

PP19: Clinical Site Dataset in eSubmissions to the FDA

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Background

As part of NDA and BLA submission packages to the FDA it is required to submit study specific data. Additionally CDER prefers to receive **summary level clinical site data** within new drug applications (NDAs), biologics licensing applications (BLAs), and NDA and BLA supplemental applications containing new clinical study reports. This is necessary for an early planning of on-site inspections by CDER to verify the integrity of submitted data.



The draft guidance

“Providing Submissions in Electronic Format - Summary Level Clinical Site Data for CDER’s Inspection Planning”

was published by the FDA (Dec. 2012)

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. The requirements of the clinical site dataset are described in the associated document **“Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER’s Inspection Planning”**.

The variables and variable names in the clinical site dataset

General information and information about included studies			Site information			Characteristics and outcomes by study, site and treatment arm		
Variable Name	Variable Label	Type	Variable Name	Variable Label	Type	Variable Name	Variable Label	Type
STUDY	Study Number	Char	SITEID	Site ID	Char	ARM	Treatment Arm	Char
STUDYTL	Study Title	Char	SCREEN	Number of Subjects Screened	Num	ENROLL	Number of Subjects Enrolled	Num
DOMAIN	Domain Abbreviation	Char	SITEEFFE	Site-Specific Treatment Effect	Num	DISCONT	Number of Subjects Discontinuations	Num
SPONNO	Sponsor Number	Num	SITEEFFS	Site-Specific Treatment Effect Standard Deviation	Num	TRTEFFE	Treatment Efficacy Endpoint	Num
SPONNAME	Sponsor Name	Char	LASTNAME	Investigator Last Name	Char	TRTEFFS	Treatment Efficacy Endpoint Standard Deviation	Num
IND	IND Number	Num	FRSTNAME	Investigator First Name	Char	CENSOR	Censored Observations	Num
UNDERIND	Under IND	Char	INITIAL	Investigator Middle Initial	Char	NSAE	Number of Non-Serious Adverse Events	Num
NDA	NDA Number	Num	PHONE	Investigator Phone Number	Char	SAE	Number of Serious Adverse Events	Num
BLA	BLA Number	Num	FAX	Investigator Fax Number	Char	DEATH	Number of Deaths	Num
SUPPNUM	Supplement Number	Num	EMAIL	Investigator Email Address	Char	PROTVIOL	Number of Protocol Violations	Num
ENDPOINT	Endpoint	Char	COUNTRY	Country	Char			
ENDTYPE	Endpoint Type	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			

Example



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

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

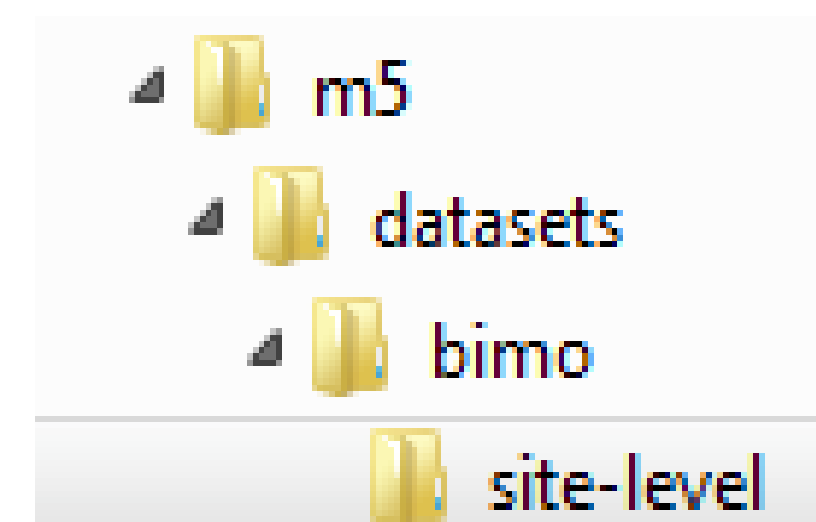
FINLMAX	FINLDISC	LASTNAME	FRSTNAME	INITIAL	PHONE	FAX	EMAIL	COUNTRY	STATE	CITY	POSTAL	STREET
-1	-1	Doe	John	M	555-123	555-129	John@mail.com	RU	Moscow	Moscow	103009	Kremlin Rd. 1
-1	-1	Doe	John	M	555-123	555-129	John@mail.com	RU	Moscow	Moscow	103009	Kremlin Rd. 1
15000.00	25000.00	Lincoln	Abraham		020-3456	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 **clnsite.xpt**. An additional **define.pdf** should also be provided.

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



define.pdf

clnsite.xpt

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

Summary Level Clinical Site Data (CLNSITE)						checklist
Variable	Label	Type	Length	Controlled Vocabulary	Source/Computation Method	
STUDY	Study Number	text	12		STUDY = [Study ID]	
STUDYTL	Study Title	text	250		STUDYTL = [Study Title]	
DOMAIN	Domain Abbreviation	text	2	CDISC/WHO	DOMAIN = [Domain]	

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

Dataset - Study	Description	Structure	Keys	Location	
CLNSITE	Summary Level Clinical Site Data	One record per investigator per treatment arm	STUDYID, SITEID, ARM	define.pdf	

STUDYID	Study ID	text	12		STUDYID = [Study ID]
ARM	Treatment Arm	text	8	ABIS	ARM = [Treatment Arm]
ENROLL	Number of Subjects Enrolled	integer	8		ENROLL = [Number of Subjects Enrolled]

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

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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>