

Table of Contents

1

Anonymization of Imaging Data

2

Educate the General Population on Data Privacy and Data Sharing

3

EU CTR Implementation

4

Internal Clinical Study Data Sharing Process

5

Patient Data Return

7

The Value of Plain Language Summaries of Trial Results

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

Alex Hughes &
Stephanie Fayolle

Leads

Blog released, completion
of public review and
finalisation of white paper

Key Achievements
This Quarter:

Identify areas where there
is a current gap in
knowledge and how to
address these challenges,
which will form
discussion points for
brainstorming ideas in
creating the next
deliverable

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Final draft to be proofread and published using a graphic design template

Project Status

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). 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

Lead

Final three scripts
completed and patient
advocacy review initiated

Key Achievements
This Quarter:

Approval of scripts after
changes requested in the
external stakeholder
feedback process and
proceed with initiation of
voice
recordings/storyboards
for video development

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Gathering feedback from the patient advocate network, to be collated upon completion. Our team will make changes based on this review.

Project Status

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.

This project will explore types of documents 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 which cannot, and protection of personal protected data.

Q2 2026

Proposed
End Date

White paper

Deliverable
Type

Christa Polidori
& Sanjay Bagani

Leads

Draft white paper is currently out for public review until 6 May

Key Achievements
This Quarter:

Collate all comments and feedback from public review and implement changes, followed by DT leadership review and approval, before publishing the final version

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Draft white paper circulated for public review comments and feedback

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 provide recommendations surrounding guidance on the internal data sharing process, as well as identify similarities/differences between external and internal data sharing processes. As many functions request data internally, this could impact on statisticians, programmers, clinicians, software developers and IT professionals.

Q4 2026

Proposed
End Date

Finalising the scope for
the extension phase of
this project

To be confirmed after the
project extension kick-off
meeting

White paper

Deliverable
Type

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Abby McDonnell &
Tamsin Sargood

Leads



Project Status: Green
Accepting New Members

- Preparing background administration activities for the 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

Successful administrative
handover of project to
MRCT

To be confirmed after
project kick-off meeting

White paper

Deliverable
Type

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Dan Boisvert &
Stephen Bamford

Leads



Project Status: Green
Accepting New Members

- MRCT will lead all activities for this initiative

Project Status

The Value of Plain Language Summaries of Trial Results

Scope

To generate evidence of the value of PLSs, a cross-industry/multi-stakeholder team will be formed to:

- Develop a survey to evaluate the value of PLSs, to be placed on designated websites where PLSs are hosted
- Collect data based on the survey and review any feedback
- Report results in the form of a white paper.

The team will meet regularly to define their objectives and work on the deliverables.

Q4 2027

Proposed
End Date

White paper

Deliverable
Type

Debra Guerreiro
& Vidhi Vashisht

Leads

Successful project kick-off in January. Since then, the team have formed three main workstreams to drive the project objectives (research, survey development, and survey dissemination). Project Leads are working closely with research and dissemination workstream members to generate meaningful data that will drive survey development.

Key Achievements
This Quarter:

- Complete analysis of existing research on the topic - April
- Identify ways to disseminate the survey on Value of PLSs - May
- Finalise the survey - August

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Research analysis is ongoing. The dissemination workstream is kicking off to consider and finalise dissemination options for the survey.

Project Status