Enhancing Capacity for **Ethical Data** Sharing in Clinical Research

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Introduction

The progression of the Open Science movement promises an exciting prospect of **sharing a wide array of health data**, but also comes with the **difficult task** of identifying the appropriate **ethical** and **governance** arrangements for sharing data. To support **researchers** navigating this space, the A**ustralian Research Data Commons (ARDC)** via the H**ealth Studies Australian National Data Asset initiative (HeSANDA)** alongside **Clinical Trial IQ (CT:IQ)** have collaborated to enhance the capacity for ethical data sharing in clinical research though the Clinical Research Data Sharing Framework project.

Clinical Research Data Sharing Framework project

This project is a national collaboration between **CT:IQ** and the **ARDC** via the **HeSANDA** initiative to to develop ethical, practical, and consistent guidance that enables the **responsible sharing** and **reuse** of **clinical trial data** across Australia. The ARDC's role includes providing the infrastructure, connections, and oversight of national data services (e.g. **Health Data Australia**), while CT:IQ brings clinical trials expertise, stakeholder networks (sponsors, sites, governance, ethics), and domain knowledge in trial operations and policy. Together, they **designed** and **delivered** a **multi-layered approach** spanning **informational**, **regulatory**, **capacity-building**, **cultural**, and **collaborative** domains to strengthen ethical data sharing in clinical research.

Approach

01 | FRAMEWORK DEVELOPMENT

Partners defined key ethical & governance principles that underpin responsible data sharing. A '**Governance Framework**' was developed, outlining the **roles & responsibilities** of researchers, institutions, data custodians, sponsors, Human Research Ethics Committees (HRECs), & consumers in supporting trustworthy data practices.

02 | STAKEHOLDER ENGAGEMENT

Through **workshops**, **focus groups**, & **consultations**, the team gathered **perspectives** from clinical researchers, trial sites, sponsors, ethics committees, & **consumer representatives**. These discussions helped identify **barriers**, **enablers**, & areas of uncertainty about the secondary use of clinical trial data; detailed in '**Consultation report**'.

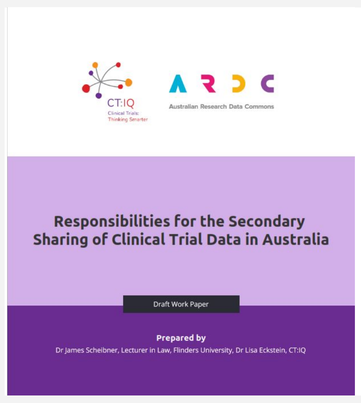
03 | BENCHMARKING

To better understand how existing ethical standards were being applied, a '**Benchmarking study**' was performed. A simulated, complex data-sharing application was designed & multiple HRECs reviewed it. Analysis revealed **gaps** & **inconsistencies** applying **existing guidance**, highlighting the need for more **harmonised practices**.

04 | SYNTHESIS OF FINDINGS

Findings from activities are being **synthesised** to identify where **additional resources** & **guidance** are needed to inform the development of a comprehensive '**Resource Toolkit**'. This will be designed to help researchers, ethics committees, data custodians, & institutions apply ethical data-sharing practices **consistently & confidently**.

Capacity Enhancing Outputs



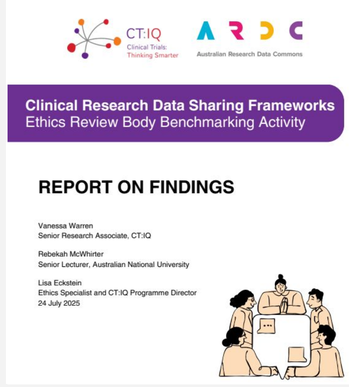
Governance Framework: Principles and responsibilities for secondary use.

Consultation Report: Insights from researchers, sponsors, sites, and HRECs.

Clinical Research Data Sharing Frameworks

Work Package 2: Consultation report on current challenges and practices regarding ethics and governance approval for data sharing

Benchmarking report: Tested consistency of ethics committee decisions.



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Resource Toolkit *(under development - to be released in December 2025):*

Practical templates, checklists, and guidance.

Why is matters

The coordination of a **nationally consistent approach** to sharing sensitive trial data while **protecting privacy** and **participant autonomy**, will both **build trust** and **confidence** in ethical, responsible data sharing practices and contributes to a stronger, more efficient **health research ecosystem in Australia**.

By aligning with global **Open Science** and **FAIR principles**, it enables secondary research, validation, and discovery, **strengthening** Australia's health **research ecosystem** and **accelerating the translation** of findings into **better health outcomes**.

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