

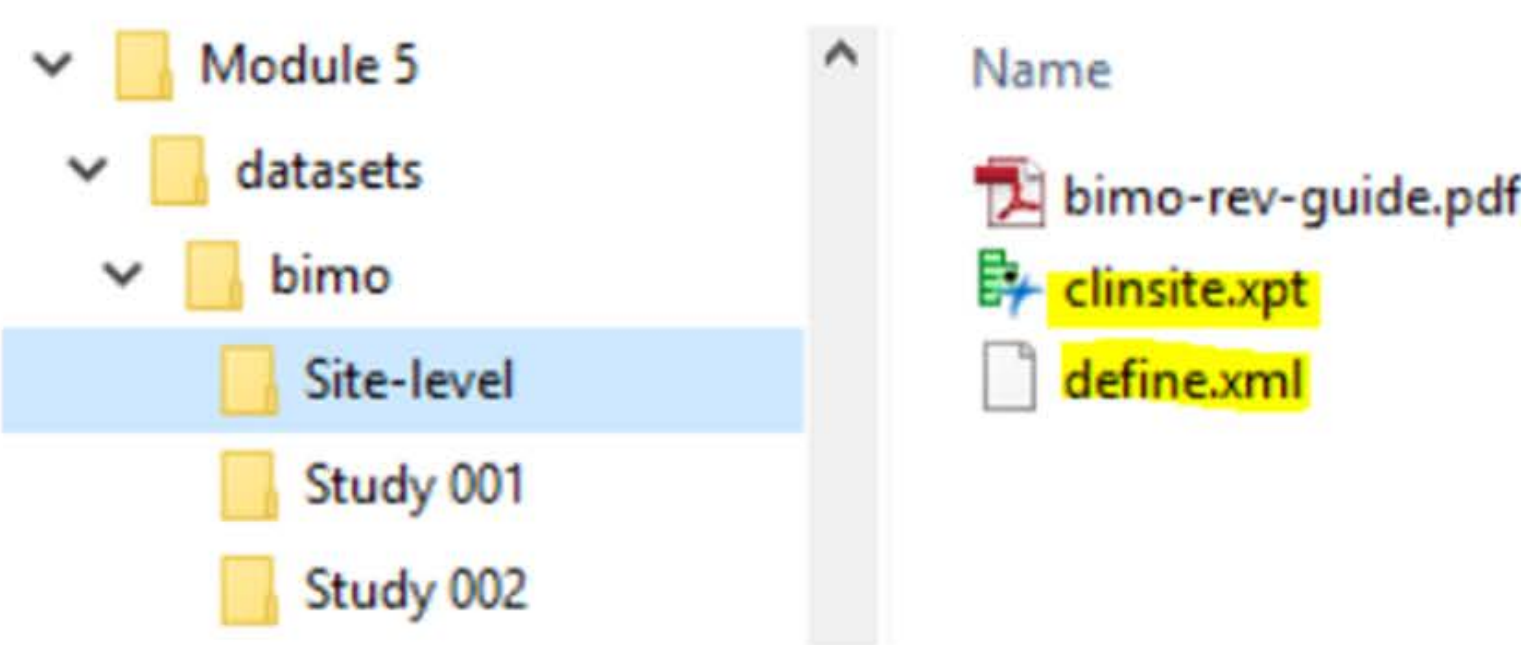
Using One Specification to Create BIMO clinsite.xpt and its Define.xml

Xiang Wang(xwang929@gmail.com), Yuanyuan Liu(Yuanyuan.Liu@bms.com),
Joe Xi (Joe.Xi@bms.com)
Bristol Myers Squibb

clinsite.xpt and its Define.xml

- key components in FDA Bio**re**search **Mon**itoring (BIMO) package
- this poster adopted the most recent version of FDA BIMO guide (August 11, 2022) at <https://www.fda.gov/media/160995/download>

Figure 2: Place the **Site-Level Dataset Define File** and BIMO Data Reviewer’s Guide in the M5 Folder



CLINSITE Spec Template

- Have the **same 10 tabs and columns** as Pinnacle 21 define spec below

Study	Datasets	Variables	ValueLevel	WhereClauses	Codelists	Dictionaries	Methods	Comments	Documents
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- Ready for Pinnacle 21 Enterprise to create define.xml with minimal modifications
- Populate **Study** and **Datasets** tabs

Attribute	Value
StudyName	XXX-XX
StudyDescription	XXX-XX: A Phase 3, Multicenter, Double-Blinded, Randomized-Controlled
ProtocolName	XXX-XX
StandardName	NA
StandardVersion	
Language	en

Dataset	Description	Class	Structure	Purpose	Key Variables	Repeating	Reference Data	Comment
CLINSITE	Summary-Level Clinical Site Dataset	BIMO	One record per study per site per arm	BIMO	STUDYID, SITEID, ARM	Yes	No	

- Variables** tab below

Order	Dataset	Variable	Label	Data Type	Length	Signific	Format	Mandatory	Codelist	Origin	Pages	Method	Predecessor	Role	Comment
4	CLINSITE	SPONSOR	Sponsor Name	Char				No		Predecessor			SOTM.TS.TSVAL where SOTM.TS.TSPARMCD = 'SPONSOR'		
5	CLINSITE	IND	IND Number	Num				No		Assigned					CLINSITE.IND
6	CLINSITE	UNDERIND	Under IND	Char				No		Assigned					CLINSITE.UNDERIND
7	CLINSITE	NDA	NDA Number	Num				No		Assigned					CLINSITE.NDA
8	CLINSITE	BLA	BLA Number	Num				No		Assigned					CLINSITE.BLA
9	CLINSITE	SUPPNUM	Supplement Number	Num				No		Assigned					CLINSITE.SUPPNUM
10	CLINSITE	SITEID	Study Site Identifier	Char				No		Predecessor			AdAm.ADSL.SITEID		
11	CLINSITE	ARM	Description of Planned Treatment Arm	Char				No		Predecessor			AdAm.ADSL.ARM		
12	CLINSITE	COHORT	Description of Planned Cohort	Char				No		Derived					CLINSITE.COHORT
13	CLINSITE	SAFPOP	Number of Subjects in Safety Population	Num				No		Derived		CLINSITE.SAFPOP			
14	CLINSITE	EFFPOP	Number of Subjects in Efficacy Population	Num				No		Derived		CLINSITE.EFFPOP			
15	CLINSITE	SCREEN	Number of Subjects Screened	Num				No		Derived		CLINSITE.SCREEN			
16	CLINSITE	DISCSTUD	Number Subjects Discort. Study	Num				No		Assigned					CLINSITE.DISCSTUD
17	CLINSITE	DISCRT	Number Subjects Discort. Study Treatment	Num				No		Assigned					CLINSITE.DISCRT
18	CLINSITE	ENDPOINT	Primary Endpoint	Char				No		Assigned					CLINSITE.ENDPOINT
19	CLINSITE	ENDPTYPE	Primary Endpoint Type	Char				No		Assigned					CLINSITE.ENDPTYPE
20	CLINSITE	TRTEFFR1	Treatment Efficacy Result for SAFPOP	Num				No		Derived		CLINSITE.TRTEFFR1			
21	CLINSITE	TRTEFFR2	Treatment Efficacy Result for EFFPOP	Num				No		Derived		CLINSITE.TRTEFFR2			
22	CLINSITE	CENSOR1	Censored Observations in SAFPOP	Num				No		Derived		CLINSITE.CENSOR1			
23	CLINSITE	CENSOR2	Censored Observations in EFFPOP	Num				No		Derived		CLINSITE.CENSOR2			
24	CLINSITE	NSAE	Number of Non-Serious Adverse Events	Num				No		Derived		CLINSITE.NSAE			
25	CLINSITE	SAE	Number of Serious Adverse Events	Num				No		Derived		CLINSITE.SAE			
26	CLINSITE	DEATH	Number of Deaths	Num				No		Derived		CLINSITE.DEATH			
27	CLINSITE	IMPDEV	Number of Important Prot. Deviations	Num				No		Derived		CLINSITE.IMPDEV			
28	CLINSITE	NOIMPDEV	Number of Non-Important Prot. Deviations	Num				No		Derived		CLINSITE.NOIMPDEV			
29	CLINSITE	FINDISC	Financial Disclosure Amount	Char				No		Assigned					CLINSITE.FINDISC
30	CLINSITE	LASTNAME	Investigator Last Name	Char				No		Assigned					CLINSITE.LASTNAME
31	CLINSITE	FRSTNAME	Investigator First Name	Char				No		Assigned					CLINSITE.FRSTNAME
32	CLINSITE	MINITIAL	Investigator Middle Initial	Char				No		Assigned					CLINSITE.MINITIAL
33	CLINSITE	PHONE	Investigator Phone Number	Char				No		Assigned					CLINSITE.PHONE
34	CLINSITE	FAX	Investigator Fax Number	Char				No		Assigned					CLINSITE.FAX
35	CLINSITE	EMAIL	InvestigatorEmail Address	Char				No		Assigned					CLINSITE.EMAIL
36	CLINSITE	COUNTRY	Country	Char				No		Assigned					CLINSITE.COUNTRY
37	CLINSITE	STATE	State	Char				No		Assigned					CLINSITE.STATE
38	CLINSITE	CITY	City	Char				No		Assigned					CLINSITE.CITY
39	CLINSITE	POSTAL	Postal Code	Char				No		Assigned					CLINSITE.POSTAL
40	CLINSITE	STREET	Street Address	Char				No		Assigned					CLINSITE.STREET
41	CLINSITE	STREET1	Street Address Continued	Char				No		Assigned					CLINSITE.STREET1

- NULL** for these five tabs: **ValueLevel**, **WhereClauses**, **Codelist**, **Dictionary**, **Documents**
- Methods** and **Comments** tab: only need to populate **“Description”** columns. Column E is used for the convenience of developing column B and will be deleted for define.xml creation in the end

ID	Name	Type	Description	Notes or Description (from FDA BIMO Guide - Reference ONLY)
CLINSITE.SAFPOP	SAFPOP	Computation		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.
CLINSITE.EFFPOP	EFFPOP	Computation		Total number of subjects in primary efficacy population as reported in the Clinical Study Report at a given site by treatment arm. Further describe the population reported as EFFPOP (e.g., Per Protocol, Full Analysis Set, Intent to Treat, modified Intent to Treat) in the clinsite define.html. 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 Data Reviewer's Guide, if a guide will be provided
CLINSITE.SCREEN	SCREEN	Computation		Total number of subjects screened (and consented) at a given site (overall number per site as subjects have not yet been assigned to 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 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.
CLINSITE.TRTEFFR1	TRTEFFR1	Computation		Summary statistic for each primary efficacy endpoint by treatment arm at a given site for subjects in SAFPOP.
CLINSITE.TRTEFFR2	TRTEFFR2	Computation		Summary statistic for each primary efficacy endpoint by treatment arm at a given site for subjects in EFFPOP.
CLINSITE.CENSOR1	CENSOR1	Computation		Total number of censored observations in SAFPOP at a given site by treatment arm for primary endpoint (e.g., applicable to time-to-event). If not applicable, leave blank
CLINSITE.CENSOR2	CENSOR2	Computation		Total number of censored observations in EFFPOP at a given site by treatment arm for primary endpoint (e.g., applicable to time-to-event). If not applicable, leave blank
CLINSITE.NSAE	NSAE	Computation		Total number of nonserious adverse events at a given site by treatment arm for subjects in the SAFPOP. 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). When events with the same preferred term have occurred on different dates for a subject, each event should be counted separately in event count.
CLINSITE.SAE	SAE	Computation		Total number of serious adverse events, excluding deaths, at a given site by treatment arm for subjects in the SAFPOP. This value should include multiple events per subject. When events with the same preferred term have occurred on different dates for a subject, each event should be counted separately in event count.
CLINSITE.DEATH	DEATH	Computation		Total number of deaths at a given site by treatment arm for subjects in the SAFPOP.
CLINSITE.IMPDEV	IMPDEV	Computation		Total number of important protocol deviations at a given site by treatment arm for subjects in the SAFPOP. A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol or associated investigational plans that is not implemented or intended as a systematic change. This value should include multiple deviations per subject and all major deviation types. Important deviations are those deviations that might significantly affect the completeness, accuracy, and/or reliability of the study data or that might significantly affect a subject's rights, safety, or well-being.
CLINSITE.NOIMPDEV	NOIMPDEV	Computation		Total number of protocol deviations, excluding important protocol deviations, at a given site by treatment arm for subjects in the SAFPOP. A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol or associated investigational plans that is not implemented or intended as a systematic change.

ID	Description	Document	Page	Notes or Description (from FDA BIMO Guide - Reference ONLY)
CLINSITE.STUDYID				Study or trial identification number.
CLINSITE.TITLE				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 clinicaltrials.gov).
CLINSITE.SPONSOR				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 § 312.3 (21CFR 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".
CLINSITE.IND				Full name of the sponsor organization conducting the study at the time of study completion, as sponsor is defined. If the sponsor name exceeds 200 characters, provide short-form sponsor name and define.
CLINSITE.UNDERIND				IND number. If study not performed under IND, leave blank.
CLINSITE.NDA				Value should equal "N" 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).
CLINSITE.BLA				FDA identification number for BLA, if available/applicable. If not applicable, leave blank.
CLINSITE.SUPPNUM				Serial number for supplemental application, if applicable. If no information is available, leave blank.
CLINSITE.SITEID				Investigator site identifier assigned by the sponsor.
CLINSITE.ARM				Plain-text label for the name given to an arm or treatment group as referenced in the clinical study report (limit 200 characters). When no arm or treatment group is available due to only screen failure subjects at site, use label "Screen Failure."
CLINSITE.COHORT				For cohort studies, the plain-text label given to a cohort as referenced in the clinical study report (limit 200 characters). When not a cohort study, leave blank.
CLINSITE.SCREEN				Total number of subjects screened (and consented) at a given site (overall number per site as subjects have not yet been assigned to 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 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.
CLINSITE.DISCSTUD				Number of subjects in the safety population who discontinued from the study by treatment arm at a given site.
CLINSITE.DISCRT				Number of subjects in the safety population who discontinued from the study treatment by treatment arm at a given site.
CLINSITE.ENDPOINT				Variable type of the primary endpoint (i.e., "continuous," "discrete," "time to event," or "other").
CLINSITE.ENDPTYPE				Total financial disclosure amount (US\$) by site calculated as the sum of disclosures for the clinical investigator and all sub-investigators, to include all required parties under the applicable regulations (21CFR 312.312, 314, 320, 330, 601, 607, 612, 614, and 660). Enter ">\$25,000" if \$25,000.00 or more; "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.
CLINSITE.FINDISC				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.
CLINSITE.LASTNAME				First name of the clinical investigator as it appears on the Form FDA 1572 or the signed investigator agreement.
CLINSITE.FRSTNAME				Middle initial of the clinical investigator, if any, as it appears on the Form FDA 1572 or the signed investigator agreement.
CLINSITE.MINITIAL				Phone number of the clinical investigator. Include country code for non-U.S. numbers.
CLINSITE.PHONE				Fax number of the clinical investigator. Include country code for non-U.S. numbers. If not available, leave blank.
CLINSITE.FAX				Email address of the clinical investigator.
CLINSITE.EMAIL				Three-letter International Organization for Standardization (ISO) 3166 country code for the country in which the site is located.
CLINSITE.COUNTRY				Unabbreviated state or province in which the site is located. If not applicable, enter "NA."
CLINSITE.STATE				Unabbreviated city, county, or village in which the site is located.
CLINSITE.CITY				Postal code in which the site is located. If not applicable, enter "NA."
CLINSITE.POSTAL				Street address and office number at which the site is located (limit 200 characters).
CLINSITE.STREET				Street address and office number at which the site is located. Use this field when the STREET variable does not permit sufficient space to fully describe street address and office number at which the site is located.
CLINSITE.STREET1				