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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 2027

Proposed
End Date

Guidance
document

Deliverable

White paper published:
Imaging Data
Anonymisation
Guideline

Key Achievements
This Quarter:

Discussions and
collation of ideas for the
next draft deliverable

Deliverables &
Targets Planned for
the Next Quarter:

Alex Hughes &
Stephanie Fayolle

Leads



Project Status: Green
Accepting New Members

- Draft in progress

Project Status

Benchmarking ClinicalTrials.gov Usage and PRS Data Quality Review

Findings: A Cross-Industry Survey and Remediation Framework

Description

This project aims to address key evidence gaps in the use of ClinicalTrials.gov by generating quantitative insights into how organisations use the registry for regulatory compliance, global transparency requirements and voluntary disclosure practices. It will also explore recurring data quality review findings identified during PRS submissions and assess how these challenges are currently addressed across the industry.

The project will establish a cross-industry, multi-stakeholder team working through two dedicated subgroups. One subgroup will develop a survey to evaluate ClinicalTrials.gov usage patterns and regulatory drivers, while the second will focus on common PRS data quality review findings and potential approaches for their resolution.

By analysing anonymised survey data, the project will identify trends, challenges and opportunities to improve reporting consistency, data quality and submission efficiency. Findings will be shared through collaborative discussions and published in a white paper, providing evidence-based recommendations to support more reliable and timely disclosure of clinical trial information.

2027

Proposed
End Date

New project launched
(kick-off 25 Aug)

Charter in Q3 2026,
survey in Q4 2026

Subgroup
suvery x2 &
white paper

Deliverable

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Ritama Gupta &
Sanjay Bagani

Leads



Project Status: Green
Accepting New Members

- Draft 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

Team review of options
and proceeding with the
use of human-centred AI
for the final three
deliverables

Key Achievements
This Quarter:

Senior leadership team
review and approval of
final scripts

Deliverables &
Targets Planned for
the Next Quarter:

Devaki
Thavarajah

Lead



Project Status: Green
Accepting New Members

- Collating supporting materials for senior leadership review and approval

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.

Q3 2027

Proposed
End Date

White paper

Deliverable

Christa Polidori
& Sanjay Bagani

Leads

White paper published:
Protecting
Commercially
Confidential Information
(CCI) While Complying
with the European Union
Clinical Trials Regulation
(EU) 536/2014

Key Achievements
This Quarter:

Collate ideas for next
draft deliverable

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- Team are discussing future topics within EU CTR implementation which would be useful for our community

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

Agreed key governance,
anonymisation and
access principles

Key Achievements
This Quarter:

Full scenario example in
production for review

Deliverables &
Targets Planned for
the Next Quarter:

Abby McDonell &
Tamsin Sargood

Leads



Project Status: Green

- Draft in progress

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

**Survey roll-out, analysis
and publication team
members confirmed,
analysis timelines
received**

**Key Achievements
This Quarter:**

**Survey analysis and
report**

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

**Debra Guerreiro
& Vidhi Vashisht**

Leads



**Project Status: Green
Accepting New Members**

- Depending on timelines, assessing frequency of core team workstream meetings

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).

Q4 2026

Proposed
End Date

Regulatory
response

Deliverable

Devaki
Thavarajah

Lead

Completed draft
deliverable

Key Achievements
This Quarter:

Awaiting updated
prototype from ISRCTN
for next round of review
and feedback collation

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Green
Accepting New Members

- ISRCTN prototype production in progress

Project Status