Clinical Site Dataset in eSubmissions to the FDA

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Background

The clinical site dataset is a summary of the characteristics and outcomes of each clinical study **at the level of the individual study site** within the application. It is required to submit clinical study data as part of new drug application (NDA) and biologics licensing application (BLA) submission packages to the FDA. Additionally FDA's CDER prefers to receive **summary level clinical site data** within NDAs, BLAs, and NDA and BLA supplemental applications containing new clinical study reports. Summarized clinical site data can be used for planning of on-site inspections by the agency.

FDA draft guidance:
"Providing Submissions in Electronic Format – Summary Level Clinical Site Data for CDER's Inspection Planning"
(published December 2012)

Clinical site dataset requirements:
"Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER's Inspection Planning"
(version 1.2 published November 2012)

Variables in the Clinical Site Dataset

- For each study submit data by site and treatment arm for the ITT population.
- Assign -1 if a numeric variable is not applicable for a study.
- For sites involved in multiple studies within an application, provide data for each study.

General information and information about included studies

Variable Name	Variable Label	Type
STUDY	Study Number	Char
STUDYTL	Study Title	Char
DOMAIN	Domain Abbreviation	Char
SPONNO	Sponsor Number	Num
SPONNAME	Sponsor Name	Char
IND	IND Number	Num
UNDERIND	Under IND	Char
NDA	NDA Number	Num
BLA	BLA Number	Num
SUPPNUM	Supplement Number	Num
ENDPOINT	Endpoint	Char
ENDTYPE	Endpoint Type	Char

Site information

Variable Name	Variable Label	Type
SITEID	Site ID	Char
SCREEN	Number of Subjects Screened	Num
SITEEFFE	Site-Specific Treatment Effect	Num
SITEEFFS	Site-Specific Treatment EffectStandard Deviation	Num
LASTNAME	Investigator Last Name	Char
FRSTNAME	Investigator First Name	Char
MINITIAL	Investigator Middle Initial	Char
PHONE	Investigator Phone Number	Char
FAX	Investigator Fax Number	Char
EMAIL	Investigator Email Address	Char
COUNTRY	Country	Char
STATE	State	Char
CITY	City	Char
POSTAL	Postal Code	Char
STREET	Street Address	Char
FINLMAX	Maximum Financial Disclosure Amount	Num
FINLDISC	Financial Disclosure Amount	Num

Characteristics and outcomes by study, site and treatment arm

Variable Name	Variable Label	Type
ARM	Treatment Arm	Char
ENROLL	Number of Subjects Enrolled	Num
DISCONT	Number of Subjects Discontinuations	Num
TRTEFFE	Treatment Efficacy Endpoint	Num
TRTEFFS	Treatment Efficacy Endpoint Standard Deviation	Num
CENSOR	Censored Observations	Num
NSAE	Number of Non-Serious Adverse Events	Num
SAE	Number of Serious Adverse Events	Num
DEATH	Number of Deaths	Num
PROTVIOL	Number of Protocol Violations	Num

Sample Clinsite Dataset

STUDY	STUDYTL	DOMAIN	SPONNO	SPONNAME	IND	UNDERIND	NDA	BLA	SUPPNUM	SITEID	ARM	ENROLL	SCREEN	DISCONT
ABC-123	Double blind …	DE	1	DrugCo, Inc.	000001	Y	200001	-1	0	001	Active	26	61	3
ABC-123	Double blind …	DE	1	DrugCo, Inc.	000001	Y	200001	-1	0	001	Placebo	25	61	4
ABC-123	Double blind …	DE	1	DrugCo, Inc.	000001	Y	200001	-1	0	002	Active	23	54	2
ABC-123	Double blind …	DE	1	DrugCo, Inc.	000001	Y	200001	-1	0	002	Placebo	25	54	1

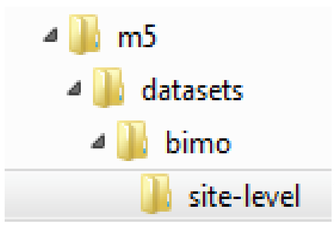
ENDPOINT	ENDTYPE	TRTEFFE	TRTEFFS	SITEEFFE	SITEEFFS	CENSOR	NSAE	SAE	DEATH	PROTVIOL
Percent Responders	Binary	0.48	0.0980	0.34	0.1405	-1	0	2	0	1
Percent Responders	Binary	0.14	0.0694	0.34	0.1405	-1	2	2	1	1
Percent Responders	Binary	0.46	0.0977	0.33	0.1275	-1	4	1	0	0
Percent Responders	Binary	0.12	0.0625	0.33	0.1275	-1	1	2	0	1

FINLMAX	FINLDISC	LASTNAME	FRSTNAME	MINITIAL	PHONE	FAX	EMAIL	COUNTRY	STATE	CITY	POSTAL	STREET
-1	-1	Doe	John	M	555-123	555-129	John@mail.com	RU	Moscow	Moscow	103009	Kremlin Rd. 1
-1	-1	Doe	John	M	555-123	555-129	John@mail.com	RU	Moscow	Moscow	103009	Kremlin Rd. 1
15000.00	25000.00	Lincoln	Abraham		020-3456	020-3459	abe@mail.com	US	Maryland	Rockville	20852	1 Rockville Pk.
15000.00	25000.00	Lincoln	Abraham		020-3456	020-3459	abe@mail.com	US	Maryland	Rockville	20852	1 Rockville Pk.

Submitting in eCTD Format

The clinical site dataset should be submitted in SAS transport file format with the name **clinsite.xpt**. An additional **define.pdf** should also be provided.

The files should be included in Module 5 – Clinical Study Reports:



define.pdf

Summary Level Clinical Site Data define.pdf for Study [redacted]

Dataset - Study [redacted]

Dataset	Description	Structure	Keys	Location
CLINSITE	Summary Level Clinical Site Data	One record per investigator per treatment arm	STUDYID, SITEID, ARM	clinsite.xpt

Summary Level Clinical Site Data (CLINSITE) — clinsite.xpt

Variable	Label	Type	Length/ Format	Controlled Terminology	Source/Computation Method
STUDY	Study Number	text	12		STUDY = "[redacted]
STUDYTL	Study Title	text	200		STUDYTL = "Comparing Two Therapies: [redacted] (shortened to fit into 200 characters)
					DOMAIN = "DE"
					SPONNO = 1
					SPONNAME = "[redacted]
					IND = [redacted]
					UNDERIND = "N"
					[redacted]
BLA	BLA Number	integer	8		BLA = -1, i.e. Not applicable
SUPPNUM	Supplement Number	integer	8		SUPPNUM = -1, i.e. Not applicable
SITEID	Site ID	text	3		Investigator site identification number assigned by the sponsor
ARM	Treatment Arm	text	85	ARM	Treatment arm for the ITT population
ENROLL	Number of Subjects Enrolled	integer	8		The number of subjects enrolled per site and treatment arm for the ITT population.

clinsite.xpt

STUDY	STUDYTL	DOMAIN	SPONNO	SPONNAME	IND	UNDERIND	NDA
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001
ABC-123	Double blind…	DE	1	DrugCo, Inc.	000001	Y	200001

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References

FDA Guidance Documents:

http://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/ucm332468.pdf

http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ucm332466.pdf