Optimizing the Use of Data Standards

Table of Contents

Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum

Scope

Develop a BIMO Frequently Asked Questions Forum to be posted on the PHUSE Advance Hub, following the same format as the SEND FAQ Forum. This forum will use questions brought forward by the pharma/CRO community via public review, presentations, PHUSE BIMO team members, etc.

Q4 2025

Proposed End Date

FAQ

Deliverable Type

Julie Maynard & Sopan Kaith

Leads

Hoping to finalise and publish last batch of FAQs

Key Achievements This Quarter:

Hosting a session at the US Connect to provide a summary of the latest FAQs

Deliverables & Targets Planned for the Next Quarter:

Project Status: Amber

- The FAQs were reviewed by the proofreading team, who had some questions on interpretation requiring project team input. Awaiting follow-up from the project team, but lead has been unresponsive. Will attempt to contact other team members to see if anyone can assist in moving this forward to complete the project.

Project Status

Building a Better MDR

Scope

Identify use cases (e.g. standards librarian versus data manager versus programmer) for MDRs (focused on cross-study data standards), functions and features and best practices of an 'ideal' vendor-neutral MDR so organisations can align services, systems and tools accordingly. This 'wish list' could be used for RFIs/RFPs as organisations evaluate (or used as requirements to build) systems and tools for their MDR needs.

Q3 2026

Proposed End Date

White paper

Deliverable Type

Rahul Madhavan, Aparna Venkat & Reema Baweja

Leads

Started organising content for the white paper and planning for subteams

Key Achievements This Quarter:

White paper in development

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Trying to focus the scope and establish subteams to focus on different sections of the paper

Project Status

phuse

Clinical Integrated Study Data & Analysis Data Reviewer's Guide

Scope

The project will begin with a literature review of medical image types (e.g., X-rays, MRIs, CT scans), formats (DICOM, NIfTI), anatomical focus, and related metadata. We will also review data handling, storage, transfer, and relevant guidance or repositories. Next, we'll identify high-impact use cases involving clinical data, aligned with the Data Transparency Working Group's aims, focusing on image metadata processing and anonymisation risks.

Proposed End Date

Q4 2025

Deliverable Type

Integrated Analysis Data Reviewer's Guide & Integrated Clinical Study Data Reviewer's Guide Templates

Key Achievements This Quarter:

icSDRG package provided to WG Leads for review

Deliverables & Targets Planned for the Next Quarter:

Publication of icSDRG package

Leads

AKiran Kundarapu, Satheesh Avvaru & Randi McFarland

Project Status

Project Status: Green

- WG Lead feedback requires team discussion. A few updates may be needed before progressing to the next step in the review and approval process.

phuse

Management of ODS Regulatory Referenced Deliverables

Scope

The scope of this project is to identify a primary and back-up representative for each PHUSE regulatory referenced deliverable, who will:

- Review updates to regulatory documents where PHUSE deliverables are referenced to ensure they are in alignment
- Identify any updates required due to updated regulatory documents
- Organise the updates, including addressing feedback from PHUSE members
- Discuss the updates with the ODS Working Group Leads to agree on the updates
- Oversee the updates and publishing of PHUSE deliverables
- Commit to serving as a representative for two years.

Proposed End Date

Ongoing

Deliverable Type

Updated documents (if updates are identified)

Key Achievements This Quarter:

N/A

Deliverables & Targets Planned for the Next Quarter:

- Updates to DRGs for alignment and consistency, content related to open-source code and estimands
- Collaborative session with the RWE WG at the US Connect to discuss RWD updates to DRGs

Leads

Janet Low & Christine Rossin

Project Status

Project Status: Green

- Leads are meeting regularly to work on cross-document alignment

SDTM ADaM Implementation FAQ

Scope

This project team was formed to address common challenges faced by SDTM and ADaM implementers and consumers. It aims to collaborate with subject matter experts (SMEs) from the industry, CDISC and the FDA. The team's goal is to collect frequently asked questions (FAQ) from the industry and assess their appropriateness. They develop and review responses and, if needed, collaborate with CDISC/the FDA for clarity. The FAQ and responses are then published on the PHUSE Advance Hub database, to provide helpful implementation and strategy information.

Ongoing

Proposed End Date

FAQ

Deliverable Type

Aatiya Zaidi & Mike Wise

Leads

N/A

Key Achievements This Quarter:

Session at the US Connect to discuss FAQs and use of AI relating to data standards

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members

- Working through several open questions to finalise responses. It has been challenging to get feedback from the FDA for the last several months.

Project Status

phuse