA members and the sector, including:

- Individualised pragmatic advice, guidance and workshop facilitation for establishing CTNs
- Support for eight Reference and three Special Interest Groups
- ACTA International Clinical Trials Conference 2019
- Twice-yearly ACTA Advisory Council meetings
- Annual General Meeting 2019
- COVID-19 tweetchats series with PRAXIS
- COVID-19 online forum
- Super webinar series held concurrently at eight live locations in capital cities across Australia and New Zealand
- Ongoing workshops and webinars on key topics

Representation on national committees, including:

- NHMRC Special Initiative in Mental Health (SIMH) - A National Centre for Innovation and Impact in Mental Health Care
- Chaired the International Advisory Group for the proposal addressing the Health Research Council 2020 Enhancing New Zealand's Clinical Trials RFP
- ARDC HeSANDA program Advisory Committee
- Clinical Trials Advisory Committee
- ClinTrial Refer General Practitioners roundtable

Response to consultations relevant to clinical trials and registries, including:

- ANZCTR changing landscape of clinical trials project
- Australian Digital Health in Cancer Care Roadmap
- Stem Cells Therapies Mission
- Renovation of International Council for Harmonisation (ICH) E6 Good Clinical Practice (GCP) guideline
- Department of Health National Teletrials Compendium
- Enabling infrastructure to support clinical trials in NSW

INTERNATIONAL CLINICAL TRIALS CONFERENCE

Sharing and working together will generate a more efficient learning health system that improves healthcare and delivers better value and importantly better quality of care.

This was the over-riding key message from our 2019 International Clinical Trials Conference which was opened by Federal Health Minister, the Hon Greg Hunt MP and hosted by several international speakers from both the United Kingdom and America.

More than 400 delegates attended four workshops and 20 conference sessions across four days as the ACTA International Clinical Trials Conference explored its vision of better health through best evidence. The conference brought together Australian and International experts in the cutting-edge design and conduct of clinical trials and registry custodianship, healthcare funding, policy and regulation, healthcare service delivery, health information technology, health economics and patient advocacy. They explored a number of topics which included revolutions in clinical trials, data access, embedding clinical trials in routine practice, maximising the value of clinical registries, improving public awareness and the vital role of consumer involvement in clinical research.

Dr Pamela Tenaerts, Executive Director of the Clinical Trial Transformation Initiative in the United States summed up the essence of the Conference in her presentation on day one when she said, “Getting better value out of clinical trials means more clinical trials to help patients.”

This statement was supported by Dr Anna Lavelle, Chair of Medicines Australia, stating,“We are here for the patient. The patient drives this.”

It is with thanks to the support of our Principle Partners, the Australian Department of Health and all our sponsors that we were able to hold the Conference in Sydney and bring so many experts together. Many of the presenters have also allowed us to share their presentations on our website under events and forums ACTA International Clinical Trials Conference 2–5 October 2019.

WEBINARS AND WORKSHOPS

Throughout the year, we held a range of education and training opportunities to facilitate knowledge sharing and professional development. Below is a snapshot of some of the events we ran.

SUPER WEBINAR – GUIDANCE ON IMPLEMENTABILITY

On 11 February 2020, ACTA held its biggest webinar to date – the Super Webinar –- to disseminate and open communication around a guide for trialists which ACTA has created, to help them optimise the results from late-phase clinical trials for implementation. The event was held online and in real time in eight major cities across Australia and New Zealand. More than 600 people registered for the two-hour event presented by ACTA's Deputy Chair, Prof Steve Webb.

SCOTT BERRY ON FDA ADAPTIVE TRIAL GUIDANCE

ACTA welcomed back Adaptive Trial design expert Scott Berry to provide an overview on FDA guidance released for Adaptive Designs for Clinical Trials of Drugs and Biologics.

Adaptive trial design workshops were held in Melbourne and Sydney, and were delivered by international leaders in the field, Dr Lorenzo Trippa and Dr Steffen Ventz of the TH Chan School of Public Health at Harvard University.

Additionally, a Bayesian Adaptive Trial Workshop was conducted in Perth. This was co-run by ACTA and Telethon Kids to help researchers and statisticians gain knowledge and practical skills to design these types of trials. This workshop was run by Bayesian clinical trial experts Ben Saville, Anna McGlothlin, Mark Jones and Julie Marsh.

DATA SAFETY AND MONITORING BOARDS FOR ADAPTIVE TRIALS

ACTA's Reference Group on Innovative Trial Design held a webinar on the challenges associated with Data Safety and Monitoring Boards (DSMBs) in adaptive trial designs. The webinar was well received, with more than 50 people attending on the day.

TWEETCHATS WITH PRAXIS

ACTA partnered with PRAXIS to run a series of TweetChats in 2020. The Twitter event was available to the general public and anyone involved in clinical trials, by using the hashtag #WhyWeDoResearch to discuss public awareness and involvement in clinical trials in Australia.

Over these sessions, the TweetChats covered subjects from involving the Australian public in COVID-19 research and making clinical information accessible, to public perceptions of clinical trials in Australia – how much is known, and what remains a mystery.

ACTA RESEARCH PRIORITISATION FRAMEWORK WEBINAR

ACTA's Clinical Trial Network Sector Expansion Reference Group ran a workshop at the Australasian Association for Academic Primary Care's (AAAPC) first virtual research conference, AAAPC 2020. The focus of the ACTA workshop was on effective and sustainable clinical trial networks. AAAPC President Dr Phyllis Lau was MC and ACTA Director Prof Chris Reid chaired the panel discussion. Prof Steve Webb (ACTA) presented an overview of ACTA's work to increase clinical trial network alliances. Prof Richard McManus (University of Oxford) shared an international perspective on success factors and challenges of networks in the UK. Prof Lena Sanci (The University of Melbourne) provided an overview of the existing Primary Care practice-based research network (PBRN) environment in Australia. This was followed by a moderated discussion with the speakers and panellists Prof Mark Nelson (ACTA/AAAPC) and Prof Kirsty Douglas (AAAPC).

NATIONAL CONSULTATION WORKSHOPS

ACTA held two national consultation workshops to engage Members, and the broader sector, to explore opportunities which continue to enhance clinical trial design, conduct and implementation. The first workshop discussed more appropriate ways of obtaining consent (within existing ethical frameworks) to participate in comparative effectiveness research (CER) trials, a priority area identified by consumers and researchers. The project report, and guidance for researchers on how to apply a proportionate consent approach in the design of clinical trials, are available on our website.

The second workshop focussed on clinical trial diversity for all under-represented and underserved groups within Australia. The workshop was attended by consumers, researchers and key stakeholders, to address the lack of inclusion of people from culturally and linguistically diverse (CALD) backgrounds within clinical trials conducted across Australia. A summary of the project can be accessed on our website.

RESOURCES

ACTA has developed a number of resources over the last financial year for new and established Clinical Trial Networks, Clinical Quality Registries and Clinical Trial Coordinating Centres within the Australian healthcare system.

The Efficient and Effective Clinical Trial Networks Reference Group developed a suite of tools based on best practice to assist new CTNs. In addition to the tools, the *Activities critical to success and growth of Clinical Trials Networks: Sector consultation report* was released, which highlights opportunities for CTNs by providing a framework for success and helping to shape best practice within the sector.

The Impact and Implementation of Clinical Trial Networks Trials Reference Group produced a report that looked at how the impact of clinical trials could be improved through better implementation. It strongly encourages that those involved in the planning, conduct and reporting of clinical trials optimise the implementability characteristics in order to have better impact in community.

Building on work to date, the Embedding Clinical Trials in Routine Care reference group also produced guidance on the requirements for low-risk ethics review in the context of comparative effectiveness research. The aim is to encourage wider use of the inherent flexibilities in the NHMRC National Statement that permits a proportionate approach to trial approval and conduct, based on the level of risk. Wider use of these flexibilities has the potential to make well-designed comparative effectiveness trials easier and quicker to conduct, which in turn will enable researchers to accelerate the generation of evidence to guide optimal health care.

Some of the other key reports from the year include:

- *Using Linked Administrative Data in Clinical Trials: A Guide for Clinical Trialists and Researchers* to accompany a four-part webinar series on the topic.
- *Guidance for New Clinical Trial Networks* as part of a suite of tools based on best practice to assist new CTNs. Included in this suite is a CTN Terms of Reference and position description for a Clinical Trial Network Executive Officer/Network Manager Duties – all of which can be adapted to suite specific needs.
- *Trial Endorsement and Review: Guidance for CTNs* to assist in establishing trial endorsement policies or guidelines.
- *Activities critical to success and growth of CTNs* report which identifies three elements crucial to network success being sustainability, engagement and infrastructure. It provides a framework for success and helping to shape best practice within the sector.
- *ACTA STInG grant advice for trial statisticians*, incorporates how to apply statistical support within a clinical trial, applying for funding for methodological research and selling a statistical track record.
- *Research Prioritisation Survey Report: Approaches and attitudes to clinical trial prioritisation in Australian Clinical Trial Networks and Coordinating Centres*, the findings from the survey will be used to perform a comparison of CTNs' current practices with best practice guidelines, and to determine implications for practice.
- *Research Prioritisation Framework* to assist CTNs and other organisations that are interested in setting priorities for the conduct of clinical trials.
- *ACTA Clinical trial awareness and access amongst culturally and linguistically diverse (CALD) populations: environmental scan* reviewed national and international initiatives aimed to increase participation in clinical trials by ethnic minority groups to further understand how to improve and develop sustainable clinical trial awareness, involvement, and access strategies for the CALD populations in Australia.
- *Applying a proportionate approach to consent in comparative effectiveness trials* illustrates international consent policy that supports proportionate consent for comparative effectiveness trials, and clarifies whether similar initiatives are permitted by the Australian regulatory and ethical frameworks.
- *Applying a proportionate approach to consent in comparative effectiveness trials* to demonstrate how to apply a proportionate approach to consent in comparative effectiveness trials conducted within Australia.

A full list of these resources can be found on the Activities and Resource sections of the ACTA website.

FEATURED RESOURCE

INVOLVING AND ENGAGING CONSUMERS

Consumer involvement and engagement in research is rapidly becoming an important global movement.

Clinical trials are all about people and researchers, and their organisations must ensure that participants know what is happening at all stages, and why their involvement is important.

To help facilitate this and ensure that trials are conducted to the highest possible standards, ACTA developed the Consumer Involvement and Engagement Toolkit, a centralised repository of best practice guidance and tools.

The aim was to facilitate consumer involvement and engagement along a clinical trial's lifecycle and support active and collaborative consumer partnerships with researchers and their organisations.

A joint initiative between ACTA and Clinical Trials: Impact & Quality (CT:IQ), the toolkit was developed by a working group of researchers, research organisations, and consumers.

How does the toolkit work?
The toolkit uses an interactive clinical trial map to provide practical advice for researchers and research organisations conducting clinical trials.

It offers guidance and tools to help plan, deliver, evaluate, and report consumer and community involvement and engagement activities.

The toolkit also aims to improve public awareness and understanding of clinical trials so consumers and the community are better equipped to influence the clinical trial agenda.

It features resources for consumers and the community offering insights into what it means to be involved in research and raising awareness around the role and value of clinical trials.

While the focus is clinical trials, much of the content is also relevant to other types of health research.

For researchers and research organisations
The toolkit map guides researchers and research organisations on how they can involve and engage consumers to help shape research throughout its lifecycle.

Information relevant to a range of topics can be located quickly and easily.

For consumers and the community
The active partnership between consumers and researchers is important to ensure decision making is with or by, rather than 'to', 'about' or 'for' them.

The toolkit helps to facilitate consumer collaboration by linking to real life stories about those who use it.

The toolkit draws on existing or adapted international resources and newly developed local resources to provide tools and guidance on consumer involvement and engagement in clinical trials in Australia.

As part of this, ACTA developed a Consumer Information Pack that describes what it means to be involved in health research and the many ways you can get involved.

ABBREVIATED FINANCIAL SUMMARY 30 JUNE 2020

STATEMENT OF SURPLUS OR DEFICIT AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2020

	2020	2019
	$	$
INCOME		
Total revenue and other income	**2,338,361**	**1,821,147**
EXPENDITURE		
Audit and legal	(11,339)	(10,841)
Consultancy expenses	(422,657)	(203,346)
Depreciation and amortisation expense	(7,587)	(18,512)
Employee benefit expenses	(1,167,564)	(1,092,333)
Event and meeting expenses	(509,719)	(44,801)
Operating expenses	(150,105)	(183,021)
Total expenditure	**(2,268,971)**	**(1,552,854)**
Net surplus/(deficit) for the year	**69,391**	**268,293**

STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2020

	2020	2019
	$	$
TOTAL ASSETS	**1,902,624**	**2,613,745**
TOTAL LIABILITIES	**1,367,938**	**2,148,391**
NET ASSETS	**534,685**	**465,355**

THANK YOU

We gratefully acknowledge the invaluable support and contributions from our Members, the Reference and Special Interest Group members and operational funding from the Australian Government's Medical Research Future Fund.

ACTA'S BOARD OF DIRECTORS

Prof John Raymond Zalcberg, OAM MBBS PhD FRACP FRACMA FAHMS FAICD
Chair
Prof Steven Anthony Rochford Webb, MBBS MPH PhD FCICM FRACP FAHMS
Deputy Chair and Company Secretary
A/Prof Katie Margaret Allan (Groom), MBBS BSc PhD FRANZCOG CMFM
Retired 28 November 2018
Ms Rebecca Lynne James
Independent Director with expertise in consumer representation
Ms Margo June MacGillivray, LLB(Hons) BA
Independent Director with expertise in governance and risk management.
Prof Vlado Perkovic, MBBS PhD FASN FRACP FAHMS Prof Christopher Michael Reid BA DipEd MSc PHD Appointed 28 November 2018
Mr Kieran Geoffrey Schneemann
Independent Director with expertise in the commercial clinical trials sector
Prof (Robert) John Simes, BSc(Med) MBBS SM FRACP MD FAHMS
Prof Judith Trotman, MBBS MD FRACP FRCPA

ACTA CENTRAL STAFF

Ms Simone Yendle
CEO and Company Secretary
Mr Nick Catton
Finance and Operations Manager (until February 2020)
Ms Karin Du Plessis
Senior Program Manager (until February 2020)
Ms Nicola Straiton
Project Manager
Ms Anitha Balagurunathan
Project Assistant
Ms Aneesha Heranjal
Project Assistant (from October 2019)
Dr Ann Wilson
Project Assistant (from October 2019)
Dr Fiona Nemeh
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Dr Thabisa Sibanda
Project Assistant (from February 2020)
Ms Madeleine Enright
Project Officer (until October 2019)
Ms Julie Armstrong
Project Officer (until December 2019)
Ms Lisa Reid
Communications Manager
Ms Chrystal Moore
Communications Coordinator
Ms Lea Hauchard
Events Coordinator (until November 2019)
Ms Katie Legge
Office Manager

REFERENCE GROUP LEADERSHIP

Efficient and Effective Clinical Trial Networks Reference Group

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

Clinical Trial Network Sector Expansion Reference Group

Prof Alex Brown
Prof Christopher Reid
Dr Jacqui Waterkeyn

Impact and Implementation of Clinical Trial Network Trials Reference Group

Prof Alan Cass
Prof Sally Green
Prof Chris Levi

Embedding Clinical Trials in Healthcare Reference Group

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

Strengthening Consumer Engagement Reference Group

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

Research Prioritisation: Tools and Criteria Reference Group

Prof Rachael Morton (stepped down after election to the Board in November 2019)
Dr Haitham Tuffaha

Innovative Trial Design Reference Group

Prof Andrew Forbes
Prof Stephane Heritier
Prof Katherine Lee
Prof Ian Marschner
Dr Annie Solterbeck

Innovative Outcome Data Reference Group

Prof Dorota Doherty
Dr Felicity Flack
A/Prof Steven Tong

SPECIAL INTEREST GROUP LEADERSHIP

ACTA Statistics in Trials Interest Group (STInG)

A/Prof Laurent Billot
Ms Sabine Braat
Prof Andrew Forbes
Prof Katherine Lee
Prof Ian Marschner
Dr Julie Marsh
Ms Elaine Pascoe
Dr Annie Solterbeck

Registries Special Interest Group

Prof Stephen McDonald

Special Interest Group for Network Managers (SIGNet)

Ms Julia Fallon-Ferguson
Ms Marilena Salvo

ACTA 2019 INTERNATIONAL CLINICAL TRIALS CONFERENCE CONVENORS

Prof Anthony Keech
Ms Susan Lohan

2020 TRIAL OF THE YEAR AWARDS JUDGES AND BOARD OBSERVERS

Prof Philip Alyward (Chair)
Prof Rachelle Buchbinder
Mr John Clements
Dr Eliza Hawkes
Dr Rana Hinman
Adj Prof Stephen Opat
A/Prof Mark Chatfield (Chair, Statistics Panel)
Dr Anneke Grobler
Dr Qiang Li
Prof Leonid Churilov
Prof Stephane Heritier
Dr Mark Jones
Prof Andrew Forbes (ACTA STInG Observer)
Prof Judith Trotman (Board Observer)

FULL MEMBERS

- Australasian Bone Marrow Transplant Recipient Registry (ABMTRR)
- Australasian Gastro-Intestinal Trials Group (AGITG)
- Australasian Kidney Trials Network (AKTN)
- Australasian Leukaemia and Lymphoma Group (ALLG)
- Australasian Lung Cancer Trials Group (ALTG)
- Australasian Myeloma Research Consortium (AMaRC)
- Australasian Radiopharmaceutical Trials Network (ARTnet)
- Australasian Rehabilitation Outcomes Centre (AROC), (incorporating Palliative Care Outcomes Collaboration-PCOC, and Electronic Persistent Pain Outcomes Centre
- -ePPOC)
- Australasian Society for Infectious Diseases Clinical Research Network (ASID)
- Australasian Stroke Trials Network (ASTN)
- Australasian College for Emergency Medicine Clinical Trials Group (ACEM)
- Australia and New Zealand Gynaecological Oncology Group (ANZGOG)
- Australia and New Zealand Sarcoma Association Limited (ANZA)
- Australia and New Zealand Society of Cardiac and Thoracic Surgeons National Cardiac Surgery Database Program (ANZSCTS)
- Australian and New Zealand Neonatal Network (ANZNN)
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
- Australian and New Zealand Children's Haematology/ Oncology Group (ANZCHOG)
- Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA)
- Australian and New Zealand Dialysis and Transplantation Registry (ANZDATA)
- Australian and New Zealand Intensive Care Society Australian Orthopaedic Association (ANZICS)
- National Joint Replacement Register (AOANJRR)
- Breast Cancer Trials
- Cooperative Trials Group for Neuro-Oncology (COGNO)
- Icon Institute of Innovation and Research
- Impact Trials, School of Medicine, Deakin University
- Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network (IMPACT)
- JDRF Australia
- Mater Misericordiae Health Services Brisbane Limited
- Melanoma and Skin Trials Limited (MASC)
- Melbourne Children's Trials Centre (MCTC)
- Menzies School of Health Research
- Neurodevelopment Australia
- Neuroscience Trials Australia (NTA)
- NHMRC Clinical Trials Centre

- NSW Drug and Alcohol Clinical Research and Improvement Network (DACRIN)
- OMICO (formerly Australian Genomic Cancer Medicine Centre)
- Paediatric Research in Emergency Departments International Collaborative (PREDICT)
- Palliative Care Clinical Studies Collaborative (PaCCSC)
- Primary Care Collaborative Cancer Clinical Trials Group, University of Melbourne (PC4)
- Prostate Cancer Outcomes Registry – Australia and New Zealand (PCOR_ANZ)
- Psycho-oncology Co-operative Research Group (PoCoG)
- School of Public Health and Preventive Medicine, Monash University (SPHPM)
- South Australian Health and Medical Research Institute (SAHMRI)
- Sydney Local Health District (SLHD)
- The George Institute for Global Health
- The University of Queensland Centre For Clinical Research (UQCCR)
- Therapeutic and Vaccine Development Research Group, The Kirby Institute
- Trans-Tasman Radiation Oncology Group (TROG Cancer Research)
- Victorian Ambulance Cardiac Arrest Registry (VACAR)
- Victorian Cardiac Outcomes Registry (VCOR)
- Victorian Orthopaedic Trauma Outcomes Registry (VOTOR) and Victorian State Trauma Registry (VSTR)

ASSOCIATE MEMBERS

- Alliance for Vascular Access Teaching and Research (AVATAR) Group
- ASPirin in Reducing Events in the Elderly – ASPREE Clinical Trial (ASPREE)
- Australia and New Zealand Musculoskeletal Clinical Trials Group (ANZMUSC)
- Australian Epilepsy Clinical Trials Network (AECTN)
- BiNational Colorectal Cancer Audit (BCCA)
- Cancer Trials Australia (CTA)
- Centre for Biostatistics and Clinical Trials (BaCT)
- Clinical Trials Network Australia New Zealand (CTANZ)
- LifeMend Neuropsychiatry Network (LIFEMend)
- Multiple Sclerosis Research Australia Clinical Trials Network (MSRCTN)
- National Endometriosis Clinical and Scientific Trials Network (NECST)
- Paediatric Trials Network Australia (PTNA)
- Queensland Centre for Mental Health Research (QCMHR)
- Regional Trials Network – Victoria (RTN-VIC)
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And a big thank you to our dedicated Affiliate Individual Members.

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