(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	jmaynar1@its.jnj.com
Sopan Kaith	sopan.kaith@tcs.com
Katie Warren (PHUSE Project Assistant)	katie@phuse.global

Objectives & Deliverables	Timelines
Kick Off Project	Apr-2021
Template & Completion Guidelines	Oct-2021
Examples	Dec-2021

CURRENT STATUS **Q3/42021**

- Sub-teams and Leads to evaluate and incorporate the PHUSE CSS feedback into the Draft Template and Completion Guidelines.
- Sub-teams and Leads to finalise the Examples and full team review of the BDRG Package to be completed on 19th November 2021.
- BDRG Package to be sent to the PHUSE Steering Committee for review on 22nd November 2021.
- PHUSE BIMO team review of comments and any updates to documents.
- Public review projected for 15th December 2021 to 31st January 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
Harini Kunduru	DSI
Karen Bleich	FDA
Kathryn Knuckles	Eli Lilly
Ke Wang	Bristol Myers Squibb
Kiran Kundarapu	Merck
Kirsty Wall	GSK
Jack Field	AstraZeneca
Lin Yuan	Astellas

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
Sai Ma	Bayer
Satheesh Avvaru	PPD
Santosh Kumar Lingala	Gilead
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
Jasmin Jobanputra	Novonordisk

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.