

Study CDISCPILLOT01**Study Information**

Study Name	Study Description
CDISCPILLOT01	CDISCPILLOT01 Data Definition

Annotated Case Report Forms

Title	Document Name
Annotated Case Report Form	blankcrf.pdf

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Location
TA	Trial Arms	Trial Design	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt
TE	Trial Elements	Trial Design	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt
TI	Trial Inclusion/Exclusion Criteria	Trial Design	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt
TS	Trial Summary	Trial Design	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt
TV	Trial Visits	Trial Design	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM	tv.xpt
DM	Demographics	Special Purpose	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
SE	Subject Elements	Special Purpose	One record per actual Element per subject	Tabulation	STUDYID, USUBJID, ETCD	se.xpt
SV	Subject Visits	Special Purpose	One record per actual visit per subject	Tabulation	STUDYID, USUBJID, VISITNUM	sv.xpt
CM	Concomitant Medications	Interventions	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID, USUBJID, CMTRT, CMSTDTC	cm.xpt
EX	Exposure	Interventions	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	ex.xpt
AE	Adverse Events	Events	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AETERM, AESTDTC, AESEQ	ae.xpt
DS	Disposition	Events	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	ds.xpt

Dataset	Description	Class	Structure	Purpose	Keys	Location
MH	Medical History	Events	One record per medical history event per subject	Tabulation	STUDYID, USUBJID, MHTERM, MHSTDTC	mh.xpt
LB	Laboratory Tests Results	Findings	One record per analyte per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, LBTESTCD, VISITNUM	lb.xpt
QS	Questionnaires	Findings	One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID, USUBJID, QSTESTCD, VISITNUM	qs.xpt
SC	Subject Characteristics	Findings	One record per characteristic per subject	Tabulation	STUDYID, USUBJID, SCTESTCD	sc.xpt
VS	Vital Signs	Findings	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM, VSTPTNUM	vs.xpt
RELREC	Related Records	Relationship	One record per related record, group of records or datasets	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELID, RELTYPE	relrec.xpt
SUPPAE	Supplemental Qualifiers for AE	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppae.xpt
SUPPDM	Supplemental Qualifiers for DM	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppdm.xpt
SUPPDS	Supplemental Qualifiers for DS	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppds.xpt
SUPPLB	Supplemental Qualifiers for LB	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	supplb.xpt

TA (Trial Arms)

Trial Arms (TA) ta.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
ARMCD	Planned Arm Code	text	ARMCD	Assigned	TOPIC	
ARM	Description of Planned Arm	text	ARM	Protocol	SYNONYM QUALIFIER	
TAETORD	Order of Element within Arm	integer		Assigned	IDENTIFIER	
ETCD	Element Code	text	ETCD	Assigned	RECORD QUALIFIER	
ELEMENT	Description of Element	text	ELEMENT	Protocol	SYNONYM QUALIFIER	
TABRANCH	Branch	text		Protocol	RULE	
TATRANS	Transition Rule	text		Protocol	RULE	
EPOCH	Epoch	text	EPOCH	Protocol	TIMING	

TE (Trial Elements)

Trial Elements (TE) te.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
ETCD	Element Code	text	ETCD	Assigned	TOPIC	
ELEMENT	Description of Element	text	ELEMENT	Protocol	SYNONYM QUALIFIER	
TESTRL	Rule for Start of Element	text		Protocol	RULE	
TEENRL	Rule for End of Element	text		Protocol	RULE	
TEDUR	Planned Duration of Element	text		Protocol	TIMING	

TI (Trial Inclusion/ Exclusion Criteria)

Trial Inclusion/ Exclusion Criteria (TI) ti.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
IETESTCD	Incl/Excl Criterion Short Name	text	IETESTCD	Assigned	TOPIC	
IETEST	Inclusion/Exclusion Criterion	text	IETEST	CRF Pages 1, 2, 3, 4, 5, 6	SYNONYM QUALIFIER	
IECAT	Inclusion/Exclusion Category	text	IECAT	Assigned	GROUPING QUALIFIER	
TIRL	Inclusion/Exclusion Criterion Rule	text		Assigned	RULE	TIRL= " "

TS (Trial Summary)

Trial Summary (TS) ts.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
TSSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each TSPARMCD
TSPARMCD	Trial Summary Parameter Short Name	text		Assigned	TOPIC	
TSPARM	Trial Summary Parameter	text		Protocol	SYNONYM QUALIFIER	
TSVAL	Parameter Value	text		Protocol	RESULT QUALIFIER	

TV (Trial Visits)

Trial Visits (TV) tv.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
VISITNUM	Visit Number	float	VISITNUM	Protocol	TOPIC	
VISIT	Visit Name	text	VISIT	Protocol	SYNONYM QUALIFIER	
VISITDY	Planned Study Day of Visit	integer		Protocol	TIMING	
ARMCD	Planned Arm Code	text	ARMCD	Protocol	RECORD QUALIFIER	
ARM	Description of Planned Arm	text	ARM	Protocol	SYNONYM QUALIFIER	
TVSTRL	Visit Start Rule	text		Protocol	RULE	
TVENRL	Visit End Rule	text		Protocol	RULE	

DM (Demographics)

Demographics (DM) dm.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
SUBJID	Subject Identifier for the Study	text		CRF Page 7	TOPIC	
RFSTDTC	Subject Reference Start Date/Time	date	ISO8601	Derived	RECORD QUALIFIER	Date/time of first study drug treatment derived from EX
RFENDTC	Subject Reference End Date/Time	date	ISO8601	Derived	RECORD QUALIFIER	Date/time of last study drug treatment derived from EX
RFXSTDTC	Date/Time of First Study Treatment	datetime	ISO8601	Derived	RECORD QUALIFIER	RFXSTDTC=RFSTDTC
RFXENDTC	Date/Time of Last Study Treatment	datetime	ISO8601	Derived	RECORD QUALIFIER	RFXENDTC=RFENDTC
RFICDTC	Date/Time of Informed Consent	datetime	ISO8601	Derived	RECORD QUALIFIER	Date of informed consent was not entered in database (see annotated CRF)
RFPENDTC	Date/Time of End of Participation	datetime	ISO8601	Derived	RECORD QUALIFIER	DSSTDTC of last disposition event
DTHDTC	Date/Time of Death	datetime	ISO8601	Derived	RECORD QUALIFIER	If DS record exists with DSDECOD="DEATH" then DTHDTC=AEENDTC.

Demographics (DM) dm.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
DTHFL	Subject Death Flag	text	Y BLANK	Derived	RECORD QUALIFIER	If DS record exists with DSDECOD="DEATH" then DEATHFL=Y.
SITEID	Study Site Identifier	text		Assigned	RECORD QUALIFIER	
AGE	Age	integer		Derived	RECORD QUALIFIER	Subject's Age at start of study drug (RFSTDTC).
AGEU	Age Units	text	AGEU	Assigned	VARIABLE QUALIFIER	AGEU="YEARS"
SEX	Sex	text	SEX	CRF Page 7	RECORD QUALIFIER	
RACE	Race	text	RACE	CRF Page 7	RECORD QUALIFIER	
ETHNIC	Ethnicity	text	ETHNIC	Derived	RECORD QUALIFIER	Derived from Origin entered on CRF: ETHNIC="HISPANIC OR LATINO" if Origin="Hispanic". Otherwise ETHNIC="NOT HISPANIC OR LATINO"
ARMCD	Planned Arm Code	text	ARMCD	Assigned	RECORD QUALIFIER	According to randomization list
ARM	Description of Planned Arm	text	ARM	Assigned	SYNONYM QUALIFIER	According to randomization list
ACTARMCD	Actual Arm Code	text	ARMCD	Derived	RECORD QUALIFIER	Derived from EX

Demographics (DM) dm.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
ACTARM	Description of Actual Arm	text	ARM	Derived	SYNONYM QUALIFIER	Derived from EX
COUNTRY	Country	text	COUNTRY	Derived	RECORD QUALIFIER	Derived from site information
DMDTC	Date/Time of Collection	date	ISO8601	CRF Page 7	TIMING	
DMDY	Study Day of Collection	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

SE (Subject Elements)

Subject Elements (SE) se.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
SESEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
ETCD	Element Code	text	ETCD	Assigned	TOPIC	
ELEMENT	Description of Element	text	ELEMENT	Protocol	SYNONYM QUALIFIER	
SESTDTC	Start Date/Time of Element	date	ISO8601	Derived	TIMING	Earliest date/time when data pertaining to that element were collected
SEENDTC	End Date/Time of Element	date	ISO8601	Derived	TIMING	Last date/time when data pertaining to that element were collected
SEUPDES	Description of Unplanned Element	text		Assigned	SYNONYM QUALIFIER	

SV (Subject Visits)

Subject Visits (SV) sv.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
VISITNUM	Visit Number	float	VISITNUM	CRF Pages 7, 22, 25, 32, 36, 42, 49, 52, 58, 67, 73, 82, 88, 90, 99, 108, 116, 121, 122, 123, 123, 125, 126, 128	TOPIC	
VISIT	Visit Name	text	VISIT	CRF Pages 7, 22, 25, 32, 36, 42, 49, 52, 58, 67, 73, 82, 88, 90, 99, 108, 116, 121, 122, 123, 123, 125, 126, 128	SYNONYM QUALIFIER	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY

Subject Visits (SV) sv.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
SVSTDTC	Start Date/Time of Visit	date	ISO8601	Derived	TIMING	Earliest date when data were collected for the corresponding visit.
SVENDTC	End Date/Time of Visit	date	ISO8601	Derived	TIMING	Lastt date when data were collected for the corresponding visit.

CM (Concomitant Medications)

Concomitant Medications (CM) cm.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
CMSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
CMSPID	Sponsor-Defined Identifier	text		Assigned	IDENTIFIER	
CMTRT	Reported Name of Drug, Med, or Therapy	text		CRF Page 124, 125, 126	TOPIC	
CMDECOD	Standardized Medication Name	text	DRUGDICT	Assigned	SYNONYM QUALIFIER	
CMINDC	Indication	text		CRF Page 124, 125, 126	RECORD QUALIFIER	
CMCLAS	Medication Class	text	DRUGDICT	Assigned	VARIABLE QUALIFIER	ATC Level 1
CMDOSE	Dose per Administration	integer		CRF Page 124, 125, 126	RECORD QUALIFIER	
CMDOSU	Dose Units	text		CRF Page 124, 125, 126	VARIABLE QUALIFIER	
CMDOSFRQ	Dosing Frequency per Interval	text	CMFREQ	CRF Page 124, 125, 126	VARIABLE QUALIFIER	

Concomitant Medications (CM) cm.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
CMROUTE	Route of Administration	text	CMROUTE	CRF Page 124, 125, 126	VARIABLE QUALIFIER	
VISITNUM	Visit Number	float	VISITNUM	CRF Page 124, 125, 126	TIMING	
VISIT	Visit Name	text	VISIT	CRF Page 124, 125, 126	TIMING	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY
CMDTC	Date/Time of Collection	date	ISO8601	CRF Page 124, 125, 126	TIMING	
CMSTDTC	Start Date/Time of Medication	date	ISO8601	CRF Page 124, 125, 126	TIMING	
CMENDTC	End Date/Time of Medication	date	ISO8601	CRF Page 124, 125, 126	TIMING	
CMSTDY	Study Day of Start of Medication	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY
CMENDY	Study Day of End of Medication	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

EX (Exposure)

Exposure (EX) ex.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
EXSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
EXTRT	Name of Actual Treatment	text	EXTRT	eDT	TOPIC	
EXDOSE	Dose per Administration	integer		eDT	RECORD QUALIFIER	
EXDOSU	Dose Units	text	EXDOSEU	eDT	VARIABLE QUALIFIER	
EXDOSFRM	Dose Form	text	EXDOSFRM	eDT	RECORD QUALIFIER	
EXDOSFRQ	Dosing Frequency per Interval	text	EXFREQ	eDT	VARIABLE QUALIFIER	
EXROUTE	Route of Administration	text	EXROUTE	eDT	VARIABLE QUALIFIER	
VISITNUM	Visit Number	float	VISITNUM	CRF Pages 25, 36, 42, 49, 52, 58, 67, 73, 82, 90, 99, 108, 116, 128	TIMING	

Exposure (EX) ex.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
VISIT	Visit Name	text	VISIT	CRF Pages 25, 36, 42, 49, 52, 58, 67, 73, 82, 90, 99, 108, 116, 128	TIMING	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY
EXSTDTC	Start Date/Time of Treatment	date	ISO8601	CRF Pages 25, 36, 42, 49, 52, 58, 67, 73, 82, 90, 99, 108, 116, 128	TIMING	
EXENDTC	End Date/Time of Treatment	date	ISO8601	CRF Page 105, 138	TIMING	
EXSTDY	Study Day of Start of Treatment	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY
EXENDY	Study Day of End of Treatment	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

AE (Adverse Events)

Adverse Events (AE) ae.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
AESEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
AESPID	Sponsor-Defined Identifier	text		CRF Page 121, 122, 123	IDENTIFIER	
AETERM	Reported Term for the Adverse Event	text		CRF Page 121, 122, 123	TOPIC	
AELLT	Lowest Level Term	text	AEDICT	Assigned	VARIABLE QUALIFIER	
AELLTCD	Lowest Level Term Code	integer		Assigned	VARIABLE QUALIFIER	
AEDECOD	Dictionary-Derived Term	text	AEDICT	Assigned	SYNONYM QUALIFIER	
AEPTCD	Preferred Term Code	integer		Assigned	VARIABLE QUALIFIER	
AEHLT	High Level Term	text	AEDICT	Assigned	VARIABLE QUALIFIER	
AEHLTCD	High Level Term Code	integer		Assigned	VARIABLE QUALIFIER	

Adverse Events (AE) ae.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
AEHLGT	High Level Group Term	text	AEDICT	Assigned	VARIABLE QUALIFIER	
AEHLGTCD	High Level Group Term Code	integer		Assigned	VARIABLE QUALIFIER	
AEBODSYS	Body System or Organ Class	text	AEDICT	Assigned	VARIABLE QUALIFIER	
AEBDSYCD	Body System or Organ Class Code	integer		Assigned	VARIABLE QUALIFIER	
AESOC	Primary System Organ Class	text	AEDICT	Assigned	VARIABLE QUALIFIER	
AESOCCD	Primary System Organ Class Code	integer		Assigned	VARIABLE QUALIFIER	
AESEV	Severity/Intensity	text	SEV	CRF Page 121, 122, 123	VARIABLE QUALIFIER	
AESER	Serious Event	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AEACN	Action Taken with Study Treatment	text		Derived	RECORD QUALIFIER	AEACN=Null (data on action taken concerning study treatment was not collected)
AEREL	Causality	text	AECAUS	CRF Page 121, 122, 123	RECORD QUALIFIER	
AEOUT	Outcome of Adverse Event	text	OUT	CRF Page 121, 122, 123	RECORD QUALIFIER	
AESCAN	Involves Cancer	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	

Adverse Events (AE) ae.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
AESCONG	Congenital Anomaly or Birth Defect	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AESDISAB	Persist or Signif Disability/Incapacity	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AESDTH	Results in Death	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AESHOSP	Requires or Prolongs Hospitalization	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AESLIFE	Is Life Threatening	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AESOD	Occurred with Overdose	text	YN	CRF Page 121, 122, 123	RECORD QUALIFIER	
AEDTC	Date/Time of Collection	date	ISO8601	Derived	TIMING	Date of final visit (SV)
AESTDTC	Start Date/Time of Adverse Event	date	ISO8601	CRF Page 121, 122, 123	TIMING	
AEENDTC	End Date/Time of Adverse Event	date	ISO8601	CRF Page 121, 122, 123	TIMING	
AESTDY	Study Day of Start of Adverse Event	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY
AEENDY	Study Day of End of Adverse Event	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

DS (Disposition)

Disposition (DS) ds.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
DSSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
DSSPID	Sponsor-Defined Identifier	text		Assigned	IDENTIFIER	
DSTERM	Reported Term for the Disposition Event	text		CRF Page 106, 139	TOPIC	
DSDECOD	Standardized Disposition Term	text	DISCCD	CRF Page 106, 139	SYNONYM QUALIFIER	
DSCAT	Category for Disposition Event	text	DSCAT	Assigned	GROUPING QUALIFIER	
VISITNUM	Visit Number	float	VISITNUM	CRF Page 106, 139	TIMING	
VISIT	Visit Name	text	VISIT	CRF Page 106, 139	TIMING	
DSDTC	Date/Time of Collection	datetime	ISO8601	CRF Page 106, 139	TIMING	

Disposition (DS) ds.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
DSSTDTC	Start Date/Time of Disposition Event	date	ISO8601	CRF Page 106, 139	TIMING	
DSSTDY	Study Day of Start of Disposition Event	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

MH (Medical History)

Medical History (MH) mh.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
MHSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
MHSPID	Sponsor-Defined Identifier	text		CRF Pages 14, 15, 121, 122, 123	IDENTIFIER	
MHTERM	Reported Term for the Medical History	text		CRF Pages 14, 15, 121, 122, 123	TOPIC	
MHLLT	Lowest Level Term	text	MHDICT	Assigned	VARIABLE QUALIFIER	
MHDECOD	Dictionary-Derived Term	text	MHDICT	Assigned	SYNONYM QUALIFIER	
MHHLT	High Level Term	text	MHDICT	Assigned	VARIABLE QUALIFIER	
MHHLGT	High Level Group Term	text	MHDICT	Assigned	VARIABLE QUALIFIER	
MHCAT	Category for Medical History	text	MHCAT	Assigned	GROUPING QUALIFIER	Category values are assigned according to the CRF Section label which was used to collect that type of medical history information.

Medical History (MH) mh.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
MHBODSYS	Body System or Organ Class	text	MHDICT	Assigned	RECORD QUALIFIER	
MHSEV	Severity/Intensity	text	SEV	CRF Pages 121, 122, 123	VARIABLE QUALIFIER	
VISITNUM	Visit Number	float	VISITNUM	CRF Pages 14, 15, 121, 122, 123	TIMING	
VISIT	Visit Name	text	VISIT	CRF Pages 14, 15, 121, 122, 123	TIMING	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY
MHDTC	Date/Time of History Collection	date	ISO8601	CRF Pages 14, 15, 121, 122, 123	TIMING	
MHSTDTC	Start Date/Time of Medical History Event	date	ISO8601	CRF Pages 12, 14	TIMING	
MHDY	Study Day of History Collection	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

LB (Laboratory Tests Results)

Laboratory Tests Results (LB) lb.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
LBSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
LBTESTCD	Lab Test or Examination Short Name	text		eDT	TOPIC	
LBTEST	Lab Test or Examination Name	text		eDT	SYNONYM QUALIFIER	
LBCAT	Category for Lab Test	text	LBCAT	eDT	GROUPING QUALIFIER	
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		Derived	RESULT QUALIFIER	LBORRES converted to standard unit (LBSTRESU)

Laboratory Tests Results (LB) lb.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
LBSTRESN	Numeric Result/Finding in Standard Units	integer		Derived	RESULT QUALIFIER	LBSTRESC converted to numeric
LBSTRESU	Standard Units	text	LBUNIT	Assigned	VARIABLE QUALIFIER	Standard unit per parameter assigned for summarizing analyses
LBSTNRLO	Reference Range Lower Limit-Std Units	integer		Derived	VARIABLE QUALIFIER	LBORNRLLO converted to standard unit (LBSTRESU)
LBSTNRHI	Reference Range Upper Limit-Std Units	integer		Derived	VARIABLE QUALIFIER	LBORNRI converted to standard unit (LBSTRESU)
LBNRIND	Reference Range Indicator	text	LBNRIND	Derived	VARIABLE QUALIFIER	If LBSTRESN > LBSTNRHI then LBNRIND="HIGH". If LBSTRESN < LBSTNRLO then LBNRIND="LOW". If LBSTRESN between LBSTNRLO and LBSTNRHI then LBNRIND="NORMAL". Selected urinalysis parameters (e.g. Ketones) are classified as NORMAL or ABNORMAL only.
LBBLFL	Baseline Flag	text	Y BLANK	Derived	RECORD QUALIFIER	If VISIT="SCREENING" then LBBLFL=Y
VISITNUM	Visit Number	float	VISITNUM	eDT	TIMING	
VISIT	Visit Name	text	VISIT	eDT	TIMING	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY

Laboratory Tests Results (LB) lb.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
LBDTC	Date/Time of Specimen Collection	datetime	ISO8601	eDT	TIMING	
LBDY	Study Day of Specimen Collection	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

QS (Questionnaires)

Questionnaires (QS) qs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
QSSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
QSTESTCD	Question Short Name	text		CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	TOPIC	

Questionnaires (QS) qs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
QSTEST	Question Name	text		CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	SYNONYM QUALIFIER	
QSCAT	Category of Question	text	QSCAT	CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	GROUPING QUALIFIER	

Questionnaires (QS) qs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
QSSCAT	Subcategory for Question	text		CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	GROUPING QUALIFIER	
QSORRES	Finding in Original Units	text		CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	RESULT QUALIFIER	
QSORRESU	Original Units	text	QSUNIT	CRF Pages 26, 59, 74, 91, 109, 130	VARIABLE QUALIFIER	

Questionnaires (QS) qs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
QSSTRESC	Character Result/Finding in Std Format	text		Derived	RESULT QUALIFIER	Derived standardized value for collect result (QSORRES)
QSSTRESN	Numeric Finding in Standard Units	integer		Derived	RESULT QUALIFIER	See Computational Method: COMPMETHOD.QSAD_QSSTR ESN
QSSTRESU	Standard Units	text	QSUNIT	Derived	VARIABLE QUALIFIER	QSSTRESU=QSORRESU
QSBLFL	Baseline Flag	text	Y BLANK	Derived	RECORD QUALIFIER	If VISIT="BASELINE" then QSBLFL="Y"
QSDRVFL	Derived Flag	text	Y BLANK	Assigned	RECORD QUALIFIER	Individual test results which were not collected on CRF but derived are flagged with QSDRVFL="Y"
VISITNUM	Visit Number	float	VISITNUM	CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	TIMING	

Questionnaires (QS) qs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
VISIT	Visit Name	text	VISIT	CRF Pages 10, 11, 26, 27, 28, 29, 38, 44, 54, 59, 60, 61, 62, 63, 69, 74, 75, 76, 77, 78, 84, 89, 91, 92, 93, 94, 95, 101, 109, 110, 111, 112, 113, 130, 131, 132, 133, 134, 156, 157	TIMING	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY
QSDTC	Date/Time of Finding	date	ISO8601	Derived	TIMING	QSDTC=SV.SVSTDTC of the respective VISIT
QSDY	Study Day of Finding	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

SC (Subject Characteristics)

Subject Characteristics (SC) sc.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
SCSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
SCTESTCD	Subject Characteristic Short Name	text		CRF Page 8	TOPIC	
SCTEST	Subject Characteristic	text		CRF Page 8	SYNONYM QUALIFIER	
SCCAT	Category for Subject Characteristic	text	SCCAT	Assigned	GROUPING QUALIFIER	Corresponds to the CRF Section label where the data were obtained from.
SCORRES	Result or Finding in Original Units	text		CRF Page 8	RESULT QUALIFIER	
SCORRESU	Original Units	text	SCUNIT	CRF Page 8	VARIABLE QUALIFIER	
SCSTRESC	Character Result/Finding in Std Format	text		Derived	RESULT QUALIFIER	SCORRES converted to standard unit
SCSTRESN	Numeric Result/Finding in Standard Units	integer		Derived	RESULT QUALIFIER	SCSTRESC converted to numeric
SCSTRESU	Standard Units	text	SCUNIT	Derived	VARIABLE QUALIFIER	SCSTRESU=SCORRESU

Subject Characteristics (SC) sc.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
SCDTC	Date/Time of Collection	date	ISO8601	CRF Page 7	TIMING	
SCDY	Study Day of Examination	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY

VS (Vital Signs)

Vital Signs (VS) vs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
DOMAIN	Domain Abbreviation	text		Assigned	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
VSSEQ	Sequence Number	integer		Derived	IDENTIFIER	Sequential number identifying records within each USUBJID
VSTESTCD	Vital Signs Test Short Name	text		CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	TOPIC	
VSTEST	Vital Signs Test Name	text		CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	SYNONYM QUALIFIER	
VSPOS	Vital Signs Position of Subject	text	VSPOS	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	RECORD QUALIFIER	

Vital Signs (VS) vs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
VSORRES	Result or Finding in Original Units	text		CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	RESULT QUALIFIER	
VSORRESU	Original Units	text	VSUNIT	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	VARIABLE QUALIFIER	
VSSTRESC	Character Result/Finding in Std Format	text		Derived	RESULT QUALIFIER	VSORRES converted to standard unit
VSSTRESN	Numeric Result/Finding in Standard Units	integer		Derived	RESULT QUALIFIER	VSSTRESC converted to numeric
VSSTRESU	Standard Units	text	VSUNIT	Assigned	VARIABLE QUALIFIER	Standard unit defined per parameter for summarizing analysis
VSSTAT	Completion Status	text	ND	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	RECORD QUALIFIER	

Vital Signs (VS) vs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
VSLOC	Location of Vital Signs Measurement	text	VSLOC	CRF Pages 17, 23, 30, 33, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	RECORD QUALIFIER	
VSBLFL	Baseline Flag	text	Y BLANK	Derived	RECORD QUALIFIER	If VISIT="BASELINE" then VSBLFL="Y"
VISITNUM	Visit Number	float	VISITNUM	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	TIMING	
VISIT	Visit Name	text	VISIT	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	TIMING	
VISITDY	Planned Study Day of Visit	integer		Derived	TIMING	TV.VISITDY
VSDTC	Date/Time of Measurements	date	ISO8601	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	TIMING	

Vital Signs (VS) vs.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
VSDY	Study Day of Vital Signs	integer		Derived	TIMING	See Computational Method: COMPMETHOD.STUDY_DAY
VSTPT	Planned Time Point Name	text	VSTPT	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	TIMING	
VSTPTNUM	Planned Time Point Number	integer	VSTPTNUM	CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	TIMING	
VSELTM	Planned Elapsed Time from Time Point Ref	text		Derived	TIMING	VSTPT expressed in the ISO 8601 format for durations
VSTPTREF	Time Point Reference	text	VSTPTREF	Assigned	TIMING	

RELREC (Related Records)

Related Records (RELREC) relrec.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		Derived	IDENTIFIER	Domain abbreviations for domains which are related to at least one other domain. Derived from parent record
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
IDVAR	Identifying Variable	text		Derived	IDENTIFIER	Derived from parent record
IDVARVAL	Identifying Variable Value	text		Derived	IDENTIFIER	Derived from parent record
RELTYPE	Relationship Type	text		Assigned	RESULT QUALIFIER	
RELID	Relationship Identifier	text		Derived	TOPIC	Records with the same RELID value can be considered as related records

SUPPAE (Supplemental Qualifiers for AE)

Supplemental Qualifiers for AE (SUPPAE) suppae.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		Assigned	IDENTIFIER	RDOMAIN="AE"
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
IDVAR	Identifying Variable	text		Assigned	IDENTIFIER	IDVAR="AESEQ"
IDVARVAL	Identifying Variable Value	text		Derived	IDENTIFIER	Value of AESEQ of corresponding parent record
QNAM	Qualifier Variable Name	text		Assigned	TOPIC	
QLABEL	Qualifier Variable Label	text		Assigned	SYNONYM QUALIFIER	
QVAL	Data Value	text		Derived	RESULT	see value level metadata
QORIG	Origin	text		Assigned	RESULT QUALIFIER	
QEVAL	Evaluator	text	QEVAL	Assigned	RESULT QUALIFIER	

SUPPDM (Supplemental Qualifiers for DM)

Supplemental Qualifiers for DM (SUPPDM) suppdm.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		Assigned	IDENTIFIER	RDOMAIN="AE"
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
IDVAR	Identifying Variable	text		Assigned	IDENTIFIER	IDVAR=" "
IDVARVAL	Identifying Variable Value	text		Assigned	IDENTIFIER	IDVARVAL=" "
QNAM	Qualifier Variable Name	text		Assigned	TOPIC	
QLABEL	Qualifier Variable Label	text		Assigned	SYNONYM QUALIFIER	
QVAL	Data Value	text		Derived	RESULT	see value level metadata
QORIG	Origin	text		Assigned	RESULT QUALIFIER	
QEVAL	Evaluator	text	QEVAL	Assigned	RESULT QUALIFIER	

SUPPDS (Supplemental Qualifiers for DS)

Supplemental Qualifiers for DS (SUPPDS) suppds.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		Assigned	IDENTIFIER	RDOMAIN="DS"
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
IDVAR	Identifying Variable	text		Assigned	IDENTIFIER	IDVAR="DSSEQ"
IDVARVAL	Identifying Variable Value	text		Derived	IDENTIFIER	Value of DSSEQ of corresponding parent record
QNAM	Qualifier Variable Name	text		Assigned	TOPIC	
QLABEL	Qualifier Variable Label	text		CRF Pages 106, 139	SYNONYM QUALIFIER	
QVAL	Data Value	text		CRF Pages 106, 139	RESULT	see value level metadata
QORIG	Origin	text		Assigned	RESULT QUALIFIER	
QEVAL	Evaluator	text	QEVAL	Assigned	RESULT QUALIFIER	

SUPPLB (Supplemental Qualifiers for LB)

Supplemental Qualifiers for LB (SUPPLB) supplb.xpt						
Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text		CRF Page 7	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text		Assigned	IDENTIFIER	RDOMAIN="LB"
USUBJID	Unique Subject Identifier	text		Derived	IDENTIFIER	Concatenation of STUDYID, DM.SITEID and DM.SUBJID
IDVAR	Identifying Variable	text		Assigned	IDENTIFIER	IDVAR="LBSEQ"
IDVARVAL	Identifying Variable Value	text		Derived	IDENTIFIER	Value of LBSEQ of corresponding parent record
QNAM	Qualifier Variable Name	text		Assigned	TOPIC	
QLABEL	Qualifier Variable Label	text		Assigned	SYNONYM QUALIFIER	
QVAL	Data Value	text		Derived	RESULT	see value level metadata
QORIG	Origin	text		Assigned	RESULT QUALIFIER	
QEVAL	Evaluator	text	QEVAL	Assigned	RESULT QUALIFIER	

Value Level Metadata

Trial Summary (TS.TSPARMCD) Value List

Trial Summary (TS.TSPARMCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
TSPARMCD	ADDON	Added on to Existing Treatments	text	YN	Protocol	
TSPARMCD	AGEMAX	Planned Maximum Age of Subjects	text		Protocol	
TSPARMCD	AGEMIN	Planned Minimum Age of Subjects	text		Protocol	
TSPARMCD	AGESPAN	Age Group	text	AGESPAN	Protocol	
TSPARMCD	COMPTRT	Comparative Treatment Name	text		Protocol	
TSPARMCD	DOSE	Dose per Administration	integer		Protocol	
TSPARMCD	DOSFRQ	Dosing Frequency	text		Protocol	
TSPARMCD	DOSU	Dose Units	text		Protocol	
TSPARMCD	INDIC	Trial Indication	text		Protocol	
TSPARMCD	LENGTH	Trial Length	text		Protocol	
TSPARMCD	OBJPRIM	Trial Primary Objective	text		Protocol	
TSPARMCD	OBJSEC	Trial Secondary Objective	text		Protocol	
TSPARMCD	PLANSUB	Planned Number of Subjects	integer		Protocol	
TSPARMCD	RANDOM	Trial is Randomized	text	YN	Protocol	

Trial Summary (TS.TSPARMCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
TSPARMCD	ROUTE	Route of Administration	text		Protocol	
TSPARMCD	SEXPOP	Sex of Participants	text	SEXPOP	Protocol	
TSPARMCD	SPONSOR	Clinical Study Sponsor	text		Protocol	
TSPARMCD	TBLIND	Trial Blinding Schema	text	TBLIND	Protocol	
TSPARMCD	TCNTRL	Control Type	text	TCNTRL	Protocol	
TSPARMCD	TDIGRP	Diagnosis Group	text		Protocol	
TSPARMCD	TINDTP	Trial Indication Type	text	TINDTP	Protocol	
TSPARMCD	TITLE	Trial Title	text		Protocol	
TSPARMCD	TPHASE	Trial Phase Classification	text	TPHASE	Protocol	
TSPARMCD	TRT	Investigational Therapy or Treatment	text		Protocol	
TSPARMCD	TTYPE	Trial Type	text	TTYPE	Protocol	

Laboratory Tests Results (LB.LBCAT) Value List

Laboratory Tests Results (LB.LBCAT) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBCAT	NULL	NULL	text		eDT	
LBCAT	CHEMISTRY	CHEMISTRY	text		eDT	
LBCAT	HEMATOLOGY	HEMATOLOGY	text		eDT	

Laboratory Tests Results (LB.LBCAT) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBCAT	OTHER	OTHER	text		eDT	
LBCAT	URINALYSIS	URINALYSIS	text		eDT	

Laboratory Tests Results (LB.LBCAT.CHEMISTRY) Value List

Laboratory Tests Results (LB.LBCAT.CHEMISTRY) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	ALB	Albumin	integer		eDT	
LBTESTCD	ALP	Alkaline Phosphatase	integer		eDT	
LBTESTCD	ALT	Alanine Aminotransferase	integer		eDT	
LBTESTCD	AST	Aspartate Aminotransferase	integer		eDT	
LBTESTCD	BILI	Bilirubin	float		eDT	
LBTESTCD	BUN	Blood Urea Nitrogen	float		eDT	
LBTESTCD	CA	Calcium	float		eDT	
LBTESTCD	CHOL	Cholesterol	float		eDT	
LBTESTCD	CK	Creatine Kinase	integer		eDT	
LBTESTCD	CL	Chloride	integer		eDT	
LBTESTCD	CREAT	Creatinine	float		eDT	
LBTESTCD	GGT	Gamma Glutamyl Transferase	integer		eDT	

Laboratory Tests Results (LB.LBCAT.CHEMISTRY) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	GLUC	Glucose	float		eDT	
LBTESTCD	K	Potassium	float		eDT	
LBTESTCD	PHOS	Phosphate	float		eDT	
LBTESTCD	PROT	Protein	integer		eDT	
LBTESTCD	SODIUM	Sodium	integer		eDT	
LBTESTCD	URATE	Urate	float		eDT	

Laboratory Tests Results (LB.LBCAT.HEMATOLOGY) Value List

Laboratory Tests Results (LB.LBCAT. HEMATOLOGY) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	ANISO	Anisocytes	integer		eDT	
LBTESTCD	BASO	Basophils	float		eDT	
LBTESTCD	EOS	Eosinophils	float		eDT	
LBTESTCD	HCT	Hematocrit	float		eDT	
LBTESTCD	HGB	Hemoglobin	float		eDT	
LBTESTCD	LYM	Lymphocytes	float		eDT	
LBTESTCD	MACROCY	Macrocytes	integer		eDT	
LBTESTCD	MCH	Ery. Mean Corpuscular Hemoglobin	float		eDT	

Laboratory Tests Results (LB.LBCAT. HEMATOLOGY) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	MCHC	Ery. Mean Corpuscular HGB Concentration	float		eDT	
LBTESTCD	MCV	Ery. Mean Corpuscular Volume	integer		eDT	
LBTESTCD	MICROCY	Microcytes	integer		eDT	
LBTESTCD	MONO	Monocytes	float		eDT	
LBTESTCD	PLAT	Platelet	integer		eDT	
LBTESTCD	POIKILO	Poikilocytes	integer		eDT	
LBTESTCD	POLYCHR	Polychromasia	integer		eDT	
LBTESTCD	RBC	Erythrocytes	float		eDT	
LBTESTCD	WBC	Leukocytes	float		eDT	

Laboratory Tests Results (LB.LBCAT.NULL) Value List

Laboratory Tests Results (LB.LBCAT.NULL) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	HBA1C	Hemoglobin A1C	float		eDT	

Laboratory Tests Results (LB.LBCAT.OTHER) Value List

Laboratory Tests Results (LB.LBCAT. OTHER) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	TSH	Thyrotropin	float		eDT	
LBTESTCD	VITB12	Vitamin B12	float		eDT	

Laboratory Tests Results (LB.LBCAT.URINALYSIS) Value List

Laboratory Tests Results (LB.LBCAT. URINALYSIS) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
LBTESTCD	COLOR	Color	text	COLOR	eDT	
LBTESTCD	KETONES	Ketones	integer		eDT	
LBTESTCD	PH	pH	integer		eDT	
LBTESTCD	SPGRAV	Specific Gravity	float		eDT	
LBTESTCD	UROBIL	Urobilinogen	integer		eDT	

Questionnaires (QS.QSTESTCD) Value List

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	ACITM01	WORD RECALL TASK	float		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM02	NAMING OBJECTS AND FINGERS (REFER TO 5 C	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM03	DELAYED WORD RECALL	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM04	COMMANDS	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM05	CONSTRUCTIONAL PRAXIS	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM06	IDEATIONAL PRAXIS	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM07	ORIENTATION	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM08	WORD RECOGNITION	integer		CRF Pages 26, 59, 74, 91, 109, 130	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	ACITM09	ATTENTION/VISUAL SEARCH TASK	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM10	MAZE SOLUTION	float		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM11	SPOKEN LANGUAGE ABILITY	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM12	COMPREHENSION OF SPOKEN LANGUAGE	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM13	WORD FINDING DIFFICULTY IN SPONTANEOUS S	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACITM14	RECALL OF TEST INSTRUCTIONS	integer		CRF Pages 26, 59, 74, 91, 109, 130	
QSTESTCD	ACTOT	ADAS-COG(11) Subscore	float		Derived	see SAP
QSTESTCD	CIBIC	EXTENT OF CHANGE, IF ANY, SINCE BASELINE	integer	CIBIC	CRF Pages 60, 75, 92, 110, 131	
QSTESTCD	DAITM01	UNDERTAKE TO WASH HIMSELF/HERSELF	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	DAITM02	UNDERTAKE TO BRUSH HIS/HER TEETH	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM03	DECIDE TO CARE FOR HIS/HER HAIR	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM04	PREPARE FOR WASHING, TAKING A BATH	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM05	WASH AND DRY COMPLETELY SAFELY	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM06	BRUSH HIS/HER TEETH	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM07	CARE FOR HIS/HER HAIR	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM08	UNDERTAKE TO DRESS HIMSELF/HERSELF	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM09	CHOOSE APPROPRIATE CLOTHING	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	DAITM10	DRESS HIMSELF/HERSELF	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM11	DRESS HIMSELF/HERSELF COMPLETELY	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM12	UNDRESS HIMSELF/HERSELF COMPLETELY	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM13	DECIDE TO USE THE TOILET AT APPROPRIATE	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM14	USE THE TOILET WITHOUT "ACCIDENTS"	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM15	DECIDE THAT HE/SHE NEEDS TO EAT	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM16	CHOOSE APPROPRIATE UTENSILS	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM17	EAT HIS/HER MEALS AT A NORMAL PACE	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	DAITM18	UNDERTAKE TO PREPARE A LIGHT MEAL	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM19	ADEQUATELY PLAN A LIGHT MEAL OR SNACK	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM20	PREPARE OR COOK A LIGHT MEAL OR A SNACK	integer	NYNAN	CRF Pages 28, 62, 77, 94, 112, 133, 156	
QSTESTCD	DAITM21	ATTEMPT TO TELEPHONE SOMEONE	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM22	FIND AND DIAL A TELEPHONE NUMBER CORRECT	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM23	CARRY OUT A TELEPHONE CONVERSATION	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM24	WRITE AND CONVEY A TELEPHONE MESSAGE	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM25	UNDERTAKE TO GO OUT	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	DAITM26	ADEQUATELY ORGANIZE AN OUTING	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM27	GO OUT AND REACH A FAMILIAR DESTINATION	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM28	SAFELY TAKE CAR, BUS, TAXI	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM29	RETURN FROM THE STORE	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM30	INTEREST IN HIS/HER PERSONAL AFFAIRS	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM31	PAY HIS/HER BILLS	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM32	ORGANIZE HIS/HER CORRESPONDENCE	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM33	HANDLE ADEQUATELY HIS/HER MONEY	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	DAITM34	DECIDE TO TAKE HIS/HER MEDICATIONS	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM35	TAKE HIS/HER MEDICATIONS AS PRESCRIBED	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM36	SHOW AN INTEREST IN LEISURE ACTIVITY	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM37	TAKE AN INTEREST IN HOUSEHOLD CHORES	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM38	PLAN AND ORGANIZE HOUSEHOLD CHORES	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM39	COMPLETE HOUSEHOLD CHORES	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	DAITM40	STAY SAFELY AT HOME BY HIMSELF/HERSELF	integer	NYNAN	CRF Pages 29, 63, 78, 95, 113, 134, 157	
QSTESTCD	MHITM01	ABRUPT ONSET	integer	PRESABSB	CRF Page 11	
QSTESTCD	MHITM02	STEPWISE DETERIORATION	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM03	FLUCTUATING COURSE	integer	PRESABSB	CRF Page 11	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	MHITM04	NOCTURNAL CONFUSION	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM05	RELATIVE PRESERVATION OF PERSONALITY	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM06	DEPRESSION	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM07	SOMATIC COMPLAINTS	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM08	EMOTIONAL INCONTINENCE	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM09	HISTORY OF HYPERTENSION	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM10	HISTORY OF STROKES	integer	PRESABSB	CRF Page 11	
QSTESTCD	MHITM11	EVIDENCE OF ASSOCIATED ATHEROSCLEROSIS	integer	PRESABSA	CRF Page 11	
QSTESTCD	MHITM12	FOCAL NEUROLOGICAL SYMPTOMS	integer	PRESABSB	CRF Page 11	
QSTESTCD	MHITM13	FOCAL NEUROLOGICAL SIGNS	integer	PRESABSB	CRF Page 11	
QSTESTCD	MMITM01	WHAT IS THE (YEAR) (SEASON) (DATE) ?	integer	SCORE5V	CRF Page 10	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	MMITM02	WHERE ARE WE: (STATE) (COUNTRY) (TOWN) ?	integer	SCORE5V	CRF Page 10	
QSTESTCD	MMITM03	NAME 3 OBJECTS: 1 SECOND TO SAY EACH.	integer	SCORE3V	CRF Page 10	
QSTESTCD	MMITM04	SERIAL 7'S. 1 POINT FOR EACH CORRECT.	integer	SCORE5V	CRF Page 10	
QSTESTCD	MMITM05	ASK FOR THE 3 OBJECTS REPEATED ABOVE.	integer	SCORE3V	CRF Page 10	
QSTESTCD	MMITM06	NAME A PENCIL, AND WATCH (2 POINTS)	integer	SCORE9V	CRF Page 10	
QSTESTCD	NPITM01	DELUSIONS PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM01D	DELUSIONS DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM01F	DELUSIONS FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM01S	DELUSIONS Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM01V	DELUSIONS SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM02	HALLUCINATIONS PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM02D	HALLUCINATIONS DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM02F	HALLUCINATIONS FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM02S	HALLUCINATIONS Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM02V	HALLUCINATIONS SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM03	AGITATION/AGRESSION PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM03D	AGITATION/AGRESSION DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM03F	AGITATION/AGRESSION FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM03S	AGITATION/AGRESSION Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM03V	AGITATION/AGRESSION SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM04	DEPRESSION/DYSPHORIA PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM04D	DEPRESSION/DYSPHORIA DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM04F	DEPRESSION/DYSPHORIA FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM04S	DEPRESSION/DYSPHORIA Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM04V	DEPRESSION/DYSPHORIA SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM05	ANXIETY PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM05D	ANXIETY DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM05F	ANXIETY FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM05S	ANXIETY Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM05V	ANXIETY SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM06	EUPHORIA/ELATION PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM06D	EUPHORIA/ELATION DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM06F	EUPHORIA/ELATION FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM06S	EUPHORIA/ELATION Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM06V	EUPHORIA/ELATION SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM07	APATHY/INDIFFERENCE PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM07D	APATHY/INDIFFERENCE DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM07F	APATHY/INDIFFERENCE FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM07S	APATHY/INDIFFEREN CE Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM07V	APATHY/INDIFFEREN CE SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM08	DISINHIBITION PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM08D	DISINHIBITION DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM08F	DISINHIBITION FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM08S	DISINHIBITION Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM08V	DISINHIBITION SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM09	IRRITABILITY/LABILITY PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM09D	IRRITABILITY/LABILITY DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM09F	IRRITABILITY/LABILITY FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM09S	IRRITABILITY/LABILITY Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM09V	IRRITABILITY/LABILITY SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM10	ABERRANT MOTOR BEHAVIOR PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM10D	ABERRANT MOTOR BEHAVIOR DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM10F	ABERRANT MOTOR BEHAVIOR FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM10S	ABERRANT MOTOR BEHAVIOR Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM10V	ABERRANT MOTOR BEHAVIOR SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM11	NIGHT-TIME BEHAVIOR PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM11D	NIGHT-TIME BEHAVIOR DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM11F	NIGHT-TIME BEHAVIOR FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM11S	NIGHT-TIME BEHAVIOR Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM11V	NIGHT-TIME BEHAVIOR SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM12	APPETITE/EATING CHANGE PRESENT	integer	PRESSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM12D	APPETITE/EATING CHANGE DISTRESS	integer	DISTSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	

Questionnaires (QS.QSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QSTESTCD	NPITM12F	APPETITE/EATING CHANGE FREQUENCY	integer	FREQSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM12S	APPETITE/EATING CHANGE Score	integer		CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPITM12V	APPETITE/EATING CHANGE SEVERITY	integer	SEVSC	CRF Pages 27, 38, 44, 54, 61, 69, 76, 84, 89, 93, 101, 111, 132	
QSTESTCD	NPTOT	NPI-X (9) Total Score	integer		Derived	see SAP

Subject Characteristics (SC.SCTESTCD) Value List

Subject Characteristics (SC.SCTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
SCTESTCD	EDLEVEL	EDUCATION LEVEL	integer		CRF Page 8	

Vital Signs (VS.VSTESTCD) Value List

Vital Signs (VS.VSTESTCD) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
VSTESTCD	DIABP	Diastolic Blood Pressure	float		CRF Pages 10, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	
VSTESTCD	HEIGHT	Height	float		CRF Page 16	
VSTESTCD	PULSE	Pulse Rate	float		CRF Pages 10, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	
VSTESTCD	SYSBP	Systolic Blood Pressure	float		CRF Pages 10, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	
VSTESTCD	TEMP	Temperature	float		CRF Pages 10, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135	
VSTESTCD	WEIGHT	Weight	float		CRF Pages 16, 30, 39, 45, 55, 64, 70, 79, 85, 96, 102, 135	

Supplemental Qualifiers for AE (SUPPAE.QNAM) Value List

Supplemental Qualifiers for AE (SUPPAE.QNAM) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QNAE	AETRTEM	TREATMENT EMERGENT FLAG	text	YN	Derived	see SAP

Supplemental Qualifiers for DM (SUPPDM.QNAM) Value List

Supplemental Qualifiers for DM (SUPPDM.QNAM) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QNAE	COMPLT16	Completers of Week 16 Population Flag	text	Y BLANK	Derived	see SAP
QNAE	COMPLT24	Completers of Week 24 Population Flag	text	Y BLANK	Derived	see SAP
QNAE	COMPLT8	Completers of Week 8 Population Flag	text	Y BLANK	Derived	see SAP
QNAE	EFFICACY	Efficacy Population Flag	text	Y BLANK	Derived	see SAP
QNAE	SAFETY	Safety Population Flag	text	Y BLANK	Derived	see SAP
QNAE	ITT	Intent to Treat Population Flag	text	Y BLANK	Derived	see SAP

Supplemental Qualifiers for DS (SUPPDS.QNAM) Value List

Supplemental Qualifiers for DS (SUPPDS.QNAM) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QNAM	ENTCRIT	PROTOCOL ENTRY CRITERIA NOT MET	integer		CRF Page 106	

Supplemental Qualifiers for LB (SUPPLB.QNAM) Value List

Supplemental Qualifiers for LB (SUPPLB.QNAM) Value List						
Variable	Value	Label	Type	Controlled Terminology	Origin	Comment
QNAM	ENDPOINT	ENDPOINT VALUE FLAG	text	Y BLANK	Derived	see SAP
QNAM	LBTMSHI	LAB RESULT/UPPER LIMIT OF NORMAL	float		Derived	LBSTRESN / LBSTNRHI

Computation Methods

Computational Method	
Reference Name	Computational Method
COMPMETHOD.QSAD_QSSTRESN	Total scores of "ALZHEIMER'S DISEASE ASSESSMENT SCALE" and "NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)" were derived as described in the SAP. For all other Test codes: LBSTRESN= LBSTRESC converted to numeric
COMPMETHOD.STUDY_DAY	(date portion of --DTC) minus (date portion of RFSTDTC) , add 1 if -- DTC >= RFSTDTC

Controlled Terminology

CodeLists

Reference Name	Code Value	Code Text
AECAUS	NONE	NONE
	POSSIBLE	POSSIBLE
	PROBABLE	PROBABLE
	REMOTE	REMOTE
AGESPAN	CHILDREN (2-11 YEARS)	CHILDREN (2-11 YEARS)
	ADOLESCENT (12-17 YEARS)	ADOLESCENT (12-17 YEARS)
	ADULT (18-65)	ADULT (18-65)
	ELDERLY (> 65)	ELDERLY (> 65)
AGEU	YEARS	YEARS
ARM	Screen Failure	Screen Failure
	Placebo	Placebo
	Xanomeline Low Dose	Xanomeline Low Dose
	Xanomeline High Dose	Xanomeline High Dose
ARMCD	Scrnfail	Screen Failure
	Pbo	Placebo

Reference Name	Code Value	Code Text
	Xan_Lo	Xanomeline Low Dose
	Xan_Hi	Xanomeline High Dose
CIBIC	1	Marked improvement
	2	Moderate improvement
	3	Minimal improvement
	4	No Change
	5	Minimal worsening
	6	Moderate worsening
	7	Marked worsening
CMFREQ	BID	BID
	EVERY MORNING	EVERY MORNING
	EVERY NIGHT	EVERY NIGHT
	ONCE	ONCE
	OTHER	OTHER
	PRN	PRN
	Q3H	Q3H
	Q4H	Q4H
	Q6H	Q6H
	Q4S	Q4S
	QD	QD

Reference Name	Code Value	Code Text
	QID	QID
	QM	QM
	QOD	QOD
	QS	QS
	TID	TID
	TIS	TIS
	TWICE	TWICE
CMROUTE	AURICULAR (OTIC)	AURICULAR (OTIC)
	INTRAMUSCULAR	INTRAMUSCULAR
	INTRAVENOUS	INTRAVENOUS
	NASAL	NASAL
	OPHTHALMIC	OPHTHALMIC
	ORAL	ORAL
	RESPIRATORY (INHALATION)	RESPIRATORY (INHALATION)
	RECTAL	RECTAL
	SUBCUTANEOUS	SUBCUTANEOUS
	SUBLINGUAL	SUBLINGUAL
	TOPICAL	TOPICAL
	TRANSDERMAL	TRANSDERMAL
	VAGINAL	VAGINAL

Reference Name	Code Value	Code Text
COLOR	N	Normal
	A	Abnormal
COUNTRY	USA	USA
DISCCD	COMPLETED	COMPLETED
	ADVERSE EVENT	ADVERSE EVENT
	DEATH	DEATH
	LACK OF EFFICACY	LACK OF EFFICACY
	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
	SCREEN FAILURE	SCREEN FAILURE
	STUDY TERMINATED BY SPONSOR	STUDY TERMINATED BY SPONSOR
	PHYSICIAN DECISION	PHYSICIAN DECISION
	PROTOCOL VIOLATION	PROTOCOL VIOLATION
	FINAL LAB VISIT	FINAL LAB VISIT
	FINAL RETRIEVAL VISIT	FINAL RETRIEVAL VISIT
DISTSC	0	0
	1	1
	2	2
	3	3

Reference Name	Code Value	Code Text
	4	4
	5	5
DSCAT	DISPOSITION EVENT	DISPOSITION EVENT
	OTHER EVENT	OTHER EVENT
ELEMENT	Screen	Screen
	Placebo	Placebo
	Low	Low
	High_Start	High_Start
	High_Middle	High_Middle
	High_End	High_End
	Follow_up	Follow_up
EPOCH	Screening	Screening
	Treatment	Treatment
ETCD	SCRN	Screen
	PBO	Placebo
	LO	Low
	HIS	High_Start
	HIM	High_Middle

Reference Name	Code Value	Code Text
	HIE	High_End
	FOLO	Follow_up
	UNPLAN	Unplanned
ETHNIC	NOT HISPANIC OR LATINO	NOT HISPANIC OR LATINO
	HISPANIC OR LATINO	HISPANIC OR LATINO
EXDOSEU	mg	mg
EXDOSFRM	PATCH	PATCH
EXFREQ	QD	QD
EXROUTE	TRANSDERMAL	TRANSDERMAL
EXTRT	PLACEBO	PLACEBO
	XANOMELINE	XANOMELINE
FREQSC	1	1
	2	2
	3	3

Reference Name	Code Value	Code Text
	4	4
IECAT	INCLUSION	INCLUSION
	EXCLUSION	EXCLUSION
IETEST	Males and postmenopausal females at least 50 years of age.	Males and postmenopausal females at least 50 years of age.
	Diagnosis of probable AD as defined by NINCDS and the ADRDA guidelines (Protocol Attachment LZZT.7).	Diagnosis of probable AD as defined by NINCDS and the ADRDA guidelines (Protocol Attachment LZZT.7).
	MMSE score of 10 to 23.	MMSE score of 10 to 23.
	Modified Hachinski Ischemic Scale score of <= 4. (Protocol Attachment LZZT.8).	Modified Hachinski Ischemic Scale score of <= 4. (Protocol Attachment LZZT.8).
	CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year.	CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year.
	Investigator has obtained informed consent signed by the patient (and/or legal representative) and by the caregiver.	Investigator has obtained informed consent signed by the patient (and/or legal representative) and by the caregiver.
	Geographic proximity to investigator's site that allows adequate follow-up.	Geographic proximity to investigator's site that allows adequate follow-up.
	Caregiver will monitor administration of prescribed medications, and will be responsible for the overall care of the patient at home.	Caregiver will monitor administration of prescribed medications, and will be responsible for the overall care of the patient at home.

Reference Name	Code Value	Code Text
	Persons who have previously completed or withdrawn from this study or any other investigating xanomeline TTS or the oral formulation of xanomeline.	Persons who have previously completed or withdrawn from this study or any other investigating xanomeline TTS or the oral formulation of xanomeline.
	Use of any investigational agent or approved Alzheimer's therapeutic medication within 30 days prior to enrollment into the study.	Use of any investigational agent or approved Alzheimer's therapeutic medication within 30 days prior to enrollment into the study.
	Serious illness which required hospitalization within 3 months of screening.	Serious illness which required hospitalization within 3 months of screening.
	Diagnosis of serious neurological conditions.	Diagnosis of serious neurological conditions.
	Episode of depression meeting DSM-IV criteria within 3 months of screening.	Episode of depression meeting DSM-IV criteria within 3 months of screening.
	A history of mental illness within the last 5 years.	A history of mental illness within the last 5 years.
	A history of syncope within the last 5 years.	A history of syncope within the last 5 years.
	Evidence from ECG recording at screening of any listed condition.	Evidence from ECG recording at screening of any listed condition.
	A history within the last 5 years of a serious cardiovascular disorder.	A history within the last 5 years of a serious cardiovascular disorder.
	A history within the last 5 years of a serious gastrointestinal disorder.	A history within the last 5 years of a serious gastrointestinal disorder.
	A history within the last 5 years of a serious endocrine disorder.	A history within the last 5 years of a serious endocrine disorder.
	A history within the last 5 years of a serious respiratory disorder (see list).	A history within the last 5 years of a serious respiratory disorder (see list).
	A history within the last 5 years of a serious genitourinary disorder.	A history within the last 5 years of a serious genitourinary disorder.

Reference Name	Code Value	Code Text
	A history within the last 5 years of a serious rheumatologic disorder.	A history within the last 5 years of a serious rheumatologic disorder.
	A known history of human immunodeficiency virus (HIV) within the last 5 years.	A known history of human immunodeficiency virus (HIV) within the last 5 years.
	A history within the last 5 years of a serious infectious disease (see list in protocol).	A history within the last 5 years of a serious infectious disease (see list in protocol).
	A history within the last 5 years of a primary or recurrent malignant disease (with exceptions, see list in protocol).	A history within the last 5 years of a primary or recurrent malignant disease (with exceptions, see list in protocol).
	Visual, hearing, or communication disabilities impairing the ability to participate in the study; (for example, inability to speak or understand English, illiteracy).	Visual, hearing, or communication disabilities impairing the ability to participate in the study; (for example, inability to speak or understand English, illiteracy).
	Laboratory test values exceeding the Lilly Reference Range III for the patient's age in any of the following analytes: creatinine, total bilirubin, SGOT, SGPT, etc.	Laboratory test values exceeding the Lilly Reference Range III for the patient's age in any of the following analytes: creatinine, total bilirubin, SGOT, SGPT, etc.
	Central laboratory test values below reference range for folate, and vitamin B12, and outside reference range for thyroid function tests.	Central laboratory test values below reference range for folate, and vitamin B12, and outside reference range for thyroid function tests.
	Positive syphilis screening with confirmatory testing.	Positive syphilis screening with confirmatory testing.
	Central laboratory test value above reference range for glycosylated hemoglobin (A1C) (insulin dependent diabetes mellitus patients only).	Central laboratory test value above reference range for glycosylated hemoglobin (A1C) (insulin dependent diabetes mellitus patients only).
	Treatment with medications within 1 month prior to enrollment (see list).	Treatment with medications within 1 month prior to enrollment (see list).

Reference Name	Code Value	Code Text
IETESTCD	INCL01	Males and postmenopausal females at least 50 years of age.
	INCL02	Diagnosis of probable AD as defined by NINCDS and the ADRDA guidelines (Protocol Attachment LZZT.7).
	INCL03	MMSE score of 10 to 23.
	INCL04	Modified Hachinski Ischemic Scale score of ≤ 4 . (Protocol Attachment LZZT.8).
	INCL05	CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year.
	INCL06	Investigator has obtained informed consent signed by the patient (and/or legal representative) and by the caregiver.
	INCL07	Geographic proximity to investigator's site that allows adequate follow-up.
	INCL08	Caregiver will monitor administration of prescribed medications, and will be responsible for the overall care of the patient at home.
	EXCL09	Persons who have previously completed or withdrawn from this study or any other investigating xanomeline TTS or the oral formulation of xanomeline.
	EXCL10	Use of any investigational agent or approved Alzheimer's therapeutic medication within 30 days prior to enrollment into the study.
	EXCL11	Serious illness which required hospitalization within 3 months of screening.

Reference Name	Code Value	Code Text
	EXCL12	Diagnosis of serious neurological conditions.
	EXCL13	Episode of depression meeting DSM-IV criteria within 3 months of screening.
	EXCL14	A history of mental illness within the last 5 years.
	EXCL15	A history of syncope within the last 5 years.
	EXCL16	Evidence from ECG recording at screening of any listed condition.
	EXCL17	A history within the last 5 years of a serious cardiovascular disorder.
	EXCL18	A history within the last 5 years of a serious gastrointestinal disorder.
	EXCL19	A history within the last 5 years of a serious endocrine disorder.
	EXCL20	A history within the last 5 years of a serious respiratory disorder (see list).
	EXCL21	A history within the last 5 years of a serious genitourinary disorder.
	EXCL22	A history within the last 5 years of a serious rheumatologic disorder.
	EXCL23	A known history of human immunodeficiency virus (HIV) within the last 5 years.
	EXCL24	A history within the last 5 years of a serious infectious disease (see list in protocol).
	EXCL25	A history within the last 5 years of a primary or recurrent malignant disease (with exceptions, see list in protocol).

Reference Name	Code Value	Code Text
	EXCL26	Visual, hearing, or communication disabilities impairing the ability to participate in the study; (for example, inability to speak or understand English, illiteracy).
	EXCL27	Laboratory test values exceeding the Lilly Reference Range III for the patient's age in any of the following analytes: creatinine, total bilirubin, SGOT, SGPT, etc.
	EXCL28	Central laboratory test values below reference range for folate, and vitamin B12, and outside reference range for thyroid function tests.
	EXCL29	Positive syphilis screening with confirmatory testing.
	EXCL30	Central laboratory test value above reference range for glycosylated hemoglobin (A1C) (insulin dependent diabetes mellitus patients only).
	EXCL31	Treatment with medications within 1 month prior to enrollment (see list).
LBCAT	CHEMISTRY	CHEMISTRY
	HEMATOLOGY	HEMATOLOGY
	OTHER	OTHER
	URINALYSIS	URINALYSIS
LBNRIND	LOW	LOW
	NORMAL	NORMAL
	HIGH	HIGH

Reference Name	Code Value	Code Text
	ABNORMAL	ABNORMAL
LBUNIT	1	1
	GI/L	GI/L
	TI/L	TI/L
	U/L	U/L
	fL	fL
	fmol(Fe)	fmol(Fe)
	g/L	g/L
	mU/L	mU/L
	mmol/L	mmol/L
	pmol/L	pmol/L
	umol/L	umol/L
MHCAT	HISTORICAL DIAGNOSIS	HISTORICAL DIAGNOSIS
	PRIMARY DIAGNOSIS	PRIMARY DIAGNOSIS
	SIGNIFICANT PRE-EXISTING CONDITION	SIGNIFICANT PRE-EXISTING CONDITION
ND	NOT DONE	NOT DONE
NYNAN	0	NO
	1	YES

Reference Name	Code Value	Code Text
	96	NOT APPLICABLE
OUT	RECOVERED/RESOLVED	RECOVERED/RESOLVED
	NOT RECOVERED/NOT RESOLVED	NOT RECOVERED/NOT RESOLVED
	FATAL	FATAL
PRESABSA	0	ABSENT
	1	PRESENT
PRESABSB	0	ABSENT
	2	PRESENT
PRESSC	0	ABSENT
	96	NOT APPLICABLE
QEVAL	CLINICAL STUDY SPONSOR	CLINICAL STUDY SPONSOR
QSCAT	ALZHEIMER'S DISEASE ASSESSMENT SCALE	ALZHEIMER'S DISEASE ASSESSMENT SCALE
	CLINICIAN'S INTERVIEW-BASED IMPRESSION OF CHANGE (CIBIC+)	CLINICIAN'S INTERVIEW-BASED IMPRESSION OF CHANGE (CIBIC+)
	DISABILITY ASSESSMENT FOR DEMENTIA (DAD)	DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

Reference Name	Code Value	Code Text
	MINI-MENTAL STATE	MINI-MENTAL STATE
	MODIFIED HACHINSKI ISCHEMIC SCORE	MODIFIED HACHINSKI ISCHEMIC SCORE
	NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)	NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)
QSUNIT	sec	sec
RACE	WHITE	WHITE
	BLACK OR AFRICAN AMERICAN	BLACK OR AFRICAN AMERICAN
	AMERICAN INDIAN OR ALASKA NATIVE	AMERICAN INDIAN OR ALASKA NATIVE
	ASIAN	ASIAN
ROLES	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

Reference Name	Code Value	Code Text
	VARIABLE QUALIFIER	VARIABLE QUALIFIER
SCCAT	EDUCATION	EDUCATION
SCORE3V	1	1
	2	2
	3	3
SCORE5V	1	1
	2	2
	3	3
	4	4
	5	5
SCORE9V	1	1
	2	2
	3	3
	4	4
	5	5
	6	6
	7	7
	8	8

Reference Name	Code Value	Code Text
	9	9
SCUNIT	YEARS	YEARS
SEV	MILD	MILD
	MODERATE	MODERATE
	SEVERE	SEVERE
SEVSC	1	1
	2	2
	3	3
SEX	F	Female
	M	Male
	U	Unknown
SEXPOP	BOTH	Both
	F	Female
	M	Male
TBLIND	DOUBLE BLIND	Double Blind Study
	OPEN LABEL	Open Label Study

Reference Name	Code Value	Code Text
	SINGLE BLIND	Single Blind Study
TCNTRL	ACTIVE	ACTIVE
	NONE	NONE
	PLACEBO	PLACEBO
TINDTP	CURE	Cure Study
	DIAGNOSIS	Diagnosis Study
	MITIGATION	Adverse Effect Mitigation Study
	PREVENTION	Prevention Study
	TREATMENT	Treatment Study
TPHASE	Phase I Trial	Phase I Trial
	Phase I/II Trial	Phase I/II Trial
	Phase II Trial	Phase II Trial
	Phase II/III Trial	Phase II/III Trial
	Phase IIa Trial	Phase IIa Trial
	Phase IIb Trial	Phase IIb Trial
	Phase III Trial	Phase III Trial
	Phase IIIa Trial	Phase IIIa Trial
	Phase IIIb Trial	Phase IIIb Trial
	Phase IV Trial	Phase IV Trial

Reference Name	Code Value	Code Text
	Phase V Trial	Phase V Trial
	NA	NA
TTYTYPE	BIO-AVAILABILITY	Bioavailability Study
	BIO-EQUIVALENCE	Therapeutic Equivalency Study
	EFFICACY	Efficacy Study
	PHARMACODYNAMIC	Pharmacodynamic Study
	PHARMACOECONOMIC	Pharmacoeconomic Study
	PHARMACOGENOMIC	Pharmacogenomic Study
	PHARMACOKINETIC	Pharmacokinetic Study
	SAFETY	Safety Study
VISIT	SCREENING 1	SCREENING 1
	UNSCHEDULED 1.1	UNSCHEDULED 1.1
	UNSCHEDULED 1.2	UNSCHEDULED 1.2
	UNSCHEDULED 1.3	UNSCHEDULED 1.3
	SCREENING 2	SCREENING 2
	BASELINE	BASELINE
	UNSCHEDULED 3.1	UNSCHEDULED 3.1
	AMBUL ECG PLACEMENT	AMBUL ECG PLACEMENT
	WEEK 2	WEEK 2
	UNSCHEDULED 4.1	UNSCHEDULED 4.1

Reference Name	Code Value	Code Text
	UNSCHEDULED 4.2	UNSCHEDULED 4.2
	WEEK 4	WEEK 4
	UNSCHEDULED 5.1	UNSCHEDULED 5.1
	AMBUL ECG REMOVAL	AMBUL ECG REMOVAL
	UNSCHEDULED 6.1	UNSCHEDULED 6.1
	WEEK 6	WEEK 6
	UNSCHEDULED 7.1	UNSCHEDULED 7.1
	WEEK 8	WEEK 8
	WEEK 10 (T)	WEEK 10 (T)
	UNSCHEDULED 8.2	UNSCHEDULED 8.2
	WEEK 12	WEEK 12
	WEEK 14 (T)	WEEK 14 (T)
	UNSCHEDULED 9.2	UNSCHEDULED 9.2
	UNSCHEDULED 9.3	UNSCHEDULED 9.3
	WEEK 16	WEEK 16
	WEEK 18 (T)	WEEK 18 (T)
	UNSCHEDULED 10.2	UNSCHEDULED 10.2
	WEEK 20	WEEK 20
	WEEK 22 (T)	WEEK 22 (T)
	UNSCHEDULED 11.2	UNSCHEDULED 11.2
	WEEK 24	WEEK 24
	UNSCHEDULED 12.1	UNSCHEDULED 12.1

Reference Name	Code Value	Code Text
	WEEK 26	WEEK 26
	UNSCHEDULED 13.1	UNSCHEDULED 13.1
	AE FOLLOW-UP	AE FOLLOW-UP
	RETRIEVAL	RETRIEVAL
	Rash followup	Rash followup
VISITNUM	1	SCREENING 1
	1.1	UNSCHEDULED 1.1
	1.2	UNSCHEDULED 1.2
	1.3	UNSCHEDULED 1.3
	2	SCREENING 2
	3	BASELINE
	3.1	UNSCHEDULED 3.1
	3.5	AMBUL ECG PLACEMENT
	4	WEEK 2
	4.1	UNSCHEDULED 4.1
	4.2	UNSCHEDULED 4.2
	5	WEEK 4
	5.1	UNSCHEDULED 5.1
	6	AMBUL ECG REMOVAL
	6.1	UNSCHEDULED 6.1
	7	WEEK 6

Reference Name	Code Value	Code Text
	7.1	UNSCHEDULED 7.1
	8	WEEK 8
	8.1	WEEK 10 (T)
	8.2	UNSCHEDULED 8.2
	9	WEEK 12
	9.1	WEEK 14 (T)
	9.2	UNSCHEDULED 9.2
	9.3	UNSCHEDULED 9.3
	10	WEEK 16
	10.1	WEEK 18 (T)
	10.2	UNSCHEDULED 10.2
	11	WEEK 20
	11.1	WEEK 22 (T)
	11.2	UNSCHEDULED 11.2
	12	WEEK 24
	12.1	UNSCHEDULED 12.1
	13	WEEK 26
	13.1	UNSCHEDULED 13.1
	101	AE FOLLOW-UP
	201	RETRIEVAL
	501	Rash followup

Reference Name	Code Value	Code Text
VSLOC	ORAL CAVITY	ORAL CAVITY
	EAR	EAR
VSPOS	STANDING	STANDING
	SUPINE	SUPINE
VSTPT	AFTER LYING DOWN FOR 5 MINUTES	AFTER LYING DOWN FOR 5 MINUTES
	AFTER STANDING FOR 1 MINUTE	AFTER STANDING FOR 1 MINUTE
	AFTER STANDING FOR 3 MINUTES	AFTER STANDING FOR 3 MINUTES
VSTPTNUM	815	AFTER LYING DOWN FOR 5 MINUTES
	816	AFTER STANDING FOR 1 MINUTE
	817	AFTER STANDING FOR 3 MINUTES
VSTPTREF	PATIENT STANDING	PATIENT STANDING
	PATIENT SUPINE	PATIENT SUPINE
VSUNIT	C	C
	F	F
	BEATS/MIN	BEATS/MIN
	cm	cm
	IN	IN

Reference Name	Code Value	Code Text
	LB	LB
	kg	kg
	mmHg	mmHg
YN	N	No
	Y	Yes
Y_BLANK	Y	Yes

External Dictionaries

Reference Name	Dictionary	Version
AEDICT	MEDDRA	8.0
DRUGDICT	WHODRUG	200604
MHDICT	MEDDRA	8.0