BIORESEARCH MONITORING TECHNICAL CONFORMANCE GUIDE

Containing Technical Specifications

For questions regarding this technical specifications document, contact CDER-BIMO-NDA-BLA-request@fda.hhs.gov

U.S. Department of Health and Human Services
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BIORESEARCH MONITORING TECHNICAL CONFORMANCE GUIDE

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Bioresearch Monitoring Technical Conformance Guide

This document provides current Food and Drug Administration (FDA) specifications 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 form for new drug applications (NDAs), biologics license applications (BLAs), and NDA or BLA supplemental applications containing clinical data that are regulated by CDER.[1] It also applies when these data and information are submitted under certain investigational new drug applications[2] (INDs) in advance of a planned NDA, BLA, or supplemental submission.

I. CLINICAL STUDY-LEVEL INFORMATION

A. Comprehensive and Readily Located List of All Clinical Sites

The recommended format for the portable document format (PDF) of the comprehensive and readily located list of all clinical sites that participated in clinical studies for each major (i.e., pivotal) study is provided in Appendix 1 of this Technical Conformance Guide.

B. Table Listing All Entities to Whom Sponsor Has Contracted Clinical Study-Related Activities

In the table listing entities to whom the sponsor has contracted clinical study-related activities, provided in a PDF for each pivotal study, the applicant should identify the location of study-related documents for each study, and whether they are sponsor or Contract Research Organization (CRO) generated. For example, these documents may include, but are not limited to, monitoring plans and reports, training records, and data analysis plans (e.g., items that some applicants organize in a Trial Master File). When the location of study-related documents has not been finalized, the applicant should provide contact information (i.e., phone number and email address) for the individual(s) who can provide updated location information upon request. This information ensures that when CDER issues an inspection assignment for the application, the inspection is of

[1] For the most current version of the technical specification entitled *Bioresearch Monitoring Technical Conformance Guide*, check the FDA Drugs guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[2] See FDA guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.* For the most recent version of a guidance, check the FDA Drugs guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

the most responsible entity for a given regulatory responsibility, and that the inspection assignment is issued for the location where records are present for review.

C. Protocol, Protocol Amendments, and Annotated Case Report Form

The protocol, protocol amendments, and annotated case report form should be included in Appendix 16 of the Clinical Study Report for each study. When these items are included in Appendix 16, there is no need to resubmit them. If the applicant is submitting a BIMO Reviewer's Guide, the applicant should note that these items are present in Appendix 16 of the Clinical Study Reports and provide hyperlinks to their locations.

These items are included in the background materials provided to the Office of Regulatory Affairs (ORA) for BIMO inspections; it is important to provide all versions of these documents so that the field investigator performing the inspection can reference the correct versions of protocols and case report forms in place at the time of the conduct of specific study procedures.

II. SUBJECT-LEVEL DATA LINE LISTINGS BY CLINICAL SITE

A. Organization of the Subject-Level Data Line Listings

Examples of the formatting for the PDF of subject-level data line listings provided for each major (i.e., pivotal) study used to support safety and efficacy in the application, including studies with different treatment indications, are provided in Appendix 2 of this Technical Conformance Guide. If the sponsor believes alternative listings or formats are preferable for their submission, proposed alternatives should be discussed with the Office of Scientific Investigations (OSI) in advance of the application submission, for example, before or during pre-NDA or -BLA meetings.

For clinical investigator sites involved in multiple studies in support of an application, the subject listings should be provided independently for each study within the study-associated PDF.

Subject-level data line listings, by clinical site, should include:

1. Consented Subjects

This by-subject, by-clinical site listing includes all subjects that consented to enroll in the study. Consented subjects that were screen failures should also be included. For subjects that consented, but were not randomized to treatment or did not receive investigational product, the reason they were not randomized or treated should be included in this listing.

2. Treatment Assignment

This by-subject, by-clinical site listing includes the treatment assignment to which the subject was randomized. If a subject mistakenly received treatment different from the subject's assigned treatment, the actual treatment received should also be included.

3. Discontinuations

This by-subject, by-clinical site listing includes:

- All subjects that discontinued during run-in period (if applicable)
- All subjects that discontinued from study treatment
- All subjects that discontinued from the study completely

For each subject, the date of and reason for discontinuation should be provided.

4. Study Population

This by-subject, by-clinical site listing identifies the protocol-defined study population in which each subject was analyzed (e.g., intent-to-treat, safety, per protocol). For subjects that did not meet criteria for inclusion in the per-protocol population, the reason they were excluded from the per-protocol population should be provided.

5. Inclusion and Exclusion Criteria

This by-subject, by-clinical site listing should display whether each subject met each inclusion and exclusion criterion defined in the protocol.

6. Adverse Events

This by-subject, by-clinical site listing should include all adverse events (i.e., nonserious adverse events and serious adverse events, including deaths), date of occurrence and time if collected, severity, whether considered serious by the clinical investigator, whether considered serious by the sponsor, action taken, whether the event led to discontinuation of study therapy, and outcome/date of resolution.

7. Important Protocol Deviations

This by-subject, by-clinical site listing should include all important protocol deviations[3] as reported in the NDA or BLA, including a description of the violation/deviation.

8. Efficacy Endpoints

[3] See FDA guidance for industry *E3 Structure and Content of Clinical Study Reports — Questions and Answers (R1)* (January 2013).

This by-subject, by-clinical site listing(s) should contain primary and key secondary efficacy parameters or events. For derived or calculated endpoints, the raw data points used to generate the derived or calculated endpoint should be provided.

9. Concomitant Medications

This by-subject, by-clinical site listing should contain all concomitant medications as required to be collected by the protocol. The date started, date stopped, dose, route of administration, and the reason for administration should be included.

10. Safety Monitoring

This by-subject, by-clinical site listing(s) should contain results of tests (e.g., laboratory, electrocardiogram) performed for safety monitoring as defined in the protocol.

B. Site-Specific Listings Format

The specified data line listings are anticipated to fit reporting requirements for most applications. If a sponsor believes additional listings are needed to permit FDA to verify key study data during inspections, additional listings should be included.

Although listings are currently requested in PDF format, CDER is in the process of developing tools to extract site-specific listings, needed for inspectional purposes, from submitted Clinical Data Interchange Standards Consortium, Study Data Tabulation Model (SDTM), and Analysis Data Model (ADaM) datasets and intends to make those tools available in the future. FDA intends to update these technical specifications to include details for the submission of SDTM and ADaM datasets, including controlled terminology standards. In anticipation of development of CDER tools for extraction of by-site, by-subject data listings, sponsors should ensure that they are prepared to submit clinical study data using standards specified in the Data Standards Catalog.[4]

III. SUMMARY-LEVEL CLINICAL SITE DATASET

A. Organization of the Site-Level Dataset

A single summary-level clinical site dataset that contains data from all major (i.e., pivotal) studies used to support safety and efficacy in the application, including studies with different treatment indications, should be provided.

For each major (i.e., pivotal) study used to support safety and efficacy, data by clinical site and treatment arm for the safety population should be provided.

[4] Available at http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.

For clinical investigator sites involved in multiple studies in support of an application, the data independently for each study within the dataset should be provided.

B. Variables and Variable Names for Site-Specific Efficacy Results

For each study and investigator site, it is critical to submit the following variables associated with efficacy and their variable names.

- Treatment Efficacy Result (TRTEFFR) — The summary statistic for each primary efficacy endpoint, by treatment arm at a site. Values reported in TRTEFFR generally reflect simple summary statistics for the primary efficacy endpoint(s). The method used for deriving the TRTEFFR should be described in the data define table provided with the clinsite.xpt file. (See discussion below for examples of summary statistics according to different types of efficacy endpoints.)
- Treatment Efficacy Result Standard Deviation (TRTEFFS) — The standard deviation of the summary statistic (TRTEFFR) for each primary endpoint, by treatment arm. The method used to calculate standard of deviation should be included in the in the data define table.
- Site-Specific Treatment Effect (SITEEFFE) — The treatment effect should be reported using the same representation as reported for the primary efficacy analysis.
- Site-Specific Treatment Effect Standard Deviation (SITEEFFS) — The standard deviation of the SITEEFFE. The method used to calculate standard of deviation should be included in the data define table.
- Endpoint (ENDPOINT) — A plain text label that describes the primary endpoint as described in the data definition file data dictionary included with each application.
- Treatment Arm (ARM) — A plain text label for the treatment arm that is used in the Clinical Study Report.

In addition, for studies whose primary endpoint is a time-to-event endpoint, it is critical to include the following data element:

- Censored Observations (CENSOR) — The number of censored observations for the given site and treatment.

If a study does not contain a time-to-event endpoint, this data element should be recorded as a missing value (if not applicable, leave blank in clinsite.xpt).

To accommodate the variety of endpoint types that can be used in analyses, it is critical that the following endpoint type definitions be referenced and summaries be provided when tabulating the site-specific summary statistic by treatment arm, TRTEFFR.

- Discrete Endpoints — Endpoints based on efficacy observations that can take on a discrete number of values (e.g., binary, categorical). Summarize discrete endpoints by an event frequency (i.e., number of events), proportion of patients with an event,

proportion of patients responding to treatment, or similar method at the site for the given treatment.

- Continuous Endpoints — Endpoints based on efficacy observations that can take on an infinite number of values. Summarize continuous endpoints by the mean, median, or other distributional quantile of the observations at the site for the given treatment.
- Time-to-Event Endpoints — Endpoints where the time to occurrence of an event is the primary efficacy measurement. Summarize time-to-event endpoints by two data elements: the number of events that occurred (TRTEFFR) and the number of censored observations (CENSOR).
- Other — If the primary efficacy endpoint cannot be summarized in terms of the previous guidelines, a single or multiple value(s) with precisely defined variable interpretations should be submitted as part of the dataset.

In all cases, the endpoint description provided in the ENDPOINT plain text label should be expressed clearly to interpret the value provided in the (TRTEFFR) variable.

The SITEEFFE should be summarized in terms of the primary efficacy analysis (e.g., difference of means, difference of proportions, odds ratio, hazard ratio) and should be defined identically for all records in the dataset regardless of treatment.

When more than one primary efficacy endpoint exists, additional rows should be added to the dataset to report additional ENDPOINT, ENDPTYPE, TRTEFFR, TRTEFFS, SITEEFFE, and SITEEFFS values by arm for each site.

It is anticipated that efficacy data for all subjects included in the SAFEPOP variable will be included in TRTEFFR, TRTEFFS, SITEEFFE, and SITEEFFS variables reported. If efficacy data is not available for all subjects reported in the SAFEPOP variable, then efficacy data for these subjects should be reported as specified in the study Data Analysis Plan, and the method used for calculation of efficacy variables should be described in the data define table provided with the clinsite.xpt file.

The summary-level clinical site dataset should be accompanied by a data definition file. The contents of the define file for a dataset and fictional examples are presented in Appendix 3 and Appendix 4 of this Technical Conformance Guide.

C. Creating the Data File (Template and Structure)

1. Submission Template for BIMO Clinical Data

A sample summary-level clinical site data submission using the variables identified in Appendix 3 of this Technical Conformance Guide is provided in Appendix 4.

2. Submitting BIMO Clinical Data in the eCTD Format

A summary-level clinical site dataset submitted with an application in the Electronic Common Document (eCTD) format should be placed in eCTD Module 5 — Clinical Study Reports using the following conventions:

- Construct a BIMO study tagging file (STF) and place it in eCTD Module 5.3.5.4 Other Study reports and related information. The study ID for this STF is BIMO.

- For the site-level dataset, use the filename clinsite.xpt.

- Link the site-level dataset files into this BIMO STF using file tags indicated below.

STF File Tag	Used For	Allowable File Formats
data-listing-dataset	Site-level datasets, across studies	.xpt
data-listing-data-definition	Define file	.pdf

- Within the directory structure, place the site-level dataset in the M5 folder as follows:

References for eCTD submissions:

- "The eCTD Backbone File Specification for Study Tagging Files" v. 2.6.1 (http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163560.pdf).

- FDA eCTD web page (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm).

- For general help with eCTD submissions submit your questions to the following email address: ESUB@fda.hhs.gov.

D. Electronic Transport Format

The summary-level clinical site data should be submitted in SAS transport file format (*.xpt). See "Study Data Technical Conformance Guide."[5]

E. Identification of the Dataset

For the leaf representing the data set, please clearly identify it in the leaf title, such as "summary-level clinical site data for inspection."

F. Submission of the Dataset

See the Technical Specifications for "Transmitting Electronic Submissions Using eCTD Specifications" (http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163567.pdf) for details on electronic transmission or physical media submissions.

[5] Available at http://www.fda.gov/downloads/forindustry/datastandards/studydatastandards/ucm384744.pdf.

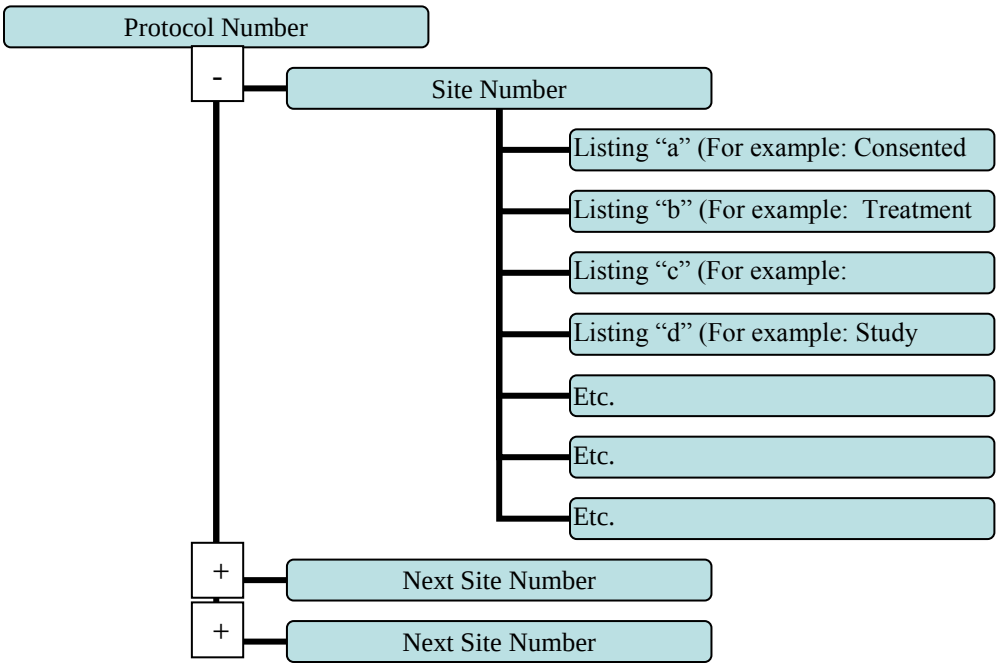
APPENDIX 1: CLINICAL STUDY-LEVEL INFORMATION

1. *Format for comprehensive and readily located list of all clinical sites that participated in clinical study*

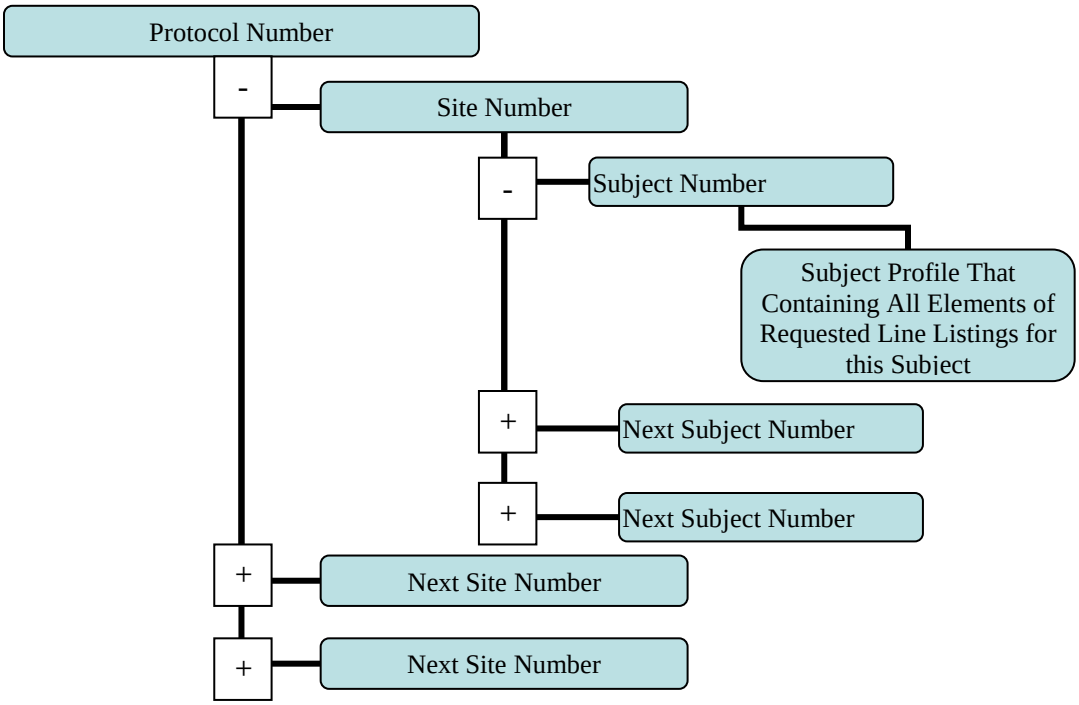
Site Identifier	**Investigator Name (Prior Clinical Investigator(s))**	**Site Address at Time of Clinical Study (Updated Site Address when exists and available)**	**Site Contact Information at Time of Clinical Study (Updated Contact Information when exists and available)**
SITEID	**LASTNAME, FRSTNAME, MINITIAL**	**FACILITY NAME STREET CITY, STATE, POSTAL COUNTRY**	**PHONE FAX EMAIL**
0001	Doe, John M.	Doe University Department of Medicine 1 Main St., Suite 100 Silver Spring, MD 20850 USA	Phone: 1-555-555-5555 Fax: 1-555-555-5555 Email: john.doe@mail.com
0002	Doe, Jean (Smith, John)	Doe University Department of Medicine 1 Main St., Suite 100 Silver Spring, MD 20850 USA	Phone: 1-555-555-5555 Fax: 1-555-555-5555 Email: john.smith@mail.com (Phone: 1-555-555-5554 Email: jean.doe@mail.com)
003	Dietric-Fischer, Inge	Hartmannstrasse 7 5300 Bonn 1 Germany	Phone:49-555-555-5555 Fax: 49-555-555-5555 Email: Dietric.Fischer@web.de

APPENDIX 2: FORMATTING SUBJECT-LEVEL DATA LINE LISTINGS BY CLINICAL SITE

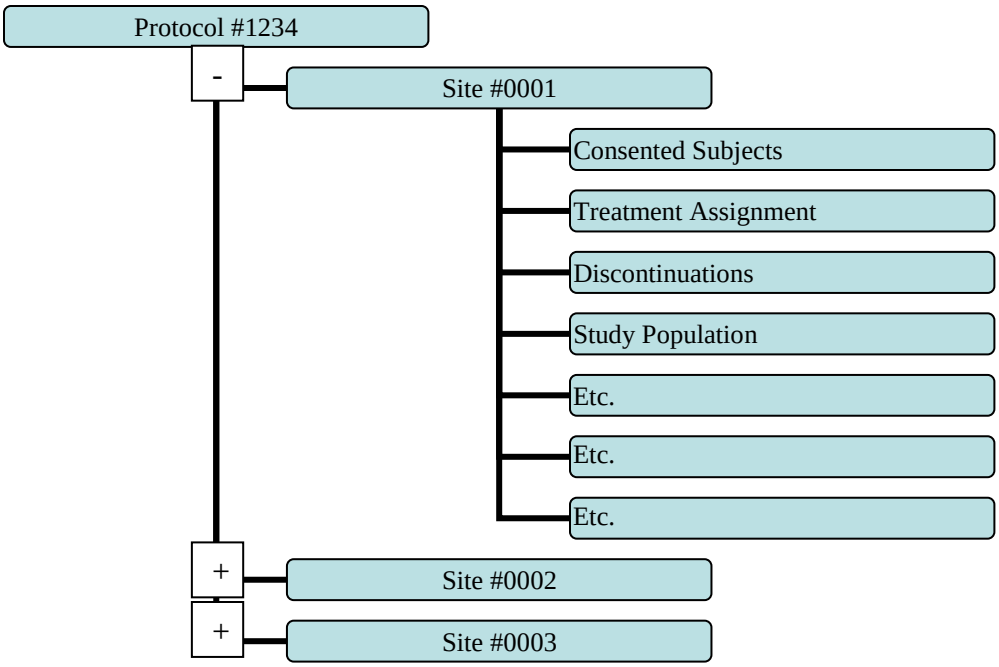
By Site, By Listing Option A:



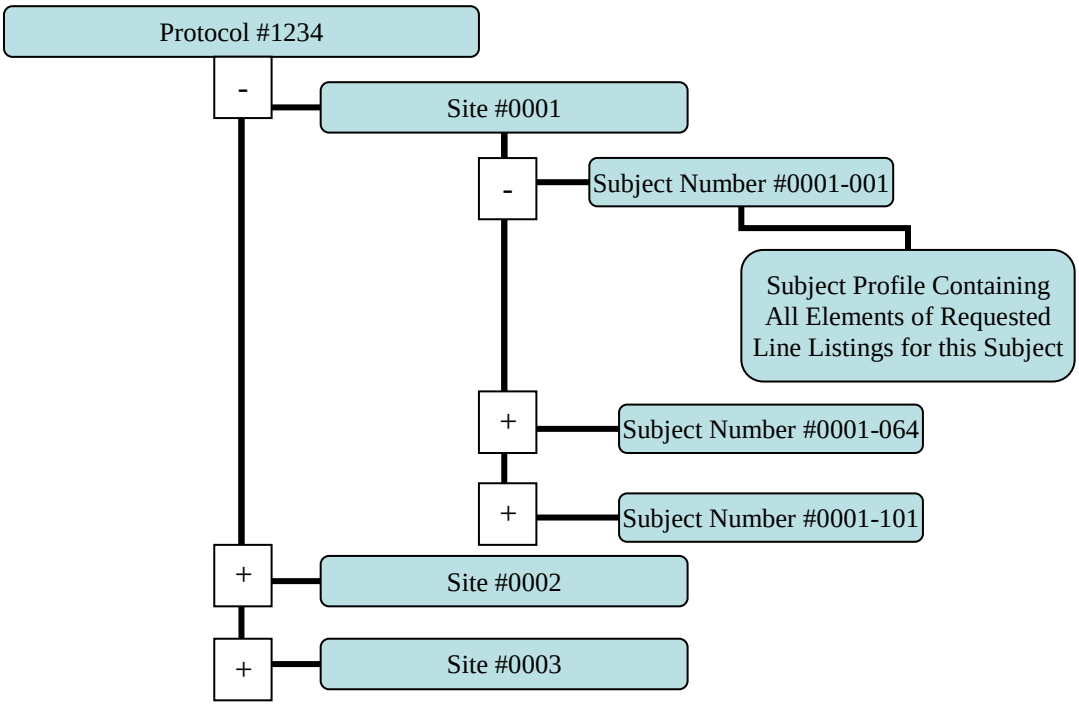
By Site, By Subject Profile Option B:



Example By Site, By Listing Option A:



Example By Site, By Listing Option B:



APPENDIX 3: CLINICAL SITE DATA ELEMENTS SUMMARY LISTING

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
1	STUDYID	Study Identifier	Char	String	Study or trial identification number.	ABC-123
2	STUDYTL	Study Title	Char	String	Title of the study as listed in the clinical study report (limit 200 characters). If the title exceeds 200 characters, provide shortened title and define (e.g., use the abbreviated title from Clinicaltrial.gov)	Double blind, randomized placebo controlled clinical study on the influence of drug X on indication Y
3	SPONCNT	Sponsor Count	Num	Integer	Total count of sponsors throughout the study. If there was a change in the sponsor while the study was ongoing, with sponsors as defined in 21 CFR 312.3, enter an integer indicating the total count of sponsors. If there was no change in the sponsor while the study was ongoing, enter "1".	1
4	SPONNAME	Sponsor Name	Char	String	Full name of the sponsor organization conducting the study at the time of study completion, as defined in 21 CFR 312.3. If the sponsor name exceeds 200 characters, provide short form sponsor name and define.	DrugCo, Inc.
5	IND	IND Number	Num	6 digit identifier	Investigational New Drug (IND) application number. If study not performed under IND, leave blank.	010010
6	UNDERIND	Under IND	Char	String	Value should equal "Y" if study at the site was conducted under an IND (i.e., a Form FDA 1572 was signed by the investigator) and "N" if study was not conducted under an IND at the site (i.e., a Form FDA 1572 was not signed by the investigator).	Y
7	NDA	NDA Number	Num	6 digit identifier	FDA new drug application (NDA) number, if available/applicable. If not applicable, leave blank.	021212
8	BLA	BLA Number	Num	6 digit identifier	FDA identification number for biologics license application, if available/applicable. If not applicable, leave blank.	123456
9	SUPPNUM	Supplement Number	Num	Integer	Serial number for supplemental application, if applicable. If no information is available, leave blank.	4
10	SITEID	Study Site Identifier	Char	String	Investigator site identifier assigned by the sponsor.	50
11	ARM	Description of Planned Treatment Arm	Char	String	Plain text label for the name given to an Arm or treatment group as referenced in the clinical study report (limit 200 characters).	Active name and dose (e.g., Active 25mg), Comparator product name (e.g., Drug x), or Placebo
12	SAFPOP	Number of Subjects in Safety Population	Num	Integer	Total number of subjects in safety population at a given site by treatment arm. When a subject has transferred from one site to another, the applicant should handle reporting of such subjects consistently across sites and include in the define file the reporting convention used. The applicant may opt to further explain the reasons subjects transferred between sites in the BIMO Reviewer's Guide, if a guide will be provided.	20

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
13	SCREEN	Number of Subjects Screened	Num	Integer	Total number of subjects screened (consented) at a given site. When a subject has transferred from one site to another, the applicant should handle reporting of such subjects consistently across sites and include the reporting convention used in the define file or the BIMO Reviewer's Guide (if provided). The applicant may opt to further explain the reasons subjects transferred between sites in the BIMO Reviewer's Guide, if provided.	100
14	DISCSTUD	Number of Subject Discons from Study	Num	Integer	Number of subjects in the safety population who discontinued from the study.	5
15	DISCTRT	Number of Subject Discons from Study Treatment	Num	Integer	Number of subjects in the safety population who discontinued from the study treatment.	10
16	ENDPOINT	Primary Endpoint	Char	String	Plain text label used to describe the primary endpoint as described in the Define file included with each application (limit 200 characters).	Average increase in blood pressure
17	ENDPTYPE	Primary Endpoint Type	Char	String	Variable type of the primary endpoint (i.e., continuous, discrete, time to event, or other).	Continuous
18	TRTEFFR	Treatment Efficacy Result	Num	Floating Point	Summary statistic for each primary efficacy endpoint by treatment arm at a given site.	0, 0.25, 1, 100
19	TRTEFFS	Treatment Efficacy Result Standard Deviation	Num	Floating Point	Standard deviation of the efficacy result (TRTEFFR) for each primary efficacy endpoint by treatment arm at a given site. If N=1, set to "0".	0.065
20	SITEEFFE	Site-Specific Treatment Effect	Num	Floating Point	Site-specific treatment effect reported using the same representation as reported for the primary efficacy analysis.	0, 0.25, 1, 100
21	SITEEFFS	Site-Specific Treatment Effect Standard Deviation	Num	Floating Point	Standard deviation of the site-specific treatment effect (SITEEFFE). If N=1, set to "0".	0.065
22	CENSOR	Number of Censored Observations	Num	Integer	Total number of censored observations at a given site by treatment arm for primary endpoint (e.g., applicable to time-to-event). If not applicable, leave blank.	5
23	NSAE	Number of Non-Serious Adverse Events	Num	Integer	Total number of non-serious adverse events at a given site by treatment arm for subjects in the safety population. This value should include multiple events per subject and all event types (i.e., not limited to only those that are deemed related to study drug or that are treatment emergent events).	10
24	SAE	Number of Serious Adverse Events	Num	Integer	Total number of serious adverse events, excluding deaths, at a given site by treatment arm for subjects in the safety population. This value should include multiple events per subject.	5

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
25	DEATH	Number of Deaths	Num	Integer	Total number of deaths at a given site by treatment arm for subjects in the safety population.	1
26	PROTVIOL	Number of Protocol Violations	Num	Integer	Total number of protocol violations at a given site by treatment arm as defined in the clinical study report. A protocol violation is an unplanned excursion from the protocol that is not implemented or intended as a systematic change. This value should include multiple violations per subject and all violation types (i.e., not limited to only significant deviations).	20
27	FINLDISC	Financial Disclosure Amount	Char	String	Total financial disclosure amount ($USD) by site calculated as the sum of disclosures for the clinical investigator and all sub-investigators to include all required parities under the applicable regulations (21 CFR Parts 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.	≥ $25,000
28	LASTNAME	Investigator Last Name	Char	String	Last name of the clinical investigator as it appears on the Form FDA 1572 or the signed investigator agreement. At sites where the clinical investigator has changed during the course of the study, the most recent clinical investigator should be listed.	Doe
29	FRSTNAME	Investigator First Name	Char	String	First name of the clinical investigator as it appears on the Form FDA 1572 or the signed investigator agreement.	John
30	MINITIAL	Investigator Middle Initial	Char	String	Middle initial of the clinical investigator, if any, as it appears on the Form FDA 1572 or the signed investigator agreement.	M
31	PHONE	Investigator Phone Number	Char	String	Phone number of the clinical investigator. Include country code for non-US numbers.	44-555-555-5555
32	FAX	Investigator Fax Number	Char	String	Fax number of the clinical investigator. Include country code for non-US numbers. If not available, leave blank.	44-555-555-5555
33	EMAIL	Investigator Email Address	Char	String	Email address of the clinical investigator.	John.doe@mail.com
34	COUNTRY	Country	Char	ISO 3166-1-alpha-3	3 letter ISO 3166 country code in which the site is located.	USA
35	STATE	State	Char	String	Unabbreviated state or province in which the site is located. If not applicable, enter NA.	Maryland
36	CITY	City	Char	String	Unabbreviated city, county, or village in which the site is located.	Silver Spring
37	POSTAL	Postal Code	Char	String	Postal code in which the site is located. If not applicable, enter NA.	20850

Variable Index	Variable Name	Variable Label	Type	Controlled Terms or Format	Notes or Description	Sample Value
38	STREET	Street Address	Char	String	Street address and office number at which the site is located. (Limit 200 characters)	2005 John Fitzgerald Kennedy Boulevard Northwest, International Technology Center, Department of Medicine and Pharmacokinetics, National Institute of Clinical Research Twin Towers Building,
39	STREET1	Street Address Continued	Char	String	Street address and office number at which the site is located. Use this field when Variable STREET does not permit sufficient space to fully describe street address and office number at which the site is located.	The Executive Wing, Suite # 209

APPENDIX 4: EXAMPLES

The following is a fictional example of a data set for a placebo-controlled trial. Four international sites enrolled a total of 205 subjects who were randomized in a 1:1 ratio to active or placebo. In the first example there is a single primary endpoint (percent of responders). In the second example there are co-primary endpoints (percent of responders and change from baseline). The site-specific efficacy effect size (SITEEFFE) is the difference between the active and the placebo treatment efficacy result. Note that since there were two treatment arms, in the first example each site contains two rows and there are a total of eight rows for the entire data set. In the second example, each site contains a total of four rows and there are a total of sixteen rows for the entire data set.

Example for Clinical Site Data Elements Summary Listing with One Endpoint

STUDYID	STUDYTL	DOMAIN	SPONNO	SPONNAME	IND	UNDERIND	NDA	BLA	SUPPNUM	SITEID	ARM	SAFPOP	SCREEN	DISCSTUD
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	001	Active	26	61	3
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	001	Placebo	25	61	4
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	002	Active	23	54	2
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	002	Placebo	25	54	4
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	003	Active	27	62	3
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	003	Placebo	26	62	5
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	004	Active	26	60	2
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	004	Placebo	27	60	1

DISCTRT	ENDPOINT	ENDTYPE	TRTEFFR	TRTEFFS	SITEEFFE	SITEEFFS	CENSOR	NSAE	SAE	DEATH	PROTVIOL	FINLDISC	LASTNAME	FRSTNAME
2	Percent Responders	Binary	0.48	0.0980	0.34	0.1405	.	0	2	0	1	< $25,000	Doe	John
1	Percent Responders	Binary	0.14	0.0694	0.34	0.1405	.	2	2	0	1	< $25,000	Doe	John
1	Percent Responders	Binary	0.48	0.1042	0.33	0.1427	.	3	2	1	0	≥ $25,000	Washington	George
3	Percent Responders	Binary	0.14	0.0694	0.33	0.1427	.	0	2	0	3	≥ $25,000	Washington	George
0	Percent Responders	Binary	0.54	0.0959	0.35	0.1448	.	2	2	0	1	≥ $25,000	Jefferson	Thomas
3	Percent Responders	Binary	0.19	0.0769	0.35	0.1448	.	3	6	0	0	≥ $25,000	Jefferson	Thomas
2	Percent Responders	Binary	0.46	0.0977	0.34	0.1275	.	4	1	0	0	unknown	Lincoln	Abraham
0	Percent Responders	Binary	0.12	0.0625	0.34	0.1275	.	1	2	0	1	unknown	Lincoln	Abraham

MINITIAL	PHONE	FAX	EMAIL	COUNTRY	STATE	CITY	POSTAL	STREET	STREET2
M	555-123-4567	555-123-4560	John@mail.com	RUS	Moscow	Moscow	103009	Kremlin Road 1	
M	555-123-4567	555-123-4560	John@mail.com	RUS	Moscow	Moscow	103009	Kremlin Road 1	
	020-3456-7891	020-3456-7890	george@mail.com	GBR	Westminster	London	SW1A 2	10 Downing St	
	020-3456-7891	020-3456-7890	george@mail.com	GBR	Westminster	London	SW1A 2	10 Downing St	
	01-89-12-34-56	01-89-12-34-51	tom@mail.com	FRA	N/A	Paris	75002	1, Rue Road	
	01-89-12-34-56	01-89-12-34-51	tom@mail.com	FRA	N/A	Paris	75002	1, Rue Road	
	555-987-6543	555-987-6540	abe@mail.com	USA	Maryland	Rockville	20852	10903 New Hampshire Avenue, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research	Building 4, Room 1375
	555-987-6543	555-987-6540	abe@mail.com	USA	Maryland	Rockville	20852	10903 New Hampshire Avenue, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research	Building 4, Room 1375

Example for Clinical Site Data Elements Summary Listing with Multiple Primary Endpoints

STUDYID	STUDYTL	DOMAIN	SPONNO	SPONNAME	IND	UNDERIND	NDA	BLA	SUPPNUM	SITEID	ARM	SAFPOP	SCREEN	DISCSTUD
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	001	Active	26	61	3
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	001	Active	26	61	3
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	001	Placebo	25	61	4
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	001	Placebo	25	61	4
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	002	Active	23	54	2
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	002	Active	23	54	2
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	002	Placebo	25	54	4
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	002	Placebo	25	54	4
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	003	Active	27	62	3
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	003	Active	27	62	3
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	003	Placebo	26	62	5
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	003	Placebo	26	62	5
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	004	Active	26	60	2
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	004	Active	26	60	2
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	004	Placebo	27	60	1
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001	.	.	004	Placebo	27	60	1

DISCTRT	ENDPOINT	ENDTYPE	TRTEFFR	TRTEFFS	SITEEFFE	SITEEFFS	CENSOR	NSAE	SAE	DEATH	PROTVIOL	FINLDISC	LASTNAME	FRSTNAME
3	Percent Responders	Binary	0.48	0.0980	0.34	0.1405	.	0	2	0	1	< $25,000	Doe	John
2	Change from Baseline	Continuous	0.74	0.0861	0.60	0.1502	.	0	2	0	1	< $25,000	Doe	John
3	Percent Responders	Binary	0.14	0.0694	0.34	0.1405	.	2	2	0	1	< $25,000	Doe	John
4	Change from Baseline	Continuous	0.14	0.0699	0.60	0.1502	.	2	2	0	1	< $25,000	Doe	John
0	Percent Responders	Binary	0.48	0.1042	0.33	0.1427	.	3	2	1	0	≥ $25,0000	Washington	George
1	Change from Baseline	Continuous	0.67	0.0983	0.52	0.1515	.	3	2	1	0	≥ $25,0000	Washington	George
4	Percent Responders	Binary	0.14	0.0694	0.33	0.1427	.	0	2	0	3	≥ $25,0000	Washington	George
3	Change from Baseline	Continuous	0.14	0.0700	0.52	0.1515	.	0	2	0	3	≥ $25,0000	Washington	George
2	Percent Responders	Binary	0.54	0.0959	0.35	0.1448	.	2	2	0	1	≥ $25,0000	Jefferson	Thomas

0	Change from Baseline	Continuous	0.65	0.0931	0.43	0.1485	.	2	2	0	1	≥ $25,0000	Jefferson	Thomas
5	Percent Responders	Binary	0.19	0.0769	0.35	0.1448	.	3	6	0	0	≥ $25,0000	Jefferson	Thomas
6	Change from Baseline	Continuous	0.19	0.0769	0.43	0.1485	.	3	6	0	0	≥ $25,0000	Jefferson	Thomas
1	Percent Responders	Binary	0.46	0.0977	0.34	0.1275	.	4	1	0	0	unknown	Lincoln	Abraham
0	Change from Baseline	Continuous	0.71	0.0891	0.5545	0.1397	.	4	1	0	0	unknown	Lincoln	Abraham
2	Percent Responders	Binary	0.12	0.0625	0.34	0.1275	.	1	2	0	1	unknown	Lincoln	Abraham
1	Change from Baseline	Continuous	0.15	0.0694	0.5545	0.1397	.	1	2	0	1	unknown	Lincoln	Abraham

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M	555-123-4567	555-123-4560	John@mail.com	RUS	Moscow	Moscow	103009	Kremlin Road 1	
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M	555-123-4567	555-123-4560	John@mail.com	RUS	Moscow	Moscow	103009	Kremlin Road 1	
.	020-3456-7891	020-3456-7890	george@mail.com	GBR	Westminster	London	SW1A 2	10 Downing St Suite 2058	
.	020-3456-7891	020-3456-7890	george@mail.com	GBR	Westminster	London	SW1A 2	10 Downing St Suite 2058	
.	020-3456-7891	020-3456-7890	george@mail.com	GBR	Westminster	London	SW1A 2	10 Downing St Suite 2058	
.	020-3456-7891	020-3456-7890	george@mail.com	GBR	Westminster	London	SW1A 2	10 Downing St Suite 2058	
.	01-89-12-34-56	01-89-12-34-51	tom@mail.com	FRA	N/A	Paris	75002	1, Rue Road	
.	01-89-12-34-56	01-89-12-34-51	tom@mail.com	FRA	N/A	Paris	75002	1, Rue Road	
.	01-89-12-34-56	01-89-12-34-51	tom@mail.com	FRA	N/A	Paris	75002	1, Rue Road	
.	01-89-12-34-56	01-89-12-34-51	tom@mail.com	FRA	N/A	Paris	75002	1, Rue Road	
.	555-987-6543	555-987-6540	abe@mail.com	USA	Maryland	Rockville	20852	2005 John Fitzgerald Kennedy Boulevard Northwest, International Technology Center, Department of Medicine and Pharmacokinetics, National Institute of Clinical Research Twin Towers Building,	The Executive Wing, Suite # 209
.	555-987-6543	555-987-6540	abe@mail.com	USA	Maryland	Rockville	20852	2005 John Fitzgerald Kennedy Boulevard Northwest, International Technology Center, Department of Medicine and Pharmacokinetics, National Institute of Clinical Research Twin Towers Building,	The Executive Wing, Suite # 209
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