

Standard	SDTM-IG 3.2
Study Name	Test Trial
Study Description	Selection of SDTM domains
Protocol Name	Test
Metadata Name	Study Test, Data Definitions
Metadata Description	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 (dm.xpt)
CM	Concomitant Medications	INTERVENTIONS	One record per recorded intervention occurrence or constant-dosing interval per subject	Tabulation	STUDYID, DOMAIN, USUBJID, CMSEQ		cm.xpt (cm.xpt)
AE	Adverse Events	EVENTS	One record per adverse event per subject	Tabulation	STUDYID, DOMAIN, USUBJID, AESEQ, AEGRPID, AESPID		ae.xpt (ae.xpt)
DD	Death Details	FINDINGS	One record per finding per subject	Tabulation	STUDYID, DOMAIN, USUBJID, DDSEQ		dd.xpt (dd.xpt)
EG	ECG	FINDINGS	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, DOMAIN, USUBJID, EGSEQ		eg.xpt (eg.xpt)
QS	Questionnaires	FINDINGS	One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID, DOMAIN, USUBJID, QSSEQ		qs.xpt (qs.xpt)
SUPPCM	Supplemental Qualifiers CM	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL,		suppcm.xpt (suppcm.xpt)

			subject		QNAM		
SUPPEG	Supplemental Qualifiers EG	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM		suppeg.xpt (<u>suppeg.xpt</u>)

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.pdf [DTHDTC (./#DTHDTC).]
DTHFL	Subject Death Flag	text	Record Qualifier	200	No Yes Response	[Origin] Derived DTHDTC not NULL Formal Expression
SITEID	Study Site Identifier	text	Record Qualifier	200		[Origin] eDT
BRTHDTC	Date/Time of Birth	datetime	Record Qualifier		ISO 8601	[Origin] CRF acrf.pdf [BRTHDTC (./#BRTHDTC).]
AGE	Age	float	Record Qualifier	200		[Origin] Derived Date of informed consent minus date of birth plus one in days Formal Expression
AGEU	Age Units	text	Variable Qualifier	200	Age Unit	[Origin] Protocol
SEX	Sex	text	Record Qualifier	200	Sex	[Origin] CRF acrf.pdf [SEX.(./#SEX).]

RACE	Race	text	Record Qualifier	200	Race	[Origin] CRF acrf.pdf [RACE_(./#RACE).]
ETHNIC	Ethnicity	text	Record Qualifier	200	Ethnic Group	[Origin] CRF acrf.pdf [ETHNIC (./#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.pdf [CMTRT (./#CMTRT).]
CMCAT	Category for Medication	text	Grouping Qualifier	200		[Origin] CRF acrf.pdf [CMCAT (./#CMCAT).]
CMSCAT	Subcategory for Medication	text	Grouping Qualifier	200		[Origin] CRF acrf.pdf [CMSCAT (./#CMSCAT).]
CMOCCUR	CM Occurrence	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf.pdf [CMOCCUR (./#CMOCCUR).]
CMREASND	Reason Medication Not Collected	text	Record Qualifier	200		[Origin] CRF acrf.pdf [CMREASND (./#CMREASND).]
CMDOSE	Dose per Administration	float	Record Qualifier	200		[Origin] CRF acrf.pdf [CMDOSE (./#CMDOSE).]
CMDOSTXT	Dose Description	text	Record Qualifier	200		[Origin] CRF acrf.pdf [CMDOSTXT (./#CMDOSTXT).]
CMDOSU	Dose Units	text	Variable Qualifier	200	Unit	[Origin] CRF acrf.pdf [CMDOSU (./#CMDOSU).]
CMDOSFRQ	Dosing Frequency per Interval	text	Variable Qualifier	200	Frequency	[Origin] CRF acrf.pdf [CMDOSFRQ (./#CMDOSFRQ).]
CMROUTE	Route of Administration	text	Variable Qualifier	200	Route of Administration	[Origin] CRF acrf.pdf [CMROUTE (./#CMROUTE).]

CMSTDTC	Start Date/Time of Medication	datetime	Timing		ISO 8601	[Origin] CRF acrf.pdf [CMSTDTC (./#CMSTDTC).]
CMENDTC	End Date/Time of Medication	datetime	Timing		ISO 8601	[Origin] CRF acrf.pdf [CMENDTC (./#CMENDTC).]
CMENRTPT	End Relative to Reference Time Point	text	Timing	200	Relation to Reference Period	[Origin] CRF acrf.pdf [CMENRTPT (./#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.pdf [AEGRPID (./#AEGRPID).]
AESPID	Sponsor-Defined Identifier	text	Identifier	200		[Origin] CRF acrf.pdf [AESPID (./#AESPID).]
AETERM	Reported Term for the Adverse Event	text	Topic	200		[Origin] CRF acrf.pdf [AETERM (./#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
AEHLGTC	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
AESOC	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.pdf [AESER (./#AESER).]
AEACN	Action Taken with Study Treatment	text	Record Qualifier	200	Action Taken with Study Treatment	[Origin] CRF acrf.pdf [AEACN (./#AEACN).]
AEREL	Causality	text	Record Qualifier	200		[Origin] CRF acrf.pdf [AEREL (./#AEREL).]
AERELNST	Relationship to Non-Study Treatment	text	Record Qualifier	200		[Origin] CRF acrf.pdf [AERELNST (./#AERELNST).]
AEOU	Outcome of Adverse Event	text	Record Qualifier	200	Outcome of Event	[Origin] CRF acrf.pdf [AEOU (./#AEOU).]
AESCONG	Congenital Anomaly or Birth Defect	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf.pdf [AESCONG (./#AESCONG).]
AESDISAB	Persist or Signif Disability/Incapacity	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf.pdf [AESDISAB (./#AESDISAB).]
AESDTH	Results in Death	text	Record Qualifier	200	No Yes Response	[Origin] CRF acrf.pdf [AESDTH (./#AESDTH).]

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

DD (Death Details) - FINDINGS

Location: dd.xpt_(dd.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
DDSEQ	Sequence Number	float	Identifier	200		[Origin] Derived Strict chronological order
DDTESTCD	Death Detail Assessment Short Name	text	Topic	8		[Origin] CRF acrf.pdf [DDTESTCD (./#DDTESTCD).]
DDTEST	Death Detail Assessment Name	text	Synonym Qualifier	40		[Origin] CRF acrf.pdf [DDTEST (./#DDTEST).]
DDORRES	Result or Finding as Collected	text	Result Qualifier	200		[Origin] CRF acrf.pdf [DDORRES (./#DDORRES).]
DDSTRESC	Character Result/Finding in Std Format	text	Result Qualifier	200		[Origin] Derived Coded value of --ORRES
DDDTC	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.pdf [EGORRES (./#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.pdf [EGSTDTC (./#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.pdf [QSTESTCD (./#QSTESTCD).]
QSTEST	Question Name	text	Synonym Qualifier	40		[Origin] CRF acrf.pdf [QSTEST (./#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.pdf [QSLOC (./#QSLOC).]
QSLAT	Laterality	text	Variable Qualifier	200	Laterality	[Origin] CRF acrf.pdf [QSLAT (./#QSLAT).]
QSDIR	Directionality	text	Variable Qualifier	200	Directionality	[Origin] CRF acrf.pdf [QSDIR (./#QSDIR).]
QSBFL	Baseline Flag	text	Record Qualifier	200	No Yes Response	[Origin] eDT
VISITNUM	Visit Number	float	Timing	200		[Origin] eDT
QSDTC	Date/Time of Finding	datetime	Timing		ISO 8601	[Origin] eDT

SUPPCM (Supplemental Qualifiers CM) - RELATIONSHIP

Location: suppcm.xpt_(suppcm.xpt)

Related Parent Dataset: CM (Concomitant Medications)						
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: CM.CMSEQ
QNAM	Qualifier Variable Name	text	Identifier	8		[Origin] CRF acrf.pdf [SUPPCM.QNAM (./#SUPPCM.QNAM).]
QLABEL	Qualifier Variable Label	text	Synonym Qualifier	40		[Origin] CRF acrf.pdf [SUPPCM.QLABEL (./#SUPPCM.QLABEL).]
QVAL VLM	Data Value	text	Result Qualifier	200		[Origin] CRF acrf.pdf [SUPPCM.QVAL (./#SUPPCM.QVAL).]
► IDVAR = "CMSEQ" and IDVARVAL = "CM.CMSEQ"	Was medication given at recom. regimen	text		20	No Yes Response	[Origin] CRF acrf.pdf [CMRRGYN (./#CMRRGYN).]
► IDVARVAL = "CMSEQ" and IDVARVAL = "CM.CMSEQ"	Why the medication not given at regimen	text		20		[Origin] CRF acrf.pdf [CMRRGRE (./#CMRRGRE).]
► IDVAR = "CMSEQ" and IDVARVAL = "CM.CMSEQ"	Reason for treatment discontinuation	text		20	Discontinuation treatment	[Origin] CRF acrf.pdf [CMRSDISC (./#CMRSDISC).]
QORIG	Origin	text	Record Qualifier	200		[Origin] Assigned
QEVAL	Evaluator	text	Record Qualifier	200	Evaluator	[Origin] Assigned

SUPPEG (Supplemental Qualifiers EG) - RELATIONSHIP

Location: suppeg.xpt_(suppeg.xpt).

Related Parent Dataset: EG (ECG)						
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.pdf [SUPPEG.QNAM (./#SUPPEG.QNAM).]
QLABEL	Qualifier Variable Label	text	Synonym Qualifier	40		[Origin] CRF acrf.pdf [SUPPEG.QLABEL (./#SUPPEG.QLABEL).]
QVAL VLM	Data Value	text	Result Qualifier	200		[Origin] CRF acrf.pdf [SUPPEG.QVAL (./#SUPPEG.QVAL).]
► USUBJID ≠ ""	ECG clinically significant	text		20	No Yes Response	[Origin] CRF acrf.pdf [EGCLSIG (./#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)
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

