

# DEFINE.XML 2.0 DESIGNER

## NOW WITH ANALYSIS RESULT METADATA

### THE ABILITY TO CREATE DEFINE.XML 2.0 FILES THAT WILL ASSIST REVIEWERS & EASE YOUR SUBMISSION PROCESS

A sufficiently documented Define file allows reviewers to interpret your datasets faster, which results in a submission that's structured to move through the process more quickly. Yet reviewers frequently report that Define.xml files are deficient. And sponsors continue to struggle creating FDA-compliant Define files due to a lack of useful tools.

#### Until now.

Pinnacle 21's Define.xml 2.0 Designer gives you everything you need to create and manage Define files. The result? Easier transmission of metadata for SDTM, SEND and ADaM datasets ... and, ultimately, faster time to market.

#### With Define.xml 2.0 Designer, you can:

- Create Define.xml 2.0 for SDTM, SEND and ADaM datasets
- Create Define.xml 2.0 with Analysis Results Metadata (ARM)
- Automatically extract metadata from SAS datasets
- Automatically extract origin page numbers from annotated CRFs
- Easily convert Define.xml 1.0 files into Define.xml 2.0
- Merge metadata from external specifications, standards, or previous studies
- Generate Define.pdf in a single click
- Validate Define.xml and its consistency with study data
- Compare Define.xml content with standards and other studies
- Create, manage, and track changes between multiple versions

Dataset	Variable	Label	Data Type	Annotated CRF	Origin	Pages
AE	STUDYID	Study Identifier	text	1	Protocol	
AE	DOMAIN	Domain Abbreviation	text	2	AE.DOMAIN	
AE	LUSUBID	Unique Subject Identifier	text	14	Derived	
AE	ASESEQ	Sequence Number	integer	1	Derived	
AE	ASEPID	Sponsor-Defined Identifier	text	4	CRF	21
AE	AETERM	Reported Term for the Adverse Event	text	25	CRF	21
AE	AEMODIFY	Modified Reported Term	text	9	Assigned	
AE	AEDICTO	Dictionary-Derived Term	text	18	AEDICT.F	Assigned
AE	AENDSYS	Body System or Organ Class	text	52	AEDICT.F	Assigned
AE	ASEV	Severity/Intensity	text	8	AESEV	CRF 21
AE	AEISER	Serious Event	text	1	NY	CRF 21
AE	AEACN	Action Taken with Study Treatment	text	30	ACN	CRF 21
AE	AEREL	Causality	text	16	AEREL	CRF 21
AE	AEISDTG	Start Date/Time of Adverse Event	date			CRF 21
AE	AENDTC	End Date/Time of Adverse Event	date			CRF 21
AE	AESDY	Study Day of Start of Adverse Event	integer	3	Derived	
AE	AENDY	Study Day of End of Adverse Event	integer	3	Derived	
AE	AENRF	End Relative to Reference Period	text	5	AENRF	CRF 21
CM	STUDYID	Study Identifier	text	7	Protocol	
CM	DOMAIN	Domain Abbreviation	text	2	CM.DOMAIN	Assigned
CM	LUSUBID	Unique Subject Identifier	text	14	Derived	
CM	CMSEQ	Sequence Number	integer	2	Derived	
CM	CMTRT	Reported Name of Drug, Med, or Therapy	text	23	CRF	9 22

Extract metadata and merge with standards

Scan datasets to extract domain, variable, codelist, and value level metadata and then merge it with standards. Finally, scan annotated CRFs to automatically populate origin page numbers.

Comparison Report: CDISC01 v1 vs SDTM A v1

Name	Description	Class	Stru	Name	Description	Class	Stru
CM	Concomitant Medications	INTERVENTIONS	Oh	CM	Concomitant Medications	INTERVENTIONS	C
DA	Drug Accountability	FINDINGS	Oh	DM	Demographics	SPECIAL_PURPOSE	C
DM	Demographics	SPECIAL_PURPOSE	Oh	DS	Disposition	EVENTS	C
DS	Disposition	EVENTS	Oh	DV	Protocol Deviations	EVENTS	C
EG	ECG Test Results	FINDINGS	Oh	EG	ECG Test Results	FINDINGS	C
EX	Exposure	INTERVENTIONS	Oh	EX	Exposure	INTERVENTIONS	C
				FA	Findings About Events or Interventions	FINDINGS	C
				HO	Hospitalization	EVENTS	C
				IM	Imaging	FINDINGS	C
LB	Laboratory Tests Results	FINDINGS	Oh	LB	Laboratory Test Results	FINDINGS	C
MH	Medical History	EVENTS	Oh	MH	Medical History	EVENTS	C
PC	Pharmacokinetic Concentrations	FINDINGS	Oh	PC	Pharmacokinetic Concentrations	FINDINGS	C
PE	Physical Examination	FINDINGS	Oh	PE	Physical Examination	FINDINGS	C
				PP	PK and PD Parameters	FINDINGS	C
				QS	Questionnaires	FINDINGS	C
				QSD1	Questionnaires - BD-II and EDSS	FINDINGS	C
				QSD2	Questionnaires - Other	FINDINGS	C
QSCG	Questionnaire-QSCG	FINDINGS	Oh				
QSCS	Questionnaire-QSCS	FINDINGS	Oh				
QSM	Questionnaire-QSM	FINDINGS	Oh				
RELREC	Related Records	RELATIONSHIP	Oh	RL	Relapses	FINDINGS	C
SC	Subject Characteristics	FINDINGS	Oh	SC	Subject Characteristics	FINDINGS	C
SE	Subject Elements	SPECIAL_PURPOSE	Oh				
SUPPAE	Supplemental Qualifiers for AE	RELATIONSHIP	Oh	SUPPAE	Supplemental Qualifiers for AE Domain	RELATIONSHIP	C
SUPPCM	Supplemental Qualifiers for CM	RELATIONSHIP	Oh	SUPPCM	Supplemental Qualifiers for CM Domain	RELATIONSHIP	C

## Compare studies and versions

Compare two studies to see the differences between them. You can even compare two versions of the same study to see how it changes over time.

## Analysis Results Metadata (ARM)

Define traceability from results in a statistical display to the data in the analysis datasets. Ensure your ARM metadata is compliant with real-time validation.

CDISC-Sample

Display	ID	Description	Dataset	Reason	Programming Code	Data References
Table 14-3.01	Table_14-3.01.R.1	Dose response analysis for ADAS-Cog changes from baseline	ADOSADAS	SPECIFIED IN SAP	proc glm data = ADOSADAS; where EFFFL = 'Y' and ANL01FL = 'Y' and AVISIT = 'Week 24' and PARAMCD = 'ADCTOT'; class SITEGR1; model CH3 = TRTPN SITEGR1; run;	ADAE[AESEFR EQ 'Y']
Table 14-3.01	Table_14-3.01.R.2	Pairwise comparisons to placebo for ADAS-Cog changes from baseline	ADOSADAS	SPECIFIED IN SAP	proc glm data = ADOSADAS; where EFFFL = 'Y' and ANL01FL = 'Y' and AVISIT = 'Week 24' and PARAMCD = 'ADCTOT'; class TRTPN SITEGR1; model CH3 = TRTPN SITEGR1 BASE; means TRTPN; ods output PDPFF CL; run;	ADAE[SITED N '1', '2', '3']
Table 14-6.02	Table_14-6.02.R.1	Incidence of Treatment Emergent Serious Adverse Events by Treatment Group	ADOSADAS	SPECIFIED IN SAP	run;	ADAE[AESEFR EQ 'Y']

## About Certara

Certara accelerates medicines using biosimulation software and technology to transform traditional drug discovery and development. Its clients include more than 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

For more information, visit [www.certara.com](http://www.certara.com).