Metadata for Derived Study built by SAS Clinical Standards Toolkit

File type (Snapshot | Transactional)	Snapshot
Unique identifier for this file	1
Version of the ODM standard used	1.2.1
Time of creation of the file containing the document	
Datetime source database queried to create this document	2013-03-01T12:53:50
Short external name for the study	Derived Study built by SAS Clinical Standards Toolkit
Description of the study	Derived Study built from data in C:\cstSampleLibrary\cdisc-adam-2.1-1.5\sascstdemodata\data
Sponsors internal name for the protocol	SAS_CST_Define Sample Protocol
Name	CDISC-ADAM 2.1
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			AE.STUDYID
USUBJID	Unique Subject Identifier	text			AE.USUBJID
AESEQ	Sequence Number	integer			AE.AESEQ Required for traceability back to SDTM AE.
AETERM	Reported Term for the Adverse Event	text			AE.AETERM
AEDECOD	Dictionary-Derived Term	text			AE.AEDECOD This is typically one of the primary variables used in an AE analysis and would be brought in from the SDTM AE domain. Equivalent to the Preferred Term (PT in MedDRA). As mentioned above, all other SDTM AE and SUPPAE domain variables needed for analysis or traceability should also be included. Include the dictionary version in the variable metadata.
AEBODSYS	Body System or Organ Class	text			AE.AEBODSYS This is typically one of the primary variables used by the Sponsor in an AE analysis and would be brought in from the SDTM AE domain. As mentioned above, all other SDTM AE and SUPPAE domain variables needed for analysis or traceability should also be included. Include the dictionary version in the variable metadata.
AEBDSYCD	Body System or Organ Class Code	integer			AE.AEBDSYCD This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata.
AELLT	Lowest Level Term	text			AE.AELLT This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata. Conditional on whether used for analysis.
AELLTCD	Lowest Level Term Code	integer			AE.AELLTCD This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata.

Adverse Event Analysis Dataset (ADAE)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
	Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, ADAE.xpt)				
AEPTCD	Preferred Term Code	integer			AE.AEPTCD This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata.
AEHLT	High Level Term	text			AE.AEHLT This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata. Conditional on whether used for analysis.
AEHLTCD	High Level Term Code	integer			AE.AEHLTCD This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata.
AEHLGT	High Level Group Term	text			AE.AEHLGT This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata. Conditional on whether used for analysis.
AEHLGTCD	High Level Group Term Code	integer			AE.AEHLGTCD This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata.
AESOC	Primary System Organ Class	text			AE.AESOC This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata. Conditional on whether a secondary SOC was used for the primary analysis. See Amendment 1 to SDTM [3].
AESOCCD	Primary System Organ Class Code	integer			AE.AESOCCD This would be copied from the SDTM AE domain or supplemental qualifier dataset. Include the dictionary version in the variable metadata.
AESTDTC	Start Date/Time of Adverse Event	datetime		ISO8601	Copied from AE.AESTDTC
ASTDTM	Analysis Start Date/Time	integer	DATETIME12.		Created from converting AE.AESTDTC from character ISO8601 format to numeric date-time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether start date-time is pertinent for study and AE.AESTDTC with time is populated in SDTM.

Adverse Event Analysis Dataset (ADAE)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
					Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, ADAE.xpt)
ASTTMF	Analysis Start Time Imputation Flag	text		TIMEFL	Created during conversion of AE.AESTDTC from character to numeric. Imputation flags are described in the ADaMIG V1.0 [2] General Timing Variable Convention #6. Conditional on whether any imputation is done for the start time.
AEENDTC	End Date/Time of Adverse Event	datetime		ISO8601	Copied from AE.AEENDTC
AENDTM	Analysis End Date/Time	integer	DATETIME12.		Created from converting AE.AEENDTC from character ISO8601 format to numeric date-time format, applying imputation rules as specified in the SAP or metadata. Conditional on whether end date-time is pertinent for study and AE.AEENDTC with time is populated in SDTM.
AENTMF	Analysis End Time Imputation Flag	text		TIMEFL	Created during conversion of AE.AEENDTC from character to numeric. Imputation flags are described in the ADaMIG V1.0 [2] General Timing Variable Convention #6. Conditional on whether any imputation is done for the end time.
ASTDY	Analysis Start Relative Day	integer			Example derivation: ASTDT - ADSL.TRTSDT + 1 if ASTDT >= TRTSDT, else ASTDT - ADSL.TRTSDT if ASTDT < TRTSDT. This variable may instead be copied from AESTDY. Conditional on whether analysis start relative day is pertinent to the study.
AENDY	Analysis End Relative Day	integer			Example derivation: AENDT - ADSL.TRTSDT + 1 if AENDT >= TRTSDT, else AENDT - ADSL.TRTSDT if AENDT < TRTSDT. This variable may instead be copied from AEENDY.
ADURN	AE Duration (N)	integer			Derive from ASTDT (or ASTDTM) and AENDT (or AENDTM)
ADURU	AE Duration Units	text			Conditional on whether ADURN is included.
AEDUR	Duration of Adverse Event	text		ISO8601	AE.AEDUR Because AEDUR is a collected field and ADURN is derived, the values will often differ. Including AEDUR in addition to ADURN can add traceability.

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**
TRTEMFL	Treatment Emergent Analysis Flag	text			Example derivation: If ADSL.TRTSDT <= ASTDT <= ADSL.TRTEDT + x days then TRTEMFL='Y'. The number x is defined by the sponsor and often incorporates the known half-life of the drug. Variable TRTEMFL is to be used for any analysis of treatment-emergent AEs. This variable is conditional on whether the concept of treatment emergent is a key feature of the AE analyses.
FUPFL	Follow-up Flag	text			Example derivation: If ASTDT > ADSL.TRTEDT then FUPFL='Y'. This variable is conditional on whether the concept of follow-up AEs is a feature of the study and whether used for analysis.
AOCCFL	1st Occurrence of Any AE Flag	text			Example derivation: Sort the data in the required order and flag the first treatment emergent record for each subject.
AOCCIFL	1st Max Sev./Int. Occurrence Flag	text			Example derivation: Sort the data in the required order and flag the first treatment emergent record for maximum severity for each subject.
DOSEAEON	Study Drug Dose at AE Onset	integer	8.		Study drug dose a subject took when adverse event occurred. Example derivation: Obtained from EX.EXDOSE where AESTDTC falls between the values of EX.EXSTDTC and EX.EXENDTC
DOSAEONU	Study Drug Dose at AE Onset Units	text			Conditional on whether DOSEAEON is included.
DOSECUM	Cumulative Study Drug Dose	float	6.2		Cumulative study drug dose at the start of the AE.
DOSECUMU	Cumulative Study Drug Dose Units	text			Conditional on whether DOSECUM is included.
AESER	Serious Event	text		NY	AE.AESER
AESEV	Severity/Intensity	text		AESEV	AE.AESEV
AESEVN	Severity/Intensity (N)	integer			Code AE.AESEV to numeric. Low intensity should correspond to low value

Adverse Event Analysis Dataset (ADAE)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, ADAE.xpt)					
ASEV	Analysis Severity/Intensity	text			Apply imputation rules for missing severity of adverse events as specified in the SAP or metadata. May change case of text, such as from all uppercase in AESEV to mixed case in ASEV.
ASEVN	Analysis Severity/Intensity (N)	integer			Code ASEV to numeric. Low intensity should correspond to low value
SEVGR1	Pooled Severity Group y	text			Pooled grouping of AE Severity for analysis (e.g. mild/moderate or severe).
SEVGR1N	Pooled Severity Group y (N)	integer			Code SEVGRy to numeric. Low intensity should correspond to low value
AEREL	Causality	text			AE.AEREL
AERELN	Causality (N)	integer			Code AE.AEREL to numeric. Low relation should correspond to low value
AREL	Analysis Causality	text			Apply imputation rules for missing causality of study drug as specified in the SAP or metadata. May change case of text, such as from all uppercase in AEREL to mixed case in AREL.
ARELN	Analysis Causality (N)	integer			Code AREL to numeric
AETOXGR	Standard Toxicity Grade	text			AE.AETOXGR
AETOXGRN	Standard Toxicity Grade (N)	integer			Code AETOXGR to numeric. Low toxicity should correspond to low value
AEACN	Action Taken with Study Treatment	text		ACN	AE.AEACN
SMQ01NAM	SMQ zz Name	text			The standardized MedDRA query's name. Would be blank for terms that are not in the SMQ. Therefore this variable could be blank if none of the terms within the SMQ are present in the dataset. Conditional on whether SMQ analysis is done.

Adverse Event Analysis Dataset (ADAE)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
SMQ01CD	SMQ zz Code	integer			The standardized MedDRA queries number code.
SMQ01SC	SMQ zz Scope	text			The search strategy for SMQs can be narrow or broad. The preferred terms that are narrow in scope have high specificity for identifying events of interest while the broad terms have high sensitivity. By definition, all narrow terms are also considered within the broad score. Therefore, to summarize all broad terms, terms with either narrow OR broad would be considered. Will be null for terms that do not meet the criteria. Conditional on whether SMQ analysis is done.
SMQ01SCN	SMQ zz Scope (N)	integer			Will be null for terms that do not meet the criteria.
CQ01NAM	Customized Query zz Name	text			The customized query (CQ) name or name of the AE of special interest category based on a grouping of MedDRA terms. Would be blank for terms that are not in the CQ. Conditional on whether CQ analysis is done. Examples: "DERMATOLOGICAL EVENTS", "CARDIAC EVENTS", "IARS (INFUSION ASSOCIATED REACTIONS)"
AGE	Age	float	8.1		
SEX	Sex	text			
TRTP	Description of Planned Arm	text			
TRTEDT	Date of Last Exposure to Treatment	integer	MMDDYY10.		
TRTSDT	Date of First Exposure to Treatment	integer	MMDDYY10.		
SAFFL	Safety Population Flag	text			
TRTPN	Planned Treatment (N)	integer			

Adverse Event Analysis Dataset Dataset (ADAE, Adverse Events SAS transport file, ADAE.xpt)

ADaM Questionnaire Analysis Data Set (ADQS)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
ADaM Questionnaire Analysis Data Set Dataset (ADQS, ADQS SAS transport file, ADQS.xpt)
STUDYID	Study Identifier	text	$40.		SDTM DM.STUDYID
USUBJID	Unique Subject Identifier	text	$40.		SDTM DM.USUBJID
TRTP	Planned Treatment	text	$40.		TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. TRTxxP (copied from ADSL) may also be needed for some analysis purposes, and may be useful for traceability and to provide context.
TRTPN	Planned Treatment (N)	integer	8.		The numeric code for TRTP. One-to-one map to TRTP.
ADT	Analysis Date	integer	MMDDYY10.		The date associated with AVAL and/or AVALC in numeric format.
ADY	Analysis Relative Day	integer	8.		The relative day of AVAL and/or AVALC. The number of days from a reference date (not necessarily DM.RFSTDTC) to ADT. The reference date should be indicated in the variable-level metadata for ADY and the reference date should be included as a variable in the given analysis dataset or alternatively in ADSL.

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**
AVISIT	Analysis Visit	text	$40.		AVISIT may contain the visit names as observe d (i.e., from SDTM VISIT), derived visit names, time window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of any of these. AVISIT is a derived field and does not have to map to VISIT from the SDTM. AVISIT represents the analysis visit of the record, but it does not mean that the record was analyzed. There are often multiple records for the same subject and parameter that have the same value of AVISIT. ANLzzFL and other variables may be needed to identify the records selected for any given analysis. See Section 3.2.6 for metadata about flag variables. AVISIT should be unique for a given analysis visit window. In the event that a record does not fall within any predefined analysis timepoint window, AVISIT can be populated in any way that the sponsor chooses to indicate this fact (i.e., blank or "Not Windowed"). The way that AVISIT is calculated, including the variables used in its derivation, should be indicated in the variable metadata for AVISIT. The values and the rules for deriving AVISIT may be different for different parameters within the same dataset. Values of AVISIT are sponsor-defined, and are often directly usable in Clinical Study Report displays.
AVISITN	Analysis Visit (N)	integer	8.		A numeric representation of AVISIT. This may be a protocol visit number, a week or cycle number, an analysis visit number, or any other number logically related to AVISIT or useful for sorting that is needed for analysis. Within a parameter, there is a one-to-one mapping between AVISITN and AVISIT so that AVISITN has the same value for each distinct AVISIT. In the event that a record does not fall within any predefined analysis timepoint window, AVISITN can be populated in any way that the sponsor chooses to indicate this fact (e.g., may be null). Values of AVISITN are sponsor-defined.

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
PARAM	Parameter	text	$200.		The description of the analysis parameter. Examples include: "Supine Systolic Blood Pressure (mm Hg)", "Log10 (Weight (kg))", "Time to First Hypertension Event (Days)", "Estimated Tumor Growth Rate", etc. PARAM should be sufficient to describe unambiguously the contents of AVAL and/or AVALC. PARAM must include test, units (if appropriate), specimen type, location, position, and any other applicable qualifying information needed, any additional information such as transformation function, and indeed any text that is needed. PARAM may be longer than 40 characters in length. PARAM is often directly usable in Clinical Study Report displays. Note that in the ADaMIG, "parameter" is a synonym of "analysis parameter."
PARAMCD	Parameter Code	text	$8.		The short name of the analysis parameter in PARAM. Values of PARAMCD should follow SAS 5 variable naming conventions (8 characters or less; starts with a letter; contains only letters and digits). There must be a one-to-one mapping with PARAM. Examples: SYSBP, LWEIGHT, HYPEREVT.
PARAMN	Parameter (N)	integer	8.		Useful for ordering and programmatic manipulation. There must be a one-to-one mapping with PARAM. Must be an integer.
AVAL	Analysis Value	integer	8.		Numeric analysis value described by PARAM. *At least one of AVAL or AVALC is required.
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)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
ADaM Questionnaire Analysis Data Set Dataset (ADQS, ADQS SAS transport file, ADQS.xpt)					
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	MMDDYY10.		
TRTSDT	Date of First Exposure to Treatment	integer	MMDDYY10.		
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			Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
USUBJID	Unique Subject Identifier	text			Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
SUBJID	Subject Identifier for the Study	text			Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
RFSTDTC	Subject Reference Start Date/Time	datetime		ISO8601	
RFENDTC	Subject Reference End Date/Time	datetime		ISO8601	
SITEID	Study Site Identifier	text			Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
AGE	Age	float	8.1		The age of the subject is a required variable in ADSL. If the variable is not a copy of DM.AGE, then an additional differently named variable must be added.
AGEU	Age Units	text		AGEU	The units for the subject's age is a required variable in ADSL. If the variable is not a copy of DM.AGEU, then an additional differently named variable must be added.
SEX	Sex	text		SEX	The sex of the subject is a required variable in ADSL. If the variable is not a copy of DM.SEX, then an additional differently named variable must be added.
RACE	Race	text		RACE	The race of the subject is a required variable in ADSL. If the variable is not a copy of DM.RACE, then an additional differently named variable must be added.
ARMCD	Planned Arm Code	text			
ARM	Description of Planned Arm	text			DM.ARM

Subject-Level Analysis Data Set (ADSL)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
Subject-Level Analysis Data Set Dataset (ADSL, Subject-Level SAS transport file, ADSL.xpt)					
VISIT1DT	Date of Visit 1	integer	MMDDYY10.		
RANDDT	Date of Randomization	integer	MMDDYY10.		Required in randomized trials
COMPLT2	Completed 2 Weeks	text			
COMPLT4	Completed 4 Weeks	text			
COMPLT6	Completed 6 Weeks	text			
TRTEDT	Date of Last Exposure to Treatment	integer	MMDDYY10.		Date of last exposure to treatment for a subject in a study. TRTEDT and/or TRTEDTM are required if there is an investigational product.
TRTSDT	Date of First Exposure to Treatment	integer	MMDDYY10.		Date of first exposure to treatment for a subject in a study. TRTSDT and/or TRTSDTM are required if there is an investigational product.
DSDECOD	Standardized Disposition Term	text			
FASFL	Full Analysis Set Population Flag	text			A character indicator variable is required for every population that is defined in the statistical analysis plan. A minimum of one subject-level population flag variable is required for every clinical trial. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
ITTFL	Intent-To-Treat Population Flag	text			A character indicator variable is required for every population that is defined in the statistical analysis plan. A minimum of one subject-level population flag variable is required for every clinical trial. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.

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**
SAFFL	Safety Population Flag	text			A character indicator variable is required for every population that is defined in the statistical analysis plan. A minimum of one subject-level population flag variable is required for every clinical trial. Additional population flags may be added. The values of subject-level population flags cannot be blank. If a flag is used, the corresponding numeric version (*FN) can also be included.
TRT01P	Planned Treatment for Period 1	text			Subject-level identifier that represents the planned treatment for period xx. In a one-period randomized trial, TRT01P would be the treatment to which the subject was randomized. TRTxxP might be derived from the SDTM DM variable ARM. At least TRT01P is required.
TRT01PN	Planned Treatment for Period 1 (N)	integer			The numeric code variable for TRTxxP. One-to-one map to TRTxxP.

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	$40.		SDTM DM.STUDYID
USUBJID	Unique Subject Identifier	text	$40.		SDTM DM.USUBJID
TRTP	Planned Treatment	text	$40.		TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. TRTxxP (copied from ADSL) may also be needed for some analysis purposes, and may be useful for traceability and to provide context.
TRTPN	Planned Treatment (N)	integer	8.		The numeric code for TRTP. One-to-one map to TRTP.
ADT	Analysis Date	integer	MMDDYY10.		The date associated with AVAL and/or AVALC in numeric format.
AVISIT	Analysis Visit	text	$40.		AVISIT may contain the visit names as observe d (i.e., from SDTM VISIT), derived visit names, time window names, conceptual descriptions (such as Average, Endpoint, etc.), or a combination of any of these. AVISIT is a derived field and does not have to map to VISIT from the SDTM. AVISIT represents the analysis visit of the record, but it does not mean that the record was analyzed. There are often multiple records for the same subject and parameter that have the same value of AVISIT. ANLzzFL and other variables may be needed to identify the records selected for any given analysis. See Section 3.2.6 for metadata about flag variables. AVISIT should be unique for a given analysis visit window. In the event that a record does not fall within any predefined analysis timepoint window, AVISIT can be populated in any way that the sponsor chooses to indicate this fact (i.e., blank or "Not Windowed"). The way that AVISIT is calculated, including the variables used in its derivation, should be indicated in the variable metadata for AVISIT. The values and the rules for deriving AVISIT may be different for different parameters within the same dataset. Values of AVISIT are sponsor-defined, and are often directly usable in Clinical Study Report displays.

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
PARAM	Parameter	text	$200.		The description of the analysis parameter. Examples include: "Supine Systolic Blood Pressure (mm Hg)", "Log10 (Weight (kg))", "Time to First Hypertension Event (Days)", "Estimated Tumor Growth Rate", etc. PARAM should be sufficient to describe unambiguously the contents of AVAL and/or AVALC. PARAM must include test, units (if appropriate), specimen type, location, position, and any other applicable qualifying information needed, any additional information such as transformation function, and indeed any text that is needed. PARAM may be longer than 40 characters in length. PARAM is often directly usable in Clinical Study Report displays. Note that in the ADaMIG, "parameter" is a synonym of "analysis parameter."
PARAMCD	Parameter Code	text	$8.		The short name of the analysis parameter in PARAM. Values of PARAMCD should follow SAS 5 variable naming conventions (8 characters or less; starts with a letter; contains only letters and digits). There must be a one-to-one mapping with PARAM. Examples: SYSBP, LWEIGHT, HYPEREVT.
AVAL	Analysis Value	integer	3.		Numeric analysis value described by PARAM. *At least one of AVAL or AVALC is required.
STARTDT	Time to Event Origin Date for Subject	integer	MMDDYY10.		The original date of risk for the time-to-event analysis. This is generally the time at which a subject is first at risk of the event of interest (as defined in the protocol or Statistical Analysis Plan). For example, this may be the randomization date or the date of first study therapy exposure.
CNSR	Censor	integer			Defines whether the event was censored (period of observation truncated prior to event being observed). It is strongly recommended to use 0 as an event indicator and positive integers as censoring indicators. It is also recommended that unique positive integers be used to indicate coded descriptions of censoring reasons. CNSR is required for time-to-event parameters.
EVNTDESC	Event or Censoring Description	text			Description of the event of interest or censoring reason.
SRCDOM	Source Domain	text			The 2-character identifier of the SDTM domain that relates to AVAL or AVALC.

Time to Event Analysis Dataset (ADTTE)

Variable	Label	Type	Display Format	Controlled Terms or Format	Comments / Derivations
Time to Event Analysis Dataset Dataset (ADTTE, ADTTE SAS transport file, ADTTE.xpt)					
SRCVAR	Source Variable	text			The name of the column (in the SDTM domain identified by SRCDOM) that relates to AVAL or AVALC.
SRCSEQ	Source Sequence Number	integer			The sequence number SEQ of the row (in the SDTM domain identified by SRCDOM) that relates to AVAL or AVALC.

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	H
M	M
S	S

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