(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.

Project Leads	Email
Julie Maynard (Johnson & Johnson)	jmaynar1@its.jnj.com
Sopan Kaith (Cytel)	sopan.kaith@cytel.com
Katie Warren (PHUSE Project Assistant)	katie@phuse.global

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

CURRENT STATUS **Q3/4 2022**

- Review the BDRG for necessary changes due to the release of BIMO TCG v3.0
- Update the BDRG package to comply with BIMO TCG v3.0
- Review and publish the updated BDRG
- PHUSE EU Connect 2022 – present the BDRG package

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

Project Members	Organisation
Aatiya Zaidi	Gilead
Adity Shelke	Pfizer
Amie Sagady	Takeda
Aohra Monceaux	Sanofi
Avinash Reddi Patti	GSK
Barbara Lockley	Industry
Bhanu Kannan	FDA
Bei Yu	FDA
Cara Alfaro	FDA
Cathy Michalsky	Teva Pharmaceuticals
Chunying Yin	Janssen Research & Development
Cynthia Kleppinger	FDA
David Postma	Pfizer
Dmitry Golubovsky	Teva Pharmaceuticals
Gabriela LopezMitnik	FDA
Harini Kunduru	DSI
Karen Bleich	FDA
Kathryn Knuckles	Eli Lilly
Ke Wang	Bristol Myers Squibb
Kiran Kundarapu	Merck
Kirsty Wall	GSK
Jack Field	AstraZeneca
Jasmin Jobanputra	Novonordisk
Jean Mulinde	FDA

Project Members	Organisation
Lisa Zhou	Janssen Research & Development
Maggie Lo	Lung Biotechnology PBC
Michael Johnson	FDA
Meng Li	AstraZeneca
Nancy Bauer	Boehringer Ingelheim
Nigel Montgomery	Roche
Phil Liu	AstraZeneca
Phyllis Smetana	UCB
Rashed Hasan	FDA
Sai Ma	Bayer
Santosh Kumar Lingala	Gilead
Saritha Bathi	Bristol Myers Squibb
Satheesh Avvaru	PPD
Shreetam Sheregar	Labcorp
Srinivasan Ramasubramanian	AbbVie
Stanley Au	FDA
Stanley Brill	Janssen Research & Development
Steve Fitzpatrick	Novartis
Steven Clark	Astellas
Todd Rider	Bristol Myers Squibb
Yan (Joy) Shen	Pfizer

Lin Yuan	Astellas

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.