(BIMO) Bio-research Monitoring Data Reviewer's Guide

Project Scope
Develop a Data Reviewer's Guide Template (referenced in the Technical Conformance Guide) and associated documents to allow up front communications regarding the sponsors interpretation of the Bio-research Monitoring Technical Conformance Guide. Initially, the scope will include the development of the template and then expand to cover the full suite of documents. The current cSDRG and ADRG templates will be considered to avoid unnecessary duplication of content. Therefore, revision of these templates are not in scope.

Problem Statement

FDA drafted the initial Bio-research Monitoring Technical Conformance Guide in December 2017, with an updated version published in July 2020 (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 FDA for planning of Bio-research Monitoring (BIMO) inspections.

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

NDA, BLA, and supplemental submissions to FDA require BIMO as a critical part of the electronic application.

There is currently a lack of clarity as each sponsor will have defined their own approach to the generation of this content, especially where there is a need to interpret the Technical Conformance Guide.

Problem Impact

This need for interpretation leads to inconsistencies between Sponsors when submitting this content to the agency. Potentially, this results in the need for Sponsors to provide additional clarification to the agency subsequent to the submission of the content.

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Objectives & Deliverables	Timelines
Publication of BDRG v3.0	Q2 2023
Presentation of BDRG v.30 in PHUSE June Webinar Wednesday	Q2 2023

CURRENT STATUS **Q4 2023**

- Leads of this project will meet with key players to identify if there is any need for major updates in the near future
- Project will now move to the Management of ODS Regulatory Referenced Deliverables Working Group project
- Project to close

Published Deliverables	
Bio-research Monitoring Data Reviewers Guide (BDRG) Package	Version 3.0, 28 June 2023
Bio-research Monitoring Data Reviewers Guide (BDRG) Package	Version 2.0, 22 June 2022
Bio-research Monitoring Data Reviewers Guide (BDRG)	Version 1.0, 05 Jan 2020