CT:IQ

Year in Review

2025

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

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 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. We are hosted by Bellberry Limited.

Since commencing operations, CT:IQ has completed eight 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
8. Beyond the Form

Two additional projects are due for completion on the coming months:

9. Clinical Research Data Sharing Frameworks (with the Australian Research Data Commons)
10. Flexible Trial Delivery Methods

CONSUMER ENGAGEMENT
- **Consumer Involvement and Engagement Toolkit** (2018-2019)
- **Learn About Clinical Research** (2019)

INVESTIGATORS AND SITES
- **Early-phase Clinical Trials Best Practice** (2019-2020)
- **Clinical Trial Site Recruitment** (2019-2020, updated 2025)

RESEARCH DESIGN
- **Beyond the Form** (2022-2025)
- **Flexible Trial Delivery Methods** (2024 - ongoing)
- **Guidelines for Biomarker Directed Therapies** (2019-2020)

ETHICS AND GOVERNANCE
- **eConsent in Clinical Trials** (2019-2020)
- **The InFORMed Project** (2021-2024)
- **Joint Statement on eSignatures** (2019-2020)
- **Clinical Research Data Sharing Frameworks** (2024-2025)

Our People 2025

Advisory Committee

Name	Position
Robyn Langham AM	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 AM	Community Engagement Consultant and Advisor, Telethon Kids Institute (until October 2025)

Executive Committee

Name	Position
Dino Cercarelli	Chief Operating Officer, ACTA
Christopher Reid	Board Chair, ACTA
Ana Svensson	Senior Director CMR, Novo Nordisk Oceania
Deborah Bell	Executive Director, Avania Clinical
John Simes	Senior Associate Director, NHMRC Clinical Trials Centre
Martijn Oostendorp	Associate Director, Clinical Trial Operations and Development at NHMRC Clinical Trials Centre
Anne McKenzie AM	Community Engagement Consultant and Advisor, Telethon Kids Institute (until October 2025)
Martha Gerges	Project Development Manager, The George Institute
Stuart Anderson	CTCM Program Manager, Medical Technology Association Australia
Kylie Sproston	Chief Executive Officer, Bellberry Limited
Trina O'Donnell	Director, Strategic Projects, Bellberry Limited

Staff

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

Steering Committee

Organisation	Category
AAAH (Australian Association for Adolescent Health),	NFP
AccessCR	Consumer
Adelaide University	Research institute
Alexion	Industry
Anne McKenzie	Consumer
ARCS	Industry
Australasian Kidney Trials Network	NFP
Australian Clinical Trials Alliance	Research institute
Bellberry Ltd	NFP
Biotronik	Industry
Cancer Trials Australia	NFP
Central Coast LHD	Government
Central Pharmacy Logistics	Industry
CMAX	Industry
Consumer representative Natalie Clarke Reynolds	Consumer
Consumer representative Sarah Lukeman	Consumer
Department of Health (Cth)	Government
Evrima	Industry
Flinders University	Research institute
Genesis Care	Research Institute
GSK	Industry
Health Translation Queensland	Government
Hunter Medical Research Institute	Research institute
Icon Cancer Group	Research institute
InGeNa	Government
IQVIA	Industry
Linear	Industry

Organisation	Category
Medical Technology Association of Australia	Industry
Medicines Australia	Industry
Minter Ellison	Other
Monash Health	Research institute
National Health and Medical Research Centre	Government
Nepean Blue Mountains LHD	Government
NeuroScience Trials Australia	Research institute
NHMRC	Research Institute
NHMRC Clinical Trials Centre	Research institute
Northern Sydney LHD	Government
Novartis	Industry
NSW Health	Government
NT Department of Health	Government
ObvioHealth	Industry
Orygen	Research institute
Patient Voices Initiative	Consumer
Praxis Australia	NFP
Queensland Health	Government
Ramsay Health Care	Research institute
Roche	Industry
RPA Institute of Haematology	Research institute
SA University	Research institute
SAHMRI (South Australian Health and Medical Research Institute)	Government
SCHN (Sydney Children's Hospitals Network)	Government
SPHERE	NFP
The Centre for Biostatistics and Clinical Trials (Peter MacCallum)	Research institute
The George Institute of Global Health	Research institute
VCCC Alliance	NFP
WA Department of Health	Government
Whitecoats Foundation	Consumer

Director's Report

Directing the CT:IQ Programme in 2025 has been an exhilarating experience. It remains an absolute joy to work with such a diverse and dedicated group of members on impactful projects that lead to meaningful and lasting change in the efficiency, quality and effectiveness of Australian clinical research.

An implementation highlight has been the rapid uptake of the InFORMed template, which CT:IQ launched in June 2024. Researchers, sites and Human Research Ethics Committees (HRECs) have enthusiastically taken up the template. We have been thrilled to hear feedback that the template has been well-received by consumer advisors, has increased the speed of drafting and reviewing PICFs, and—most importantly—is perceived as improving the quality of participant consent.

The year has also seen the release of impactful resources across multiple other CT:IQ projects, reflecting the unfailing commitment of project team members and the leadership of Senior Research Officer Gudrun Wells. This includes launch of the Beyond the Form project in May 2025, and the first tranche of outputs from the Flexible Trial Delivery Methods project in November 2025. CT:IQ is also thrilled to be partnering with the ARDC on the Clinical Trial Data Sharing Frameworks project, and the outputs of this project are scheduled for release in December 2025.

CT:IQ's magic comes from the diverse people who engage with us in open, curious and collaborative discussions. We were delighted to hold two face-to-face workshops in 2025: a Flexible Trial Delivery workshop in Melbourne in July, and a Clinical Research Data Sharing Frameworks project co-hosted with the ARDC and Bellberry Ltd in Sydney in October. These events offered essential feedback on our emerging work and helped members connect and reconnect across sectors.

Dr Lisa Eckstein and ARCS CEO Dr Tim Boyle

Especially crucial for CT:IQ's work is our incredible consumer members, both on our Steering Committee and as part of our project teams. It was therefore a special joy to be awarded the ARCS Patient-Centred Award for CT:IQ's work in promoting the voice of the patient or participant.

I am excited to continue CT:IQ's journey alongside you in 2026 as we look forward to finalisation of the Flexible Trial Delivery and Clinical Research Data Sharing Frameworks projects, and the launch of two new CT:IQ projects.

Dr Lisa Eckstein

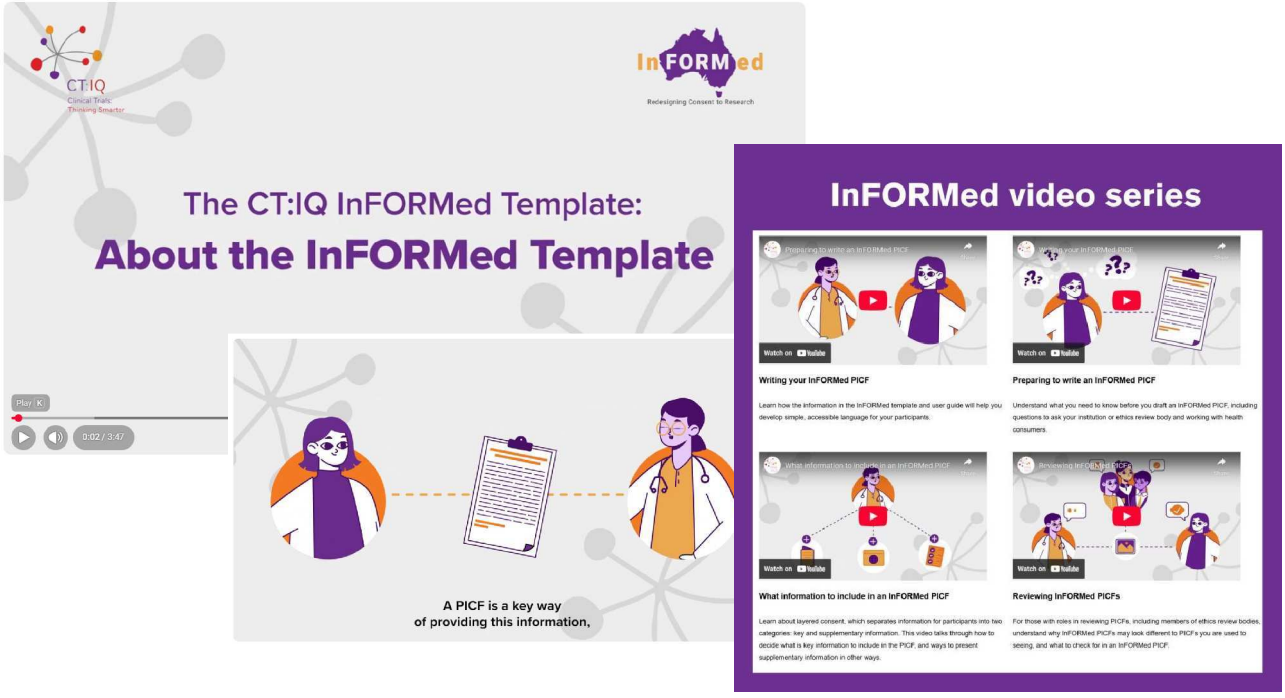
Current Projects

Implementation of the InFORMed Project: Redesigning Consent to Research

CT:IQ has been receiving a steady stream of positive feedback on the InFORMed Participant Information and Consent Form (PICF) template and guide since its release in June 2024, including across sites, sponsors, researchers and consumers.

As part of CT:IQ's implementation plan, we developed a series of short explainer videos to explain key concepts behind why we developed the template, how to use it to draft a PICF, and how to review PICFs that have used the template. The videos are available on the dedicated project page www.informedpicf.com.au.

The project reached an exciting milestone in November 2025 with the release of the NSW Health revised Human Research Ethics Committees – Standardised Participant Information and Consent Form (PICF). The Guidelines endorses the use of the InFORMed Template for use in health and medical research across NSW Health Organisations. This brings the InFORMed template a significant step closer to becoming the national PICF benchmark.



Beyond the Form: Engaging Participants Throughout Clinical Research

In May 2025, the Beyond the Form project launched its toolkit for best-practice communication between researchers and participants. The project draws on data gathered from literature reviews, interviews and workshops, synthesised into tools for researchers and reviewers. The toolkit provides practical advice on how to plan for and conduct a variety of communication activities during a trial and after it has finished.

To mark the toolkit's launch, the project team ran a webinar looking specifically at one of these activities that had proved particularly charged in interviews and workshops: sharing research results with participants. We were delighted to have a strong panel including Gen Handley (clinical trial participant), Angela Watt (HREC member), and Sophie Seck (Medicines Australia). Having these voices helped demonstrate the importance of working towards the return of results to participants as standard practice in Australia, and some of the practical issues that require resolution for this to become a reality.

CT:IQ is continuing to promote this toolkit to the sector to promote best-practice communication throughout the life of a research project.

Graphic recording by Dr Sue Pillans for Beyond the Form webinar: Sharing Clinical Research Results with Australian Participants

Flexible Trial Delivery

This has been a busy year for the Flexible Trial Delivery project. Building on the incredible input from the 2024 workshop, the project team considered how best to develop appropriate resources. This included careful review of both national and international initiatives to ensure outputs are aligned with best practice.

40 Steering Committee members convened in Melbourne in July 2025 to share feedback on two draft project outputs:

- A design checklist for those developing and delivering clinical trials in Australia, and
- A plain language introduction to the concept of flexible trial delivery.

This vibrant workshop enabled us to work through these drafts, and share case studies of how implementing these principles impacts aspects of trial conduct.

Flexible Trial Delivery Workshop, Melbourne July 2025

The revised documents were released to the sector at the ACTA 2025 Clinical Trials and Registries Symposium, 17-19 November 2025.

CT:IQ has also partnered with AccessCR to bring together a participant subcommittee to review project outputs and guide the development of a tool to promote discussions between sites and participants on selection of flexible trial delivery methods. This is anticipated to be released in early 2026.

Clinical Research Data Sharing Frameworks

The Clinical Research Data Sharing Frameworks project is a collaboration between CT:IQ and the ARDC to develop practical guidance to support the trustworthy sharing of clinical research data in Australia.

CT:IQ undertook extensive consultation with clinical trialists, researchers accessing clinical trial for secondary research, and research office staff to better understand the enablers and barriers to data sharing. Read the consultation report.

Led by Vanessa Warren and Rebekah McWhirter, CT:IQ also undertook an Australian-first Shared Ethical Debate (ShED) exercise to understand how Australian Human Research Ethics Committees (HRECs) were reviewing applications for clinical trial data sharing, including for waivers of the requirement for consent. The results of this exercise have been made available in the Executive Summary and Ethics Review Body Benchmarking Activity full report.

The ShED activity and results were the topic of lively discussion at the sold-out ARDC/CT:Q/Bellberry Ltd Best Practice Workshop on the Ethical Review of Clinical Trial Data Sharing held at the NHMRC Clinical Trials Centre on 15 September 2025.

Learn more about the ShED project and the results:

Finalised project outputs, including a toolkit of clinical trial data sharing governance, will be released in December 2025.

Best Practices in the Ethical Review of Clinical Research Data Sharing Frameworks Workshop in Sydney, September 2025

Updating the Clinical Trial Site Recruitment (GREET) Guide and New AI in Trial Recruitment Supplement

The CT:IQ Clinical Trial Site Recruitment Guide was first released in 2020 and has remained one of the most highly utilised CT:IQ resources. In March 2025, CT:IQ released a refreshed version of the GREET Guide, including updated links and additional resources.

CT:IQ also identified areas where there have been significant changes to how trials recruit since development of the GREET Guide. In March 2025, the CT:IQ Steering Committee meeting endorsed expanding the GREET Guide to cover these areas, including the use of Artificial Intelligence (AI) in trial recruitment.

The AI in Clinical Trial Recruitment supplement was released in October 2025. It includes use cases for AI in recruitment, legal and ethical impacts of AI in trial recruitment practices, and considerations for those reviewing projects that use AI.

Meetings and Presentations

Executive and Steering Committee Meetings

Executive Committee Meetings

The CT:IQ Executive Committee met on a six-weekly schedule over 2025, with representation from its four founding member organisations (Bellberry Limited, 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 2025 -
19 March 2025 and 16 October 2025

Public Presentations and Conferences

Event	Title	Speakers	Date
WA HesANDA Node Presentation	Clinical Research Data Sharing Frameworks Improving the efficiency and quality of clinical research data sharing decisions	Lisa Eckstein	18 March 2025
Monash HeSANA Node Webinar	Unlocking Potential: Exploring the Secondary Use of Health Research Data	Lisa Eckstein	27 March 2025
Health Translation Queensland Human Research Ethics and Governance Collaborative Group Webinar	CT:IQ's program of work	Lisa Eckstein	24 April 2025
HREC Chairs meeting	Presentation on CTIQ Secondary Data Sharing Project	Lisa Eckstein	9 May 2025
CT:IQ webinar	Sharing Clinical Research Results with Australian Participants	Lisa Eckstein, Gudrun Wells, Sophie Seck, Angela Watt, Gen Handley	20 May 2025
ARCS 2025	Clinical Research Data Sharing: Towards Clear and Consistent Governance Frameworks	Lisa Eckstein	4 June 2025
CT:IQ Flexible Trial Delivery Workshop	Flexible Trial Delivery Workshop	Lisa Eckstein, Gudrun Wells, Deborah Robins, Sarah Lukeman, Alison McIvor, Janelle Bowden, Leila Lotfi, Nadine Herron	21 July 2025
Australian Biobanking Network Association Webinar	Redesigning Consent to Data Sharing Research: The CT:IQ InFORMed Project	Lisa Eckstein	12 August 2025
NHMRC Clinical Trial Centre	The Beyond the Form Toolkit	Gudrun Wells, Sarah Lukeman	10 September 2025

Event	Title	Speakers	Date
Australian Centre for Health Engagement, Evidence and Values: Seminar	Improving HREC review through shared ethical debate	Lisa Eckstein	11 September 2025
CT:IQ/ARDC/Bb workshop Clinical Research Data Sharing Frameworks	Best Practices in the Ethical Review of Clinical Trial Data Sharing	Lisa Eckstein, Leanne Weekes, Malcolm Crompton, Mark Taylor, Mark Maclean, Jonathan Williams, Beck McWhirter, Vanessa Warren, Annette Brannauck-Mayer, Ben Canny, Gordon McGurk, Alison McIvor, Maya Pinn, Heather Renton	15 September 2025
A-CTEC webinar	The Beyond the Form Toolkit	Gudrun Wells, Sarah Lukeman, Lisa Eckstein	20 November 2025
6th Australian & New Zealand HREC Conference	The Informed Project Sharing research results with participants	Lisa Eckstein, James Cokayne Gudrun Wells	25 November 2025 26 November 2025
Australasian Association of Health Law and Bioethics	HREC Decision-Making and Data Sharing in Clinical Research: Improving Review Through Shared Ethical Debate	Lisa Eckstein	8 December 2025

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