Data Transparency

Project Leads:
Alex Hughes & Stephanie Fayolle

Proposed Project End Date:
Q2 2026

Project Scope:

The scope of this project remains flexible, but initially we plan a literature review. The types of image files will be reviewed (X-rays, (f)MRIs, CT scans, etc.), their formats (DICOM, NIfTI, etc.), their positions (limbs, heads, organs, etc.) and all associated metadata. There will also be a discussion on data handling, storage and transfer. Any guidance and repositories will be reviewed.
We will then focus on use cases that will have the most impact based on interest and complexity. Any use cases being presented will be in the context of a request alongside clinical data, in keeping with the main drivers behind the Data Transparency Working Group. There will be a strong focus on processing metadata associated with images, as that is where the strengths of the Working Group lie (processing and anonymising data) and where most of the risk lies in the sharing of images.

Deliverable:
Guidance on how to de-identify images and associated data in the context of data transparency.

Anonymization of Imaging Data

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

Planned outline for white paper sections

Deliverables & Targets Planned for the Next Quarter:

Working towards white paper ready for public review

Project Lead:
Devaki Thavarajah

Proposed Project End Date:
Q2 2026

Project Scope:

Creating engaging content on data privacy and data sharing in clinical trials which can be understood and used by the general population (any member of the public regardless of their sector or profession).

Deliverable:
An introductory video and six additional videos in our series, approximately three to five minutes each, covering data privacy and data sharing in clinical trials.

Educate the General Population on Data Privacy and Data Sharing

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Finalised script for fifth and sixth episodes
- Great input from our project team, including new members
- Complete the script writing process for the seventh episode (final video)

Deliverables & Targets Planned for the Next Quarter:

- All script episodes to be completed and ready for final audio and animation development

Project Leads:
Christa Polidori & Sanjay Bagani

Proposed Project End Date:
Q2 2026

Project Scope:

The EU Clinical Trials Regulation (CTR) has sweeping new requirements for the publication of clinical trial documents of trials conducted in the European Union. Documents will be subject to publication earlier in clinical development than before. The EU CTR has important implications for the planning of trials in the EU and for how sponsors prepare clinical trial documents. Stakeholders include any sponsor conducting an EU trial, including pharmaceutical and biotechnology companies and academic institutions. The initial deliverable for this project will build on a poster prepared by this Working Group outlining avenues of data disclosure. Types of documents to be published under the EU CTR, their timelines for publication, mechanisms for protecting confidential commercial information (CCI), and protection of personal protected data will be addressed.

Deliverable:
White paper

EU CTR Implementation

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

First draft white paper almost completed

Deliverables & Targets Planned for the Next Quarter:

Working towards white paper ready for public review

Project Leads:
Lauren Hepburn &
Abby McDonell

Deliverable:
Guideline
This GTP deliverable is our reference point, similar to the **Good Clinical Practices** guideline created by the International Conference on Harmonization

Key Achievements This Quarter:

Guideline published

Proposed Project End Date:
Q3 2025

Good Transparency Practices

Project Scope:

Define a set of best practices for data transparency and create a Good Transparency Practice guidance. The document will have a similar format to the Good Clinical Practice guidance created by the International Conference on Harmonization (ICH).

Project Status:
Green

Deliverables & Targets Planned for the Next Quarter:

N/A – Project Closing

Project Accepting New Members: N/A - Project Closing

Project Lead:
Arlene Coleman

Proposed Project End Date:
Q4 2026

Deliverable:
White paper

Internal Clinical Study Data Sharing Process

Key Achievements This Quarter:

Project kick-off meeting scheduled to discuss the path forward in this project as an extension of the GTP project and focusing on use cases which would be of further help for the industry

Project Scope:

This project will gather feedback across industry on internal data sharing, to provide a white paper summarising the results. The white paper will provide recommendations surrounding guidance on the internal data sharing process, as well as identify similarities and differences between the external and the internal data sharing processes. Since many functions request for data internally, this could impact on statisticians, programmers, clinicians, software developers and IT.

Project Status:
Green

Project Accepting New Members: Yes

Deliverables & Targets Planned for the Next Quarter:

Identify another Co-Lead alongside Abby McDonell and plan an outline for the deliverable

Rare Disease/Small Population Data Sharing

Project Leads:
Karolina Stępniak & Helen Spotswood

Proposed Project End Date:
Q3 2025

Project Scope:
Currently, there is not a single document that provides guidance, recommendations and methodologies for handling the re-identification risk when sharing data from rare diseases/small populations.

The focus of the white paper is on the increased risk in the context of a controlled access platform. The aim is to produce a document that will be a foundation for future work.

Deliverable:
White paper

Project Status:
Green

Project Accepting New Members: N/A - Project Closing

Key Achievements This Quarter:

White paper published

Deliverables & Targets Planned for the Next Quarter:

N/A - Project Closing

Project Lead:
Devaki Thavarajah

Proposed Project End Date:
Q3 2025

Project Scope:

This project will focus on gathering feedback from our PHUSE Community on the new guidance to accompany the MHRA's updated clinical trials regulations (available via this link) and how it is written.

Deliverable:

All stakeholder feedback responses collated into one PDF document for submission to HRA

Stakeholder Review of UK MHRA Clinical Trials Regulation Guidance

Project Status:
Green

Project Accepting New Members: No

Key Achievements This Quarter:

Stakeholder feedback collated through survey questions and facilitated two team meetings whereby interactive and open-ended discussions took place to gather thoughts and comments

Deliverables & Targets Planned for the Next Quarter:

Preparation of final submission to HRA due 10 September 2025