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# Anonymization of Imaging Data

## Description

This project focuses on developing guidance for sharing medical imaging data within the context of data transparency. It begins with a literature review covering image modalities (e.g. X-ray, MRI, CT), formats (e.g. DICOM, NIfTI), anatomical regions, and associated metadata, alongside current practices for data handling, storage and transfer.

Medical images present unique challenges due to their complexity and the sensitive metadata they contain, which poses significant privacy risks. At the same time, demand for access to image data is increasing alongside broader data sharing requests.

The project will identify high-impact use cases aligned with clinical data requests and prioritise those based on relevance and complexity. A key focus will be metadata processing and anonymisation, where risks are highest.

The outputs will summarise existing guidance, identify gaps, and provide a foundation for consistent, industry-wide approaches to image data sharing.

Q2 2026

Proposed  
End Date

Guidance  
document

Deliverable

The team has reviewed edits of the white paper from both the leadership and the public review period and approved for publication.

A technical guidance document, which is the next deliverable, is being reviewed. Members are encouraged to provide feedback and indicate sections they would like to contribute to, especially regarding areas requiring further development or real-world examples.

Key Achievements  
This Quarter:

The first deliverable (white paper) will next be sent to our internal proofreader, who will review it for grammar and overall consistency. As part of our standard process, we will incorporate the suggested changes and raise any content-related queries with the Project Leads before proceeding to the design phase.

Deliverables &  
Targets Planned for  
the Next Quarter:

Alex Hughes &  
Stephanie Fayolle

Leads



Project Status: Green  
Accepting New Members

- Background administration activities for proofreading in progress.

Project Status

# Educate the General Population on Data Privacy and Data Sharing

## Description

This project develops engaging, accessible content on data privacy and data sharing for a general audience, regardless of background or expertise. It builds on the approach of the Data Transparency Terminology Harmonisation project, extending it beyond technical users to address commonly asked questions in a clear and practical way.

With growing public interest in how data is collected, used and shared, much existing information remains too complex or technical for widespread understanding. This initiative aims to bridge that gap by creating content that is easy to understand, relevant and actionable for non-specialists.

The project will deliver user-friendly educational materials that improve awareness, understanding and confidence in data privacy and sharing topics. By making accurate information more accessible, it will support more informed public engagement and promote better understanding of data use across society.

Q2 2027

Proposed  
End Date

Educational  
multi-modal  
materials

Deliverable

Exploration of AI techniques to inject additional creativity into the methods for deliverables development to modify our final scripts 4-6 into new mediums of communicating information.

Key Achievements  
This Quarter:

Finalisation of updated content and project timelines with external vendor to integrate words/images/audio and continue achieving the production of high-quality content.

Deliverables &  
Targets Planned for  
the Next Quarter:

Devaki  
Thavarajah

Lead



Project Status: Green  
Accepting New Members

- Modification of final three draft deliverables, which will be updated accordingly, taking into consideration multimedia expertise within our network.

Project Status

# EU CTR Implementation

## Description

This project addresses the implications of the EU Clinical Trials Regulation (CTR) on the publication of clinical trial documents. The regulation introduces earlier and broader disclosure requirements, including the routine publication of documents such as the Investigator's Brochure, significantly impacting how sponsors plan and prepare trial documentation.

The project will examine the types of documents subject to publication, expected timelines, and the application of deferral mechanisms to protect confidential commercial information (CCI). It will also clarify which documents can be redacted, the extent of permissible redactions, and considerations for protecting personal data.

Target stakeholders include pharmaceutical and biotechnology companies, as well as academic sponsors conducting trials in the EU. Building on prior work, the project may expand existing materials into a comprehensive deliverable outlining disclosure pathways, requirements, and practical considerations.

The outputs will provide clear, actionable guidance to support compliance, improve planning, and ensure appropriate protection of sensitive information under the EU CTR.

Q2 2026

Proposed  
End Date

The Project Leads are working closely with the team to action the remaining public review comments for the white paper. Once these updates have been incorporated, the revised document will be shared with the Working Group Leads for final review ahead of publication.

Key Achievements  
This Quarter:

Finalisation and  
publication of white  
paper.

Deliverables &  
Targets Planned for  
the Next Quarter:

White paper

Deliverable

Christa Polidori  
& Sanjay Bagani

Leads



Project Status: Green  
Accepting New Members

- Draft in progress.

Project Status

# Internal Clinical Study Data Sharing Process

## Description

The project will use representative internal data flow scenarios to illustrate how existing PHUSE Good Transparency Practice (GTP) principles can be applied in practice to internal sharing of clinical trial data involving anonymised data reuse. Scenarios may include cross-functional data access, internal analytics and secondary research, affiliate data sharing, and sharing with trusted internal or quasi-internal partners.

The scope includes identification and description of typical internal data flow scenarios, illustration of how GTP principles apply in a proportionate manner, and use of schemas or flow diagrams to clarify roles, governance considerations, and key decision points across internal data flows.

The project will remain principle-based and scenario-driven, and will not introduce prescriptive requirements, technical implementation standards, or a separate or narrowed framework for internal data sharing.

**Q2 2027**

**Proposed  
End Date**

**White paper/  
illustrative  
materials**

**Deliverable**

**KOM, identified key  
contributors and  
members of the WG.**

**Key Achievements  
This Quarter:**

**Project initiation and  
confirmation of scope and  
data flow scenarios.**

**Deliverables &  
Targets Planned for  
the Next Quarter:**

**Abby McDonell &  
Tamsin Sargood**

**Leads**



**Project Status: Green**

- Project initiation/scope development.

**Project Status**

# The Value of Plain Language Summaries of Trial Results

## Description

This project aims to generate quantitative evidence on the value of plain language summaries (PLSs) through a cross-industry, multi-stakeholder collaboration. The team will design and deploy a survey on platforms hosting PLSs to collect feedback from trial participants and the general public, followed by analysis and reporting in a white paper.

While significant effort has been invested in producing PLSs to enhance transparency and engagement, there is limited measurable evidence of their impact and use. This initiative addresses that gap by capturing real-world insights into how PLSs are accessed, understood and valued by their intended audiences.

The outputs will provide evidence-based recommendations to support continued investment in PLS development and dissemination. In addition, findings will help identify opportunities to improve content, usability, and overall user experience, strengthening the effectiveness of PLSs in communicating clinical trial results.

**Q4 2027**

**Proposed  
End Date**

**Survey &  
White paper**

**Deliverable**

**Insightful discussions around development of the survey evaluating the value of plain language summaries. The team are systematically approaching each component (Survey Platform, Results Analysis, Distribution and Publication).**

**Key Achievements  
This Quarter:**

**Finalisation and  
dissemination of survey.**

**Deliverables &  
Targets Planned for  
the Next Quarter:**

**Debra Guerreiro  
& Vidhi Vashisht**

**Leads**



**Project Status: Green  
Accepting New Members**

- Survey development in progress.

**Project Status**

# Review of ISRCTN Results System Updated Prototype (Version 2)

## Description

This project is an extension to stakeholder review of the UK MHRA Clinical Trials Regulations and the ISRCTN Results System Prototype (Version 1).

**Q3 2026**

**Proposed  
End Date**

**Regulatory  
response**

**Deliverable**

**Devaki  
Thavarajah**

**Lead**

Version 2 of the prototype was released by ISRCTN in May. Our team swiftly provided comments within the short turnaround review period. Comments were promptly addressed by the ISRCTN team and a successful meeting between ISRCTN and PHUSE took place in June to discuss the next steps.

PHUSE are currently collecting additional feedback from our internal team based on discussions with ISRCTN on how best to improve the plain language summaries module of the updated prototype, which will be integrated into the next version.

**Key Achievements  
This Quarter:**

Finalisation and publication of PHUSE responses and supporting materials to provide readers with context of this journey in reviewing each prototype.

**Deliverables &  
Targets Planned for  
the Next Quarter:**



**Project Status: Green  
Accepting New Members**

- Draft in progress.

**Project Status**