

## ***Datasets for Study CDISC01***

<b>Dataset</b>	<b>Description</b>	<b>Class</b>	<b>Structure</b>	<b>Purpose</b>	<b>Keys</b>
SV	Subject Visits	TRIAL DESIGN	One record per subject per actual visit	Tabulation	STUDYID, USUBJID, SVSTDTC, SVENDTC, VISITNUM, SVUPDES
TA	Trial Arms	TRIAL DESIGN	One record per element per arm	Tabulation	STUDYID, ARMCD, TAETORD
TE	Trial Elements	TRIAL DESIGN	One record per element	Tabulation	STUDYID, ETCDD
TI	Trial Inclusion	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD
TS	Trial Summary	TRIAL DESIGN	One record per parameter value	Tabulation	STUDYID, TSPARMCD, TSVAL
TV	Trial Visits	TRIAL DESIGN	One record per planned visit per arm	Tabulation	STUDYID, VISITNUM, ARMCD
CO	Comments	SPECIAL PURPOSE	One record per comment per subject	Tabulation	STUDYID, USUBJID, COSEQ, IDVAR, IDVARVAL
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID
CM	Concomitant Medications	INTERVENTIONS	One record per medication intervention episode per subject	Tabulation	STUDYID, USUBJID, CMCAT, CMTRT, CMSTDTC, CMENDTC, CMDOSTXT, CMDOSU, CMINDC, CMDOSFRQ
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC, EXDOSE
AE	Adverse Events	EVENTS	One record per event per subject	Tabulation	STUDYID, USUBJID, AESTDTC, AEENDTC, AEDECOD, AETERM
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSSTDTC, DSCAT, DSTERM
MH	Medical History	EVENTS	One record per medical history event per subject	Tabulation	STUDYID, USUBJID, MHCAT, MHTERM, MHSTDTC
DA	Drug Accountability	FINDINGS	One record per accountability observation	Tabulation	STUDYID, USUBJID, DADTC, VISITNUM, DATPT, DAGRPID, DASPID, DATESTCD
EG	ECG	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, USUBJID, EGDTC, VISITNUM, EGCAT, EGSPID, EGTESTCD
IE	Inclusion/Exclusion Exceptions	FINDINGS	One record per I/E criteria not met per subject	Tabulation	STUDYID, USUBJID, IECAT, IETESTCD, VISITNUM
LB	Laboratory Tests	FINDINGS	One record per lab test per time point per visit subject	Tabulation	STUDYID, USUBJID, LBDTC, VISITNUM, LBCAT, LBTESTCD
PE	Physical Exam	FINDINGS	One record per body system per visit per subject	Tabulation	STUDYID, USUBJID, PEDTC, VISITNUM, PESPID, PETESTCD

## *Datasets for Study CDISC01*

<b>Dataset</b>	<b>Description</b>	<b>Class</b>	<b>Structure</b>	<b>Purpose</b>	<b>Keys</b>
QS	Questionnaires	FINDINGS	One record per question per time point per vsit per subject	Tabulation	STUDYID, USUBJID, QSCAT, QSDTC, VISITNUM, QSSPID, QSTESTCD
SC	Subject Characteristics	FINDINGS	One record per characteristic per subject	Tabulation	STUDYID, USUBJID, SCTESTCD
VS	Vital Signs	FINDINGS	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSDTC, VISITNUM, VSSPID, VSTESTCD, VSPOS
SUPPAE	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
SUPPCM	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
SUPPDM	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
SUPPEX	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
SUPPLB	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
SUPPSV	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM
SUPPVS	Supplemental Qualifier	RELATED	One record per qualifier value	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM

## ***Subject Visits Dataset (SV)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
VISIT	Visit Name	text		CRF	TIMING	
VISITNUM	Visit Number	integer		DERIVED	TOPIC	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	
SVSTDTC	Start Date/Time of Visit	text		CRF	TIMING	
SVENDTC	End Date/Time of Visit	text		CRF	TIMING	
SVUPDES	Description of Unplanned Visit	text		CRF	SYNONYM QUALIFIER	

## ***Trial Arms Dataset (TA)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
ARMCD	Arm Code	text		SPONSOR DEFINED	TOPIC	
ARM	Description of Arm	text		SPONSOR DEFINED	SYNONYM QUALIFIER	
TAETORD	Order of Element within Arm	integer		SPONSOR DEFINED	IDENTIFIER	
ETCD	Element Code	text		SPONSOR DEFINED	RECORD QUALIFIER	
ELEMENT	Description of Element	text		SPONSOR DEFINED / PROTOCOL	SYNONYM QUALIFIER	
TABRANCH	Branch	text		SPONSOR DEFINED / PROTOCOL	RULE	
TATRANS	Transition Rule	text		SPONSOR DEFINED / PROTOCOL	RULE	

### ***Trial Elements Dataset (TE)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
ETCD	Element Code	text		SPONSOR DEFINED	RECORD QUALIFIER	
ELEMENT	Description of Element	text		SPONSOR DEFINED / PROTOCOL	SYNONYM QUALIFIER	
TESTRL	Rule for Start of Element	text		SPONSOR DEFINED / PROTOCOL	RULE	
TEDUR	Planned Duration of Element	text		SPONSOR DEFINED / PROTOCOL	TIMING	

### ***Trial Inclusion Dataset (TI)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
IETESTCD	Inclusion/Exclusion Criterion Short Name	text		SPONSOR DEFINED	TOPIC	
IETEST	Inclusion/Exclusion Criterion	text		SPONSOR DEFINED	SYNONYM QUALIFIER	
IECAT	Inclusion/Exclusion Category	text	IECAT_F	SPONSOR DEFINED	GROUPING QUALIFIER	

### ***Trial Summary Dataset (TS)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
TSSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	
TSPARMCD	Trial Summary Parameter Short Name	text		DERIVED	TOPIC	
TSPARM	Trial Summary Parameter	text		DERIVED	SYNONYM QUALIFIER	
TSVAL	Parameter Value	text		SPONSOR DEFINED	RESULT QUALIFIER	

## ***Trial Visits Dataset (TV)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
VISIT	Visit Name	text		SPONSOR DEFINED	TOPIC	
VISITNUM	Visit Number	integer		CRF	IDENTIFIER	
VISITDY	Planned Study Day of Visit	integer		SPONSOR DEFINED	TIMING	
ARMCD	Arm Code	text		SPONSOR DEFINED	RECORD QUALIFIER	

## Comments Dataset (CO)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
COSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
COREF	Comment Reference	text		CRF	RECORD QUALIFIER	
COVAL	Comment	text		CRF Page 19	RESULT QUALIFIER	

## Demographics Dataset (DM)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
SUBJID	Subject Identifier for the Study	text		CRF Page 3	TOPIC	
RFSTDTC	Subject Reference Start Date/Time	text		SPONSOR DEFINED	TIMING	
RFENDTC	Subject Reference End Date/Time	text		SPONSOR DEFINED	TIMING	
SITEID	Study Site Identifier	text		CRF Page 3	RECORD QUALIFIER	
BIRTHDTC	Date/Time of Birth	text		CRF Page 3	RESULT QUALIFIER	
AGE	Age in AGEU at RFSTDTC	integer		DERIVED	RESULT QUALIFIER	Screening Date - Birth date
AGEU	Age Units	text		DERIVED	VARIABLE QUALIFIER	Defaulted to YEARS
SEX	Sex	text	SEX	CRF Page 3	RESULT QUALIFIER	
RACE	Race	text	RACEF	CRF Page 3	RESULT QUALIFIER	Mixed case
ETHNIC	Ethnicity	text	ETHNIC2F	CRF Page 3	RESULT QUALIFIER	Mixed case
ARMCD	Planned Arm Code	text		DERIVED	RESULT QUALIFIER	Derived from TA based on randommization number.
ARM	Description of Planned Arm	text		DERIVED	SYNONYM QUALIFIER	Derved from TA
COUNTRY	Country	text		DERIVED	RESULT QUALIFIER	Equal to USA

## Concomitant Medications Dataset (CM)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
CMSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
CMSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	ID of original SAS dataset
CMTRT	Reported Name of Drug, Med, or Therapy	text		CRF Pages 6, 35	TOPIC	
CMMODIFY	Modified Reported Name	text		SPONSOR DEFINED	SYNONYM QUALIFIER	
CMDECOD	Standardized Medication Name	text	DRUGDICT_F	DERIVED	SYNONYM QUALIFIER	WHODRUG Version 2002/04
CMCAT	Category for Medication	text	CMCAT_F	CRF Pages 6, 35	GROUPING QUALIFIER	Sponsor controlled terminology
CMINDC	Indication	text		CRF Pages 6, 35	RECORD QUALIFIER	
CMCLAS	Medication Class	text		DERIVED	VARIABLE QUALIFIER	WHODRUG Version 2002/04. Coded to ATC level 3 based on CMINDIC
CMCLASCD	Medication Class Code	text		DERIVED	VARIABLE QUALIFIER	WHODRUG Version 2002/04. Coded to ATC level 3 based on CMINDIC
CMDOSTXT	Dose Description	text		CRF Page 35	RESULT QUALIFIER	
CMDOSU	Dose Units	text	CUNITF	CRF Pages 6, 35	VARIABLE QUALIFIER	
CMDOSFRQ	Dosing Frequency Per Interval	text	CFREQF	CRF Page 35	VARIABLE QUALIFIER	

## Concomitant Medications Dataset (CM)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
CMROUTE	Route of Administration	text	CROUTEF	CRF Page 35	VARIABLE QUALIFIER	
CMSTDTC	Start Date/Time of Medication	text		CRF Pages 6, 35	TIMING	
CMENDTC	End Date/Time of Medication	text		CRF Pages 6, 35	TIMING	
CMSTDY	Study Day of Start of Medication	integer		DERIVED	TIMING	Default derivation = CMSTDTC - RFSTDTC +1 if CMSTDTC is on or after RFSTDTC, Default derivation = CMSTDTC - RFSTDTC if CMSTDTC preceeds RFSTDTC. If CMSTDTC is incomplete then use the imputed date CMSTRD_D from SUPPQUAL
CMENDY	Study Day of End of Medication	integer		DERIVED	TIMING	Default derivation = CMENDTC - RFSTDTC +1 if CMENDTC is on or after RFSTDTC,Default derivation = CMENDTC - RFSTDTC if CMENDTC preceeds RFSTDTC. If CMENDTC is incomplete then use the imputed date CMSTPD_D from SUPPQUAL,
CMSTRF	Start Relative to Reference Period	text	STENRF	DERIVED	TIMING	For Safety Patients only to be inserted by Statistical Programming. Use in place of phase flags to denote start of medication: values BEFORE, DURING, or AFTER. Can be derived even if the date is partially or completely available.
CMENRF	End Relative to Reference Period	text	STENRF	CRF Page 35	TIMING	If the patients are non-safety (SAFETY='N') then check continuation flag but do not impute date. For SAFETY='Y' patients first check the continuation flag and if not available set flag by using complete or imputed dates. To be inserted by Statistical Pro

## Exposure Dataset (EX)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
EXSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
EXSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	
EXTRT	Name of Actual Treatment	text		DERIVED	TOPIC	Derived from ARM, ARMCD; Mixed case
EXDOSE	Dose per Administration	integer		DERIVED	RESULT QUALIFIER	Derived from ARM, ARMCD; Mixed case
EXDOSU	Dose Units	text		DERIVED	VARIABLE QUALIFIER	Derived from ARM, ARMCD
EXDOSFRM	Dose Form	text		DERIVED	VARIABLE QUALIFIER	Derived from ARM, ARMCD
EXDOSTOT	Total Daily Dose Using EXDOSU	integer		DERIVED	RESULT QUALIFIER	Derived: number of tablets per day times EXDOSE
EXSTDTC	Start Date/Time of Treatment	text		CRF Page 19	TIMING	
EXENDTC	End Date/Time of Treatment	text		CRF Page 19	TIMING	
EXSTDY	Study Day of Start of Treatment	integer		DERIVED	TIMING	Calculation: = EXSTDTC-RFSTDTC+1 if EXSTDTC is on or after RFSTDTC, Calculation = EXSTDTC - RFSTDTC if EXSTDTC precedes RFSTDTC.
EXENDY	Study Day of End of Treatment	integer		DERIVED	TIMING	Calculation: = EXENDTC-RFSTDTC+1 if EXENDTC is on or after RFSTDTC, Calculation = EXENDTC - RFSTDTC if EXENDTC precedes RFSTDTC.+1
VISITNUM	Visit Number	integer		CRF Page 19	TIMING	

**Exposure Dataset (EX)**

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
VISIT	Visit Name	text		CRF	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from TV domain

## Adverse Events Dataset (AE)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
AESEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
AESPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	ID of original SAS dataset
AETERM	Reported Term for the Adverse Event	text		CRF Page 34	TOPIC	
AEMODIFY	Modified Reported Term	text		SPONSOR DEFINED	SYNONYM QUALIFIER	
AEDECOD	Dictionary-Derived Term	text	AEDICT_F	DERIVED	SYNONYM QUALIFIER	MedDRA version 8.0
AEBODSYS	Body System or Organ Class	text		DERIVED	RESULT QUALIFIER	MedDRA version 8.0
AESEV	Severity/Intensity	text	AESEVRF	CRF Page 34	RECORD QUALIFIER	
AESER	Serious Event	text	NY	CRF Page 34	RECORD QUALIFIER	
AEACN	Action Taken with Study Treatment	text	AEACTION	CRF Page 34	RECORD QUALIFIER	
AEREL	Causality	text	AERELF	CRF Page 34	RESULT QUALIFIER	
AESTDTC	Start Date/Time of Adverse Event	text		CRF Page 34	TIMING	
AEENDTC	End Date/Time of Adverse Event	text		CRF Page 34	TIMING	
AESTDY	Study Day of Start of Adverse Event	integer		DERIVED	TIMING	Calculation: = AESTDTC-RFSTDTC+1 if AESTDTC is on or after RFSTDTC,

## *Adverse Events Dataset (AE)*

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
AEENDY	Study Day of End of Adverse Event	integer		DERIVED	TIMING	Calculation: = AEENDTC-RFSTDTC+1 if AEENDTC is on or after RFSTDTC,
AEENRF	End Relative to Reference Period	text	STENRF	CRF Page 34	TIMING	Derived: If AE is Ongoing and AEENDTC is missing then AEENRF = 'AFTER'

## ***Disposition Dataset (DS)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
DSSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
DSSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	ID of original SAS dataset
DSTERM	Reported Term for the Disposition Event	text		CRF Page 33	TOPIC	
DSDECOD	Standardized Disposition Term	text	DSDECOD_F	CRF Pages 3, 13, 33	SYNONYM QUALIFIER	Sponsor defined controlled terminology
DSCAT	Category for Disposition Event	text	DSCAT_F	SPONSOR DEFINED	GROUPING QUALIFIER	Sponsor defined controlled terminology
EPOCH	Trial Epoch	text		DERIVED	TIMING	Period for disposition event (treatment or screening)
DSSTDTC	Start Date/Time of Disposition Event	text		CRF Pages 3, 13, 33	TIMING	
DSSTDY	Study Day of Start of Disposition Event	integer		DERIVED	TIMING	Calculation: = DSSTDTC-RFSTDTC+1 if DSSTDTC is on or after RFSTDTC,

## **Medical History Dataset (MH)**

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
MHSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
MHSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	ID of original SAS dataset
MHTERM	Reported Term for the Medical History	text		CRF Pages 4, 5	TOPIC	
MHCAT	Category for Medical History	text	MHCAT_F	CRF Pages 4, 5	GROUPING QUALIFIER	Equal to Medical or Surgical History or Psychiatric History dependent on the origin of the record
MHBODSYS	Body System or Organ Class	text	MHBODSYS_F	DERIVED	RESULT QUALIFIER	Sponsor defined controlled terminology
MHDTC	Date/Time of History Collection	text		CRF Pages 4, 5	TIMING	
MHSTDTC	Start Date/Time of Medical History Event	text		CRF Pages 4, 5	TIMING	

## Drug Accountability Dataset (DA)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
DASEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
DASPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	ID of original SAS dataset
DATESTCD	Short Name of Accountability Assessment	text		CRF Page 18	TOPIC	
DATEST	Name of Accountability Assessment	text		CRF Page 18	SYNONYM QUALIFIER	
DACAT	Category of Accountability Assessment	text		SPONSOR DEFINED	GROUPING QUALIFIER	
DAORRES	Accountability Assessment in Original Units	text		CRF Page 18	RESULT QUALIFIER	
DAORRESU	Accountability Assessment Original Units	text		DERIVED	VARIABLE QUALIFIER	
DASTRESC	Accountability Assessment in Std Format	text		DERIVED	RESULT QUALIFIER	Equal to DAORRES
DASTRESN	Accountability Assessment in Std Units	integer		DERIVED	RESULT QUALIFIER	Equal to numeric value of DAORRES
DASTRESU	Accountability Assessment Standard Units	text		DERIVED	VARIABLE QUALIFIER	Equal to DAORRESU

## Drug Accountability Dataset (DA)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
VISITNUM	Visit Number	integer		CRF Page 18	TIMING	
VISIT	Visit Name	text		CRF Page 18	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from TV
DADTC	Date/Time of Drug Accountability Assessment	text		CRF Page 18	TIMING	
DADY	Study Day of Accountability Assessment	integer		DERIVED	TIMING	

## ECG Dataset (EG)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
EGSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
EGSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	ECG parameter ordering variable
EGTESTCD	ECG Test or Examination Short Name	text		CRF Page 9	TOPIC	CDISC Controlled Terminology
EGTEST	ECG Test or Examination Name	text		CRF Page 9	SYNONYM QUALIFIER	
EGPOS	ECG Position of Subject	text		DERIVED	RECORD QUALIFIER	Equal to SUPINE
EGORRES	Result or Finding in Original Units	text		CRF Page 9	RESULT QUALIFIER	
EGORRESU	Original Units	text		CRF Page 9	VARIABLE QUALIFIER	
EGSTRESC	Character Result/Finding in Std Format	text		DERIVED	RESULT QUALIFIER	Equal to EGORRES
EGSTRESN	Numeric Result/Finding in Standard Units	float		DERIVED	RESULT QUALIFIER	If the value of EGORRES is numeric then EGSTRESN is the numeric equivalent of EGORRES.
EGSTRESU	Standard Units	text		DERIVED	VARIABLE QUALIFIER	Equal to EGORRESU
EGBLFL	Baseline Flag	text	NY	DERIVED	RECORD QUALIFIER	Derivation of baseline: Safety patients only: EGBLFL=Y for last non missing record on or before the first dose date (RFSTDTDC).
EGDRVFL	Derived Flag	text	NY	DERIVED	RECORD QUALIFIER	Equal to Y for derived EGTESTCDs QTCB and QTCF

## ECG Dataset (EG)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
EGEVAL	Evaluator	text		DERIVED	RECORD QUALIFIER	Equal to INVESTIGATOR
VISITNUM	Visit Number	integer		CRF Page 9	TIMING	
VISIT	Visit Name	text		CRF Page 9	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from TV
EGDTC	Date/Time of ECG	text		CRF Page 9	TIMING	
EGDY	Study Day of ECG	integer		DERIVED	TIMING	Calculation: = EGDTC-RFSTDTC+1 if EGDTC is on or after RFSTDTC, Calculation = EGDTC - RFSTDTC if EGDTC precedes RFSTDTC.

## ***Inclusion/Exclusion Exceptions Dataset (IE)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IESEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
IESPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	
IETESTCD	Inclusion/Exclusion Criterion Short Name	text		CRF Page 1	TOPIC	
IETEST	Inclusion/Exclusion Criterion	text		CRF Page 1	SYNONYM QUALIFIER	
IECAT	Inclusion/Exclusion Category	text	IECAT_F	CRF Page 1	GROUPING QUALIFIER	
IEORRES	I/E Criterion Original Result	text	NYNA	CRF Page 1	RESULT QUALIFIER	
IESTRESC	I/E Criterion Result in Std Format	text	NYNA	DERIVED	RESULT QUALIFIER	
VISITNUM	Visit Number	integer		CRF Page 1	TIMING	
VISIT	Visit Name	text		CRF Page 1	TIMING	
IEDTC	Date/Time of Collection	text		CRF	TIMING	

## **Laboratory Tests Dataset (LB)**

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
LBSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
LBREFID	Specimen ID	text		EDT	IDENTIFIER	Accession number
LBSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	Panel name from originating panel
LBTESTCD	LAB Test or Examination Short Name	text		EDT	TOPIC	Sponsor defined Controlled Terminology
LBTEST	LAB Test or Examination Name	text		EDT	SYNONYM QUALIFIER	
LBCAT	Category for Lab Test	text	LBCAT_F	EDT	GROUPING QUALIFIER	Sponsor defined Controlled Terminology
LBORRES	Result or Finding in Original Units	text		EDT	RESULT QUALIFIER	
LBORRESU	Original Units	text		EDT	VARIABLE QUALIFIER	
LBORNRLLO	Reference Range Lower Limit in Orig Unit	text		EDT	VARIABLE QUALIFIER	
LBORNRLHI	Reference Range Upper Limit in Orig Unit	text		EDT	VARIABLE QUALIFIER	
LBSTRESC	Character Result/Finding in Std Format	text		EDT	RESULT QUALIFIER	
LBSTNRC	Reference Range for Char Rslt-Std Units	text		EDT	VARIABLE QUALIFIER	

## *Laboratory Tests Dataset (LB)*

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
LBSTRESN	Numeric Result/Finding in Standard Units	float		EDT	RESULT QUALIFIER	
LBSTRESU	Standard Units	text		EDT	VARIABLE QUALIFIER	
LBSTNRLO	Reference Range Lower Limit-Std Units	float		EDT	VARIABLE QUALIFIER	
LBSTNRHI	Reference Range Upper Limit-Std Units	float		EDT	VARIABLE QUALIFIER	
LBNRIND	Reference Range Indicator	text	HLN	DERIVED	VARIABLE QUALIFIER	
LBBLFL	Baseline Flag	text	NY	DERIVED	RECORD QUALIFIER	Derivation of baseline: Safety patients only: LBBLFL=Y for last non missing record on or before the first dose date (RFSTDTC).
LBFAST	Fasting Status	text	NY	EDT	RECORD QUALIFIER	
VISITNUM	Visit Number	integer		DERIVED	TIMING	
VISIT	Visit Name	text		EDT	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from TV
LBDTC	Date/Time of Specimen Collection	text		EDT	TIMING	
LBDY	Study Day of Specimen Collection	integer		DERIVED	TIMING	Calculation: = LBDTC-RFSTDTC+1 if LBDTC is on or after RFSTDTC, Calculation = LBDTC - RFSTDTC if LBDTC precedes RFSTDTC.

## Physical Exam Dataset (PE)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
PESEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
PESPID	Sponsor-Defined Identifier	text		CRF Page 7	IDENTIFIER	
PETESTCD	Body System Examined Short Name	text		CRF Page 7	TOPIC	
PETEST	Body System Examined	text		CRF Page 7	SYNONYM QUALIFIER	
PEORRES	Verbatim Examination Finding	text		CRF Page 7	RESULT QUALIFIER	
PESTRESC	Character Result/Finding in Std. Format	text		DERIVED	RESULT QUALIFIER	
PESTRESN	Numeric Result/Finding in Standard Units	integer		DERIVED	RESULT QUALIFIER	
PESTRESU	Standard Units	text		DERIVED	VARIABLE QUALIFIER	
PEBLFL	Baseline Flag	text	NY	DERIVED	RECORD QUALIFIER	Derivation of baseline: Safety patients only: PEBLFL=Y for last non missing record on or before the first dose date (RFSTDTC).
VISITNUM	Visit Number	integer		CRF Page 7	TIMING	
VISIT	Visit Name	text		CRF Page 7	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from SV

## Physical Exam Dataset (PE)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
PEDTC	Date/Time of Examination	text		CRF Page 7	TIMING	
PEDY	Study Day of Examination	integer		DERIVED	TIMING	Calculation: = PEDTC-RFSTDTC+1 if PEDTC is on or after RFSTDTC, Calculation = PEDTC - RFSTDTC if PEDTC precedes RFSTDTC.

## Questionnaires Dataset (QS)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
QSSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
QSSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	Original SAS dataset identifier concatenated with sponsor defined sequence
QSTESTCD	Question Short Name	text		CRF	TOPIC	
QSTEST	Question Name	text		CRF	SYNONYM QUALIFIER	
QSCAT	Category of Question	text		SPONSOR DEFINED	GROUPING QUALIFIER	Questionnaire name from CRF; Questionnaire version if appropriate.
QSORRES	Finding in Original Units	text		CRF	RESULT QUALIFIER	Character results contain mixed case data
QSSTRESC	Character Result/Finding in Std Format	text		DERIVED	RESULT QUALIFIER	If questionnaire result is a numerically relevant code then code stored here; else character result equal to QSORRES. Character results contain mixed case data
QSSTRESN	Numeric Finding in Standard Units	integer		DERIVED	RESULT QUALIFIER	When QSORRES is numeric then QSSTRESN equal to numeric result
QSBLFL	Baseline Flag	text	NY	DERIVED	RECORD QUALIFIER	Derivation of baseline: Safety patients only: QSBLFL=Y for last non missing record on or before the first dose date (RFSTDTC).
VISITNUM	Visit Number	integer		DERIVED	TIMING	
VISIT	Visit Name	text		CRF	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from TV
QSDTC	Date/Time of Finding	text		DERIVED	TIMING	

## Questionnaires Dataset (QS)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
QSDY	Study Day of Finding	integer		DERIVED	TIMING	Calculation: = QSDTC-RFSTDTC+1 if QSDTC is on or after RFSTDTC, Calculation = QSDTC - RFSTDTC if QSDTC precedes RFSTDTC.
QSEVAL	Evaluator	text		CRF	RECORD QUALIFIER	

## Subject Characteristics Dataset (SC)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
SCSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
SCSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	Original SAS dataset
SCTESTCD	Subject Characteristic Short Name	text		CRF Page 3	TOPIC	
SCTEST	Subject Characteristic	text		DERIVED	SYNONYM QUALIFIER	
SCORRES	Result or Finding in Original Units	text		CRF Page 3	RESULT QUALIFIER	
SCSTRESC	Character Result/Finding in Std Format	text		DERIVED	RESULT QUALIFIER	Equal to SCORRES
SCDTC	Date/Time of Collection	text		CRF Page 3	TIMING	
SCDY	Study Day of Examination	integer		DERIVED	TIMING	Calculation: = SCDTC-RFSTDTC+1 if SCDTC is on or after RFSTDTC, Calculation = SCDTC - RFSTDTC if SCDTC precedes RFSTDTC.

## Vital Signs Dataset (VS)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
VSSEQ	Sequence Number	integer		DERIVED	IDENTIFIER	Sequential number uniquely identifying the records within the domain by USUBJID and generated using the key sequence from the domain level metadata
VSSPID	Sponsor-Defined Identifier	text		SPONSOR DEFINED	IDENTIFIER	Original dataset name concatenated with sponsor sequence
VSTESTCD	Vital Signs Test Short Name	text		CRF Page 8	TOPIC	
VSTEST	Vital Signs Test Name	text		CRF	SYNONYM QUALIFIER	
VSPOS	Vital Signs Position of Subject	text		CRF Page 8	RECORD QUALIFIER	All results SITTING position
VSORRES	Result or Finding in Original Units	text		CRF Page 8	RESULT QUALIFIER	
VSORRESU	Original Units	text		CRF Page 8	VARIABLE QUALIFIER	
VSSTRESC	Character Result/Finding in Std Format	text		DERIVED	RESULT QUALIFIER	Data collected in non-standard units (i.e. lbs, inches) is converted using standard conversion factors to standard units.
VSSTRESN	Numeric Result/Finding in Standard Units	float		DERIVED	RESULT QUALIFIER	When VSSTRESC contains numeric data the numeric equivalent is derived in VSSTRESN
VSSTRESU	Standard Units	text		CRF OR DERIVED	VARIABLE QUALIFIER	Standard unit representation
VSBLFL	Baseline Flag	text	NY	DERIVED	RECORD QUALIFIER	Derivation of baseline: Safety patients only: VSBLFL=Y for last non missing record on or before the first dose date (RFSTDTC).
VISITNUM	Visit Number	integer		CRF Page 8	TIMING	
VISIT	Visit Name	text		CRF Page 8	TIMING	
VISITDY	Planned Study Day of Visit	integer		DERIVED	TIMING	Derived from TV

## Vital Signs Dataset (VS)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
VSDTC	Date/Time of Measurements	text		CRF Page 8	TIMING	
VSDY	Study Day of Vital Signs	integer		DERIVED	TIMING	Calculation: = VSDTC-RFSTDTC+1 if VSDTC is on or after RFSTDTC, Calculation = VSDTC - RFSTDTC if VSDTC precedes RFSTDTC.

### **Supplemental Qualifier Dataset (SUPPAE)**

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	
QEVAL	Evaluator	text		DERIVED	RESULT QUALIFIER	

### ***Supplemental Qualifier Dataset (SUPPCM)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	
QEVAL	Evaluator	text		DERIVED	RESULT QUALIFIER	

### ***Supplemental Qualifier Dataset (SUPPDM)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	
QEVAL	Evaluator	text		DERIVED	RESULT QUALIFIER	

### ***Supplemental Qualifier Dataset (SUPPEX)***

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	

## Supplemental Qualifier Dataset (SUPPLB)

Variable	Description	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	

### **Supplemental Qualifier Dataset (SUPPSV)**

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	

## **Supplemental Qualifier Dataset (SUPPVS)**

<b>Variable</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Role</b>	<b>Comment</b>
STUDYID	Study Identifier	text		CRF Page 3	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		DERIVED	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		SPONSOR DEFINED	IDENTIFIER	Concatenation of STUDYID.SUBJID
IDVAR	Identifying Variable	text		DERIVED	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		DERIVED	IDENTIFIER	
QNAM	Qualifier Variable Name	text		DERIVED	TOPIC	
QLABEL	Qualifier Variable Label	text		DERIVED	SYNONYM QUALIFIER	
QVAL	Data Value	text		DERIVED	RESULT	
QORIG	Origin	text		CRF OR DERIVED	RESULT QUALIFIER	

### ***Value Level Metadata (ValueList.DA.DATESTCD)***

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
DATESTCD	DADISNO	Dispense study medication	integer		CRF Page 18	
DATESTCD	DARETNO	Return study medication	integer		CRF Page 18	

### ***Value Level Metadata (ValueList.EG.EGTESTCD)***

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
EGTESTCD	INTP	ECG Interpretation	text	NABCLIN	CRF Page 9	
EGTESTCD	PR	PR Interval	integer		CRF Page 9	
EGTESTCD	QRS	QRS Interval	integer		CRF Page 9	
EGTESTCD	QT	QT Interval	integer		CRF Page 9	
EGTESTCD	QTcB	QTc Interval Bazett	float		EGSTRESN	
EGTESTCD	QTcF	QTc Interval Fridericia	float		EGSTRESN	
EGTESTCD	VRATE	Ventricular Rate	integer		CRF Page 9	

**Value Level Metadata (ValueList.IE.IETESTCD)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
IETESTCD	INCL03	Did not respond to a standard course of medication Abc	text	NYNA	CRF Page 1	

### Value Level Metadata (ValueList.LB.LBTESTCD)

Source Variable	Value	Description	Type	Controlled Terminology	Origin	Comment
LBTESTCD	CHMB12	Cobalamin (Vitamin B12)	integer		EDT	
LBTESTCD	CHMBUN	Blood Urea Nitrogen	float		EDT	
LBTESTCD	CHMFA	Folic Acid	float		EDT	
LBTESTCD	CHMTSB	Bilirubin, Total	float		EDT	
LBTESTCD	HEMHCT	Hematocrit	float		EDT	
LBTESTCD	HEMHGB	Hemoglobin	integer		EDT	
LBTESTCD	HEMLACC	Lymphocytes Absolute Cell Count	float		EDT	
LBTESTCD	URNGLU	Glucose	text		EDT	
LBTESTCD	URNOB	Occult Blood	text		EDT	
LBTESTCD	URNPH	pH	integer		EDT	

### ***Value Level Metadata (ValueList.PE.PETESTCD)***

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
PETESTCD	PE01	Appearance/Skin	text		CRF Page 7	
PETESTCD	PE02	Head/Neck (Including Thyroid)	text		CRF Page 7	
PETESTCD	PE03	Eyes-Ears-Nose-Throat	text		CRF Page 7	
PETESTCD	PE04	Cardiovascular	text		CRF Page 7	
PETESTCD	PE05	Pulmonary	text		CRF Page 7	
PETESTCD	PE06	Abdomen	text		CRF Page 7	
PETESTCD	PE07	Neurological	text		CRF Page 7	
PETESTCD	PE08	Musculoskeletal	text		CRF Page 7	

### ***Value Level Metadata (ValueList.SC.SCTESTCD)***

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
SCTESTCD	EDUCATN	Education	text	EDUCATNF	CRF Page 3	
SCTESTCD	FAMILY	Family Status	text	FAMILYF	CRF Page 3	
SCTESTCD	INITIALS	Subject Initials	text		CRF Page 3	
SCTESTCD	RACEOTH	Additional Race	text		CRF Page 3	

### ***Value Level Metadata (ValueList.VS.VSTESTCD)***

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
VSTESTCD	DIABP	Diastolic Blood Pressure	integer		CRF Page 8	
VSTESTCD	HEIGHT	Height	float		CRF Page 8	
VSTESTCD	PULSE	Pulse Rate	integer		CRF Page 8	
VSTESTCD	SYSBP	Systolic Blood Pressure	integer		CRF Page 8	
VSTESTCD	WEIGHT	Weight	float		CRF Page 8	

### Value Level Metadata (ValueList.QS.QSCAT)

Source Variable	Value	Description	Type	Controlled Terminology	Origin	Comment
QSCAT	Clinical Global Impressions	Clinical Global Impressions	text		CRF Page 21	
QSCAT	Cornell Scale for Depression in Dementia	Cornell Scale for Depression in Dementia	text		CRF Page 11	
QSCAT	Mini Mental State Examination	Mini Mental State Examination	text		CRF Page 10	
QSCAT	CGIGLOB	Global Improvement	integer	CGIIMP	CRF	
QSCAT	CSDD01	Anxiety	integer	GENSYMP	CRF	
QSCAT	CSDD02	Sadness	integer	GENSYMP	CRF	
QSCAT	CSDD03	Lack of Reactivity to Pleasant Events	integer	GENSYMP	CRF	
QSCAT	CSDD04	Irritability	integer	GENSYMP	CRF	
QSCAT	CSDD05	Agitation	integer	GENSYMP	CRF	
QSCAT	CSDD06	Retardation	integer	GENSYMP	CRF	
QSCAT	CSDD07	Multiple Physical Complaints	integer	GENSYMP	CRF	
QSCAT	CSDD08	Loss of Interest	integer	GENSYMP	CRF	
QSCAT	CSDD09	Appetite Loss	integer	GENSYMP	CRF	
QSCAT	CSDD10	Weight Loss	integer	GENSYMP	CRF	
QSCAT	CSDD11	Lack of Energy	integer	GENSYMP	CRF	
QSCAT	CSDD12	Diurnal Variation of Mood	integer	GENSYMP	CRF	
QSCAT	CSDD13	Difficulty Falling Asleep	integer	GENSYMP	CRF	
QSCAT	CSDD14	Multiple Awakenings During Sleep	integer	GENSYMP	CRF	
QSCAT	CSDD15	Early Morning Awakening	integer	GENSYMP	CRF	
QSCAT	CSDD16	Suicide	integer	GENSYMP	CRF	
QSCAT	CSDD17	Poor Self-Esteem	integer	GENSYMP	CRF	
QSCAT	CSDD18	Pessimism	integer	GENSYMP	CRF	
QSCAT	CSDD19	Mood-Congruent Delusions	integer	GENSYMP	CRF	
QSCAT	CSDDTOT	Total Score	integer		CRF	
QSCAT	MMSEA1	Orientation time score	integer		CRF	
QSCAT	MMSEA2	Orientation place score	integer		CRF	
QSCAT	MMSEB	Registration	integer		CRF	
QSCAT	MMSEC	Attention and Calculation	integer		CRF	

**Value Level Metadata (ValueList.QS.QSCAT)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
QSCAT	MMSED	Recall	integer		CRF	
QSCAT	MMSEET	Language	integer		CRF	
QSCAT	MMSETOT	Total Score	integer		CRF	

**Value Level Metadata (ValueList.SUPPAE.QNAM)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
QNAM	AETRTEM	Treatment Emergent	text	NY	DERIVED	If it was not present prior to the RFSTDTC, or it was present prior to the RFSTDTC but increased in severity during the treatment period then equal Y..
QNAM	HLGTERM	MEDDRA HIGHER LEVEL GROUP TERM	text		DERIVED	Derived
QNAM	HLTERM	MEDDRA HIGHER LEVEL TERM	text		DERIVED	Derived
QNAM	LLTERM	MEDDRA LOWER LEVEL TERM	text		DERIVED	Derived

### **Value Level Metadata (ValueList.SUPPCM.QNAM)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
QNA	ATC5CODE	WHO_DRUG ATC Level 4 Code	text		DERIVED	Derived
QNA	ATC5TERM	ATC5 Drug Class Term	text		DERIVED	Derived
QNA	CPREFCD	WHO_DRUG Drug Code	text		DERIVED	Derived
QNA	PDDREAS	Reason for discontinuation	text		CRF Page 6	
QNA	PDRESP	Response	text		CRF Page 6	

### ***Value Level Metadata (ValueList.SUPPDM.QNAM)***

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
QNA	RAND	Randomized Population Flag	text	NY	CRF Page 13	
QNA	RANDNO	Randomization Number	text		CRF	
QNA	SAFETY	Safety Population Flag	text	NY	DERIVED	

**Value Level Metadata (ValueList.SUPPEX.QNAM)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
QNA1	SMNO	Number of tablets per day	text		CRF Page 19	

### Value Level Metadata (ValueList.SUPPLB.QNAM)

Source Variable	Value	Description	Type	Controlled Terminology	Origin	Comment
QNAM	LBCSIND	Reference Range Indicator - PCS Flag	text	CSIND_F	DERIVED	Only created if value qualifies as potentially clinically significant high (CH) or low (CL) based on the high and low ranges specified in the Statistical Analysis Plan..

**Value Level Metadata (ValueList.SUPPSV.QNAM)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
QNAM	SVSTDY	Actual Study Day of Visit	text		DERIVED	

### Value Level Metadata (ValueList.SUPPVS.QNAM)

Source Variable	Value	Description	Type	Controlled Terminology	Origin	Comment
QNAM	VSCSIND	Reference Range Indicator - PCS Flag	text	CSIND_F	DERIVED	Only created if value qualifies as potentially clinically significant high (CH) or low (CL) based on the high and low ranges specified in the Statistical Analysis Plan..

### **Value Level Metadata (ValueList.TS.TSPARMCD)**

<b>Source Variable</b>	<b>Value</b>	<b>Description</b>	<b>Type</b>	<b>Controlled Terminology</b>	<b>Origin</b>	<b>Comment</b>
TSPARMCD	ADDON	ADDED ON TO EXISTING TREATMENT	text		DERIVED	
TSPARMCD	AEDCTV	ADVERSE EVENT DICTIONARY VERSION	text		DERIVED	
TSPARMCD	AEDICT	ADVERSE EVENT DICTIONARY	text		DERIVED	
TSPARMCD	AGEMAX	PLANNED MAXIMUM AGE OF SUBJECTS	text		DERIVED	
TSPARMCD	AGEMIN	PLANNED MINIMUM AGE OF SUBJECTS	text		DERIVED	
TSPARMCD	AGESPAN	AGE GROUP	text		DERIVED	
TSPARMCD	AGEU	AGE UNITS	text		DERIVED	
TSPARMCD	DOSFRQ	FREQUENCY	text		DERIVED	
TSPARMCD	DOSU	TEST PRODUCT DOSE UNITS	text		DERIVED	
TSPARMCD	DRUGDCTV	DRUG DICTIONARY VERSION	text		DERIVED	
TSPARMCD	DRUGDICT	DRUG DICTIONARY	text		DERIVED	
TSPARMCD	INDIC	TRIAL INDICATIONS	text		DERIVED	
TSPARMCD	LENGTH	LENGTH OF TRIAL	text		DERIVED	
TSPARMCD	OBJPRIM	TRIAL PRIMARY OBJECTIVE	text		DERIVED	
TSPARMCD	OBJSEC	TRIAL SECONDARY OBJECTIVE	text		DERIVED	
TSPARMCD	PLANSUB	PLANNED NUMBER OF SUBJECTS	text		DERIVED	
TSPARMCD	RANDOM	TRIAL IS RANDOMIZED	text		DERIVED	
TSPARMCD	ROUTE	TEST PRODUCT ROUTE OF ADMINISTRATION	text		DERIVED	
TSPARMCD	SEXPOP	SEX OF PARTICIPANTS	text		DERIVED	
TSPARMCD	SPONSOR	SPONSORING ORGANIZATION	text		DERIVED	
TSPARMCD	TBLIND	TRIAL BLINDING SCHEMA	text		DERIVED	
TSPARMCD	TCNTRL	TYPE OF CONTROL	text		DERIVED	
TSPARMCD	TINDTP	TRIAL INDICATION TYPE	text		DERIVED	
TSPARMCD	TITLE	TRIAL TITLE	text		DERIVED	
TSPARMCD	TPHASE	TRIAL PHASE	text		DERIVED	
TSPARMCD	TRT	REPORTED NAME OF TEST PRODUCT	text		DERIVED	
TSPARMCD	TTYPE	TYPE OF TRIAL	text		DERIVED	

## ***Computational Algorithms***

<b>Reference Name</b>	<b>Computation Method</b>
COMPMETHOD.QTCB	$QTcB = QT \text{ interval} / \text{square root of } (60 / \text{heart rate})$
COMPMETHOD.QTCF	$QTcF = QT \text{ interval} / \text{cubic root of } (60 / \text{heart rate})$

**Controlled Terminology (Code Lists)**  
**AEACTF, Reference Name (AEACTF)**

<b>Code value</b>	<b>Code Text</b>
NONE	NONE
STUDY DRUG DOSE REDUCED	STUDY DRUG DOSE REDUCED
STUDY DRUG STOPPED TEMPORARILY	STUDY DRUG STOPPED TEMPORARILY
STUDY DRUG DISCONTINUED	STUDY DRUG DISCONTINUED

**Controlled Terminology (Code Lists)**  
**AERELF, Reference Name (AERELF)**

<b>Code value</b>	<b>Code Text</b>
NOT RELATED	NOT RELATED
POSSIBLY RELATED	POSSIBLY RELATED
RELATED	RELATED

***Controlled Terminology (Code Lists)***  
***AESEVRF,Reference Name (AESEVRF)***

<b>Code value</b>	<b>Code Text</b>
MILD	MILD
MODERATE	MODERATE
SEVERE	SEVERE

**Controlled Terminology (Code Lists)**  
**CFREQF, Reference Name (CFREQF)**

<b>Code value</b>	<b>Code Text</b>
QD	QD
BID	BID
TID	TID
QID	QID
QOD	QOD
STAT	STAT
Once a week	Once a week
Once a month	Once a month
PRN	PRN
Other	Other

**Controlled Terminology (Code Lists)**  
**CGIIMP, Reference Name (CGIIMP)**

<b>Code value</b>	<b>Code Text</b>
Very much improved	Very much improved
Much Improved	Much Improved
Minimally Improved	Minimally Improved
No change	No change
Minimally worse	Minimally worse
Much worse	Much worse
Very much worse	Very much worse

**Controlled Terminology (Code Lists)**  
**CMCAT\_F,Reference Name (CMCAT\_F)**

<b>Code value</b>	<b>Code Text</b>
Concomitant Medications	Concomitant Medications
Psychotropic Drug Treatment History	Psychotropic Drug Treatment History

**Controlled Terminology (Code Lists)**  
**CROUFEF,Reference Name (CROUFEF)**

<b>Code value</b>	<b>Code Text</b>
PO	PO
SC	SC
IM	IM
IV	IV
Rectal	Rectal
Topical	Topical
Nasal	Nasal
Inhaled	Inhaled
SL	SL
Other	Other

**Controlled Terminology (Code Lists)**  
**CSIND\_F,Reference Name (CSIND\_F)**

<b>Code value</b>	<b>Code Text</b>
CH	CLINICALLY SIGNIFICANT HIGH
CL	CLINICALLY SIGNIFICANT LOW

**Controlled Terminology (Code Lists)**  
**CUNITF,Reference Name (CUNITF)**

<b>Code value</b>	<b>Code Text</b>
mg	mg
ug	ug
g	g
mL	mL
ug/Kg	ug/Kg
mg/Kg	mg/Kg
mL/Kg	mL/Kg
mL/hr	mL/hr
IU	IU
Tab(s)	Tab(s)
Cap(s)	Cap(s)
Other	Other

***Controlled Terminology (Code Lists)***  
***DSCAT\_F,Reference Name (DSCAT\_F)***

<b>Code value</b>	<b>Code Text</b>
DISPOSITION EVENT	DISPOSITION EVENT
PROTOCOL MILESTONE	PROTOCOL MILESTONE

**Controlled Terminology (Code Lists)**  
**DSDECOD\_F,Reference Name (DSDECOD\_F)**

<b>Code value</b>	<b>Code Text</b>
ADVERSE EVENT	ADVERSE EVENT
COMPLETED	COMPLETED
DID NOT MEET CRITERIA	DID NOT MEET CRITERIA
INFORMED CONSENT	INFORMED CONSENT
RANDOMIZED	RANDOMIZED

***Controlled Terminology (Code Lists)***  
***EDUCATNF,Reference Name (EDUCATNF)***

<b>Code value</b>	<b>Code Text</b>
Some High School	Some High School
High School Graduate/GED	High School Graduate/GED
Some College	Some College
College Graduate	College Graduate
Graduate Degree & Beyond	Graduate Degree & Beyond
Other	Other

***Controlled Terminology (Code Lists)***  
***ETHNIC2F,Reference Name (ETHNIC2F)***

<b>Code value</b>	<b>Code Text</b>
HISPANIC OR LATINO	HISPANIC OR LATINO
NOT HISPANIC OR LATINO	NOT HISPANIC OR LATINO

**Controlled Terminology (Code Lists)**  
**FAMILYF, Reference Name (FAMILYF)**

<b>Code value</b>	<b>Code Text</b>
Single	Single
Married	Married
Separated	Separated
Living With Partner	Living With Partner
Divorced	Divorced
Widowed	Widowed

**Controlled Terminology (Code Lists)**  
**GENSYMP, Reference Name (GENSYMP)**

<b>Code value</b>	<b>Code Text</b>
Absent	Absent
Mild	Mild
Severe	Severe

**Controlled Terminology (Code Lists)**  
**HLN,Reference Name (HLN)**

<b>Code value</b>	<b>Code Text</b>
H	H
L	L
N	N
ABNORMAL	ABNORMAL

**Controlled Terminology (Code Lists)**  
**IECAT\_F,Reference Name (IECAT\_F)**

<b>Code value</b>	<b>Code Text</b>
EXCLUSION	EXCLUSION
INCLUSION	INCLUSION

**Controlled Terminology (Code Lists)**  
**LBCAT\_F,Reference Name (LBCAT\_F)**

<b>Code value</b>	<b>Code Text</b>
Chemistry	Chemistry
Hematology	Hematology
Urinalysis	Urinalysis

**Controlled Terminology (Code Lists)**  
**MHBODSYS\_F,Reference Name (MHBODSYS\_F)**

<b>Code value</b>	<b>Code Text</b>
Allergies	Allergies
Endocrine-Metabolic	Endocrine-Metabolic
Eyes-Ears-Nose-Throat	Eyes-Ears-Nose-Throat
Genitourinary	Genitourinary
Musculoskeletal	Musculoskeletal
Neurological	Neurological

**Controlled Terminology (Code Lists)**  
**MHCAT\_F,Reference Name (MHCAT\_F)**

<b>Code value</b>	<b>Code Text</b>
MEDICAL AND SURGICAL HISTORY	MEDICAL AND SURGICAL HISTORY
PSYCHIATRIC HISTORY	PSYCHIATRIC HISTORY

***Controlled Terminology (Code Lists)***  
***NABCLIN, Reference Name (NABCLIN)***

<b>Code value</b>	<b>Code Text</b>
Normal	Normal
Abnormal/Not CS	Abnormal/Not CS
Abnormal/CS	Abnormal/CS

**Controlled Terminology (Code Lists)**  
**NY,Reference Name (NY)**

<b>Code value</b>	<b>Code Text</b>
N	NO
U	UNKNOWN
Y	YES

**Controlled Terminology (Code Lists)**  
**NYNA, Reference Name (NYNA)**

<b>Code value</b>	<b>Code Text</b>
N	NO
NA	NOT APPLICABLE
Y	YES

**Controlled Terminology (Code Lists)**  
**RACEF, Reference Name (RACEF)**

<b>Code value</b>	<b>Code Text</b>
WHITE	WHITE
BLACK	BLACK
ASIAN	ASIAN
HISPANIC	HISPANIC
OTHER	OTHER

**Controlled Terminology (Code Lists)**  
**RoleCodeList,Reference Name (RoleCodeList)**

<b>Code value</b>	<b>Code Text</b>
GROUPING QUALIFIER	GROUPING QUALIFIER
IDENTIFIER	IDENTIFIER
QUALIFIER	QUALIFIER
RECORD QUALIFIER	RECORD QUALIFIER
RESULT	RESULT
RESULT QUALIFIER	RESULT QUALIFIER
RULE	RULE
SYNONYM QUALIFIER	SYNONYM QUALIFIER
TIMING	TIMING
TOPIC	TOPIC
VARIABLE QUALIFIER	VARIABLE QUALIFIER

**Controlled Terminology (Code Lists)**  
**SEX, Reference Name (SEX)**

<b>Code value</b>	<b>Code Text</b>
F	FEMALE
M	MALE
U	UNKNOWN

**Controlled Terminology (Code Lists)**  
**STENRF,Reference Name (STENRF)**

<b>Code value</b>	<b>Code Text</b>
BEFORE	BEFORE
DURING	DURING
AFTER	AFTER
DURING/ AFTER	DURING/ AFTER
U	U

## ***Controlled Terminology (External dictionaries)***

	<b>External dictionary</b>	<b>Dictionary Version</b>
ADVERSE EVENT DICTIONARY	MEDDRA	8.0
DRUG DICTIONARY	WHODRUG	200204