Data Transparency

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Anonymization of Imaging Data

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 existing 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.

Q2 2026

Proposed End Date

Guidance document

Deliverable Type

Draft paper received from Dan Boisvert at Biogen, which is in line with the goals of this project and therefore will be used as the first deliverable. The authors will be acknowledged for their work.

Key Achievements This Quarter:

Draft paper will be sent for PHUSE deliverables leadership committee review and circulated for public review, amended as required and published thereafter.

Deliverables & Targets Planned for the Next Quarter:

Alex Hughes &
Stephanie Fayolle

Leads

Project Status: Green
Accepting New Members

- Draft in progress

Project Status

phuse

Educate the General Population on Data Privacy and Data Sharing

Scope

To create engaging content on data privacy and data sharing that can be understood and used by the general population (any member of the public regardless of their sector or profession) covering topics such as what is being done to share clinical trial data and information, where data goes and how it is used, what data privacy is, why it is needed, why it is important and the differences between mandatory vs. voluntary data sharing. The project is to follow a similar approach to the Data Transparency (DT) Terminology Harmonisation project, this time aiming towards a more general audience to address commonly asked questions surrounding data privacy and data sharing. The Terminology Harmonisation project creates an excellent set of deliverables better suited for those who work with data sharing on a more technical level.

Q2 2026

Proposed End Date

Educational video series

Deliverable Type

Devaki Thavarajah

Leads

Several new members joined the team. We continue having high-engagement discussions and sharing new perspectives as we refine and review the last three scripts

Key Achievements This Quarter:

Patient advocate review and finalisations based on community feedback

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Draft in progress

Project Status

phuse

EU CTR Implementation

Scope

The EU Clinical Trial 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, and documents such as the Investigator's Brochure will be routinely published for the first time. 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 may build on a poster previously prepared by this Working Group outlining avenues of data disclosure, the types of document to be published under the EU CTR, their possible timelines for publication, the deferral mechanism for protecting confidential commercial information (CCI), which documents can be redacted for CCI, and protection of personal protected data.

Q2 2026

Proposed End Date

White paper

Deliverable Type

Christa Polidori & Sanjay Bagani

Leads

Insightful discussions and input to develop a high-quality white paper outlining the key considerations and requirements

Key Achievements This Quarter:

First draft white paper to be circulated for PHUSE deliverables leadership committee review and public review thereafter

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Draft in progress

Project Status

Internal Clinical Study Data Sharing Process

Scope

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

Q4 2026

Proposed End Date

White paper

Deliverable Type

Arlene Coleman

Leads

New Co-Lead identified (Tasmin Sargood) to lead alongside Abby McDonell

Key Achievements This Quarter:

To be confirmed after project extension kick-off meeting

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Preparing background administration activities for project extension

Project Status

Participant Data Return

Scope

The Working Group project team will create, disseminate and analyse a survey to pharmaceutical companies on their clinical trial information and current processes regarding the results. The survey results will form the basis of a white paper.

Q2 2026

Proposed End Date

White paper

Deliverable Type

Dan Boisvert & Stephen Bamford

Leads

Survey results collated and findings summarised in a blog post, which has been finalised and published (link). As part of the next steps, a draft playbook for the topic of participant data return is under development.

Met with the leadership team at MRCT, who are interested in partnering with us on this project. MRCT have done a lot of work in this space and are excited to work with us.

Key Achievements This Quarter:

Draft playbook review and finalisation

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green

- Draft in progress

Project Status