Optimizing the Use of Data Standards

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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.

Q2 2026

Proposed End Date

FAQ

Deliverable Type

Sopan Kaith

Lead

Advance Session at the US Connect sharing common misperceptions was well received

Key Achievements This Quarter:

Finalise last batch of FAQs for publishing

Deliverables & Targets Planned for the Next Quarter:

Project Status: Amber

- Team is going through proofreading feedback and updating responses and screenshots accordingly

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 (or as requirements to build) as organisations evaluate systems and tools for their MDR needs.

Q3 2026

Proposed End Date

White paper

Deliverable Type

Aparna Venkat, Rahul Madhavan & Reema Baweja

Leads

Key Achievements This Quarter:

- Advance Session at the US Connect shared an overview of the draft white paper
- Had collaborative discussion and collected additional survey responses
- White paper is drafted and undergoing updates following the Connect

Deliverables & Targets Planned for the Next Quarter:

Draft white paper shared for Leads' review

Project Status: Green

- Draft white paper being finalised. Plan to share with ODS Leads around end of April

Project Status

Clinical Integrated Study Data & Analysis Data Reviewer's Guide

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.

Proposed End Date

Q2 2026

Deliverable Type

- 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

Key Achievements This Quarter:

Updates shared in the US Connect Advance Session

Deliverables & Targets Planned for the Next Quarter:

Share updated icSDRG package with the ODS Leads for review

Leads

AKiran Kundarapu, Randi McFarland & Satheesh Avvaru

Project Status

Project Status: Green

- Reviewing feedback from initial Leads' review, updating the Completion Guidelines and Example accordingly

Electronic Data Submission in Japan

Scope

To raise awareness of eData submission to the PMDA globally, focusing on PMDA requirements and practical challenges. To provide ideas for improvements for the eData submission process/deliverables and to discuss better solutions for both the PMDA and sponsors/CROs.

Proposed End Date

Q3 2027

Deliverable Type

White paper

Leads

Rie Kageyama, Shinichi Hotta, Tomohiko Funai & Yoshiko Kitagawa

Key Achievements This Quarter:

N/A

Deliverables & Targets Planned for the Next Quarter:

Drafting white paper

Project Status

Project Status: Green

- Draft in progress

Management of ODS Regulatory Referenced Deliverables

Scope

The scope of this project is to update and maintain PHUSE regulatory referenced deliverables:

- 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
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Oversee the updates and publishing of PHUSE deliverables.

- Two leads are appointed for each deliverable, who are asked to commit to serving for two years.

Ongoing

Proposed End Date

Updated documents (if updates are identified)

Deliverable Type

Christine Rossin & Janet Low

Leads

Shared updates on alignment of documents and other minor updates in the US Connect Advance Session

Key Achievements This Quarter:

Finalise updates including examples

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Accepting New Members - *to update DRG examples following recent alignment efforts and other minor updates*

- Updates in progress

Project Status

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

No update

Key Achievements This Quarter:

Publish latest FAQs

Deliverables & Targets Planned for the Next Quarter:

Project Status: Amber
Accepting New Members

- Finalising latest questions. Need to evaluate the project - whether to continue as is (not as many questions coming in lately), evolve to better fit needs of the industry, or conclude the project.

Project Status

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