



2023-24

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.



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About Us

Our Aim

CT:IQ develops practical resources to support excellence in Australian clinical trials. Our diverse membership includes a wide range of Australian clinical trial stakeholders, including industry, academia, government, health services and consumers, who come together to select and collaborate on projects that can improve policy and practice across the sector. Through our evidence-based and multidisciplinary approach, we generate high-quality, balanced outputs that drive nation-wide change.

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 founded in 2018 by 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.

Since commencing operations, CT:IQ has completed seven continuous improvement projects:

1. Consumer Involvement and Engagement Toolkit (with the Australian Clinical Trials Alliance)
2. Electronic Consent in Clinical Trials
3. Early-phase Clinical Trials Best Practice
4. Clinical Trial Site Recruitment
5. Joint Statement on eSignatures
6. InFORMed: Redesigning Consent to Research
7. Learn About Clinical Research

Our People 2023-2024

Advisory Committee

Name	Position
Dr Robyn Langham	Therapeutics Goods Administration (TGA)
Terrie O'Brien	Office of Health and Medical Research (OHMR), Department of Health
Andrew Wilson	Pharmaceutical Benefits Advisory Committee (PBAC)
Cathy Schapper	National Health and Medical Research Council (NHMRC)
Anne McKenzie	Community Engagement Consultant and Advisor, Telethon Kids Institute (until October 2023)

Executive Committee

Name	Position
Dino Cercarelli	COO, ACTA
Chris Reid	Board Chair, ACTA
Ana Svensson	Senior Director CMR Novo Nordisk Oceania
Deborah Bell	Avania Clinical
Martijn Oostendorp	Associate Director, Clinical Trial Operations and Development at NHMRC Clinical Trials Centre
Anne McKenzie	Community Engagement Consultant and Advisor, Telethon Kids Institute (from October 2023)
Jasmine Katakos	Head of Operations, The George Institute
Stuart Anderson	CTCM Program Manager, MTAA
Kylie Sproston	CEO, Bellberry Ltd
Trina O'Donnell	Director, Strategic Projects, Bellberry Ltd

Staff

Name	Position
Lisa Eckstein	CT:IQ Program Director
Gudrun Wells	CT:IQ Research Officer
Vanessa Warren	CT:IQ Research Officer

Steering Committee

Organisation	Category
Australian Clinical Trials Alliance	Research institute
Bellberry Ltd	NFP
Medicines Australia	Industry
Medical technology Association of Australia	Industry
NHMRC Clinical Trials Centre	Research institute
Anne McKenzie	Consumer
The George Institute of Global Health	Research institute
Department of Health	Government
National Health and Medical research Centre	Government
ARCS	Industry
The Centre for Biostatistics and Clinical Trials (Peter MacCallum)	Research institute
Biotronik	Industry
Health Translation Queensland	Government
Cancer Trials Australia	NFP
CanTeen	Consumer
CMAX	Industry
Sarah Lukeman	Consumer
Natalie Clarke Reynolds	Consumer
Victorian Department of Jobs, Precincts and Regions (DJPR)	Government
Evrima	Industry
GSK	Industry
Icon Cancer Group	Research institute
InGeNa	Government
IQVIA	Industry
Linear	Industry

Organisation	Category
NeuroScience Trials Australia	Research institute
Novartis	Industry
NSW Health	Government
Orygen	Research institute
Patient Voices Initiative	Consumer
Praxis Australia	NFP
Queensland Health	Government
SAMHRI	Government
Adelaide University	Research institute
Flinders University	Research institute
Crown Princess Mary	Research institute
SA University	Research institute
SPHERE	NFP
VCCC Alliance	NFP
Whitecoats Foundation	Consumer
Monash Health	Research institute
PPD	Industry
RPA Institute of Haematology	Research institute
Consentic	NFP
AccessCR	Consumer
Minter Ellison	Other
Ramsay Health Care	Research institute
Roche	Industry
CSIRO	Government
Fortrea	Industry
ObvioHealth	Industry
NT Department of Health	Government
Hunter Medical Research Institute	Research institute
Genesis Care	Research Institute
WA Department of Health	Government

Director's Report



2023-2024 has been a year of consolidation, with the launch of the major InFORMed project, key milestones reached for the Beyond the Form project, and the launch of new projects on Clinical Research Data Sharing Frameworks and Flexible Trial Delivery Methods.

The launch of the InFORMed Participant Information and Consent Form (PICF) on 13 June 2024 marked the culmination of three years of work by the dedicated project team, extensive consumer consultation, and a beta-testing phase to seek feedback broadly from clinical research stakeholders, including researchers, Human Research Ethics Committees, and sponsors. I am excited to usher in the implementation phase of the InFORMed project to position Australia at the forefront of consumer-centred consent practices.

The year has also marked steady progress on the Beyond the Form project, a partnership with the Victorian Comprehensive Cancer Care (VCCC) Alliance to develop best-practices for engaging with participants throughout their clinical research journey. Activities this year have focused on data gathering and awareness raising, including publication of a white paper on the use of ongoing communication strategies with current medical research participants and consumers; interviews with current research staff on their current communication strategies; and—crucially—workshops with former research participants on their communication expectations and preferences.

In August 2023, CT:IQ Steering Committee members came together in Sydney to select the next tranche of projects. Attendees considered five new project ideas brought forward by member organisations, with the highest-ranking ideas being strengthening the clinical research workforce, clinical research data sharing, and decentralised clinical trials. It is exciting to start to see these projects take shape supported by vibrant new project teams.

Another highlight of the year was the workshop in Melbourne on 23 May 2024 to brainstorm current flexible trial delivery methods in use in Australia, their respective enablers and barriers, and opportunities for the future. It was energising to have so much of our CT:IQ community together sharing ideas and experiences including consumers, researchers, representatives of sites, sponsors and contract research organisations, Human Research Ethics Committee members, and others. It is days like these that show the magic of CT:IQ at work. The day resulted in a list of practical ideas for improving the efficiency, effectiveness and quality of flexible trial activities in Australia, which will be considered by the project team.

The year ahead will focus on developing these new CT:IQ projects, promoting implementation of existing projects, and establishing virtual and in-person opportunities for sharing ideas and experiences across our diverse membership pool.

Dr Lisa Eckstein

Our Projects

The InFORMed Project: Redesigning Consent to Research



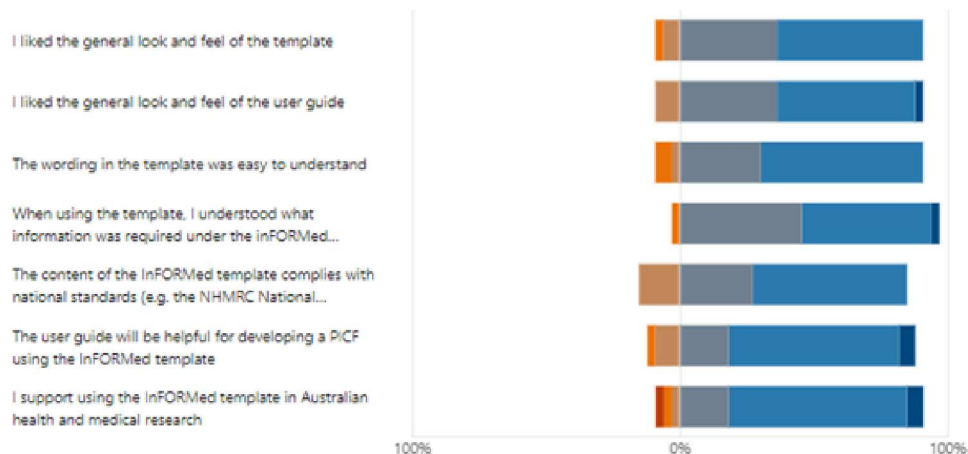
The beta-testing version of the InFORMed Project Participant Information and Consent Form and an associated user guide were launched on 13 June 2023. This led into a six-month opportunity for researchers, sponsors, HRECs and others to use the outputs and assess whether they are fit-for-purpose in the real world. CT:IQ received 35 submissions on the template, which were overwhelmingly positive.

10. Please provide your feedback on the following statements by choosing one of the options for each statement.

Note, if you are on a mobile device, you may need to scroll to see all available options

[More Details](#)

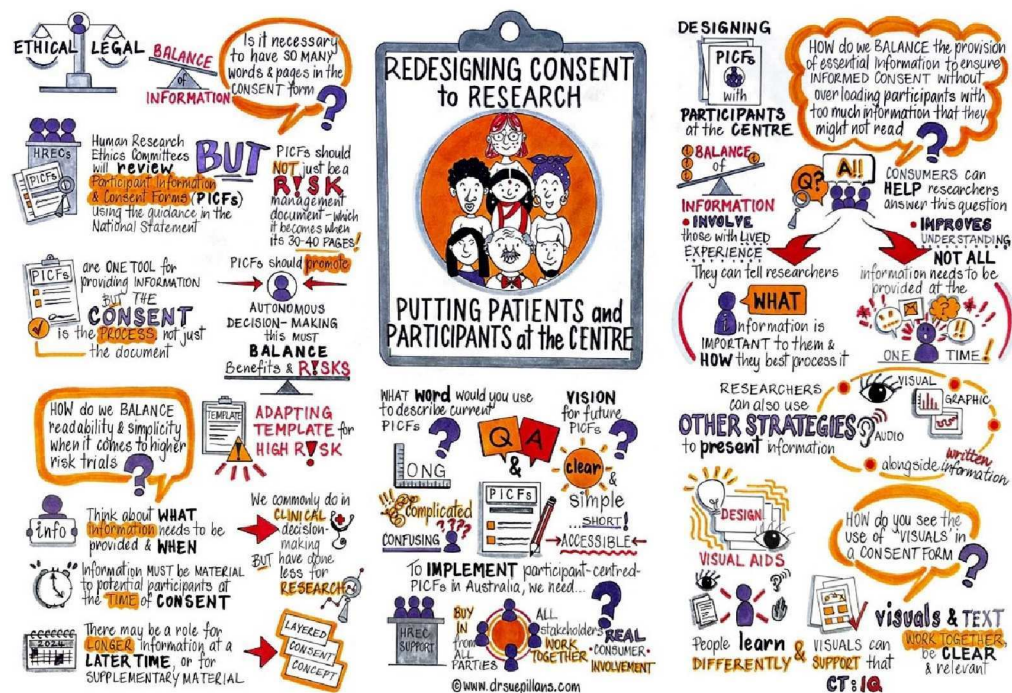
Strongly disagree Disagree Neutral Agree Strongly Agree Not applicable



The project team reconvened in January 2024 to consider suggestions for refinement received through the beta-testing process. Key considerations and responses were as follows:

Feedback	Response
Use of the term 'consumer' in template and user guide	Refined into 'consumer', 'participant' and 'potential participant'
Requests for additional information and clarity on use of data and tissue for further research	Clarification of consent as part of study consent for <i>publication of results</i> . Refinement of consent for future research using data and tissue samples
Additional information needed on what happens on participant withdrawal and when the study ends	Information added into the template to prompt ongoing access to study drug (if relevant), provision of plain language summary and how participant data will be handled post-withdrawal
Important study-related lifestyle changes or restrictions should be better showcased.	New section to highlight important restrictions/changes in lifestyle that are required, e.g., contraception
Clarification on when a witness is needed	Clarified that a witness is only needed in circumstances where a decision maker required assistance to read the form
Formatting of template does not always respond when new text is added	Formatting adjusted to more consistently respond to template adjustments

The finalised template and user guide were launched on 13 June 2024 at the ARCS conference. CT:IQ also held a webinar on the InFORMed project, including discussion of ethical and legal considerations, practical considerations, and future implementation. The webinar is available on the CT:IQ website and was recorded in a visual storyboard by Dr Sue Pillans.



CT:IQ is in ongoing discussions with the National Health and Medical Research Council and state and territory government departments to progress implementation.

Beyond the Form: Engaging Participants Throughout Clinical Research



The Beyond the Form project seeks to establish how research teams can better facilitate two-way communication between research teams and participants after the participant has commenced in a clinical research project. In partnership with the VCCC Alliance, we have worked to understand both the current situation in Australia, and what recommendations CT:IQ can make to improve communication in future projects.

This year has been a big year for the project, with many data gathering and awareness raising activities conducted, including presentations to ACTA 2023, the 4th National HREC Conference and ARCS 2024.



Our qualitative research phase has now completed, with twenty interviews with staff working in clinical research, and three workshops with 22 past research participants conducted. The participant workshops were a fascinating discussion of how communication impacts many different types of research participants, and there were many useful ideas generated to guide the development of communication plans in the future.

The team has also worked with WEHI to develop a pilot project to evaluate some of the recommendations as a sub-study in a clinical trial. This will be a valuable addition to our understanding of how to implement and evaluate our recommendations for improving communication.

Flexible Trial Delivery



At the 23 August 2023 CT:IQ meeting, the Steering Committee considered CT:IQ activities relating to decentralised clinical trials. To best complement existing activities in the sector, the scope and direction of the project was amended to Flexible Trial Delivery. This was approved by the Executive Committee on 1 September 2023 with the first phase being a mapping report on the current decentralised clinical trial landscape in Australia. Dr Tanya Symons was engaged to produce this report, which was published on the CT:IQ website in December 2023. The report highlighted extensive activity—in particular, through the Australian teletrials projects. However, there was an identified need for broader consideration of additional models for decentralisation.

To further scope the project and explore issues of most pertinence to the sector, CT:IQ invited all Steering Committee members or their delegates to a workshop in Melbourne on 23 May 2024. We were thrilled to welcome 22 attendees who spent the day strategising creative strategies for the clinical research sector to deliver trial activities flexibly, as well as the information that researchers, sponsors, HREC members, consumers, policymakers would need to know to adopt these strategies. The workshop was an invaluable opportunity to springboard off the diverse backgrounds and experiences of our members. A big thank you to our presenters and panelists on the day: Taylor Major, Megan Foggin, Belinda Fazekas, Sarah Lukeman, Ann Single, Trina O'Donnell, Gillian Mason, and Carrie Bloomfield.



Clinical Research Data Sharing Frameworks

A project on clinical research data sharing governance was also identified by Steering Committee members at the 23 August 2023 meeting. An opportunity was identified to partner with the Australian Research Data Commons (ARDC) on the project.

On 11 April 2024, CT:IQ and the ARDC commenced the Clinical Research Data Sharing Frameworks project to develop practical guidance to support efficient and trustworthy sharing of clinical research data in Australia. A joint CT:IQ/ARDC committee has been established to guide the project.

The project includes four work packages, each with dedicated research staff:

- Development of a governance framework for data sharing, led by Dr James Scheibner (Flinders University)
- Consultations with stakeholders to identify burdens and barriers to clinical research data sharing and areas of need, led by Dr Lisa Eckstein (CT:IQ) and Dr Lene Seidler (NHMRC Clinical Trials Centre)
- Benchmarking practices of ethics review bodies based on a shared ethical decision-making methodology, led by Dr Rebekah McWhirter (Australia National University) and Ms Vanessa Warren (University of Tasmania)
- Development of a clinical research data sharing toolkit (TBD)

The project is due to be completed by October 2025.

MEET OUR TEAM.

PROJECT:
Clinical Research Data Sharing Frameworks

Vanessa Warren Rebekah McWhirter James Scheibner Dr Lisa Ecksten Dr Anna Lene Seidler

Meetings and Presentations

Executive and Steering Committee meetings

CT:IQ Executive and Steering Committee members met regularly throughout the 2023-24 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 2023-24, with representation from its four founding member organisations (Bellberry Ltd, The George Institute for Global Health, NHMRC CTC, and ACTA) in addition to Medicines Australia, the Medical Technology Association of Australia, and consumer representative Anne McKenzie AO.

Steering Committee Meetings

The CT:IQ Steering Committee held two meetings in 2023-24 as well as an in-person workshop.

Steering Committee Meeting 8 August 2023

A hybrid Steering Committee meeting was held on 8 August 2023. The meeting was attended by 20 members in person and 21 members online. Attendees were provided with descriptions of five ideas for future CT:IQ projects prior to the meeting. Attendees ranked the project proposals based on their capacity to improve the quality, efficiency, and effectiveness of clinical research. Attendees then worked in small groups to further develop the highest ranked project proposals. There was agreement to take three projects to the Executive Committee for further consideration (decentralised clinical trials, strengthening the clinical research workforce, and clinical research data sharing), with other projects to be considered as additional CT:IQ capacity becomes available. CT:IQ passes on its gratitude to Ms Gillian Mason for her expert facilitation of the day.

Steering Committee Workshop May 2024

CT:IQ invited Steering Committee members or their delegate to a workshop in Melbourne on 23 May 2024 on flexible trial activities. The workshop findings will feed into the ongoing CT:IQ Flexible Trial Delivery project.

Public Presentations and Conferences

Event	Title	Speakers	Date
A-CTEC	The InFORMed Project	Lisa Eckstein, Sarah Lukeman, Kathleen Irish	6 July 2023
ARCS Special Interest Group	The InFORMed Project	Lisa Eckstein, Sarah Lukeman	5 September 2023
ANZGOG Study Coordinators Workshop	The InFORMed Project	Lisa Eckstein	Oct 2023
4th National HREC Conference	The InFORMed Project Beyond the Form	Lisa Eckstein Gudrun Wells	December 2023
CT:IQ Webinar	Redesigning Consent to Research: Putting Patients and Participants at the Centre	Lisa Eckstein, Radhika Butala, Rebeka McWhirter, Sonja Read, James Cokayne, Magdalena McGuire, Sarah Lukeman, Fleur O'Hare, Jeremy Kenner, Liz Wilson, Tanya Symons	17 May 2024
ARCS 2024	The InFORMed Project – template launch Beyond the Form	Lisa Eckstein, James Chan, Sonja Read, Jerneen Williams, Melissa Hagan, Kathryn Gamble Eleonora Kay, Gudrun Wells, Sarah Lukeman	June 2024

Looking to the Future


The year ahead looks to be one of exciting new developments. The launch of the InFORMed project template and user guide provides an opportunity to focus on strategies to promote uptake across the Australian health and medical research sector. CT:IQ's new projects on clinical research data sharing frameworks and flexible trial delivery methods will also provide valuable opportunities to inform the efficiency, quality and efficacy of Australian clinical research.

An additional focus for the year will be strengthening the opportunities to listen to and learn from the sector. This includes through feedback on existing CT:IQ resources, ideas for new projects, and engagement with complementary projects and outputs in Australia and internationally.


We look forward to working alongside all in the Australian clinical research sector in the year to come.

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