BIMO Frequently Asked Questions Forum

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Question

Is there Reference of latest PHUSE BDRG in latest FDA CDER BIMO TCG?

Answer

Yes,
As per latest FDA CDER BIMO TCG V3.0 (11th August , 2022), Page 2, there is a footnote 4 that references and provides a link for the latest version of PHUSE BDRG (Hint: Within the link click on "Bio-research Monitoring Data Reviewers Guide (BDRG) Package" that should open latest version of PHUSE BDRG. We believe this footer link would be available in the future FDA CDER BIMO TCG release as well).

Please reference the below snapshot from the latest FDA CDER BIMO TCG V3.0 (11th August , 2022), Page 2, footnote 4

[3] See ICH guidance for industry *E3 Structure and Content of Clinical Study Reports* (July 1996).

[4] A specific template for a BIMO Data Reviewer's Guide is not specified. However, an example can be found at https://advance.phuse.global/display/WEL/Deliverables.

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PHUSE portal

White paper [Useful and applicable]

BIMO Submission Standards / Guidance

Standardized Format for Electronic Submission of BIMO

BIMO Technical Conformance Guide (TCG)

Question

Where to refer for Geopolitical Entities, Names and Codes (GENC) code list mentioned in the FDA CDER BIMO Technical Conformance Guide (TCG) v3.0?

Answer

You can refer to FDA (GENC) code list provided at the location https://evs.nci.nih.gov/ftp1/GENC/ [Refer the latest (GENC) code list file from this hyperlink].
We believe in the future FDA CDER BIMO TCG release the above link would be mentioned with some additional instructions for Sponsor/Applicant.

Question

In the BIMO TCG V3.0 Section IV. Submitting BIMO Clinical Data in the eCTD format, the file name of the BIMO Data Reviewer's Guide is listed as "bimo-rev-guide.pdf" whereas the PHUSE BDRG names the document as "bdrg.pdf" (consistency with other study data and analysis reviewer's guides). Can we submit using naming conventions for the BDRG that are different than the BIMO TCG as long as we identify them in the BDRG 'Section 9. eCTD Folder Structure Skeleton for BIMO Items in MODULE 5'? Will "bimo-rev-guide.pdf" file name be modified in a future BIMO TCG version to be "bdrg.pdf"?

Answer

FDA CDER BIMO TCG V3.0 has referenced BIMO Reviewer's Guide as BIMO Data Reviewer's Guide (For Example: As per latest FDA CDER BIMO TCG V3.0 (11th August, 2022), Page 2, there is a footnote 4 that references and provides a link for the latest version of PHUSE BDRG (Hint: Within this link click on "Bio-research Monitoring Data Reviewers Guide (BDRG) Package" that should open latest version of PHUSE BDRG. We believe this footer link would be available in the future FDA CDER BIMO TCG release as well).

PHUSE BIMO team acronyms BIMO Data Reviewer's Guide as BDRG and also recommends BIMO Data Reviewer's Guide deliverable file name as "bdrg.pdf" as defined in the PHUSE BDRG Package documentation instead of filename "bimo-rev-guide.pdf" that is recommended in FDA CDER BIMO TCG V3.0. Yes, we can identify this deliverable as "bdrg.pdf" in the BDRG 'Section 9. eCTD Folder Structure Skeleton for BIMO Items in MODULE 5'.

Future BIMO TCG release is expected to reference BIMO Data Reviewer's Guide with standard acronym as BDRG and also update BIMO Data Reviewer's Guide deliverable file name to "bdrg.pdf".

Question

Whenever FDA CDER TCG new version is released what should be the ideal time frame for Sponsor OR Applicant to implement them in their BIMO submission Packages to FDA.

Answer

FDA has not published formal policy regarding the time allotted for implementation of changes when a new version of a TCG is published. An updated BIMO TCG would become effective immediately upon publication. However, recognizing that some BIMO TCG updates may require changes in SOPs and/or processes, we suggest implementing revised BIMO TCG on all BIMO submission packages within 6-12 months of its release depending on the complexity of the updates in the release. Below you can refer to a hypothetical scenario of BIMO TCG release (with complexity) on Sponsor/Applicant BIMO submission Packages that are READY/ONGOING/Planning for BIMO submission to FDA CDER.

Difference between FDA CDER Vs FDA CBER BIMO submission

Pre-Submission FDA Meeting Planning/Discussion

Question

For BIMO Submission to FDA, During pre-submission meeting/discussion how effectively sponsor/applicant can plan/discuss BIMO requirement for smooth review of BIMO submission packages to FDA.

Answer

For BIMO, Sponsor/Applicant can effectively plan for pre-submission meeting/discussion by bringing critical topics for discussion/suggestion /acceptance at least on below areas:

- Clarify/Identify major (pivotal) studies that should be part of BIMO submission to FDA
- For identified major (pivotal) studies, Clarify/Identify input data of agreed major (pivotal) studies data to be used for BIMO submission to FDA
- Any data not available/not compatible for alignment with latest BIMO TCG release.
- FDA CDER BIMO TCG version to be followed (Highly recommended and expectation is for latest BIMO TCG released by FDA), also do check for your in-house BIMO processes align with the FDA CDER BIMO TCG version that is followed and if any challenges raise it/plan for the discussion.
- Review of Latest FDA CDER TCG V3.0 AND Latest PHUSE BDRG V3.0, to have fair idea of information that will be required to be followed/part of BIMO submission deliverables to FDA, and if any challenges documenting in BDRG then raise it/plan for the discussion.
- Any Learnings/Experience from other BIMO submission FDA IRs that needs to be clarified from FDA perspective.

So, overall If any items related to BIMO deliverables are unclear based on your review of the most current BIMO TCG posted, then questions related to BIMO deliverables may be included with your pre-submission meeting packet. In cases when BIMO deliverable questions will be submitted, we suggest that applicant/sponsor request input on these questions from CDER/OC/OSI/GCPAB staff, along with other members of the pending application FDA review team.

BIMO Clinical Data consistency with SDTM/ADAM

Question

For PART III : SUMMARY-LEVEL CLINICAL SITE DATASET, FDA CDER BIMO TCG V3.0 requires COUNTRY variable to use FDA GENC Code List instead of ISO 3166-1-alpha-3.
Should SDTM/ADaM datasets from FDA CSR Submission also use FDA GENC Code List?

Answer

No,

If your BIMO submission package is based on FDA CDER BIMO TCG V3.0, Within PART III : SUMMARY-LEVEL CLINICAL SITE DATASET, Country (Including State) variable is highly recommended to be based on FDA GENC code List.

If your BIMO submission package is based on BIMO TCG (V1.0 / V2.0), Within clinsite data set Country variable is highly recommended to be based on ISO 3166-1 Alpha-3 code list ONLY.

For your Data Package submission as per the CDISC SDTM/ADAM Implementation guidelines, Country variable should be based on the ISO 3166-1 Alpha-3 code list ONLY. Moreover, this does not seem a question for PHUSE BIMO FAQs team, we suggest send query on preparation of SDTM /ADAM to edata@fda.hhs.gov

Question

As per BIMO TCG V3.0, For the Clinsite data set variable ARM has variable label "Description of Planned Treatment Arm", whereas in SDTM.DM variable ARM has variable label "Description of Planned Arm"
Is it acceptable to use the label from DM.ARM in clinsite.arm ?

Answer

For Sponsors/Applicant that are using BIMO TCG V3.0 (Or any future BIMO TCG) for their BIMO submission, it is highly recommended that they are aligned with that BIMO TCG that is used by them for their BIMO submission. From clinsite data set perspective aligning with Data set name, data set label, variable name, variable label, variable derivation criteria...etc....as this will help FDA reviewer to review BIMO submission deliverables smoothly from the BIMO TCG and inspection perspective.

BDRG consistency with cSDRG/ADRG

Consistency among BIMO Submission to FDA

Question

1. Background about Financial Disclosure Form/Statement collected for Current Principal Clinical Investigator and all Sub-Investigators per SITE and how it is applicable BIMO CDER submission and under which eCTD submission module.
2. For Part III – Summary-level Clinical Site Dataset : How do we assign a particular Financial Disclosure Amount category per SITE when there are various combinations of Financial Disclosure Amount category among Current Principal Clinical Investigator and all Sub-Investigators per SITE.

Answer

1) Background about Financial Disclosure Form/Statement:

Whenever a sponsor selects a new Investigator [.i.e. Current Principal Clinical Investigator OR Sub-Investigators] to participate in a clinical investigation, Sponsor/Applicant receives completed and signed Form FDA 1572 as per regulations (21 CFR 54) from each new investigator and also completed and signed financial disclosure form or the drug company-specific Financial disclosure form/statement [Prior/After completion of Study at SITE, For BIMO it would be 'After completion of Study at SITE' that would be relevant] from each new investigator.
The completed and signed financial disclosure form or the drug company-specific Financial disclosure form/statement received by Sponsor/applicant from new investigator are ideally captured in FORM FDA 3455 including an attachment with detailed information about those financial interests and arrangements (This will have questionnaire on Financial Disclosure Amount categorical value of >=$25000 to be answered as YES/NO/Left unanswered, So YES means >=$25000, NO would mean <$25000 or Left unanswered could lead to sponsor/applicant for couple of attempt of due-diligence to confirm if the new investigator should finally be classified as >=$25000 OR <$25000 OR “unknown” (i.e., unable to obtain information from investigator at site) OR “masked” if information on this item is available but it has not been provided by the sender due to security, privacy, or other reasons.

2) As per latest FDA CDER BIMO TCG V3.0 (11th August , 2022):
For Part III – Summary-level Clinical Site Dataset, variable FINLDISC (Financial Disclosure Amount), a particular Financial Disclosure Amount category per SITE needs to be assigned
Where Total financial disclosure amount (US$) by site calculated as the sum of disclosures for the Current Principal Clinical Investigator and all Sub-Investigators, to include all required parities under the applicable regulations (21 CFR 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860). Enter “>=$25,000,” “< $25,000,”unknown” if a proper value is applicable but is not known (i.e., unable to obtain information from investigator at site), or “masked” if information on this item is available but it has not been provided by the sender due to security, privacy, or other reasons.

Note:-
- Sponsor/Applicant collects, maintains and finalized financial interests and arrangements information as Financial Disclosure tracker for use in the BIMO Module 1 Administrative information (.i.e. 1.3.4 Financial certification and disclosure - Financial Disclosure tracker) AND BIMO Module 5 (.i.e. 5.3.5.4 Other Study reports and related information - Part III – Summary-level Clinical Site Dataset) eCTD deliverables.
Important Note: Between BIMO Module 1 Administrative information (.i.e. 1.3.4 Financial certification and disclosure - Financial Disclosure tracker) AND BIMO Module 5 (.i.e. 5.3.5.4 Other Study reports and related information - Part III – Summary-level Clinical Site Dataset) , finalized financial interests and arrangements information should be consistent where applicable.
- Use for Financial Disclosure tracker in BIMO Module 5 (.i.e. 5.3.5.4 Other Study reports and related information - Part III – Summary-level Clinical Site Dataset) eCTD deliverable has below challenges:-
As SITE may have Current Principal Clinical Investigator AND multiple Sub-Investigators with Financial Disclosure Amount categorical value of "<$25000",">=$25000",“unknown” OR “masked”, it would be challenging for Sponsor/Applicant [Regulatory/Programming/ClinOps/eSubmission Functional team] to assign one Total Financial Disclosure Amount categorical value for a SITE when there is various Financial Disclosure Amount categorical values for a SITE. So to overcome this challenge below algorithm can be used to assign one Financial Disclosure Amount categorical value for a SITE:-
- If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with at least one Total Financial Disclosure Amount categorical value of ">=$25000" then assign
FINLDISC=">=$25000" for that SITE.
ELSE - If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with Financial Disclosure Amount categorical value of ">=$25000" ONLY then assign
FINLDISC=">=$25000" for that SITE.
ELSE - If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with Financial Disclosure Amount categorical value of "<$25000" ONLY then assign
FINLDISC="<$25000" for that SITE.
ELSE - If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with Financial Disclosure Amount categorical value of “unknown” ONLY then assign
FINLDISC=“unknown” for that SITE.
ELSE - If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with Financial Disclosure Amount categorical value of “masked” ONLY then assign
FINLDISC=“masked” for that SITE.
ELSE - If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with Financial Disclosure Amount categorical value of “unknown” AND "masked" ONLY then assign FINLDISC=“unknown” for that SITE.
ELSE - If a SITE has Current Principal Clinical Investigator AND multiple Sub-Investigators with NO Financial Disclosure Amount categorical value of ">=$25000" AND [at least one Financial Disclosure Amount categorical value of “unknown” OR "masked"] then assign FINLDISC=“unknown” for that SITE.

BIMO Submission Deliverables

Part I (Item A) - List of All Clinical Sites

Question

Among Investigator (Current Principal Clinical Investigator AND/or multiple Sub-Investigators) for a SITE, which of investigator information should be reported in Part I (Item A) – List of All Clinical Sites as well as in Part III – Summary-level Clinical Site Dataset?

Answer

As per FDA CDER BIMO TCG :-
For BIMO Part I (Item A) – List of All Clinical Sites PDF deliverable for each of the major (i.e. pivotal) studies for each SITE that participated in the study (i.e. SITE that have screened one subject with a signed informed consent) there is Current Principal Clinical Investigator information .i.e. LAST NAME, FIRST NAME,Middle INITIAL,PHONE, FAX and EMAIL (along with Prior Principal Clinical Investigator(s) information<if applicable> .i.e. LAST NAME, FIRST NAME,Middle INITIAL,PHONE, FAX and EMAIL) information needs to be provided as recommended in the 2nd and 4th column as per format "APPENDIX 1: CLINICAL STUDY-LEVEL INFORMATION, Table A: Format for Clinical Site Lists" mentioned in the latest FDA CDER BIMO TCG version 3.0.

For Part III – Summary-level Clinical Site Dataset deliverable for each of the major (i.e. pivotal) studies for each SITE that participated in the study (i.e. SITE that have screened one subject with a signed informed consent) there is ONLY Current Principal Clinical Investigator Information .i.e. LAST NAME, FIRST NAME,Middle INITIAL,PHONE,FAX and EMAIL information needs to be provided as separate variables in the clinsite data set (But, NO Prior Principal Clinical Investigator(s) information AND NO multiple Sub-Investigators NAME information is needed).

Part I (Item B) - Entities Contact Information and Trial-related Files

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Part I (Item C1) - Protocol and Amendments

Part I (Item C2) - Annotated Case Report Form (aCRF)

Part II - Subject-level Data Line Listings by Clinical Site

Question

For FDA CDER BIMO Part II - deliverable should we use source as SDTM/ADAM data sets and should it match to FDA study data submission for CSR OR equivalent other FDA study data submission?

Answer

For FDA CDER BIMO Part II - Subject-level Data Line Listings by Clinical Site deliverable, there is information that is displayed, reported or summarized based on the inputs from SDTM, ADAM AND other external transfer data sets (eDT) which are based on FDA CSR submission OR equivalent FDA submission data.

Since ADAM contains SDTM as well as additional analysis reporting requirements, therefore between SDTM/ADAM, we highly recommend to use ADAM as an input data along with other external transfer data sets (eDT) for FDA CDER BIMO Part II - Subject-level Data Line Listings by Clinical Site deliverable.

Sponsor/applicant can discuss during their pre-submission meetings with FDA for input data [Based on the Week # /Data-Cut applied...etc..] to be used for the approval/support labelling of their application and then establish agreement.

Part III - Summary-level Clinical Site Dataset

Question

Is there a tool to generate define.xml for Part III – Summary-level Clinical Site Dataset (clinsite.xpt)?

Answer

Yes, based on the finalized Part III – Summary-level Clinical Site Dataset (clinsite.xpt) and it's finalized metadata/specification, You can use the following either of the below application/tool/automated programs :
1) Pinnacle 21 (Enterprise version)
2) Pinnacle 21 (Community version)
3) Sponsor/Applicant Inhouse validated and tested SAS programs and/or SAS macros
4) Sponsor/Applicant Inhouse validated and tested R programs and/or R Functions and/or R applications and/or R Packages.
5) Sponsor/Applicant Inhouse validated and tested Python programs and/or Python Functions and/or Python applications and/or Python Packages.
etc....

Part IV - BIMO Data Reviewer’s Guide (BDRG)

General

eCTD Folder Structure for BIMO

About eCTD

How your BIMO preparation and submission is related to eCTD

Where and how to use eCTD within BIMO submission to FDA

Submitting BIMO Clinical Data in the eCTD Format

Question

For Part III – Summary-level Clinical Site Dataset (clinsite.xpt) , is define.xml mandatory?

Answer

Yes, when submitting the clinsite.xpt it should be accompanied by a define.xml file. As per latest FDA CDER BIMO TCG V3.0, which provides current FDA specifications, recommendations, and general considerations for preparing and submitting Clinical Study-Level Information, Subject-Level Data Line Listings by Clinical Site, and a Summary-Level Clinical Site Dataset that are used by the Center for Drug Evaluation and Research (CDER) for planning of Bioresearch Monitoring (BIMO) inspections in electronic format.

Moreover, as per latest FDA CDER BIMO TCG V3.0 (11th August , 2022) document :
- Under III. SUMMARY-LEVEL CLINICAL SITE DATASET -> Section B. Variables and Variable Names for Site-Specific Efficacy Results - It is mentioned that The summary-level clinical site dataset should be accompanied by a data definition file.
- Under IV. SUBMITTING BIMO CLINICAL DATA IN THE eCTD FORMAT -> Section A. Study Tagging File (Table 1: STF File Tags) mention data definition file i.e. define.xml as one of the requested item by FDA CDER for the submission, please refer the below snapshot.
- Under IV. SUBMITTING BIMO CLINICAL DATA IN THE eCTD FORMAT -> Section D. File Format - it is mentioned that the summary-level clinical site data set should be submitted in SAS transport file format (*.xpt). The define file for the summary-level clinical site data set should be submitted in Extensible Markup Language (define.xml) format. Here the requirement to submit a complete and informative define.xml file with complete metadata that describes the summary-level clinical site data set (clinsite.xpt).

Requested Item	STF File Tag	Used For	Required File Formats
III.A..1	Protocol-or-amendment	Protocol and Protocol Amendments, by study	.pdf
III.A..1	annotated-crf	Sample annotated case report form, by study	.pdf
III.B	data-listing-dataset	Data listings, by study (Line listings, by site)	.pdf
III.C	data-listing-dataset	Site-level dataset, across studies	.xpt
III.C	data-listing-data-definition	Define file	.xml
Optional	data-listing-dataset	BIMO Data Reviewer's Guide	.pdf

BIMO Submission Conformance Rules

Is it mandatory (Yes or No)

Question

Are there any FDA conformance rules for Part III – Summary-level Clinical Site Dataset (clinsite.xpt and define.xml) ?

Answer

For Part III – Summary-level Clinical Site Dataset (clinsite.xpt and define.xml):

As of now, there are no FDA/CDISC conformance rules, But, If there are any validation checks created by this (validated industry tool) OR (Sponsor /Applicant In house validated Tool/Programming applications to align with the followed latest FDA CDER BIMO TCG release), then these tools /application and it's validation checks for now can be utilized on the Part III – Summary-level Clinical Site Dataset (clinsite.xpt and define.xml). Any valid anomalies/deviations that are flagged by the tool/validation checks should be fixed OR addressed in the latest BDRG [Under Section 5. Part III – Summary-level Clinical Site Dataset .i.e. Section 5.4 Conformance Inputs and 5.5 Conformance Issues Summary] which will be part of their BIMO submission deliverables.

BIMO deliverable applicable and where to document

Guidance/Recommendation for BIMO submission conformance rules

General BIMO Submission - Inspections Questions and Sponsor Response

Type of FDA IRs

BIMO Submission FDA inspection questions and Sponsor response

Impact of notifying valid missing information on FDA Inspections

Tips or Recommendations - Sponsors Planning for BIMO Submission

Need for BIMO submission (Yes/No)

Question

Is the BIMO Data Reviewer's Guide (BDRG) Mandatory for BIMO submissions to FDA CDER?

Answer

The FDA CDER BIMO Technical Conformance Guide (TCG) v3.0 lists the BDRG .i.e. BDRG (BIMO) Bio-research Monitoring Data Reviewer's Guide as optional deliverable.

Purpose of BDRG:-
The Core purpose of the BIMO Data Reviewer's Guide (BDRG) is to provide an overview of sponsor considerations for preparing and submitting BIMO clinical data (Part I - Clinical study-level information, Part II - Subject-level data line listings by clinical site and Part III - Summary-level clinical site dataset) to support safety and efficacy in the applications that are used by the FDA's Center for Drug Evaluation and Research (CDER) for the planning of Bioresearch Monitoring (BIMO) inspections in electronic Common Technical Document (eCTD) format for <<New Drug Applications (NDAs) OR Biologics License Applications (BLAs) OR supplemental New Drug Applications (sNDAs) OR supplemental Biologics License Applications (sBLAs) OR Investigational New Drug Applications (INDs)>>. FDA CDER uses this information to plan BIMO inspections and provide information to the Office of Regulatory Affairs (ORA) investigators who conduct those inspections.

Providing the information described in the BDRG deliverable gives FDA CDER reviewers a greater understanding of provided BIMO submission Package/deliverable and may avoid future information requests (IRs) during the application review cycle; therefore, its submission is recommended to avoid delays in the planning and conduct of BIMO inspections when they are indicated.

About PHUSE BDRG:
PHUSE BDRG (CDER) (BIMO) Bio-research Monitoring Data Reviewer's Guide: Under PHUSE 'Optimizing the Use of Data Standards' Working group, Project named by 'BDRG' was initiated and developed by it's core project team (Consisting of 50+ members from across Pharma Industry, along with active representation from both the FDA CDER and the FDA CBER divisions and some contribution from PHUSE BIMO FAQ Forum Core project team) for Sponsor/Applicant BIMO submission deliverable [Containing this finalized BDRG as one of deliverable] to FDA CDER Only.

Note:
- PHUSE BDRG (CDER) Project team created Standardized BDRG Template, BDRG Completion Guidelines and 3 BDRG Examples, that can used by Sponsor/Applicant to document in BDRG Template with their consideration, any informed deviations from the followed FDA CDER BIMO Technical Conformance Guide (BIMO TCG) latest release.

- Latest PHUSE BDRG v3.0 was released on 28th June, 2023 and available for across Pharma Industry Sponsor/Applicant and FDA CDER use in their BIMO submission.

It is the PHUSE BIMO team's strong recommendation to submit a BDRG as part of your BIMO submission package/deliverable.

Question

Would BIMO deliverables be required for submissions that are for an existing label update?

Anwser

When labeling supplements contain results from major (i.e., pivotal) clinical studies that will be used to update the product label, BIMO deliverables should be submitted.

Initiation (Right time to prepare for BIMO submission)

Communication with FDA [SDSP within Briefing book]

Identifying major (i.e., pivotal) study

Question

Why do the BIMO FDA CDER submission requests only apply to major (i.e., pivotal) studies?

Answer

Yes,
All FDA CDER TCG versions so far emphasis that requests are ONLY for major (i.e., pivotal) study(ies) used to support safety and efficacy in the application submission. However, when a sponsor/applicant is unsure of which studies to should be included in their BIMO application/submission package, FDA recommends that they work with their FDA CDER point of contact during the pre-submission meetings (.i.e. in FDA Type A/B/C meetings) to identify which studies should be included in the BIMO package to be submitted.

Query during BIMO submission preparation (Submission related/FDA or PHUSE Guidance documents)

Question

The BIMO Technical Conformance Guide (BIMO TCG) and the PHUSE BDRG mention BIMO submissions to FDA CDER. What about BIMO Technical Conformance Guide (BIMO TCG) and PHUSE BDRG for BIMO submissions to FDA CBER?

Answer

BIMO TCG (CDER): Is a FDA CDER-initiated BIMO Technical Conformance Guidance Document. Note: Latest FDA CDER BIMO TCG v3.0 was released on 11th August , 2022.

PHUSE BDRG (CDER) Bio-research Monitoring Data Reviewer's Guide: Under PHUSE 'Optimizing the Use of Data Standards' Working group, Project named by 'BDRG' was initiated and developed by it's core project team (Consisting of 50+ members from across Pharma Industry, along with active representation from both the FDA CDER and the FDA CBER divisions and some contribution from PHUSE BIMO FAQ Forum Core project team) for Sponsor/Applicant BIMO submission deliverable [Where finalized BDRG is one of the deliverable] to FDA CDER Only. Note: Latest PHUSE BDRG v3.0 was released on 28th June, 2023 and available for across Pharma Industry Sponsor/Applicant and FDA CDER only use in their BIMO submission.

BIMO TCG (CBER) and PHUSE BDRG (CBER) : FDA CBER-initiated BIMO Technical Conformance Guidance Document AND PHUSE BDRG (CBER) is not available at this time. It is recommended that Sponsor/Applicant discuss all BIMO submission needs [w.r.t Content or information] with submission FDA CBER point of contact during their pre-submission meetings (.i.e. in FDA Type A/B/C meetings).

Question

What is the purpose of including PART III : SUMMARY-LEVEL CLINICAL SITE DATASET in the BIMO package? How FDA CDER uses this dataset? Does FDA CDER use it to generate any reports?

Answer

As per BIMO TCG in general, PART III : SUMMARY-LEVEL CLINICAL SITE DATASET is included in the BIMO submission for FDA CDER in order for FDA to perform Model Simulation/Analysis that assists in determination of whether SITE inspections will be conducted, and when conducted the SITE (s) for inspection.

Question

In Part III – Summary-level Clinical Site Dataset, The variable label for variables .i.e. EFFPOP and NOIMPDEV are longer than 40 characters. Suggest a solution?

Answer

As per FDA CDER BIMO TCG V3.0 (11th August , 2022),

In Part III – Summary-level Clinical Site Dataset, below variables variable label can be modified/updated in different ways in order to be readable, traceable AND most importantly meet eCTD TECHNICAL CONFORMANCE GUIDE and STUDY DATA TECHNICAL CONFORMANCE GUIDE, Technical Specifications Document for having The length of Variable Descriptive Labels that should not exceed the maximum permissible Characters Length of 40 characters.

So, the following variable label update is recommended

EFFPOP No. of Subjects in Efficacy Population
NOIMPDEV No. of Non-Important Protocol Deviations

New FDA CDER BIMO TCG released

Question

How will be Sponsor/Applicant informed OR be aware OR communicated on new FDA CDER TCG release?

Answer

On FDA Portal "(https://www.fda.gov/regulatory-information/search-fda-guidance-documents#subscribe) directs to Page "Search for FDA Guidance Documents"

At top of the above web page link, Click on "Subscribe to Email Updates" and provide details.
OR
At bottom of the above web page link, Click on "Sign up for Guidance Documents email updates" and provide details.

We highly recommend that the Sponsor/Applicant Functional Team most responsible for updating internal SOPs related to BIMO deliverables subscribe to the above FDA portal web page link, to facilitate dissemination of new BIMO deliverable standards when they are released.

Working with External Files for BIMO Submission

SITE contact information

Clinical investigator contact information

Entities Contact Information and Trial-related Files

FD information

Geopolitical Entities, Names and Codes (GENC) code list

Miscellaneous