Contribution ID: **293** Type: **Poster**

Enhancing Capacity for Ethical Data Sharing in Clinical Research

Monday 13 October 2025 19:10 (20 minutes)

With the onset of the Open Science movement, research sites and clinical research sponsors are becoming increasingly entrusted with the storage of large amounts of research data and samples. The prospect of sharing a wide array of health data is an exciting one, as the collaboration of ideas and the expansion of shared knowledge promises to lead to accelerated research outcomes. However, identifying the appropriate ethical and governance arrangements for sharing data, especially clinical trials data, can be difficult. Further, unduly restrictive governance may prevent valuable new research from proceeding. Finally, insufficiently informed governance may breach participant privacy and autonomy interests.

Responsible sharing of clinical research data requires consideration of complex ethical, regulatory, legal and institutional requirements. To support researchers navigating this space, the Australian Research Data Commons (ARDC) via the Health Studies Australian National Data Asset initiative (HeSANDA) in collaboration with Clinical Trial IQ (CT:IQ) is developing practical principles and guidance for researchers, HRECs, data custodians, research institutions, and consumers to support trustworthy sharing of clinical research data in Australia.

Here we showcase our multifaceted approach to address the legal, ethical, and practical challenges of data sharing for clinical research, which included a series of interlinked activities. This includes the creation of a *Governance Framework*, which outlines the regulatory and ethical responsibilities for data sharing. This was supplemented by a *Consultation Report*, which captured insights from workshops with key stakeholders and identified knowledge gaps around secondary data use. To evaluate how ethics review bodies apply existing standards, a *Benchmarking exercise* tested the consistency of decisions on a simulated complex data sharing application. Findings from these activities are directly informing the design of a *Resource Toolkit*, a suite of skills-based materials aimed at improving awareness, decision-making, and practice in ethical data sharing across the clinical research community.

The development of these practical principles and guidance resouces aims to foster more trustworthy and responsible data sharing practices, contributing to a more impactful and efficient data sharing ecosystem in Australia.

Primary authors: Dr GOUDA-VOSSOS, Amany (Australian Research Data Commons); KANG, Kristan (Australian Research Data Commons); Dr ECKSTEIN, Lisa (Bellberry (Clinical Trials IQ - CT:IQ))

Presenter: Dr GOUDA-VOSSOS, Amany (Australian Research Data Commons)

Session Classification: Poster Session

Track Classification: SciDataCon Persistent Themes: Policy and Practice of Data in Research