

<b>Standard</b>	SDTM-IG 3.2
<b>Study Name</b>	Test Trial
<b>Study Description</b>	Selection of SDTM domains
<b>Protocol Name</b>	Test
<b>Metadata Name</b>	Study Test, Data Definitions
<b>Metadata Description</b>	Study Test, Data Definitions

### Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, DOMAIN, USUBJID		dm.xpt ( <a href="#">dm.xpt</a> )
CM	Concomitant Medications	INTERVENTIONS	One record per recorded intervention occurrence or constant-dosing interval per subject	Tabulation	STUDYID, DOMAIN, USUBJID, CMSEQ		cm.xpt ( <a href="#">cm.xpt</a> )
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, DOMAIN, USUBJID, AESEQ, AEGRPID, AESPID		ae.xpt ( <a href="#">ae.xpt</a> )
DD	Death Details	FINDINGS	One record per finding per subject	Tabulation	STUDYID, DOMAIN, USUBJID, DDSEQ		dd.xpt ( <a href="#">dd.xpt</a> )
EG	ECG	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, DOMAIN, USUBJID, EGSEQ		eg.xpt ( <a href="#">eg.xpt</a> )
QS	Questionnaires	FINDINGS	One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID, DOMAIN, USUBJID, QSSEQ		qs.xpt ( <a href="#">qs.xpt</a> )
SUPPCM	Supplemental Qualifiers CM	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM		suppcm.xpt ( <a href="#">suppcm.xpt</a> )
SUPPEG	Supplemental Qualifiers EG	RELATIONSHIP	One record per IDVAR,	Tabulation	STUDYID, RDOMAIN,		suppeg.xpt ( <a href="#">suppeg.xpt</a> )

			IDVARVAL, and QNAM value per subject		USUBJID, IDVAR, IDVARVAL, QNAM		
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**DM (Demographics) - SPECIAL PURPOSE**

Location: dm.xpt\_(dm.xpt)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] eDT
SUBJID	Subject Identifier for the Study	text	Topic	200		[Origin] eDT
RFSTDTC	Subject Reference Start Date/Time	datetime	Record Qualifier		ISO 8601	[Origin] Assigned
RFENDTC	Subject Reference End Date/Time	datetime	Record Qualifier		ISO 8601	[Origin] Assigned
RFXSTDTC	Date/Time of First Study Treatment	datetime	Record Qualifier		ISO 8601	[Origin] Derived First exposure to IMP
RFXENDTC	Date/Time of Last Study Treatment	datetime	Record Qualifier		ISO 8601	[Origin] Derived Last exposure to IMP
RFICDTC	Date/Time of Informed Consent	datetime	Record Qualifier		ISO 8601	[Origin] Assigned
RFPENDTC	Date/Time of End of Participation	datetime	Record Qualifier		ISO 8601	[Origin] Assigned
DTHDTC	Date/Time of Death	datetime	Record Qualifier		ISO 8601	[Origin] CRF acrf [DTHDTC (acrf.pdf#DTHDTC).]
DTHFL	Subject Death Flag	text	Record Qualifier	200	No Yes Response	[Origin] Derived DTHDTC not NULL <sup>Formal</sup> Expression
SITEID	Study Site Identifier	text	Record Qualifier	200		[Origin] eDT
BRTHDTC	Date/Time of Birth	datetime	Record Qualifier		ISO 8601	[Origin] CRF acrf [BRTHDTC (acrf.pdf#BRTHDTC).]
AGE	Age	float	Record Qualifier	200		[Origin] Derived Date of informed consent minus date of birth plus one in days <sup>Formal</sup> Expression
AGEU	Age Units	text	Variable	200	Age Unit	[Origin] Protocol

			Qualifier			
SEX	Sex	text	Record Qualifier	200	Sex	[Origin] CRF acrf [SEX_(acrf.pdf#SEX)_]
RACE	Race	text	Record Qualifier	200	Race	[Origin] CRF acrf [RACE_(acrf.pdf#RACE)_]
ETHNIC	Ethnicity	text	Record Qualifier	200	Ethnic Group	[Origin] CRF acrf [ETHNIC_(acrf.pdf#ETHNIC)_]
ARMCD	Planned Arm Code	text	Record Qualifier	20		[Origin] Assigned
ARM	Description of Planned Arm	text	Synonym Qualifier	200		[Origin] Assigned
ACTARMCD	Actual Arm Code	text	Record Qualifier	20		[Origin] Assigned
ACTARM	Description of Actual Arm	text	Synonym Qualifier	200		[Origin] Assigned
COUNTRY	Country	text	Record Qualifier	200	Country	[Origin] Protocol

## CM (Concomitant Medications) - INTERVENTIONS

Location: cm.xpt\_(cm.xpt)

Related Supplemental Qualifiers Dataset: SUPPCM (Supplemental Qualifiers CM)						
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] Predecessor: Copy of DM.USUBJID
CMSEQ	Sequence Number	float	Identifier	200		[Origin] Derived Strict chronological order
CMTRT	Reported Name of Drug, Med, or Therapy	text	Topic	200		[Origin] CRF acrf [CMTRT_(acrf.pdf#CMTRT)_]
CMCAT	Category for Medication	text	Grouping Qualifier	200		[Origin] CRF acrf [CMCAT_(acrf.pdf#CMCAT)_]
CMSCAT	Subcategory for Medication	text	Grouping Qualifier	200		[Origin] CRF acrf [CMSCAT_(acrf.pdf#CMSCAT)_]
CMOCCUR	CM Occurrence	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [CMOCCUR_(acrf.pdf#CMOCCUR)_]
CMREASND	Reason Medication Not Collected	text	Record Qualifier	200		[Origin] CRF acrf [CMREASND_(acrf.pdf#CMREASND)_]

CMDOSE	Dose per Administration	float	Record Qualifier	200		[Origin] CRF acrf [CMDOSE (acrf.pdf#CMDOSE).]
CMDOSTXT	Dose Description	text	Record Qualifier	200		[Origin] CRF acrf [CMDOSTXT (acrf.pdf#CMDOSTXT).]
CMDOSU	Dose Units	text	Variable Qualifier	200	Unit	[Origin] CRF acrf [CMDOSU (acrf.pdf#CMDOSU).]
CMDOSFRQ	Dosing Frequency per Interval	text	Variable Qualifier	200	Frequency	[Origin] CRF acrf [CMDOSFRQ (acrf.pdf#CMDOSFRQ).]
CMROUTE	Route of Administration	text	Variable Qualifier	200	Route of Administration	[Origin] CRF acrf [CMROUTE (acrf.pdf#CMROUTE).]
CMSTDTC	Start Date/Time of Medication	datetime	Timing		ISO 8601	[Origin] CRF acrf [CMSTDTC (acrf.pdf#CMSTDTC).]
CMENDTC	End Date/Time of Medication	datetime	Timing		ISO 8601	[Origin] CRF acrf [CMENDTC (acrf.pdf#CMENDTC).]
CMENRTPT	End Relative to Reference Time Point	text	Timing	200	Relation to Reference Period	[Origin] CRF acrf [CMENRTPT (acrf.pdf#CMENRTPT).]

## AE (Adverse Events) - EVENTS

Location: ae.xpt\_(ae.xpt)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] Predecessor: Copy of DM.USUBJID
AESEQ	Sequence Number	float	Identifier	200		[Origin] Derived Strict chronological order
AEGRPID	Group ID	text	Identifier	200		[Origin] CRF acrf [AEGRPID (acrf.pdf#AEGRPID).]
AESPID	Sponsor-Defined Identifier	text	Identifier	200		[Origin] CRF acrf [AESPID (acrf.pdf#AESPID).]
AETERM	Reported Term for the Adverse Event	text	Topic	200		[Origin] CRF acrf [AETERM (acrf.pdf#AETERM).]

AELLT	Lowest Level Term	text	Variable Qualifier	200	Medical Dictionary for Regulatory Activities MedDRA 24.1	[Origin] Derived Coded from AETERM
AELLTCD	Lowest Level Term Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 24.1	[Origin] Derived Coded from AETERM
AEDECOD	Dictionary-Derived Term	text	Synonym Qualifier	200	Medical Dictionary for Regulatory Activities MedDRA 24.1	[Origin] Derived Coded from AETERM
AEPTCD	Preferred Term Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 24.1	[Origin] Derived Coded from AETERM
AEHLT	High Level Term	text	Variable Qualifier	200	Medical Dictionary for Regulatory Activities MedDRA 24.1	[Origin] Derived Coded from AETERM
AEHLTCD	High Level Term Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 24.1	[Origin] Derived Coded from AETERM
AEHLGT	High Level Group Term	text	Variable Qualifier	200	Medical Dictionary for Regulatory Activities MedDRA 24.1	[Origin] Derived Coded from AETERM
AEHLGTCD	High Level Group Term Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 24.1	[Origin] Derived Coded from AETERM
AEBODSYS	Body System or Organ Class	text	Record Qualifier	200		[Origin] Derived Coded from AETERM
AEBDSYCD	Body System or Organ Class Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 24.1	[Origin] Derived Coded from AETERM
AESOC	Primary System Organ Class	text	Variable Qualifier	200	Medical Dictionary for Regulatory Activities MedDRA 24.1	[Origin] Derived Coded from AETERM
AESOCCD	Primary System Organ Class Code	integer	Variable Qualifier	8	Medical Dictionary for Regulatory Activities - Code MedDRA 24.1	[Origin] Derived Coded from AETERM
AESER	Serious Event	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESER (acrf.pdf#AESER).]
AEACN	Action Taken with Study Treatment	text	Record Qualifier	200	Action Taken with Study Treatment	[Origin] CRF acrf [AEACN (acrf.pdf#AEACN).]
AEREL	Causality	text	Record Qualifier	200		[Origin] CRF acrf [AEREL (acrf.pdf#AEREL).]
AERELNST	Relationship to Non-Study Treatment	text	Record Qualifier	200		[Origin] CRF

						acrf [AERELNST (acrf.pdf#AERELNST). ]
AEOUT	Outcome of Adverse Event	text	Record Qualifier	200	Outcome of Event	[Origin] CRF acrf [AEOUT (acrf.pdf#AEOUT). ]
AESCONG	Congenital Anomaly or Birth Defect	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESCONG (acrf.pdf#AESCONG). ]
AESDISAB	Persist or Signif Disability/Incapacity	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESDISAB (acrf.pdf#AESDISAB). ]
AESDTH	Results in Death	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESDTH (acrf.pdf#AESDTH). ]
AESHOSP	Requires or Prolongs Hospitalization	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESHOSP (acrf.pdf#AESHOSP). ]
AESLIFE	Is Life Threatening	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESLIFE (acrf.pdf#AESLIFE). ]
AESOD	Occurred with Overdose	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESOD (acrf.pdf#AESOD). ]
AESMIE	Other Medically Important Serious Event	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AESMIE (acrf.pdf#AESMIE). ]
AECONTRT	Concomitant or Additional Trtmnt Given	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf [AECONTRT (acrf.pdf#AECONTRT). ]
AETOXGR	Standard Toxicity Grade	text	Record Qualifier	200	Common Terminology Criteria for Adverse Events V3.0	[Origin] CRF acrf [AETOXGR (acrf.pdf#AETOXGR). ]
AESTDTC	Start Date/Time of Adverse Event	datetime	Timing		ISO 8601	[Origin] CRF acrf [AESTDTC (acrf.pdf#AESTDTC). ]
AEENDTC	End Date/Time of Adverse Event	datetime	Timing		ISO 8601	[Origin] CRF acrf [AEENDTC (acrf.pdf#AEENDTC). ]
AEENTPT	End Reference Time Point	text	Timing	200	Relation to Reference Period	[Origin] CRF acrf [AEENTPT (acrf.pdf#AEENTPT). ]

## DD (Death Details) - FINDINGS

Location: dd.xpt\_(dd.xpt).

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Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] Predecessor: Copy of DM.USUBJID
DDSEQ	Sequence Number	float	Identifier	200		[Origin] Derived Strict chronological order
DDTESTCD	Death Detail Assessment Short Name	text	Topic	8		[Origin] CRF acrf [DDTESTCD (acrf.pdf#DDTESTCD).] ]
DDTEST	Death Detail Assessment Name	text	Synonym Qualifier	40		[Origin] CRF acrf [DDTEST (acrf.pdf#DDTEST).] ]
DDORRES	Result or Finding as Collected	text	Result Qualifier	200		[Origin] CRF acrf [DDORRES (acrf.pdf#DDORRES).] ]
DDSTRESC	Character Result/Finding in Std Format	text	Result Qualifier	200		[Origin] Derived Coded value of -- ORRES
DDTTC	Date/Time of Collection	datetime	Timing		ISO 8601	[Origin] eDT

## EG (ECG) - FINDINGS

Location: eg.xpt\_(eg.xpt)

Related Supplemental Qualifiers Dataset: SUPPEG (Supplemental Qualifiers EG)						
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] Predecessor: Copy of DM.USUBJID
EGSEQ	Sequence Number	float	Identifier	200		[Origin] Derived Strict chronological order
EGTESTCD	ECG Test or Examination Short Name	text	Topic	8	ECG Test Code	[Origin] Protocol
EGTEST	ECG Test or Examination Name	text	Synonym Qualifier	40	ECG Test Name	[Origin] Protocol
EGORRES	Result or Finding in Original Units	text	Result Qualifier	200		[Origin] CRF acrf [EGORRES (acrf.pdf#EGORRES).] ]

EGSTRESC	Character Result/Finding in Std Format	text	Result Qualifier	200	ECG Result	[Origin] Derived Coded value of -- ORRES
EGBLFL	Baseline Flag	text	Record Qualifier	200	No Yes Response	[Origin] eDT
VISITNUM	Visit Number	float	Timing	200		[Origin] eDT
EGDTC	Date/Time of ECG	datetime	Timing		ISO 8601	[Origin] Predecessor: EG.EGSTDTC
EGSTDTC	Start Date/Time of Observation	datetime	Timing		ISO 8601	[Origin] CRF acrf [EGSTDTC (acrf.pdf#EGSTDTC).]

## QS (Questionnaires) - FINDINGS

Location: qs.xpt\_(qs.xpt).

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] Predecessor: Copy of DM.USUBJID
QSSEQ	Sequence Number	float	Identifier	200		[Origin] Derived Strict chronological order
QSTESTCD	Question Short Name	text	Topic	8		[Origin] CRF acrf [QSTESTCD (acrf.pdf#QSTESTCD).]
QSTEST	Question Name	text	Synonym Qualifier	40		[Origin] CRF acrf [QSTEST (acrf.pdf#QSTEST).]
QSCAT	Category of Question	text	Grouping Qualifier	200	Questionnaire Category	[Origin] Protocol
QSORRES	Finding in Original Units	text	Result Qualifier	200		[Origin] Protocol
QSSTRESC	Character Result/Finding in Std Format	text	Result Qualifier	200		[Origin] Derived Coded value of -- ORRES
QSLOC	Location Used for the Measurement	text	Record Qualifier	200	Anatomical Location	[Origin] CRF acrf [QSLOC (acrf.pdf#QSLOC).]
QSLAT	Laterality	text	Variable Qualifier	200	Laterality	[Origin] CRF acrf [QSLAT (acrf.pdf#QSLAT).]
QSDIR	Directionality	text	Variable Qualifier	200	Directionality	[Origin] CRF acrf [QSDIR (acrf.pdf#QSDIR).]
QSBFLFL	Baseline Flag	text	Record Qualifier	200	No Yes Response	[Origin] eDT





Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	200		[Origin] Protocol
RDOMAIN	Related Domain Abbreviation	text	Identifier	4	SDTM Domain Abbreviation	[Origin] Assigned
USUBJID	Unique Subject Identifier	text	Identifier	200		[Origin] Predecessor: Copy of DM.USUBJID
IDVAR	Identifying Variable	text	Identifier	200		[Origin] Assigned
IDVARVAL	Identifying Variable Value	text	Identifier	200		[Origin] Predecessor: EG.EGSEQ
QNAM	Qualifier Variable Name	text	Identifier	8		[Origin] CRF acrf [SUPPEG.QNAM (acrf.pdf#SUPPEG.QNAM).]
QLABEL	Qualifier Variable Label	text	Synonym Qualifier	40		[Origin] CRF acrf [SUPPEG.QLABEL (acrf.pdf#SUPPEG.QLABEL).]
QVAL <a href="#">VLM</a>	Data Value	text	Result Qualifier	200		[Origin] CRF acrf [SUPPEG.QVAL (acrf.pdf#SUPPEG.QVAL).]
► USUBJID ≠ ""	ECG clinically significant	text		20	No Yes Response	[Origin] CRF acrf [EGCLSIG (acrf.pdf#EGCLSIG).]
QORIG	Origin	text	Record Qualifier	200		[Origin] Assigned
QEVAL	Evaluator	text	Record Qualifier	200	Evaluator	[Origin] Assigned

## CodeLists

### SDTM Domain Abbreviation [CL.DOMAINS,C66734]

Permitted Value (Code)	Display Value (Decode)
AE [C49562]	Adverse Events
CM [C49568]	Concomitant Medications
DD [C95087]	Death Details
DM [C49572]	Demographics
EG [C49626]	ECG
QS [C49609]	Questionnaires

### No Yes Response [CL.C66742.NY,C66742]

Permitted Value (Code)	Display Value (Decode)
N [C49487]	N
Y [C49488]	Y

**Age Unit [CL.C66781.AGEU,C66781]**

Permitted Value (Code)	Display Value (Decode)
YEARS [C29848]	YEARS

**Sex [CL.C66731.SEX,C66731]**

Permitted Value (Code)	Display Value (Decode)
F [C16576]	F
M [C20197]	M
U [C17998]	U
UNDIFFERENTIATED [C45908]	UNDIFFERENTIATED

**Race [CL.C74457.RACE,C74457]**

Permitted Value (Code)	Display Value (Decode)
AMERICAN INDIAN OR ALASKA NATIVE [C41259]	AMERICAN INDIAN OR ALASKA NATIVE
ASIAN [C41260]	ASIAN
BLACK OR AFRICAN AMERICAN [C16352]	BLACK OR AFRICAN AMERICAN
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER [C41219]	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
WHITE [C41261]	WHITE
NOT REPORTED [C43234]	NOT REPORTED
UNKNOWN [C17998]	UNKNOWN

**Ethnic Group [CL.C66790.ETHNIC,C66790]**

Permitted Value (Code)	Display Value (Decode)
HISPANIC OR LATINO [C17459]	HISPANIC OR LATINO
NOT HISPANIC OR LATINO [C41222]	NOT HISPANIC OR LATINO
NOT REPORTED [C43234]	NOT REPORTED
UNKNOWN [C17998]	UNKNOWN

**Country [CL.C66786.COUNTRY,C66786]**

Permitted Value (Code)	Display Value (Decode)
DNK [C16496]	DNK

**Unit [CL.C71620.UNIT,C71620]**

Permitted Value (Code)	Display Value (Decode)
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ug [C48152]	ug
mg [C28253]	mg
g [C48155]	g
mL [C28254]	mL
APPLICATION [C25397]	APPLICATION
IU	International Unit
TABLET [C48542]	TABLET
CAPSULE [C48480]	CAPSULE
OTHER	Other

#### Frequency [CL.C71113.FREQ,C71113]

Permitted Value (Code)	Display Value (Decode)
BID [C64496]	BID
PRN [C64499]	PRN

#### Route of Administration [CL.C66729.ROUTE,C66729]

Permitted Value (Code)	Display Value (Decode)
ORAL [C38288]	ORAL
SUBCUTANEOUS [C38299]	SUBCUTANEOUS
TOPICAL [C38304]	TOPICAL
TRANSDERMAL [C38305]	TRANSDERMAL

#### Relation to Reference Period [CL.C66728.STENRF,C66728]

Permitted Value (Code)	Display Value (Decode)
AFTER [C38008]	AFTER
BEFORE [C25629]	BEFORE
COINCIDENT [C25456]	COINCIDENT
DURING [C25490]	DURING
DURING/AFTER [C49640]	DURING/AFTER
ONGOING [C53279]	ONGOING
UNKNOWN [C17998]	UNKNOWN

#### Anatomical Location [CL.C74456.LOC,C74456]

Permitted Value (Code)	Display Value (Decode)
FACE [C13071]	FACE
GENITALIA [C25177]	GENITALIA
HAND [C32712]	HAND
HEAD [C12419]	HEAD

LIMB, LOWER [C12742]	LIMB, LOWER
LIMB, UPPER [C12671]	LIMB, UPPER
SCALP [C89807]	SCALP
TRUNK [C33816]	TRUNK

#### Laterality [CL.C99073.LAT,C99073]

Permitted Value (Code)	Display Value (Decode)
LEFT [C25229]	LEFT
RIGHT [C25228]	RIGHT
NA	NOT APPLICABLE

#### Directionality [CL.C99074.DIR,C99074]

Permitted Value (Code)	Display Value (Decode)
ANTERIOR [C25231]	ANTERIOR
POSTERIOR [C25622]	POSTERIOR
NA	NOT APPLICABLE

#### Evaluator [CL.C78735.EVAL,C78735]

Permitted Value (Code)	Display Value (Decode)
INVESTIGATOR [C25936]	INVESTIGATOR

#### ECG Test Code [CL.C71153.EGTESTCD,C71153]

Permitted Value (Code)	Display Value (Decode)
INTP [C41255]	INTP

#### ECG Test Name [CL.C71152.EGTEST,C71152]

Permitted Value (Code)	Display Value (Decode)
Interpretation [C41255]	Interpretation

#### ECG Result [CL.C71150.EGSTRESC,C71150]

Permitted Value (Code)	Display Value (Decode)
INCOMPLETE ECG [C114167]	INCOMPLETE ECG
OTHER INCORRECT ELECTRODE PLACEMENT [C114176]	OTHER INCORRECT ELECTRODE PLACEMENT
PAUSE [C119250]	PAUSE

### Questionnaire Category

Permitted Value (Code)	Display Value (Decode)
BSPI	Body Sites of Psoriasis Involvement

### Discontinuation treatment

Permitted Value (Code)	Display Value (Decode)
INADEQUATE EFFICACY	Inadequate efficacy
ADVERSE EVENT	Adverse event
OTHER	Other

### Action Taken with Study Treatment [CL.C66767.ACN,C66767]

Permitted Value (Code)	Display Value (Decode)
DOSE NOT CHANGED [C49504]	DOSE NOT CHANGED
DOSE REDUCED [C49505]	DOSE REDUCED
DOSE INCREASED [C49503]	DOSE INCREASED
DRUG INTERRUPTED [C49501]	DRUG INTERRUPTED
DRUG WITHDRAWN [C49502]	DRUG WITHDRAWN
NOT APPLICABLE [C48660]	NOT APPLICABLE
UNKNOWN [C17998]	UNKNOWN

### Outcome of Event [CL.C66768.OUT,C66768]

Permitted Value (Code)	Display Value (Decode)
FATAL [C48275]	FATAL
NOT RECOVERED/NOT RESOLVED [C49494]	NOT RECOVERED/NOT RESOLVED
RECOVERED/RESOLVED [C49498]	RECOVERED/RESOLVED
RECOVERED/RESOLVED WITH SEQUELAE [C49495]	RECOVERED/RESOLVED WITH SEQUELAE
RECOVERING/RESOLVING [C49496]	RECOVERING/RESOLVING
UNKNOWN [C17998]	UNKNOWN

### Common Terminology Criteria for Adverse Events V3.0

Permitted Value (Code)	Display Value (Decode)
0	0
1	1

2	2
3	3
4	4
5	5

### External Dictionaries

Reference Name	External Dictionary	Dictionary Version
Medical Dictionary for Regulatory Activities	MedDRA	24.1
Medical Dictionary for Regulatory Activities - Code	MedDRA	24.1