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# 2022-23

## Annual Report

# Acknowledgement of Country

**CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.**



# Table of Contents

04	<u>About Us</u>
05	<u>Our People</u>
07	<u>Director's Report</u>
08	<u>Our Projects</u>
08	<u>The InFORMed Project: Redesigning Consent to Research</u>
09	<u>Beyond the Form: Engaging Participants Throughout Clinical Research</u>
10	<u>Meetings and Presentations</u>
10	<u>Executive and Steering Committee Meetings</u>
10	<u>Public Presentations and Conferences</u>
11	<u>Looking to the Future</u>

# About Us

## Our Aim

To develop and implement recommendations that will improve the impact, quality, and efficiency of clinical trials, leading to more rapid, lower cost and higher quality evaluation of healthcare interventions in Australia. This is achieved through selecting and undertaking continuous improvement projects that address agreed areas of need among CT:IQ members.

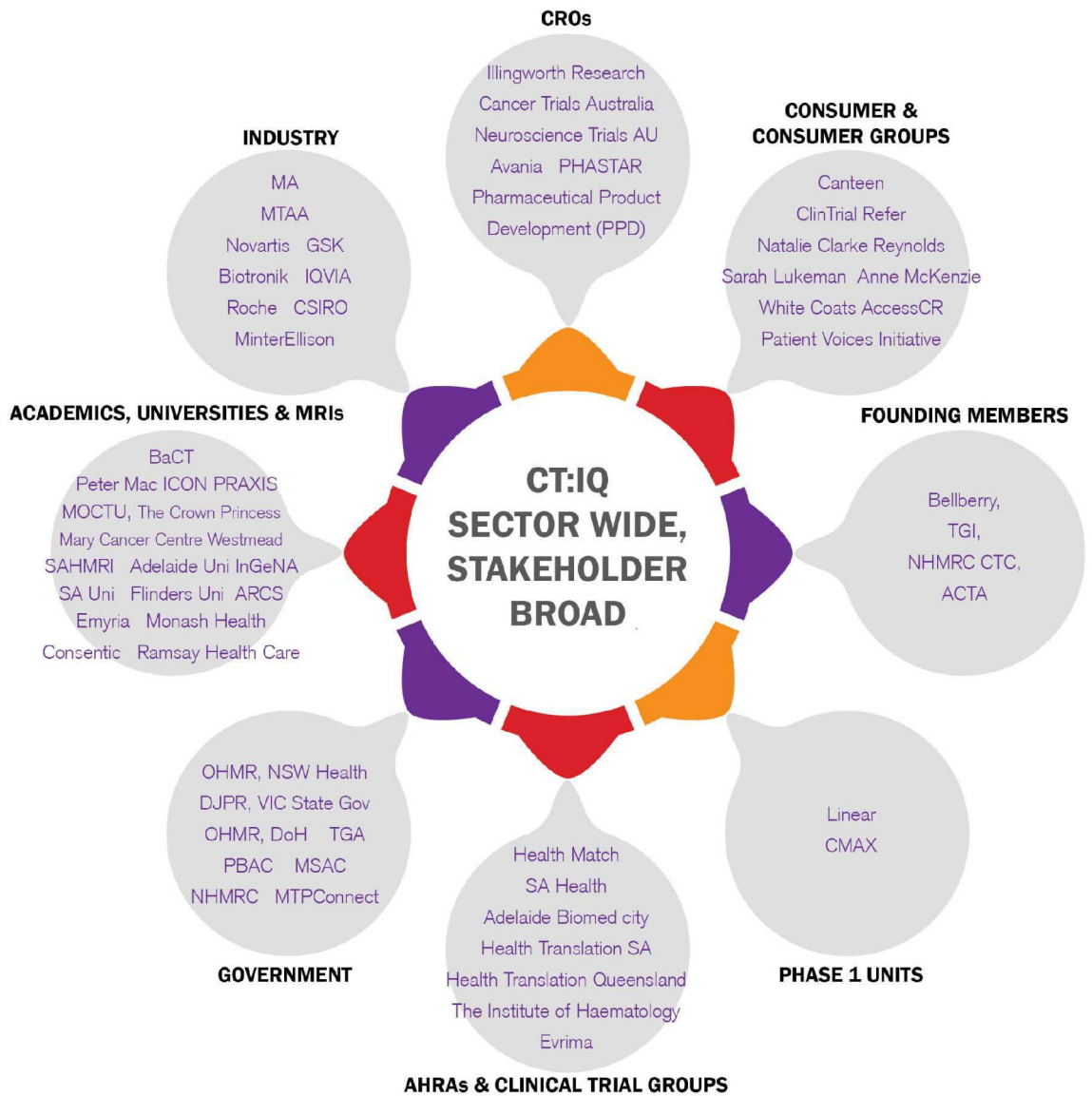
## Our Vision

To act as a platform for all stakeholder voices to come together and continually improve the clinical research sector in Australia, enabling efficient and effective, patient-centred, clinical research projects.

## Our History

CT:IQ is an Australian member-based organisation formed in 2018 by four founding members, Bellberry, ACTA, NHMRC CTC and The George Institute for Global Health. For its first three years of its operation, CT:IQ benefited from MTPConnect Growth Centre Funding.

CT:IQ's membership has expanded to now include over 50 organisations across the Australian clinical research sector, including government, industry, researchers, drug and device organisations, sites, phase I units, HRECs, interest groups and consumers.



# Our People

## Advisory Committee

Name	Position
Terrie O'Brien	Director – Clinical Trials Policy Section, Australian Government Department of Health
Anne McKenzie	Community Engagement Consultant and Advisor, Telethon Kids Institute
Jillian Barr	Director, Ethics and Integrity, National Health and Medical Research Council
Prue Torrance	Executive Director, Research Quality & Priorities, National Health and Medical Research Council
Andrew Wilson	Chair, Pharmaceutical Benefits Advisory Committee

## Executive Committee

Name	Position
Kylie Sproston	CEO, Bellberry Ltd
Trina O'Donnell	Director, Strategic Projects, Bellberry Ltd
Jasmine Katakos	Head of Operations, The George Institute
John Simes	Co-Director, Cancer Trials, NHMRC Clinical Trials Centre
Hannora Jurkovic	Associate Director, Clinical Trial Operations & Development, NHMRC Clinical Trials Centre
Ana Svensson	Senior Director CMR Novo Nordisk Oceania
Stewart Hay	CEO, ACTA (until December 2022)
John Zalberg	ACTA Board Director (until December 2022)
Fiona Nemeh	Senior Project Officer, ACTA (until December 2022)
Stuart Anderson	CTCM Program Manager, MTAA
Deborah Bell	Executive Director, Business Development, Avania

## Staff

Name	Position
Lisa Eckstein	CT:IQ Programme Director
Sonia Harvey	CT:IQ Project Manager (until March 2023)
Gudrun Wells	CT:IQ Research Officer (from May 2023)

# Steering Committee

ACCESSCR

Adelaide  
BioMed  
City

Anne McKenzie  
(Consumer  
Representative)



Central Adelaide  
Local Health  
Network



Department of  
Health

Department of  
Jobs, Precincts and  
Regions (DJPR) Vic



Flinders  
University



ILLINGWORTH  
RESEARCH GROUP



MinterEllison.



MSAC



Natalie Clark  
Reynolds  
(Consumer  
Representative)



Patient Voice Initiative



SA Department of  
Health &  
Wellbeing



Sarah Lukeman  
(Consumer  
Representative)



University of  
Adelaide

University of  
South Australia



# Director's Report



The 2022-2023 financial year has been an exciting period of my Directorship. Having had a chance to settle into the role, the year provided opportunities to deepen my connections with members from across the CT:IQ universe and get closely involved with ongoing projects.

Perhaps the standout of the year has been the launch of the beta-testing version of the InFORMed project: Redesigning Consent to Research at ARCS23 in June. This was the culmination of two years of mammoth effort, spearheaded by CT:IQ Programme Manager Sonia Harvey alongside 35 project team members. It has been heartening to see the immense interest in the InFORMed project among the sector, with more than 362 downloads at the time of writing and several HRECs and others already making the decision to implement the template. I am incredibly excited to see what further traction the project can garner in the year to come.

In September 2022, I also had the opportunity to start up a new CT:IQ project in partnership with the Victorian Comprehensive Cancer Care (VCCC) Alliance—Beyond the Form: Engaging Participants through Clinical Research. In many respects, Beyond the Form takes over from where the InFORMed project leaves off by asking what happens after the time of initial consent? How are researchers engaging with participants throughout the duration of their research involvement, and what do participants value when it comes to engagement strategies. This project explores an aspect of the clinical research lifecycle that has received comparatively little attention, and yet is incredibly important for showing respect to participants and potentially improving participant retention.

More than anything else, CT:IQ is about its members, and the spirit of collaboration in which these diverse players in the clinical research ecosystem develop shared solutions to common problems. I am grateful to all members who give of their time to attend meetings, join project teams, and otherwise come to the table. It is wonderful to have been able to welcome six new CT:IQ members this year: CSIRO; Ramsay Health Care; Minter Ellison; Roche; Access CR and Consentic. Welcome, and I'm excited to continue to work alongside you all in the year to come.

Thank you all for this opportunity to work alongside you.

Dr Lisa Eckstein



# Our Projects

## The InFORMed Project: Redesigning Consent to Research



CT:IQ Project Number 7: The Informed Project commenced in 2021, with the ambitious goal of developing a new nationally consistent, simplified, and consumer-centred Participant Information and Consent Form (PICF) template for the Australian health and medical research sector. The project consciously started with a blank page with an overarching question of what information does a potential participant need to make an informed choice whether to participate in a research project.

To answer this question, approximately 35 project team members led by CT:IQ Project Manager Sonia Harvey worked tirelessly to research best practices in the literature, conduct stakeholder surveys, and generate a draft template for testing.

The 2022/23 financial year marked several key milestones in the evolution of this project:

**Partnership with HeSANDA:** As a component of the InFORMed project, CT:IQ partnered with the Health Studies Australian National Data Asset (HeSANDA) Program to develop a Data Sharing Statement for use in Australian health and medical research PICFs. This allowed the organisations to work synergistically to tackle the vexed issue of ensuring a legally and ethically robust consent statement for the use and sharing of research data. A project team was established for this component of the work including select members of InFORMed and HeSANDA nodes.

**Consumer Focus groups:** Dr Tanya Symons conducted three dedicated consumer focus groups to seek grounded feedback on the draft InFORMed template. This was an opportunity for the InFORMed project team to co-develop PICFs with study teams for three demonstration projects. The resulting PICFs were then presented to focus groups comprised of persons with lived experience of the disease or topic being researched. Results from these focus groups were pivotal for further refining the InFORMed template and drafting a user guide.

**Launch of beta-testing version:** On 8 June 2023, the beta-testing version of the InFORMed template and user guide was launched at ARCS23. This was a pivotal opportunity to present the project to the broader Australian research sector and commence the feedback-gathering stage of the project. Feedback will remain open throughout 2023 to allow researchers, HRECs, and others the chance to thoroughly test the template and user guide. With this feedback, the template will be further refined in early 2024 before seeking endorsement for it to be hosted on the NHMRC website.

# Beyond the Form: Engaging Participants Throughout Clinical Research



CT:IQ's ninth continuous improvement project was launched in September 2022 as a partnership with the VCCC Alliance. The project seeks to understand when and how to engage with participants throughout their clinical research involvement. The project team includes members of CT:IQ as well as the VCCC Alliance, led by CT:IQ Research Officer Ms Gudrun Wells.

Early highlights have included a well-received presentation at ARCS23 and the commissioning of a rapid review white paper on engagement strategies that have been evaluated in the peer-reviewed and broader literature.

Recently, the project has commenced its qualitative research phase, seeking surveys and interviews with research personnel to unpack engagement strategies currently in place along with barriers to, and facilitators of, participant engagement more broadly.



## Beyond the Form: Engaging Participants Throughout Clinical Research

Next steps will include a better understanding of consumer preferences and values when it comes to ongoing engagement. This will include surveying current or past participants about their experiences of communication in clinical research, as it is important to illuminate communication issues about which researchers may not be aware. In addition, the project team will work with consumer groups to assess emerging themes and strategies from the white paper and researcher surveys and interviews. Through the VCCC Alliance, the project will also undertake a pilot of available engagement strategies to look at feasibility for implementation.

# Meetings and Presentations

## Executive and Steering Committee meetings

CT:IQ Executive and Steering Committee members met regularly throughout the 2022-23 financial year, providing opportunities for members to come together to hear about on ongoing CT:IQ projects, and to provide feedback on potential new projects.

### Executive Committee Meetings

The CT:IQ Executive Committee met on a six-weekly schedule in 2022-23, with representation from the four founding member organisations, Medicines Australia, and the Medical Technology Association of Australia.

The Executive Committee operates as CT:IQ's key decision-making body, with overarching responsibility for project selection and operation.

### Steering Committee Meeting 21 October 2022

A virtual Steering Committee meeting was held on 21 October 2022. Thirty-six members attended. Key agenda items included an update on consumer consultation for the InFORMed project by Tanya Symons, information on development of the National Data Sharing Statement, and an update on the Beyond the Form project. Steering Committee members also considered a potential new CT:IQ project on compensation for trial-related injury. All members agreed or somewhat agreed that CT:IQ should consider a project in this space and requested a refined project plan for consideration in early 2023.

### Steering Committee Meeting 30 March 2023

A virtual Steering Committee meeting was held on 30 March 2023 to review a project plan on compensation for trial-related injuries. Forty-one members attended. The project plan generated considerable interest and support. However, there was insufficient endorsement to commence the project at this time. Members agreed to reconsider a project in this space in the future.

## Public Presentations and Conferences

Event	Title	Speaker/s	Date
Australia-New Zealand Site Solutions Summit (SCRS)	The InFORMed Project	Kath Irish, Simon Windsor, Skye Nolan, and Angela Scheppokat	July 2022
National HREC Conference	The InFORMed Project	Lisa Eckstein, Tanya Symons	November 2022
ARCS Consumer Interest Group	The InFORMed Project	Lisa Eckstein, Tanya Symons, Sarah Lukeman	March 2023
ARCS 2023	Launch of InFORMed Project	Lisa Eckstein, Eleonora Kay	June 2023
	Beyond the Form	Lisa Eckstein, Tanya Symons, James Cokayne, Jeremy Kenner	June 2023
	Low risk clinical research	Lisa Eckstein, Tanya Symons, James Cokayne, Jeremy Kenner	June 2023

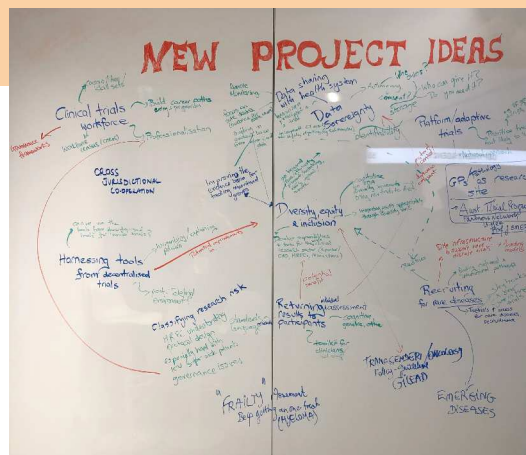


### Targeted Presentations

- Southern Cross University Clinical Trials Research and Ethics Workshop
- NSW Health Bi-Annual Ethics and Governance Roundtable
- New South Wales Regional Health Community of Practice
- InGENA Quarterly Forum
- ACTA Special Interest Group for Clinical Trial Network Managers (SIGNet) meeting

CT:IQ provided sponsorship for the ARCS DIRT Summit on Digitalisation of Clinical Trials. The Summit led to the development of a white paper to define common terms used in decentralised trials, to provide a common and consistent language for the sector.

# Looking to the Future



The year to come will allow CT:IQ to continue to build on the foundations laid in 2022-23 while embarking on exciting new initiatives.

The 2023-24 financial year will mark a period of refinement for the InFORMed project as we turn our focus to consultation with the Australian research sector: what has the beta-version gotten right and what needs further refinement? Listening and acting on this feedback will put us in a strong position to seek widespread implementation of the Participant Information and Consent Form template and user guide in the first half of 2024.

The Beyond the Form project is gathering momentum, and the upcoming year promises to be an exciting one. We anticipate releasing a white paper on engagement strategies presently being adopted by health and medical researchers. We are also looking forward to learning from investigators, clinical research coordinators and—most importantly—consumers, about the ongoing engagement strategies that they would like to see happen in Australian clinical research.

CT:IQ is also now in a position to commence new continuous improvement projects. We will be looking to our members to guide us on what projects they think are most important to improving the efficiency, quality, and effectiveness of Australian clinical research. We are excited to embark on these new journeys with you all.

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