Operationalising Responsible Data Sharing and Reuse in a Clinical Trials Unit

Jo Smith[1], Zoe Johnson[1], Jodie Heap[2]

UK Registered Clinical Trials Unit Network

Keele UNIVERSITY

Introduction

Within many Clinical Trials Units (CTUs), data access and data sharing processes have evolved through layered documentation, disparate storage locations and manual workflows, creating burden for both requesters and reviewers. Furthermore, these processes may not fully align with FAIR (Findable, Accessible, Interoperable and Reusable) and CARE (Collective Benefit, Authority to Control, Responsibility and Ethics) principles.

Keele Clinical Trials Unit are reviewing and streaming the current process and furthermore embracing FAIR and CARE principles.

Methods / Approach

Existing data access and sharing processes were mapped and reviewed with key stakeholders. Workflows, repositories, request mechanisms, review criteria and governance arrangements were assessed to inform a redesigned approach to simplify the current process, reduce barriers to access research data, align with FAIR and CARE principles and define data packs (Figure 1).

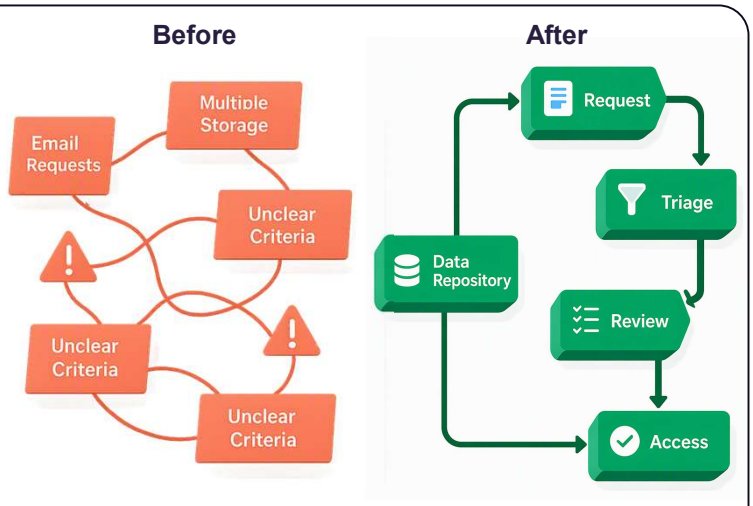

Figure 1. Data request workflow before and after process simplification

Results Structure

Feedback received from the review has been summarised and collated into two key categories (Figure 2).

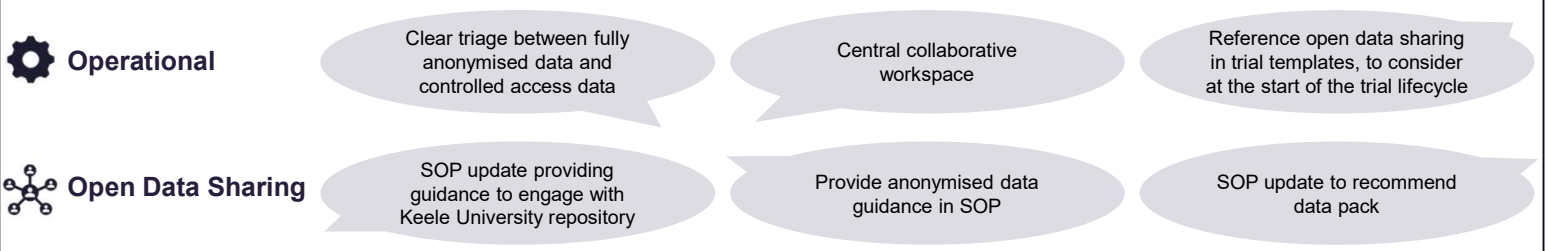

Figure 2. Stakeholder feedback summary

Timeline

As this work is ongoing, outputs are being developed and implemented in phases (Figure 3).

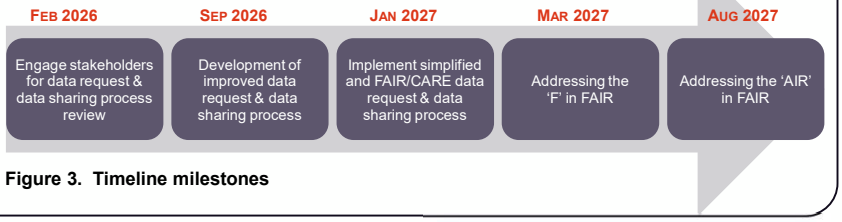

Figure 3. Timeline milestones

Potential Relevance and Impact

Streamlined, FAIR and CARE aligned data request and data access processes improve the efficiency, transparency, reproducibility and consistency of research data access and reuse (Figure 4).

By reducing administrative barriers and supporting responsible data sharing, this approach enables greater collaboration, increases opportunities for data reproducibility and reuse, enhances research outputs, and ultimately contributes to improved healthcare outcomes.

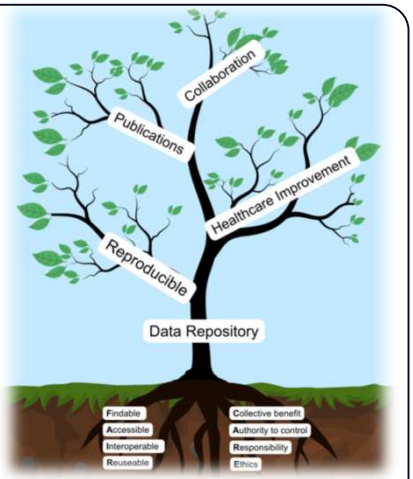

Figure 4. The foundation for maximising the impact of research data

Contact: Jo Smith – j.smith2@keele.ac.uk

Contact: Keele CTU – ctu.operations@keele.ac.uk

Visit the repo: https://doi.org/10.21252/qzdy-9282

[1] Keele Clinical Trials Unit, Faculty of Medicine & Health Sciences, Keele University

[2] Keele Academic Services, Directorate of Information and Digital Services, Keele University

THIS IS KEELE