

Optimizing the Use of Data Standards

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Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum

Description

This project develops a Bioresearch Monitoring (BIMO) Frequently Asked Questions (FAQ) Forum on the PHUSE Advance Hub, aligned with the established SEND FAQ format. The forum consolidates questions from the pharma and CRO community, including inputs from public reviews, presentations, and PHUSE BIMO team members.

The FDA's BIMO Technical Conformance Guide (2017; updated 2020) defines requirements for electronic submissions supporting BIMO inspections, including clinical study-level information, subject-level data listings by site, and the clinical site dataset (clinsite.xpt). BIMO is a critical component of NDA, BLA and supplemental submissions, with organisations developing approaches based on this guidance.

Work on the PHUSE Bioresearch Monitoring Data Reviewer's Guide (BDRG) highlights ongoing industry questions. Many are captured in the BDRG Communication Tracker, alongside broader queries arising from implementation and review activities. A centralised FAQ forum provides consistent, coordinated responses to support both sponsors and regulators.

Q3 2026

Proposed
End Date

FAQ

Deliverable

Sopan Kaith

Lead

Finalised last batch of
FAQs incorporating
proofreading feedback.

Key Achievements
This Quarter:

Publish final batch of
FAQs.

Deliverables &
Targets Planned for
the Next Quarter:



Project Status: Amber

- Ready to publish.

Project Status

Building a Better MDR

Description

This project defines use cases, functions, features, and best practices for an ideal vendor-neutral metadata repository (MDR) focused on cross-study data standards. It captures the needs of key users, such as standards librarians, data managers, and programmers, to ensure the MDR supports end-to-end standards management, consumption and automation. The output will serve as a 'wish list' of requirements that organisations can use for RFIs, RFPs, or internal system development when evaluating MDR solutions.

MDR implementations often require significant investment but may fail to deliver value if misaligned with organisational needs. Many organisations face challenges in effectively managing, documenting and operationalising metadata, limiting downstream reuse and automation.

A well-designed MDR enables efficient standards implementation and maintenance, improves traceability and compliance, and supports scalable automation. Establishing clear requirements and best practices will help organisations maximise return on investment and align systems, services and processes with evolving data standards needs.

Q3 2026

Proposed
End Date

N/A - working on editing
the white paper.

Final draft ready for
review.

White paper

Deliverable

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Aparna Venkat,
Rahul Madhavan
& Reema Baweja

Leads



Project Status: Amber

- White paper being edited for brevity.

Project Status

Clinical Integrated Study Data & Analysis Data Reviewer's Guide

Description

This project addresses the limitation that cSDRG and ADRG templates are designed for single studies, while sponsors increasingly use them for integrated study data and analysis. It focuses on adapting these templates to effectively capture and document information across multiple studies.

The project will evaluate whether a single integrated reviewer's guide or two separate guides (for integrated study data and integrated analysis data) provides the most effective approach. The aim is to ensure clarity, consistency and usability for regulators reviewing integrated submissions.

Key deliverables include a standardised template, comprehensive completion guidelines, and example documents to demonstrate best practice. These outputs will support sponsors in producing clear, consistent and fit-for-purpose reviewer's guides for integrated datasets, improving review efficiency and submission quality.

Q3 2026

Proposed
End Date

- 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

Deliverable

Completed incorporation of ODS Leads' feedback.

Key Achievements
This Quarter:

Final package ready for review.

Deliverables &
Targets Planned for
the Next Quarter:

AKiran Kundarapu,
Randi McFarland &
Satheesh Avvaru

Leads



Project Status: Amber

- Final alignment updates being incorporated.

Project Status

Electronic Data Submission in Japan

Description

This project aims to raise global awareness of PMDA eData submission requirements, focusing on practical challenges and opportunities for improvement. It supports the development of clearer, more efficient processes and solutions for both regulators and sponsors/CROs.

Key objectives include delivering a white paper that highlights differences between FDA and PMDA electronic data submission requirements, providing a streamlined reference for adapting CRT packages across agencies. The project will also develop an AI-powered prompt library to support compliance checks against PMDA regulations, improving submission quality and efficiency through the use of Generative AI.

In addition, the team will create and deliver a presentation with practical guidance and tips for PMDA eData submissions, to be shared through webinars or PHUSE events (e.g. SDEs or Connects), promoting best practices and broader industry understanding.

Q3 2027

Proposed
End Date

N/A

Submit for Global
PHUSE review during
2026 Q3.

White paper

Deliverable

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Rie Kageyama,
Shinichi Hotta,
Tomohiko Funai &
Yoshiko Kitagawa

Leads



Project Status: Green

- White paper is nearing completion, preparing for submission.

Project Status

Management of ODS Regulatory Referenced Deliverables

Description

This project establishes a structured process to maintain PHUSE regulatory referenced deliverables by appointing primary and back-up representatives for each. These representatives will ensure alignment with evolving regulatory guidance by reviewing updates, identifying required changes, coordinating feedback, and overseeing revisions and publication.

The Optimizing the Use of Data Standards Working Group maintains key deliverables, including the cSDRG, ADRG, SDSP and BDRG, with additional outputs planned. Currently, no formal maintenance process exists, and original project teams no longer meet regularly, creating a risk of misalignment with regulatory guidance.

This project introduces a sustainable, scalable approach to ongoing maintenance, ensuring deliverables remain current, consistent and aligned with regulatory expectations. Updated templates, examples and guidance will continue to support sponsors in meeting FDA and other regulatory requirements.

Ongoing

Proposed
End Date

Updated
documents (if
updates are
identified)

Deliverable

Wrapping up alignment
work.

Key Achievements
This Quarter:

Templates and
completion guidelines
ready for review.

Deliverables &
Targets Planned for
the Next Quarter:

Christine Rossin
& Janet Low

Leads



Project Status: Amber
Accepting New Members - Yes* - seeking new co-lead for SDSP

- Completing alignment updates. Templates and completion guidelines to be shared first, with updated examples to come later this year.

Project Status

SDTM ADaM Implementation FAQ

Description

This project was initiated following the Standards Implementation Nuances sessions held at the March 2016 US CSS and the June 2016 EU CSS, which highlighted common challenges faced by SDTM and ADaM implementers and consumers. Discussions also revealed numerous questions relating to data submission requirements across regulatory agencies, including the FDA, PMDA and NMPA, demonstrating the need for a centralised forum and knowledge base.

The project team collaborates with industry subject matter experts (SMEs), CDISC and regulatory agencies to address these challenges. Its objectives are to collect frequently asked questions from the industry, assess their relevance, and develop clear, consistent responses. Where necessary, the team engages with CDISC and regulatory bodies to ensure accuracy and clarity.

All validated FAQs and responses are published on the PHUSE website, providing a reliable, accessible resource to support consistent implementation and informed decision-making across the industry.

Ongoing

Proposed
End Date

N/A - discussions
ongoing.

- Create social group on LinkedIn.
- Publish additional responses to the Advance Hub and LinkedIn.

FAQ

Deliverable

Key Achievements
This Quarter:

Deliverables &
Targets Planned for
the Next Quarter:

Aatiya Zaidi &
Mike Wise

Leads



Project Status: Green
Accepting New Members

- Working out creation and administration of LinkedIn group to better socialise SDTM/ADaM Q&A.

Project Status