(BIMO) Bio-research Monitoring Data Reviewers 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.

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Objectives & Deliverables	Timelines
Finalisation of full BDRG package (assessing/incorporating comments from public review):	Q2 2022
Publication of BDRG	Q2 2022

CURRENT STATUS **Q2/3 2022**

- Published BDRG Package
- Submitted New Project Request which is currently pending approval: Bioresearch Monitoring (BIMO) Frequently Asked Questions Forum
- Project currently on hold until Q4 2022

Published Deliverables	
Bio-research Monitoring Data Reviewers Guide (BDRG) Package	22 June 2022

Project Members	Organisation
Aatiya Zaidi	Gilead
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Satheesh Avvaru	PPD
Santosh Kumar Lingala	Gilead
Shreetam Sheregar	Labcorp
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Steve Fitzpatrick	Novartis
Steven Clark	Astellas
Todd Rider	Bristol Myers Squibb
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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.