

Metadata for Derived Study built by SAS Clinical Standards Toolkit

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Description of the study	Derived Study built from data in c:\cstSampleLibrary\cdisc-adam-2.1-1.7\sascstdemodata\data
Sponsors internal name for the protocol	SAS_CST_Define Sample Protocol
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Description	CDISC-ADAM 2.1
DefineVersion	1.0.0
StandardName	CDISC ADAM
StandardVersion	2.1

Analysis Datasets for Derived Study built by SAS Clinical Standards Toolkit

Dataset	Description	Class	Structure	Purpose	Keys	Location
ADAE	Adverse Event Analysis Dataset	ADAE	One record per subject per each AE recorded in SDTM AE domain	Analysis	STUDYID, USUBJID, AETERM, AESTDTC	Adverse Events SAS transport file, adae.xpt
ADQS	ADaM Questionnaire Analysis Data Set	BDS	One record per subject per parameter per analysis visit	Analysis	STUDYID, USUBJID, PARAMCD, ADT	ADQS SAS transport file, adqs.xpt
ADSL	Subject-Level Analysis Data Set	ADSL	One record per subject	Analysis	STUDYID, USUBJID	Subject-Level SAS transport file, adsl.xpt
ADTTE	Time to Event Analysis Dataset	BDS	One record per subject per parameter per analysis visit	Analysis	STUDYID, USUBJID, PARAMCD, ADT	ADTTE SAS transport file, adtte.xpt

Adverse Event Analysis Dataset (ADAE)

Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, adae.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
STUDYID	Study Identifier	text			
USUBJID	Unique Subject Identifier	text			
AESEQ	Sequence Number	integer			
AETERM	Reported Term for the Adverse Event	text			
AEDECOD	Dictionary-Derived Term	text			
AEBODSYS	Body System or Organ Class	text			
AEBDSYCD	Body System or Organ Class Code	integer			
AELLT	Lowest Level Term	text			
AELLTCD	Lowest Level Term Code	integer			
AEPTCD	Preferred Term Code	integer			
AEHLT	High Level Term	text			
AEHLTCD	High Level Term Code	integer			
AEHLGT	High Level Group Term	text			

Adverse Event Analysis Dataset (ADAE)

Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, adae.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
AEHLGTCD	High Level Group Term Code	integer			
AESOC	Primary System Organ Class	text			
AESOCCD	Primary System Organ Class Code	integer			
AESTDTC	Start Date/Time of Adverse Event	datetime		ISO8601	
ASTDTM	Analysis Start Date/Time	integer	DATETIME19.		
ASTTMF	Analysis Start Time Imputation Flag	text		TIMEFL	
AEENDTC	End Date/Time of Adverse Event	datetime		ISO8601	
AENDTM	Analysis End Date/Time	integer	DATETIME19.		
AENTMF	Analysis End Time Imputation Flag	text		TIMEFL	
ASTDY	Analysis Start Relative Day	integer			
AENDY	Analysis End Relative Day	integer			
ADURN	AE Duration (N)	integer			
ADURU	AE Duration Units	text			

Adverse Event Analysis Dataset (ADAE)

Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, adae.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
AEDUR	Duration of Adverse Event	text		ISO8601	
TRTEMFL	Treatment Emergent Analysis Flag	text			
FUPFL	Follow-up Flag	text			
AOCCFL	1st Occurrence of Any AE Flag	text			
AOCCIFL	1st Max Sev./Int. Occurrence Flag	text			
DOSEAEON	Study Drug Dose at AE Onset	integer	8.		
DOSAEONU	Study Drug Dose at AE Onset Units	text			
DOSECUM	Cumulative Study Drug Dose	float	6.2		
DOSECUMU	Cumulative Study Drug Dose Units	text			
AESER	Serious Event	text		NY	
AESEV	Severity/Intensity	text		AESEV	
AESEVN	Severity/Intensity (N)	integer			
ASEV	Analysis Severity/Intensity	text			

Adverse Event Analysis Dataset (ADAE)

Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, adae.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
ASEVN	Analysis Severity/Intensity (N)	integer			
SEVGR1	Pooled Severity Group y	text			
SEVGR1N	Pooled Severity Group y (N)	integer			
AEREL	Causality	text			
AERELN	Causality (N)	integer			
AREL	Analysis Causality	text			
ARELN	Analysis Causality (N)	integer			
AETOXGR	Standard Toxicity Grade	text			
AETOXGRN	Standard Toxicity Grade (N)	integer			
AEACN	Action Taken with Study Treatment	text		ACN	
SMQ01NAM	SMQ zz Name	text			
SMQ01CD	SMQ zz Code	integer			
SMQ01SC	SMQ zz Scope	text			
SMQ01SCN	SMQ zz Scope (N)	integer			
CQ01NAM	Customized Query zz Name	text			

Adverse Event Analysis Dataset (ADAE)

Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, adae.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
AGE	Age	float	8.1		
SEX	Sex	text			
TRTP	Description of Planned Arm	text			
TRTEDT	Date of Last Exposure to Treatment	integer	DATE11.		
TRTSDT	Date of First Exposure to Treatment	integer	DATE11.		
SAFFL	Safety Population Flag	text			
TRTPN	Planned Treatment (N)	integer			

ADaM Questionnaire Analysis Data Set (ADQS)

ADaM Questionnaire Analysis Data Set Dataset (ADQS, ADQS SAS transport file, adqs.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
STUDYID	Study Identifier	text			
USUBJID	Unique Subject Identifier	text			
TRTP	Planned Treatment	text			
TRTPN	Planned Treatment (N)	integer			
ADT	Analysis Date	integer	DATE11.		
ADY	Analysis Relative Day	integer			
AVISIT	Analysis Visit	text			
AVISITN	Analysis Visit (N)	integer	8.1		
PARAM	Parameter	text			
PARAMCD	Parameter Code	text			
PARAMN	Parameter (N)	integer			
AVAL	Analysis Value	integer	8.3		
QSSEQ	Sequence Number	integer			
QSCAT	Category of Question	text			
QSSCAT	Subcategory for Question	text			
QSORRES	Finding in Original Units	text			
QSORRESU	Original Units	text			

ADaM Questionnaire Analysis Data Set (ADQS)

ADaM Questionnaire Analysis Data Set Dataset (ADQS, ADQS SAS transport file, adqs.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
QSSTRESC	Character Result/Finding in Std Format	text			
QSSTRESU	Standard Units	text			
AGE	Age	float	8.1		
SEX	Sex	text			
TRTEDT	Date of Last Exposure to Treatment	integer	DATE11.		
TRTSDT	Date of First Exposure to Treatment	integer	DATE11.		
SAFFL	Safety Population Flag	text			

Subject-Level Analysis Data Set (ADSL)

Subject-Level Analysis Data Set Dataset (ADSL, Subject-Level SAS transport file, adsl.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
STUDYID	Study Identifier	text			
USUBJID	Unique Subject Identifier	text			
SUBJID	Subject Identifier for the Study	text			
RFSTDTC	Subject Reference Start Date/Time	datetime		ISO8601	
RFENDTC	Subject Reference End Date/Time	datetime		ISO8601	
SITEID	Study Site Identifier	text			
AGE	Age	float	8.1		
AGEU	Age Units	text		AGEU	
SEX	Sex	text		SEX	
RACE	Race	text		RACE	
ARMCD	Planned Arm Code	text			
ARM	Description of Planned Arm	text			
VISIT1DT	Date of Visit 1	integer	DATE11.		
RANDDT	Date of Randomization	integer	DATE11.		
COMPLT2	Completed 2 Weeks	text			

Subject-Level Analysis Data Set (ADSL)

Subject-Level Analysis Data Set Dataset (ADSL, Subject-Level SAS transport file, adsl.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
COMPLT4	Completed 4 Weeks	text			
COMPLT6	Completed 6 Weeks	text			
TRTEDT	Date of Last Exposure to Treatment	integer	DATE11.		
TRTSDT	Date of First Exposure to Treatment	integer	DATE11.		
DSDECOD	Standardized Disposition Term	text			
FASFL	Full Analysis Set Population Flag	text			
ITTFL	Intent-To-Treat Population Flag	text			
SAFFL	Safety Population Flag	text			
TRT01P	Planned Treatment for Period 1	text			
TRT01PN	Planned Treatment for Period 1 (N)	integer			

Time to Event Analysis Dataset (ADTTE)

Time to Event Analysis Dataset Dataset (ADTTE, ADTTE SAS transport file, adtte.xpt)					
Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
STUDYID	Study Identifier	text			
USUBJID	Unique Subject Identifier	text			
TRTP	Planned Treatment	text			
TRTPN	Planned Treatment (N)	integer			
ADT	Analysis Date	integer	DATE11.		
AVISIT	Analysis Visit	text			
PARAM	Parameter	text			
PARAMCD	Parameter Code	text			
AVAL	Analysis Value	integer	3.		
STARTDT	Time to Event Origin Date for Subject	integer	DATE11.		
CNSR	Censor	integer			
EVNTDESC	Event or Censoring Description	text			
SRCDOM	Source Domain	text			
SRCVAR	Source Variable	text			
SRCSEQ	Source Sequence Number	integer			

Parameter Value Level Metadata - Parameter Value List VL.ADQS.AVAL

VL.ADQS.AVAL						
Source Variable	Where PARAMCD=	Where PARAM=	Type	Display Format	Controlled Terms or Format	Comments / Derivations
AVAL	ACITM01	Word Recall Task	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM02	Naming Objects and Fingers	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM03	Delayed Word Recall	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM04	Commands	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM05	Constructional Praxis	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM06	Ideational Praxis	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM07	Orientation	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM08	Word Recognition	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD

Parameter Value Level Metadata - Parameter Value List VL.ADQS.AVAL

VL.ADQS.AVAL						
Source Variable	Where PARAMCD=	Where PARAM=	Type	Display Format	Controlled Terms or Format	Comments / Derivations
AVAL	ACITM09	Attention/Visual Search Task	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM10	Maze Solution	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM11	Spoken Language Ability	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM12	Comprehension of Spoken Language	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM13	Word Finding Difficulty in Spontaneous Speech	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM14	Recall of Test Instructions	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACTOT	ADAS-COG(11) Subscore	integer			Origin:Derived Derivation:ACTOT = Sum of ADAS scores for items 1,2,4,5,6,7,8,11,12,13,and 14
AVAL	CIBIC	Extent Of Change, if Any, Since Baseline Cibic	integer			

Controlled Terminology (Code Lists) - CL.ACN

ACN, reference name (CL.ACN)	
Coded Value	Decode
DOSE INCREASED	Dose Increased
DOSE NOT CHANGED	Dose Not Changed
DOSE REDUCED	Dose Reduced
DRUG INTERRUPTED	Drug Interrupted
DRUG WITHDRAWN	Drug Withdrawn
NOT APPLICABLE	Not Applicable
UNKNOWN	Unknown

Controlled Terminology (Code Lists) - CL.AESEV

AESEV, reference name (CL.AESEV)	
Coded Value	Decode
MILD	Mild Adverse Event
MODERATE	Moderate Adverse Event
SEVERE	Severe Adverse Event

Controlled Terminology (Code Lists) - CL.AGEU

AGEU, reference name (CL.AGEU)	
Coded Value	Decode
DAYS	Day
HOURS	Hour
MONTHS	Month
WEEKS	Week
YEARS	Year

Controlled Terminology (Code Lists) - CL.NY

NY, reference name (CL.NY)	
Coded Value	Decode
N	No
NA	Not Applicable
U	Unknown
Y	Yes

Controlled Terminology (Code Lists) - CL.RACE

RACE, reference name (CL.RACE)	
Coded Value	Decode
AMERICAN INDIAN OR ALASKA NATIVE	American Indian or Alaska Native
ASIAN	Asian
BLACK OR AFRICAN AMERICAN	African American
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	Native Hawaiian or Other Pacific Islander
WHITE	White

Controlled Terminology (Code Lists) - CL.SEX

SEX, reference name (CL.SEX)	
Coded Value	Decode
F	Female
M	Male
U	Unknown
UN	Intersex

Controlled Terminology (Code Lists) - CL.TIMEFL

TIMEFL, reference name (CL.TIMEFL)	
Coded Value	Decode
H	Hours Minutes Seconds Imputed
M	Minutes Seconds Imputed
S	Seconds Imputed

Analysis Derivations

Reference Name	Analysis Derivation
CM.ADQS.AVAL.ACITM01	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM02	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM03	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM04	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM05	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM06	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM07	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM08	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM09	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM10	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM11	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM12	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM13	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACITM14	QS.QSSTRESN where QSTESTCD=PARAMCD
CM.ADQS.AVAL.ACTOT	ACTOT = Sum of ADAS scores for items 1,2,4,5,6,7,8,11,12,13,and 14