

Optimizing the Use of Data Standards

Project Leads:
Julie Maynard &
Sopan Kaith

Deliverable:
PHUSE BIMO FAQ Forum

*Key Achievements This
Quarter:*

Proposed Project End Date:
Q3 2025

Last of the FAQs sent
for proofreading

*Bioresearch Monitoring
(BIMO) Frequently Asked
Questions Forum*

Project 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.

Project Status:
Green

*Deliverables & Targets
Planned for the Next
Quarter:*

Publishing the last of
the FAQs

*Project Accepting New
Members: No*

Project Leads:
Rahul Madhavan, Aparna Venkat & Reema Baweja

Proposed Project End Date:
Q2 2026

Project 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.

Deliverable:
White paper

Building a Better MDR

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

Held kick-off meeting, gathering information from team members

Deliverables & Targets Planned for the Next Quarter:

Starting regular meeting series

Project Leads:
Kiran Kundarapu, Satheesh
Avvaru & Randi McFarland

Proposed Project End Date:
Q4 2025

Project Scope:
The cSDRG and ADRG apply to a single study. Sponsors have used these templates when creating reviewer's guides for integrated study data and integrated analysis data. The template has to be changed to document the information for multiple studies. There is an opportunity to create a template for integrated study data and integrated analysis data. The project team will determine if this can be accomplished in one reviewer's guide or two separate reviewer's guides. Deliverables include a template, completion guidelines and example documents.

Deliverable:
iADRG project: Integrated Analysis Data
Reviewer's Guide (iADRG) Template,
Completion Guidelines and 2 Examples

icSDRG Project: Integrated Clinical Study
Data Reviewer's Guide (icSDRG) Template,
Completion Guidelines and Example

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

Project Status:
Green

*Project Accepting New
Members: No*

*Key Achievements
This Quarter:*

Finishing team review
of completion
guidelines

*Deliverables & Targets
Planned for the Next
Quarter:*

Provide icSDRG
package for public
review

Project Leads:
Janet Low & Christine Rossin

Proposed Project End Date:
Ongoing

Project 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.

Deliverable:
Updated documents if updates are identified

Management of ODS Regulatory Referenced Deliverables

Project Status:
Green

*Project Accepting New
Members: N/A*

*Key Achievements This
Quarter:*

Identified replacement
deliverable representatives

*Deliverables & Targets
Planned for the Next
Quarter:*

Working on
alignment/consistency
across docs

Project Leads:
Aatiya Zaidi & Mike Wise

Proposed Project End Date:
Ongoing

Deliverable:
Ongoing implementation
support to the Community

*Key Achievements This
Quarter:*

Published more FAQ

*SDTM ADaM
Implementation FAQ*

Project 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.

Project Status:
Green

*Project Accepting New
Members: Yes*

*Deliverables & Targets
Planned for the Next
Quarter:*

Continue to address
questions in key areas