

Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum



Project Scope

The scope of this project is to 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, and so on.

Problem Statement

The FDA drafted the initial Bioresearch Monitoring Technical Conformance Guide in December 2017, with an updated version published in July 2020. Reference: Bioresearch Monitoring Technical Conformance Guide <https://www.fda.gov/media/85061/download>. The guide provides specifications for preparing and submitting the following components in electronic format that are used by the FDA for the planning of bioresearch monitoring (BIMO) inspections:

- Clinical Study-Level Information
- Subject-Level Data Line Listings by Clinical Site
- Summary-Level Clinical Site Dataset (clinsite.xpt)

The NDA, BLA and supplemental submissions to the FDA require BIMO as a critical part of the electronic application. Pharma companies and CROs have individually developed BIMO standards based on the recent guidance from the FDA. A coordinated approach to responses to frequently asked BIMO questions can benefit sponsors as well as the FDA.

Problem Impact

It was apparent during the creation of the PHUSE Bioresearch Monitoring Data Reviewer's Guide (BDRG) that organisations implementing BIMO submission packages have outstanding questions. The BDRG team captured a lot of those questions in our Communication Tracker (repository of questions and team responses). While most questions were directed at the BDRG effort, there were many general questions that came up during review, presentations etc.

Project Leads		Email	Objectives & Deliverables		Timelines
Julie Maynard, <i>Johnson & Johnson</i>		jmaynar1@its.jnj.com	Populate BIMO FAQ table of contents with questions and answers which have been completed in the FAQ Tracker		Q1 2024
Sopan Kaith, <i>Alexion AstraZeneca Rare Disease</i>		sopan.kaith@alexion.com			
Nicola Newton, <i>PHUSE Project Assistant</i>		nicky@phuse.global			

CURRENT STATUS Q1 2024

- Meetings to discuss FAQs entered in the FAQ Tracker or communicated to the team
- Created the BIMO FAQ Global Survey and reviewed by PHUSE