

# ***Datasets for Study H9X-MC-GBCK***

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<b>Dataset</b>	<b>Description</b>	<b>Class</b>	<b>Structure</b>	<b>Purpose</b>	<b>Keys</b>	<b>Location</b>
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, ETCDD	te.xpt
TI	Trial Inclusion/Exclusion Criteria	Trial Design	One record per I/E criterion	Tabulation	STUDYID, IETESTCD, TIVERS	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, ARMCD	tv.xpt
CO	Comments	Special Purpose	One record per comment per subject	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVARVAL, COVAL	co.xpt
DM	Demographics	Special Purpose	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt
RELREC	Related Records	Special Purpose	One record per related record, group of records, or datasets	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELID	relrec.xpt
SE	Subject Elements	Special Purpose	One record per actual element per subject	Tabulation	STUDYID, USUBJID, SESTDTC, SEENDTC	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, CMENDTC, VISITNUM, CMDOSTOT	cm.xpt
EX	Exposure	Interventions	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC, VISITNUM, EXGRPID	ex.xpt
SU	Substance Use	Interventions	One record per substance type per reported occurrence per subject	Tabulation	STUDYID, USUBJID, SUCAT, SUSCAT, SUTRT	su.xpt
AE	Adverse Events	Events	One record per adverse event per subject	Tabulation	STUDYID, USUBJID, AEDECOD, AESTDTC, AETERM, AESEV	ae.xpt
DS	Disposition	Events	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC, DSTERM, DSCAT, DSSCAT	ds.xpt
MH	Medical History	Events	One record per medical history event per subject	Tabulation	STUDYID, USUBJID, MHTERM, MHLLTCD, MHSTDTC, MHENDTC, MHGRPID	mh.xpt
DA	Drug Accountability	Findings	One record per drug accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD, DADTC, VISITNUM, DAREFID	da.xpt

<b>Dataset</b>	<b>Description</b>	<b>Class</b>	<b>Structure</b>	<b>Purpose</b>	<b>Keys</b>	<b>Location</b>
EG	ECG Test Results	Findings	One record per ECG observation per time point per visit per subject	Tabulation	STUDYID, USUBJID, EGTESTCD, VISITNUM, EGTPTREF, EGTPTNUM, EGCAT, EGDTC, EGGRPID, EGREFID, EGORRES	eg.xpt
FA	Findings About Events or Interventio	Findings	One record per finding per object per time point per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, FATESTCD, FAOBJ, VISITNUM, FADTC, FAGRPID, FAORRES	fa.xpt
LB	Laboratory Tests Results	Findings	One record per lab test per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, LBCAT, VISITNUM, LBDTC, LBPTPTNUM, LBSPID, LBTESTCD, LBSTAT, LBGRPID, LBREFID, LBSPEC	lb.xpt
PC	Pharmacokinetic Concentrations	Findings	One record per analyte per planned time point number per time point reference per visit per subject	Tabulation	STUDYID, USUBJID, PCCAT, VISITNUM, PCDTC, PCTPTNUM, PCSPEC, PCTESTCD, PCREFID	pc.xpt
QS	Questionnaires	Findings	One record per questionnaire per question per time point per visit per subject	Tabulation	STUDYID, USUBJID, QSTESTCD, VISITNUM, QSTPTNUM, QSDTC, QSCAT, QSSPID, QSORRES	qs.xpt
SC	Subject Characteristics	Findings	One record per characteristic per subject	Tabulation	STUDYID, USUBJID, SCTESTCD, SCCAT, VISITNUM	sc.xpt
VS	Vital Signs	Findings	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM, VSTPTREF, VSTPTNUM, VSCAT, VSDTC, VSGRPID, VSPOS	vs.xpt
SUPPAE	Supplemental Qualifiers for AE	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppae.xpt
SUPPCM	Supplemental Qualifiers for CM	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppcm.xpt
SUPPDA	Supplemental Qualifiers for DA	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppda.xpt
SUPPDM	Supplemental Qualifiers for DM	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppdm.xpt
SUPPDS	Supplemental Qualifiers for DS	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppds.xpt
SUPPEG	Supplemental Qualifiers for EG	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppeg.xpt
SUPPEX	Supplemental Qualifiers for EX	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppex.xpt
SUPPFA	Supplemental Qualifiers for FA	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppfa.xpt

Dataset	Description	Class	Structure	Purpose	Keys	Location
SUPPLB	Supplemental Qualifiers for LB	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	supplb.xpt
SUPPMH	Supplemental Qualifiers for MH	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	suppmh.xpt
SUPPPC	Supplemental Qualifiers for PC	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject.	Tabulation	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, QNAM	supppc.xpt

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'TA'.
ARMCD	Planned Arm Code	text	ARM_F	Assigned	Topic	
ARM	Description of Planned Arm	text		Assigned	Synonym Qualifier	
TAETORD	Order of Element within Arm	integer		Assigned	Identifier	
ETCD	Element Code	text	ETCD_F	Assigned	Record Qualifier	
ELEMENT	Description of Element	text		Assigned	Synonym Qualifier	
TABRANCH	Branch	text		Protocol	Rule	
TATRANS	Transition Rule	text		Protocol	Rule	
EPOCH	Epoch	text	EPOCH_F	Assigned	Timing	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'TE'.
ETCD	Element Code	text	ETCD_F	Assigned	Topic	
ELEMENT	Description of Element	text		Assigned	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	ISO8601	Assigned	Timing	

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***Trial Inclusion/Exclusion Criteria (TI)***

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'TI'.
IETESTCD	Incl/Excl Criterion Short Name	text		Assigned	Topic	
IETEST	Inclusion/Exclusion Criterion	text		Protocol	Synonym Qualifier	
IECAT	Inclusion/Exclusion Category	text	TICAT_F	Protocol	Grouping Qualifier	
IESCAT	Inclusion/Exclusion Subcategory	text		Assigned	Grouping Qualifier	Null for all records.
TIRL	Inclusion/Exclusion Criterion Rule	text		Assigned	Rule	Null for all records.
TIVERS	Protocol Criteria Versions	text		Protocol	Record Qualifier	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'TS'.
TSSEQ	Sequence Number	integer		Assigned	Identifier	Sequence number assigned to be unique within the domain and TSPARMCD.
TSGRPID	Group ID	text		Assigned	Identifier	Null for all records.
TSPARMCD	Trial Summary Parameter Short Name	text	TSPARMCD_F	Assigned	Topic	
TSPARM	Trial Summary Parameter	text		Assigned	Synonym Qualifier	
TSVAL	Parameter Value	text		Protocol	Result Qualifier	
TSVAL1	Parameter Value	text		Protocol	Result Qualifier	
TSVAL2	Parameter Value	text		Protocol	Result Qualifier	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'TV'.
VISITNUM	Visit Number	integer	VIS_F	Assigned	Topic	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text	VISIT_F	Assigned	Synonym Qualifier	
VISITDY	Planned Study Day of Visit	integer		Assigned	Timing	
ARMCD	Planned Arm Code	text		Assigned	Record Qualifier	Null for all records.
ARM	Description of Planned Arm	text		Assigned	Synonym Qualifier	Null for all records.
TVSTRL	Visit Start Rule	text		Protocol	Rule	
TVENRL	Visit End Rule	text		Protocol	Rule	

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STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'CO'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Record Qualifier	If the value of COVAL is mapped from the EG dataset, then RDOMAIN is set equal to EG. Otherwise, RDOMAIN is set equal to (Blank).
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
COSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
COGRPID	Group ID	text		Assigned	Identifier	COGRPID = COSEQ.
IDVAR	Identifying Variable	text		Assigned	Record Qualifier	
IDVARVAL	Identifying Variable Value	text		Assigned	Record Qualifier	Equivalent to corresponding domain SEQ or REFID.
COREF	Comment Reference	text		Assigned	Record Qualifier	Null for all records.
COVAL	Comment	text		eDT, CRF Page 47	Topic	
COVAL1	Comment	text		eDT	Topic	
COVAL2	Comment	text		eDT	Topic	
COEVAL	Evaluator	text		Assigned	Record Qualifier	
CODTC	Date/Time of Comment	text	ISO8601	Assigned	Timing	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'DM'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
SUBJID	Subject Identifier for the Study	text		CRF Page 7	Topic	
RFSTDTC	Subject Reference Start Date/Time	text	ISO8601	Derived	Record Qualifier	Equal to the first study drug date/time. Null for screen failures and for subjects who discontinued prior to first study drug,
RFENDTC	Subject Reference End Date/Time	text	ISO8601	Derived	Record Qualifier	Equal to the last Disposition Date
RFXSTDTC	Date/Time of First Study Treatment	text	ISO8601	CRF Page 39	Record Qualifier	
RFXENDTC	Date/Time of Last Study Treatment	text	ISO8601	CRF Page 43	Record Qualifier	
RFICDTC	Date/Time of Informed Consent	text	ISO8601	CRF Page 7	Record Qualifier	
RFPENDTC	Date/Time of End of Participation	text	ISO8601	Derived	Record Qualifier	Equal to the last Disposition Date
DTHDTC	Date/Time of Death	text	ISO8601	CRF Pages 33, 45 Pages 33, 45	Record Qualifier	
DTHFL	Subject Death Flag	text	Y_F	Assigned	Record Qualifier	
SITEID	Study Site Identifier	text		Derived	Record Qualifier	Unique identifier for a site within a study.
INVID	Investigator Identifier	text		eDT	Record Qualifier	
INVNAM	Investigator Name	text		eDT	Synonym Qualifier	
BRTHDTC	Date/Time of Birth	text	ISO8601	CRF Page 8	Record Qualifier	

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
AGE	Age	integer		Derived	Record Qualifier	Age at Reference Start Date (RFSTDTC). Null for Screen Failures and subjects who discontinue prior to treatment start.
AGEU	Age Units	text	AGEU_F	Assigned	Variable Qualifier	
SEX	Sex	text	SEX_F	CRF Page 8	Record Qualifier	
RACE	Race	text	RACE_F	CRF Page 8	Record Qualifier	
ETHNIC	Ethnicity	text	ETHNIC_F	CRF Page 8	Record Qualifier	
ARMCD	Planned Arm Code	text	ARM_F	Derived	Record Qualifier	Treatment group to which the subject was randomized. If subject was not randomized, ARMCD = 'NOTASSGN'. If subject was not enrolled in the study, then ARMCD = 'SCRNFAIL'.
ARM	Description of Planned Arm	text		Derived	Synonym Qualifier	Treatment group to which the subject was randomized. If subject was not randomized, ARM = 'NOT ASSIGNED'. If subject was not enrolled in the study, then ARM = 'SCREEN FAILURE'.
ACTARMCD	Actual Arm Code	text	ARM_F	Derived	Record Qualifier	Populated with the value found in ARMCD.
ACTARM	Description of Actual Arm	text		Derived	Synonym Qualifier	Populated with the value found in ARM.
COUNTRY	Country	text	ISO3166	eDT	Record Qualifier	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent Sequence Number or Group Id value referred to IDVAR.
RELTYPE	Relationship Type	text		Assigned	Identifier	Null for all records.
RELID	Relationship Identifier	text		Assigned	Identifier	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'SE'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
SESEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
ETCD	Element Code	text	ETCD_F	Assigned	Topic	
ELEMENT	Description of Element	text		Assigned	Synonym Qualifier	
SESTDTC	Start Date/Time of Element	text	ISO8601	Derived	Timing	Derived from SVSTDTC, based on element start rules as defined in TE domain.
SEENDTC	End Date/Time of Element	text	ISO8601	Derived	Timing	Equivalent to the Start Date of the next Element. If it is the subject's last Element, the SEENDTC will be equivalent the subject's last visit date.
SESTDY	Study Day of Start of Subject Element	integer		Assigned	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
SEENDY	Study Day of End of Subject Element	integer		Assigned	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
TAETORD	Planned Order of Elements within Arm	integer		Derived	Timing	Derived based on ETCD as defined in TA.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
SEUPDES	Description of Unplanned Element	text		Assigned	Synonym Qualifier	Null for all records.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'SV'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
VISITNUM	Visit Number	integer	VIS_F	Derived	Topic	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text	VISIT_F	Derived	Synonym Qualifier	Populated with the value found in TV.VISIT.
VISITDY	Planned Study Day of Visit	integer		Assigned	Timing	
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
SVSTDTC	Start Date/Time of Visit	text	ISO8601	Derived	Timing	At Visit1 SESTET is set equal to the value found in DS.DSSDTC for the same visit. For records after Visit 1, SESTET is set equal to the value in SVENDTC of the prior visit + 1 day.
SVENDTC	End Date/Time of Visit	text	ISO8601	CRF Page 6	Timing	
SVSTDY	Study Day of Start of Visit	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
SVENDY	Study Day of End of Visit	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
SVUPDES	Description of Unplanned Visit	text		Assigned	Synonym Qualifier	Null for all records.

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# Concomitant Medications (CM)

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'CM'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
CMSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
CMGRPID	Group ID	text		Assigned	Identifier	Null for all records.
CMSPID	Sponsor-Defined Identifier	text		CRF Pages 14, 20, 21, 22	Identifier	
CMTRT	Reported Name of Drug, Med, or Therapy	text		CRF Pages 14, 20, 21, 22	Topic	
CMMODIFY	Modified Reported Name	text		Assigned	Synonym Qualifier	Null for all records.
CMDECOD	Standardized Medication Name	text	CMDICT_F	Assigned	Synonym Qualifier	Coded values are from the Who Drug Dictionary that was current when the data was collected. Versions: 01Jun2008, 01Dec2008, 01Jun2009, 01Dec2009, 01Jun2010, 01Dec2010.
CMCAT	Category for Medication	text	CMCAT_F	Assigned	Grouping Qualifier	Populated based on the value found in treatment type.
CMSCAT	Subcategory for Medication	text	CMSCAT_F	Assigned	Grouping Qualifier	
CMRESP	CM Pre-Specified	text	Y_F	Assigned	Record Qualifier	Null for all records.
CMOCCUR	CM Occurrence	text	YN_F	Assigned	Record Qualifier	Null for all records.
CMSTAT	Completion Status	text		Assigned	Record Qualifier	Null for all records.
CMREASND	Reason Medication Not Collected	text		Assigned	Record Qualifier	Null for all records.
CMINDC	Indication	text		Assigned	Record Qualifier	Null for all records.

# Concomitant Medications (CM)

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
CMCLAS	Medication Class	text		Assigned	Variable Qualifier	Null for all records.
CMCLASCD	Medication Class Code	text		Assigned	Variable Qualifier	Null for all records.
CMDOSE	Dose per Administration	integer		Assigned	Record Qualifier	Null for all records.
CMDOSTXT	Dose Description	text		Assigned	Record Qualifier	Null for all records.
CMDOSU	Dose Units	text	CMDOSU_F	CRF Page 21	Variable Qualifier	
CMDOSFRM	Dose Form	text		Assigned	Record Qualifier	Null for all records.
CMDOSFRQ	Dosing Frequency per Interval	text		Assigned	Variable Qualifier	Null for all records.
CMDOSTOT	Total Daily Dose	integer		CRF Page 21	Record Qualifier	
CMDOSRGM	Intended Dose Regimen	text		Assigned	Variable Qualifier	Null for all records.
CMROUTE	Route of Administration	text		Assigned	Variable Qualifier	Null for all records.
CMLOC	Location of Dose Administration	text		Assigned	Record Qualifier	Null for all records.
CMVAMT	Treatment Vehicle Amount	integer		Assigned	Record Qualifier	Null for all records.
CMVAMTU	Treatment Vehicle Amount Units	text		Assigned	Variable Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	CMSTDTC must be >or = to the SESTET, but < the next SESTET. If CMSTDTC < SESTET where VISIT = VISIT1, then VISIT = VISIT1.If CMSTDTC > last SVENDTC, then VISIT = VISIT of the last SVENDTC.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM



Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
CMSTDTC	Start Date/Time of Medication	text	ISO8601	CRF Pages 14, 20, 21, 22	Timing	
CMENDTC	End Date/Time of Medication	text	ISO8601	CRF Pages 14, 20, 21, 22	Timing	
CMSTDY	Study Day of Start of Medication	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
CMENDY	Study Day of End of Medication	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
CMDUR	Duration of Medication	text	ISO8601	Assigned	Timing	Null for all records.
CMSTRF	Start Relative to Reference Period	text		Assigned	Timing	Null for all records.
CMENRF	End Relative to Reference Period	text	ENRF_F	CRF Pages 20, 21, 22	Timing	
CMSTRTPT	Start Relative to Reference Time Point	text		Derived	Timing	If the CMSTDTC is before the informed consent date (DM_RFICDTC) (or null or partial), set to 'BEFORE'. Otherwise, set to 'AFTER'.
CMSTTPT	Start Reference Time Point	text		Assigned	Timing	If CMSTRTPT is populated, set to INFORMED CONSENT DATE. Otherwise, set to null.
CMEVLINT	Evaluation Interval	text	ISO8601	Assigned	Timing	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'EX'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
EXSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
EXGRPID	Group ID	text		Assigned	Identifier	Null for all records.
EXREFID	Reference ID	text		eDT	Identifier	Null for all records.
EXSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
EXTRT	Name of Actual Treatment	text	EXTRT_F	Derived	Topic	If DM_ARMCD = 'A-1', set to 'PLACEBO', If DM_ARMCD = 'A-2', 'A-3', 'A-4', 'A-5', or 'A-6', set to 'LY2189265'.
EXCAT	Category for Treatment	text	EXCAT_F	Assigned	Grouping Qualifier	
EXSCAT	Subcategory for Treatment	text		Assigned	Grouping Qualifier	Null for all records.
EXSTAT	Completion Status	text	NOTDONE_F	Assigned	Record Qualifier	Null for all records.
EXREASND	Reason Not Done	text		Assigned	Record Qualifier	Null for all records.
EXDOSE	Dose per Administration	float		eDT	Record Qualifier	Provided electronically by the site personnel.
EXDOSTXT	Dose Description	text		Assigned	Record Qualifier	Null for all records.
EXDOSU	Dose Units	text	EXDOSU_F	Protocol	Variable Qualifier	Set to 'mg'.
EXDOSFRM	Dose Form	text	EXDOSFRM_F	Protocol	Record Qualifier	Set to 'SOLUTION'.
EXDOSFRQ	Dosing Frequency per Interval	text	EXDOSFRQ_F	Protocol	Variable Qualifier	

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
EXDOSTOT	Total Daily Dose	integer		Assigned	Record Qualifier	Null for all records.
EXDOSRGM	Intended Dose Regimen	text		Assigned	Variable Qualifier	Null for all records.
EXROUTE	Route of Administration	text	EXROUTE_F	Protocol	Variable Qualifier	Set to 'SUBCUTANEOUS'.
EXLOT	Lot Number	text		Assigned	Record Qualifier	Null for all records.
EXLOC	Location of Dose Administration	text		Assigned	Record Qualifier	Null for all records.
EXTRTV	Treatment Vehicle	text		Protocol	Record Qualifier	Null for all records.
EXVAMT	Treatment Vehicle Amount	integer		Assigned	Variable Qualifier	Null for all records.
EXVAMTU	Treatment Vehicle Amount Units	text		Assigned	Variable Qualifier	Null for all records.
EXADJ	Reason for Dose Adjustment	text		Assigned	Record Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
TAETORD	Order of Element within Arm	integer		Derived	Timing	Matches the value in SE for the given element.
EPOCH	Epoch	text		Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
EXSTDTC	Start Date/Time of Treatment	text	ISO8601	CRF Pages 39, 42	Timing	
EXENDTC	End Date/Time of Treatment	text	ISO8601	CRF Page 43	Timing	
EXSTDY	Study Day of Start of Treatment	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
EXENDY	Study Day of End of Treatment	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
EXDUR	Duration of Treatment	text	ISO8601	Assigned	Timing	Null for all records.
EXTPT	Planned Time Point Name	text		Assigned	Timing	Null for all records.
EXTPTNUM	Planned Time Point Number	integer		Assigned	Timing	Null for all records.
EXELTM	Planned Elapsed Time from Time Point Ref	text		Assigned	Timing	Null for all records.
EXTPTREF	Time Point Reference	text		Assigned	Timing	Null for all records.
EXRFTDTC	Date/Time of Reference Time Point	text	ISO8601	Derived	Timing	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'SU'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
SUSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
SUGRPID	Group ID	text		Assigned	Identifier	Null for all records.
SUSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
SUTRT	Reported Name of Substance	text		Assigned, CRF Page 38	Topic	
SUCAT	Category for Substance Use	text		Assigned	Grouping Qualifier	Null for all records.
SUSCAT	Subcategory for Substance Use	text		Assigned	Grouping Qualifier	Null for all records.
SUPRESP	SU Pre-Specified	text	Y_F	Assigned	Record Qualifier	
SUOCCUR	SU Occurrence	text	YN_F	CRF Page 38	Record Qualifier	
SUSTAT	Completion Status	text	NOTDONE_F	Assigned	Record Qualifier	Null for all records.
SUREASND	Reason Substance Use Not Collected	text		Assigned	Record Qualifier	Null for all records.
SUDOSE	Substance Use Consumption	integer		Assigned	Record Qualifier	Null for all records.
SUDOSTXT	Substance Use Consumption Text	text		Assigned	Record Qualifier	Null for all records.
SUDOSU	Consumption Units	text		Assigned	Variable Qualifier	Null for all records.
SUDOSFRM	Dose Form	text		Assigned	Record Qualifier	Null for all records.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
SUDOSFRQ	Use Frequency Per Interval	text		Assigned	Variable Qualifier	Null for all records.
SUDOSTOT	Total Daily Consumption	integer		Assigned	Record Qualifier	Null for all records.
SURROUTE	Route of Administration	text		Assigned	Variable Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
SUSTDTC	Start Date/Time of Substance Use	text	ISO8601	Assigned	Timing	Null for all records.
SUENDTC	End Date/Time of Substance Use	text	ISO8601	Assigned	Timing	Null for all records.
SUSTDY	Study Day of Start of Substance Use	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
SUENDY	Study Day of End of Substance Use	integer		Derived	Timing	Null for all records.
SUDUR	Duration of Substance Use	text	ISO8601	Assigned	Timing	Null for all records.
SUSTRF	Start Relative to Reference Period	text		Assigned	Timing	Null for all records.
SUENRF	End Relative to Reference Period	text	ENRF_F	Assigned	Timing	Null for all records.
SUENRTPT	End Relative to Reference Time Point	text		Assigned	Timing	
SUENTPT	End Reference Time Point	text		Assigned	Timing	Set to 'VISIT4'.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'AE'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
AESEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
AEGRPID	Group ID	text		CRF Page 19	Identifier	
AEREFID	Reference ID	text		Assigned	Identifier	
AESPID	Sponsor-Defined Identifier	text		Derived	Identifier	Set to 1 for each record and increased incrementally by 1 for each change in severity.
AETERM	Reported Term for the Adverse Event	text		CRF Page 19	Topic	
AEMODIFY	Modified Reported Term	text		Assigned	Synonym Qualifier	Null for all records.
AELLT	Lowest Level Term	text	AEDICT_F	Assigned	Variable Qualifier	
AELLTCD	Lowest Level Term Code	integer		Assigned	Variable Qualifier	
AEDECOD	Dictionary-Derived Term	text	AEDICT_F	Assigned	Synonym Qualifier	
AEPTCD	Preferred Term Code	integer		Assigned	Variable Qualifier	
AEHLT	High Level Term	text	AEDICT_F	Assigned	Variable Qualifier	
AEHLTCD	High Level Term Code	integer		Assigned	Variable Qualifier	
AEHLGT	High Level Group Term	text	AEDICT_F	Assigned	Variable Qualifier	
AEHLGTCD	High Level Group Term Code	integer		Assigned	Variable Qualifier	

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
AECAT	Category for Adverse Event	text	AECAT_F	Assigned	Grouping Qualifier	Set to 'GENERAL ADVERSE EVENTS'.
AESCAT	Subcategory for Adverse Event	text		Assigned	Grouping Qualifier	Null for all records.
AEPRESP	Pre-Specified Adverse Event	text		Assigned	Record Qualifier	Null for all records.
AEBODSYS	Body System or Organ Class	text	AEDICT_F	Assigned	Record Qualifier	
AEBDSYCD	Body System or Organ Class Code	integer		Assigned	Variable Qualifier	
AESOC	Primary System Organ Class	text	AEDICT_F	Assigned	Variable Qualifier	
AESOCCD	Primary System Organ Class Code	integer		Assigned	Variable Qualifier	
AELOC	Location of Event	text		Assigned	Record Qualifier	Null for all records.
AESEV	Severity/Intensity	text	AESEV_F	CRF Page 19	Record Qualifier	
AESER	Serious Event	text	YN_F	CRF Page 19	Record Qualifier	
AEACN	Action Taken with Study Treatment	text		Assigned	Record Qualifier	Null for all records.
AEACNOTH	Other Action Taken	text		Assigned	Record Qualifier	Null for all records.
AEREL	Causality	text	YN_F	CRF Page 19	Record Qualifier	
AERELNST	Relationship to Non-Study Treatment	text		CRF Page 19	Record Qualifier	
AEPATT	Pattern of Adverse Event	text		Assigned	Record Qualifier	Null for all records.
AEOUT	Outcome of Adverse Event	text	AEOUT_F	CRF Page 19	Record Qualifier	



Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
AESCONG	Congenital Anomaly or Birth Defect	text	Y_F	CRF Page 19	Record Qualifier	
AESDISAB	Persist or Signif Disability/Incapacity	text	Y_F	CRF Page 19	Record Qualifier	
AESDTH	Results in Death	text	Y_F	CRF Page 19	Record Qualifier	
AESHOSP	Requires or Prolongs Hospitalization	text	Y_F	CRF Page 19	Record Qualifier	
AESLIFE	Is Life Threatening	text	Y_F	CRF Page 19	Record Qualifier	
AESMIE	Other Medically Important Serious Event	text	Y_F	CRF Page 19	Record Qualifier	
AECONTRT	Concomitant or Additional Trtmnt Given	text	YN_F	Assigned	Record Qualifier	Null for all records.
AETOXGR	Standard Toxicity Grade	text		Assigned	Record Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT. This represents the change in severity visit, when there was a change.
VISIT	Visit Name	text		Derived	Timing	AESTDTC must be ≥ to SESTET, but < the next SESTET. If AESTDTC < SESTET where VISIT = VISIT1, then set VISIT = VISIT1. If AESTDTC > last SVENDTC, then set VISIT = VISIT of that last SVENDTC.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
AESTDTC	Start Date/Time of Adverse Event	text	ISO8601	CRF Page 19	Timing	
AEENDTC	End Date/Time of Adverse Event	text	ISO8601	Derived, CRF Page 19	Timing	If the Event changes in severity, then AEENDTC= to the day prior to the change, unless the change in severity occurred on the same day as AESTDTC. In that case, AEENDTC equals the AESTDTC.
AESTDY	Study Day of Start of Adverse Event	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
AEENDY	Study Day of End of Adverse Event	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
AEDUR	Duration of Adverse Event	text	ISO8601	Assigned	Timing	Null for all records.
AEENRF	End Relative to Reference Period	text	ENRF_F	CRF Page 19	Timing	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'DS'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
DSSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
DSGRPID	Group ID	text		Assigned	Identifier	Null for all records.
DSREFID	Reference ID	text		Assigned	Identifier	Null for all records.
DSSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
DSTERM	Reported Term for the Disposition Event	text		CRF Pages 17, 33, 34, 45	Topic	
DSDECOD	Standardized Disposition Term	text	DSDECOD_F	CRF Pages 17, 33, 34, 45	Synonym Qualifier	
DSCAT	Category for Disposition Event	text	DSCAT_F	Assigned	Grouping Qualifier	
DSSCAT	Subcategory for Disposition Event	text	DSSCAT_F	Assigned	Grouping Qualifier	
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
DSDTC	Date/Time of Collection	text	ISO8601	Assigned	Timing	Null for all records.
DSSTDTC	Start Date/Time of Disposition Event	text	ISO8601	CRF Pages 7, 23	Timing	
DSSTDY	Study Day of Start of Disposition Event	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'MH'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
MHSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
MHGRPID	Group ID	text		CRF Pages 13, 19	Identifier	
MHREFID	Reference ID	text		Assigned	Identifier	Null for all records.
MHSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
MHTERM	Reported Term for the Medical History	text	MHDICT_F	CRF Pages 13, 19	Topic	
MHMODIFY	Modified Reported Term	text		Assigned	Synonym Qualifier	Null for all records.
MHLLT	Lowest Level Term	text	MHDICT_F	Assigned	Variable Qualifier	
MHLLTCD	Lowest Level Term Code	integer		Assigned	Variable Qualifier	MedDRA version 11.0.
MHDECOD	Dictionary-Derived Term	text	MHDICT_F	Assigned	Synonym Qualifier	
MHPTCD	Preferred Term Code	integer		Assigned	Variable Qualifier	
MHHLT	High Level Term	text	MHDICT_F	Assigned	Variable Qualifier	
MHHLTCD	High Level Term Code	integer		Assigned	Variable Qualifier	
MHHLGT	High Level Group Term	text	MHDICT_F	Assigned	Variable Qualifier	
MHHLGTCD	High Level Group Term Code	integer		Assigned	Variable Qualifier	

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
MHCAT	Category for Medical History	text	MHCAT_F	Derived	Grouping Qualifier	If the MHENDTC is prior to the Informed Consent Date, then MHCAT = HISTORICAL ILLNESS. If the MHENDTC is on or after the Informed Consent Date, then MHCAT = PRE-EXISTING CONDITION.
MHSCAT	Subcategory for Medical History	text		Assigned	Grouping Qualifier	Null for all records.
MHPRESP	Medical History Event Pre-Specified	text	Y_F	Assigned	Record Qualifier	Null for all records.
MHOCCUR	Medical History Occurrence	text		Assigned	Record Qualifier	Null for all records.
MHSTAT	Completion Status	text	NOTDONE_F	Assigned	Record Qualifier	Null for all records.
MHREASND	Reason Medical History Not Collected	text		Assigned	Record Qualifier	Null for all records.
MHBODSYS	Body System or Organ Class	text	MHDICT_F	Assigned	Record Qualifier	
MHBDSYCD	Body System or Organ Class Code	integer		Assigned	Variable Qualifier	
MHSOC	Primary System Organ Class	text	MHDICT_F	Assigned	Variable Qualifier	
MHSOCCD	Primary System Organ Class Code	integer		Assigned	Variable Qualifier	
MHSEV	Severity/Intensity	text	AESEV_F	CRF Page 19	Record Qualifier	
MHSER	Serious Event	text	YN_F	CRF Page 19	Record Qualifier	
MHREL	Causality	text		CRF Page 19	Record Qualifier	
MHRELNST	Relationship to Non-Study Treatment	text		CRF Page 19	Record Qualifier	
MHOUT	Outcome of Adverse Event	text		CRF Page 19	Record Qualifier	

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
MHSCONG	Congenital Anomaly or Birth Defect	text	Y_F	CRF Page 19	Record Qualifier	
MHSDISAB	Persist or Signif Disability/Incapacity	text	Y_F	CRF Page 19	Record Qualifier	
MHSDTH	Results in Death	text	Y_F	CRF Page 19	Record Qualifier	
MHSHOSP	Requires or Prolongs Hospitalization	text	Y_F	CRF Page 19	Record Qualifier	
MHSLIFE	Is Life Threatening	text	Y_F	CRF Page 19	Record Qualifier	
MHSMIE	Other Medically Important Serious Event	text	Y_F	CRF Page 19	Record Qualifier	
MHTOXGR	Toxicity Grade	text		Assigned	Record Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Set to 'VISIT1'.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
MHDTC	Date/Time of History Collection	text	ISO8601	Assigned	Timing	Null for all records.
MHSTDTC	Start Date/Time of Medical History Event	text	ISO8601	CRF Page 19	Timing	
MHENDTC	End Date/Time of Medical History Event	text	ISO8601	CRF Pages 13, 19	Timing	
MHDY	Study Day of History Collection	integer		Derived	Timing	Null for all records.
MHSTDY	Study Day of Start of Observation	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
MHENDY	Study Day of End of Observation	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
MHENRF	End Relative to Reference Period	text	ENRF_F	Derived, CRF Page 19	Timing	MHENRF = DURING/AFTER if 'Ongoing' is selected. Else, will be null.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'DA'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
DASEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
DAGRPID	Group ID	text		Assigned	Identifier	Null for all records.
DAREFID	Reference ID	text		eDT	Identifier	Populated with the treatment dispensed package number.
DASPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
DATESTCD	Short Name of Accountability Assessment	text		Assigned	Topic	
DATEST	Name of Accountability Assessment	text		Assigned	Synonym Qualifier	
DACAT	Category of Assessment	text	DACAT_F	Assigned	Grouping Qualifier	Set to 'STUDY TREATMENT'.
DASCAT	Subcategory of Assessment	text	DASCAT_F	Assigned	Grouping Qualifier	
DAORRES	Assessment Result in Original Units	text		eDT	Result Qualifier	
DAORRESU	Original Units	text		Assigned	Variable Qualifier	Set to 'PACKAGE'.
DASTRESC	Assessment Result in Std Format	text		Derived	Result Qualifier	Equivalent to DAORRES.
DASTRESN	Numeric Result/Finding in Standard Units	integer		Derived	Result Qualifier	Numeric equivalent of DASTRESC.
DASTRESU	Assessment Standard Units	text		Assigned	Variable Qualifier	Sponsor defined standardized units.
DASTAT	Completion Status	text		Assigned	Record Qualifier	Null for all records.



Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
DAREASND	Reason Not Performed	text		Assigned	Record Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
DADTC	Date/Time of Accountability Assessment	text	ISO8601	Assigned	Timing	
DADY	Study Day of Accountability Assessment	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'EG'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
EGSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
EGGRPID	Group ID	text		Assigned	Identifier	
EGREFID	ECG Reference ID	text		eDT	Identifier	
EGSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
EGTESTCD	ECG Test or Examination Short Name	text		eDT	Topic	
EGTEST	ECG Test or Examination Name	text		eDT	Synonym Qualifier	
EGCAT	Category for ECG	text		Assigned	Grouping Qualifier	Null for all records.
EGSCAT	Subcategory for ECG	text		Assigned	Grouping Qualifier	Null for all records.
EGPOS	ECG Position of Subject	text		Assigned	Record Qualifier	Null for all records.
EGORRES	Result or Finding in Original Units	text		eDT	Result Qualifier	
EGORRESU	Original Units	text		eDT	Variable Qualifier	
EGSTRESC	Character Result/Finding in Std Format	text		eDT	Result Qualifier	Provided electronically by the performing lab.
EGSTRESN	Numeric Result/Finding in Standard Units	float		Derived	Result Qualifier	Numeric equivalent of EGSTRESC.
EGSTRESU	Standard Units	text		Assigned	Variable Qualifier	Sponsor defined standardized units.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
EGSTAT	Completion Status	text	NOTDONE_F	Derived	Record Qualifier	If EGORRES is NOT populated, then EGSTAT = 'NOT DONE'. Else, EGSTAT = null.
EGREASND	Reason ECG Not Performed	text		eDT	Record Qualifier	Null for all records.
EGXFN	ECG External File Name	text		Assigned	Record Qualifier	Null for all records.
EGNAM	Vendor Name	text		Assigned	Record Qualifier	
EGLOC	Lead Location Used for Measurement	text		Assigned	Record Qualifier	Null for all records.
EGMETHOD	Method of ECG Test	text	EGMETH_F	Assigned	Record Qualifier	Set to '12 LEAD UNSPECIFIED'.
EGBLFL	Baseline Flag	text	Y_F	Derived	Record Qualifier	Last non-missing result prior or equal to first dose of study drug. Null for subjects who were not treated.
EGDRVFL	Derived Flag	text		Assigned	Record Qualifier	Null for all records.
EGEVAL	Evaluator	text	EGEVAL_F	Assigned	Record Qualifier	Set to 'INTERPRETER'.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
EGDTC	Date/Time of ECG	text	ISO8601	eDT	Timing	
EGENDTC	End Date/Time of Observation	text	ISO8601	eDT	Timing	Null for all records.
EGDY	Study Day of ECG	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
EGENDY	Study Day of End of Observation	integer		Derived	Timing	Null for all records.
EGTPT	Planned Time Point Name	text		Assigned	Timing	Null for all records.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
EGTPTNUM	Planned Time Point Number	integer		Assigned	Timing	Null for all records.
EGELTM	Planned Elapsed Time from Time Point Ref	text	ISO8601	Assigned	Timing	Null for all records.
EGTPTREF	Time Point Reference	text		Assigned	Timing	Null for all records.
EGRFTDTC	Date/Time of Reference Time Point	text	ISO8601	Derived	Timing	Null for all records.
EGEVLINT	Evaluation Interval	text	ISO8601	eDT	Timing	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'FA'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
FASEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
FAGRPID	Group ID	text		CRF Pages 24, 26, 29, 41	Identifier	
FAREFID	Reference ID	text		Assigned	Identifier	Null for all records.
FASPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
FATESTCD	Findings About Test Short Name	text		Assigned	Topic	
FATEST	Findings About Test Name	text		Assigned	Synonym Qualifier	
FAOBJ	Object of the Observation	text		Assigned	Record Qualifier	
FACAT	Category for Findings About	text	FACAT_F	Assigned	Grouping Qualifier	
FASCAT	Subcategory for Findings About	text		Assigned	Grouping Qualifier	Null for all records.
FAORRES	Result or Finding in Original Units	text		CRF Pages 16, 24, 25, 26, 29, 37, 41, 44	Result Qualifier	
FAORRESU	Original Units	text		CRF Pages 16, 41	Variable Qualifier	
FASTRESC	Character Result/Finding in Std Format	text		Derived	Result Qualifier	Result value after conversion to standard units.
FASTRESN	Numeric Result/Finding in Standard Units	float		Derived	Result Qualifier	Numeric equivalent of FASTRESC.
FASTRESU	Standard Units	text		Assigned	Variable Qualifier	Sponsor defined standardized units.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
FASTAT	Completion Status	text	NOTDONE_F	CRF Pages 24, 41	Record Qualifier	
FAREASND	Reason Not Performed	text		Assigned	Record Qualifier	Null for all records.
FALOC	Location of the Finding About	text		Assigned	Variable Qualifier	Null for all records.
FABLFL	Baseline Flag	text		Assigned	Record Qualifier	Last non-missing result prior or equal to first dose of study drug. Null for subjects who were not treated.
FAEVAL	Evaluator	text		Assigned	Record Qualifier	
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT, using FADTC or FASTDTC
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
FADTC	Date/Time of Collection	text	ISO8601	CRF Page 24	Timing	Populated with the value found in SV.VISIT for that occurrence.
FASTDTC	Start Date/Time of Observation	text	ISO8601	CRF Pages 25, 26, 29, 41	Timing	
FAENDTC	End Date/Time of Observation	text	ISO8601	Assigned	Timing	Null for all records.
FADY	Study Day of Collection	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
FASTDY	Study Day of Start of Observation	integer		Derived	Timing	Calculated using RFSTDTC. If Date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
FAENDY	Study Day of End of Observation	integer		Derived	Timing	Null for all records.
FAEVLINT	Evaluation Interval	text	ISO8601	Assigned	Timing	

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'LB'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
LBSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
LBGRPID	Group ID	text		Assigned	Identifier	
LBREFID	Specimen ID	text		eDT	Identifier	
LBSPID	Sponsor-Defined Identifier	text		CRF Pages 28, 35	Identifier	
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_F	Assigned	Grouping Qualifier	
LBSCAT	Subcategory for Lab Test	text		Assigned	Grouping Qualifier	Null for all records.
LBORRES	Result or Finding in Original Units	text		eDT, CRF Pages 28, 35	Result Qualifier	
LBORRESU	Original Units	text		eDT, CRF Pages 28, 35	Variable Qualifier	
LBORNRLO	Reference Range Lower Limit in Orig Unit	text		eDT	Variable Qualifier	
LBORNRHI	Reference Range Upper Limit in Orig Unit	text		eDT, CRF Page 28	Variable Qualifier	
LBSTRESC	Character Result/Finding in Std Format	text		Derived	Result Qualifier	Result value after conversion to standard units.
LBSTRESN	Numeric Result/Finding in Standard Units	float		Derived	Result Qualifier	Numeric equivalent of LBSTRESC.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
LBSTRESU	Standard Units	text		Assigned	Variable Qualifier	Sponsor defined standardized units.
LBSTNRLO	Reference Range Lower Limit-Std Units	float		Derived	Variable Qualifier	Result value of the lower limit of the reference range after conversion to standard units.
LBSTNRHI	Reference Range Upper Limit-Std Units	float		Derived	Variable Qualifier	Result value of the upper limit of the reference range after conversion to standard units.
LBSTNRC	Reference Range for Char Rslt-Std Units	text		eDT	Variable Qualifier	Null for all records.
LBNRIND	Reference Range Indicator	text		Derived	Variable Qualifier	Values of HIGH, LOW, NORMAL and ABNORMAL based on the Standardized Lab Results and Reference Ranges.
LBRESCAT	Result Category	text		Assigned	Variable Qualifier	Null for all records.
LBSTAT	Completion Status	text	NOTDONE_F	eDT, CRF Pages 28, 35	Record Qualifier	
LBREASND	Reason Test Not Done	text		eDT	Record Qualifier	Null for all records.
LBNAM	Vendor Name	text		Assigned	Record Qualifier	
LBLOINC	LOINC Code	text		Assigned	Synonym Qualifier	Null for all records.
LBSPEC	Specimen Type	text		eDT	Record Qualifier	
LBSPCCND	Specimen Condition	text		Assigned	Record Qualifier	Null for all records.
LBLOC	Location Used for the Measurement	text		Assigned	Record Qualifier	Null for all records.
LBMETHOD	Method of Test or Examination	text		Assigned	Record Qualifier	Null for all records.
LBBLFL	Baseline Flag	text	Y_F	Derived	Record Qualifier	Last non-missing result prior or equal to first dose of study drug. Null for subjects who were not treated.
LBFAST	Fasting Status	text		Assigned	Record Qualifier	Null for all records.



Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
LBDRVFL	Derived Flag	text	Y_F	Assigned	Record Qualifier	Null for all records.
LBTOX	Toxicity	text		Assigned	Variable Qualifier	Null for all records.
LBTOXGR	Standard Toxicity Grade	text		Assigned	Variable Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
LBDTC	Date/Time of Specimen Collection	text	ISO8601	eDT, CRF Pages 28, 35	Timing	
LBENDTC	End Date/Time of Specimen Collection	text	ISO8601	eDT	Timing	Null for all records.
LBDY	Study Day of Specimen Collection	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
LBENDY	Study Day of End of Observation	integer		Derived	Timing	Null for all records.
LBTPPT	Planned Time Point Name	text		eDT, CRF Page 35	Timing	
LBTPPTNUM	Planned Time Point Number	integer	LBTPPTNUM_F	Assigned	Timing	
LBELTM	Planned Elapsed Time from Time Point Ref	text		Assigned	Timing	
LBTPPTREF	Time Point Reference	text		Assigned	Timing	
LBRFTDTC	Date/Time of Reference Time Point	text	ISO8601	Derived	Timing	Equivalent to the Date Referenced in LBTPPTREF.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'PC'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
PCSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
PCGRPID	Group ID	text		Assigned	Identifier	Null for all records.
PCREFID	Reference ID	text		eDT	Identifier	
PCSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
PCTESTCD	Pharmacokinetic Test Short Name	text		eDT	Topic	
PCTEST	Pharmacokinetic Test Name	text		eDT	Synonym Qualifier	
PCCAT	Test Category	text	PCCAT_F	Assigned	Grouping Qualifier	Set to 'ANALYTE'.
PCSCAT	Test Subcategory	text		Assigned	Grouping Qualifier	Null for all records.
PCORRES	Result or Finding in Original Units	text		eDT	Result Qualifier	
PCORRESU	Original Units	text		eDT	Variable Qualifier	
PCSTRESC	Character Result/Finding in Std Format	text		Derived	Result Qualifier	Result value after conversion to standard units for the results that are not below or above the limit of quantitation.
PCSTRESN	Numeric Result/Finding in Standard Units	float		Derived	Result Qualifier	Numeric equivalent of PCSTRESC.
PCSTRESU	Standard Units	text		Assigned	Variable Qualifier	Sponsor defined standardized units.
PCSTAT	Completion Status	text	NOTDONE_F	eDT	Record Qualifier	

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
PCREASND	Reason Test Not Done	text		eDT	Record Qualifier	Null for all records.
PCNAM	Vendor Name	text		eDT	Record Qualifier	
PCSPEC	Specimen Material Type	text		Derived	Record Qualifier	Set to 'PLASMA'.
PCSPCCND	Specimen Condition	text		eDT	Record Qualifier	Null for all records.
PCMETHOD	Method of Test or Examination	text		Assigned	Record Qualifier	Null for all records.
PCFAST	Fasting Status	text		eDT	Record Qualifier	Null for all records.
PCDRVFL	Derived Flag	text	Y_F	Assigned	Record Qualifier	Null for all records.
PCLLOQ	Lower Limit of Quantitation	integer		Assigned	Variable Qualifier	Set to 5.0
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
PCDTC	Date/Time of Specimen Collection	text	ISO8601	eDT	Timing	
PCENDTC	End Date/Time of Specimen Collection	text	ISO8601	eDT	Timing	Null for all records.
PCDY	Actual Study Day of Specimen Collection	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
PCENDY	Study Day of End of Observation	integer		Derived	Timing	Null for all records.
PCTPT	Planned Time Point Name	text		eDT	Timing	Null for all records.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
PCTPTNUM	Planned Time Point Number	integer		Assigned	Timing	Null for all records.
PCELTm	Planned Elapsed Time from Time Point Ref	text		Assigned	Timing	Null for all records.
PCTPTREF	Time Point Reference	text		Assigned	Timing	Null for all records.
PCRFTDTC	Date/Time of Reference Point	text	ISO8601	Derived	Timing	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'QS'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
QSSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
QSGRPID	Group ID	text		Assigned	Identifier	Null for all records.
QSSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
QSTESTCD	Question Short Name	text		Assigned	Topic	
QSTEST	Question Name	text		Assigned	Synonym Qualifier	
QSCAT	Category of Question	text	QSCAT_F	Assigned	Grouping Qualifier	Set to 'CARDIOVASCULAR RISK ASSESSMENT'.
QSSCAT	Subcategory for Question	text		Assigned	Grouping Qualifier	Null for all records.
QSORRES	Finding in Original Units	text		CRF Page 15	Result Qualifier	
QSORRESU	Original Units	text		Assigned	Variable Qualifier	Null for all records.
QSSTRESC	Character Result/Finding in Std Format	text		Derived	Result Qualifier	Equivalent to QSORRES.
QSSTRESN	Numeric Finding in Standard Units	integer		Derived	Result Qualifier	Numeric equivalent of QSSTRESC.
QSSTRESU	Standard Units	text		Assigned	Variable Qualifier	Null for all records.
QSSTAT	Completion Status	text	NOTDONE_F	Assigned	Record Qualifier	Null for all records.
QSREASND	Reason Not Performed	text		Assigned	Record Qualifier	Null for all records.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
QSLOC	Location Used for the Measurement	text		Assigned	Record Qualifier	Null for all records.
QSMETHOD	Method of Determination	text		Assigned	Record Qualifier	Null for all records.
QSBFL	Baseline Flag	text	Y_F	Derived	Record Qualifier	Last non-missing result prior or equal to first dose of study drug. Null for subjects who were not treated.
QSDRVFL	Derived Flag	text	Y_F	Assigned	Record Qualifier	Null for all records.
QSEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
QSDTC	Date/Time of Finding	text	ISO8601	Derived	Timing	Populated with the value found in SV.VISIT for that occurrence.
QSENDTC	End Date/Time of Observation	text	ISO8601	Assigned	Timing	Null for all records.
QSDY	Study Day of Finding	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
QSENDY	Study Day of End of Observation	integer		Derived	Timing	Null for all records.
QSTPT	Planned Time Point Name	text		Assigned	Timing	Null for all records.
QSTPTNUM	Planned Time Point Number	integer		Assigned	Timing	Null for all records.
QSELT	Planned Elapsed Time from Time Point Ref	text		Assigned	Timing	Null for all records.
QSTPTREF	Time Point Reference	text		Assigned	Timing	Null for all records.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
QSRFTDTC	Date/Time of Reference Time Point	text	ISO8601	Derived	Timing	Equivalent to the Date Referenced in QSTPTREF.
QSEVLINT	Evaluation Interval	text	ISO8601	Assigned	Timing	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'SC'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
SCSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
SCGRPID	Group ID	text		Assigned	Identifier	Null for all records.
SCSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
SCTESTCD	Subject Characteristic Short Name	text		Assigned	Topic	
SCTEST	Subject Characteristic	text		Assigned	Synonym Qualifier	
SCCAT	Category for Subject Characteristic	text	SCCAT_F	Assigned	Grouping Qualifier	
SCSCAT	Subcategory for Subject Characteristic	text		Assigned	Grouping Qualifier	Null for all records.
SCORRES	Result or Finding in Original Units	text		CRF Page 23	Result Qualifier	
SCORRESU	Original Units	text		Assigned	Variable Qualifier	Null for all records.
SCSTRESC	Character Result/Finding in Std Format	text		Derived	Result Qualifier	Equivalent to SCORRES.
SCSTRESN	Numeric Result/Finding in Standard Units	integer		Derived	Result Qualifier	Numeric equivalent of SCSTRESC.
SCSTRESU	Standard Units	text		Assigned	Variable Qualifier	Null for all records.
SCSTAT	Completion Status	text	NOTDONE_F	Assigned	Record Qualifier	Null for all records.
SCREASND	Reason Not Performed	text		Assigned	Record Qualifier	Null for all records.



Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	The SCSTDTC must be >or = to the SESTET, but < the next SESTET. If SCSTDTC < SESTET where VISIT = VISIT1, then VISIT = VISIT1. If SCSTDTC > last SVENDTC, then VISIT = VISIT of that last SVENDTC.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
SCDTC	Date/Time of Collection	text	ISO8601	Derived	Timing	Set to informed consent date.
SCDY	Study Day of Examination	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
DOMAIN	Domain Abbreviation	text		Assigned	Identifier	Set to 'VS'.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
VSSEQ	Sequence Number	integer		Derived	Identifier	Sequence number assigned to be unique within the domain and USUBJID and assigned according to record sequence as determined by designated key variables for the domain.
VSGRPID	Group ID	text		Assigned	Identifier	Assigned by visit/time point/ position. The first set of results within a visit time point/position will always be 1 and will increase by 1 for each additional set.
VSSPID	Sponsor-Defined Identifier	text		Assigned	Identifier	Null for all records.
VSTESTCD	Vital Signs Test Short Name	text		Assigned	Topic	
VSTEST	Vital Signs Test Name	text		Assigned	Synonym Qualifier	
VSCAT	Category for Vital Signs	text	VSCAT_F	Assigned	Grouping Qualifier	
VSSCAT	Subcategory for Vital Signs	text		Assigned	Grouping Qualifier	Null for all records.
VSPOS	Vital Signs Position of Subject	text		CRF Page 12	Record Qualifier	
VSORRES	Result or Finding in Original Units	text		CRF Pages 10, 11, 12	Result Qualifier	
VSORRESU	Original Units	text		CRF Pages 10, 11, 12	Variable Qualifier	
VSSTRESC	Character Result/Finding in Std Format	text		Derived	Result Qualifier	Equivalent to VSORRES.
VSSTRESN	Numeric Result/Finding in Standard Units	float		Derived	Result Qualifier	Numeric equivalent of VSSTRESC.
VSSTRESU	Standard Units	text		Assigned	Variable Qualifier	Sponsor define standardized units.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
VSSTAT	Completion Status	text	NOTDONE_F	Assigned	Record Qualifier	Null for all records.
VSREASND	Reason Not Performed	text		Assigned	Record Qualifier	Null for all records.
VSLOC	Location of Vital Signs Measurement	text		Assigned	Record Qualifier	Null for all records.
VSBLFL	Baseline Flag	text	Y_F	Derived	Record Qualifier	Last non-missing result prior or equal to first dose of study drug. Null for subjects who were not treated.
VSDRVFL	Derived Flag	text	YN_F	Assigned	Record Qualifier	Null for all records.
VISITNUM	Visit Number	integer	VIS_F	Derived	Timing	Numeric equivalent of alphanumeric variable VISIT.
VISIT	Visit Name	text		Derived	Timing	Populated with the value found in SV.VISIT.
EPOCH	Epoch	text	EPOCH_F	Derived	Timing	Populated with the TA.EPOCH value corresponding to VISITNUM
VSDTC	Date/Time of Measurements	text	ISO8601	Derived	Timing	Populated with the value found in SV.VISIT for that occurrence.
VSDY	Study Day of Vital Signs	integer		Derived	Timing	Calculated using RFSTDTC. If date is on or after RFSTDTC, then Study Day = (Date - RFSTDTC) + 1. If Date is prior to RFSTDTC, then Study Day = (Date - RFSTDTC).
VSTPT	Planned Time Point Name	text		Assigned	Timing	Null for all records.
VSTPTNUM	Planned Time Point Number	integer		Assigned	Timing	Null for all records.
VSELTM	Planned Elapsed Time from Time Point Ref	text		Assigned	Timing	Null for all records.
VSTPTREF	Time Point Reference	text		Assigned	Timing	Null for all records.
VSRFTDTC	Date/Time of Reference Time Point	text	ISO8601	Derived	Timing	Equivalent to the Date Referenced in VSTPTREF.

Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'AESEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned, CRF Page 19	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'CMSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned, CRF Pages 14, 21, 22	Variable Qualifier	
QVAL	Data Value	text		Assigned, CRF Pages 14, 21, 22	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'DASEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Null for all records.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Null for all records.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned, CRF Page 8	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'DSSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'EGSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'EXSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'FASEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'LBSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'MHSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned, CRF Page 19	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Variable	Label	Type	Controlled Terms Format	Origin	Role	Comments
STUDYID	Study Identifier	text		Protocol	Identifier	Set to 'H9X-MC-GBCK'.
RDOMAIN	Related Domain Abbreviation	text		Assigned	Identifier	Equal to the domain of the parent record.
USUBJID	Unique Subject Identifier	text		Derived	Identifier	Concatenation of STUDYID, INVID and SUBJID.
IDVAR	Identifying Variable	text		Assigned	Identifier	Set to 'PCSEQ'.
IDVARVAL	Identifying Variable Value	text		Derived	Identifier	Equivalent to corresponding domain SEQ or REFID.
QNAM	Qualifier Variable Name	text		Assigned	Topic	
QLABEL	Qualifier Variable Label	text		Assigned	Variable Qualifier	
QVAL	Data Value	text		Assigned	Result Qualifier	
QORIG	Origin	text		Assigned	Variable Qualifier	
QEVAL	Evaluator	text		Assigned	Record Qualifier	Null for all records.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DISPAMT	Dispensed Amount	integer		eDT		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
HRMEAN	Summary (Mean) Heart Rate	integer		eDT		
INTP	Interpretation	text	EG_INTP_F	eDT		
PRMEAN	Summary (Mean) PR Duration	integer		eDT		
QRS DUR	Summary (Mean) QRS Duration	integer		eDT		
QTcB	QTcB - Bazett's Correction Formula	integer		eDT		
QTcBPROL	QTcB Prolongation	text		eDT		
QTcF	QTcF - Fridericia's Correction Formula	float		eDT		
QTMEAN	Summary (Mean) QT Duration	integer		eDT		
RRMEAN	Summary (Mean) RR Duration	float		eDT		
T70	Rhythm Assessment	text		eDT		
T71	Axis Assessment	text		eDT		
T72	Conduction Assessment	text		eDT		
T73	Morphology Assessment	text		eDT		
T75	ST Segment Assessment	text		eDT		
T76	T Wave Assessment	text		eDT		
T78	U Wave Assessment	text		eDT		
T79	Other ECG Assessment	text		eDT		
T80	Comparison To Baseline ECG	text		eDT		
T81	Comparison To Previous ECG	text		eDT		
T84	Myocardial Ischemia	text		eDT		



Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
T85	Myocardial Injury	text		eDT		
T86	Myocardial Infarction	text		eDT		
T98	QTc Interval (Regression Correction)	float		eDT		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
AJDTHTP	Adjudication Death Type	text		CRF Page 25		
AJECRES2	Adj review cnfirm Unstble Angina	text		CRF Page 26		
AJECRES4	Adj confirm Transient Ischemic Attack	text		CRF Page 26		
AJECRES5	Adj confirm Congestive Heart Failure	text		CRF Page 26		
AJECRES9	Adj review confirms Pancreatitis	text	YN_F	CRF Page 29		
AJIVT	Adjudication Intervention	text		CRF Page 26		
AJMICRIT	MI Criteria	text		CRF Page 26		
AJMIQWCR	Q-wave Criteria	text		CRF Page 26		
AJMISTCR	ST Elevation Criteria	text		CRF Page 26		
AJPNCD2	Pancreatitis adjudication diagnosis	text	AJPNCD2_F	CRF Page 29		
AJPNCD4	Pancreatic complications	text	AJPNCD4_F	CRF Page 29		
AJPNCD5	Contributing pancreatic risk factors	text	AJPNCD5_F	CRF Page 29		
AJPNCRS1	Type of pancreatitis	text	AJPNCRS1_F	CRF Page 29		
AJPNCRS3	Pancreatitis severity	text	AJPNCRS3_F	CRF Page 29		
AJSTKSEV	Stroke severity	text		CRF Page 26		
AJSTKTP	Adjudication Stroke Type	text		CRF Page 26		
BGCONC	Blood Glucose Concentration	float		CRF Page 41		
EPIDUR	Duration	float		CRF Page 16		
HYAW	What was the Subject's awareness of the	text	HYAW_F	CRF Page 41		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
HYDOSED	What was the date of last study drug	text		CRF Page 41		
HYOCCPER	When did the hypoglycemic event occur?	text	HYOCCPER_F	CRF Page 41		
HYOUT	What was the hypoglycemic event outcome?	text	HYOUT_F	CRF Page 41		
HYRN1	Number of hypoglycemic episodes	integer		CRF Page 37		
HYRN2	Number of severe hypoglycemic episodes	integer		CRF Page 37		
HYRN3	Number of times subject treated with	integer		CRF Page 37		
HYRN4	Number of times subject treated with IV	integer		CRF Page 37		
HYSEV	Severity	text	HYSEV_F	CRF Page 41		
HYTRT	How was the hypoglycemic event treated?	text	HYTRT_F	CRF Page 41		
HYTRTFLG	Was the Subject capable of treating self	text	YN_F	CRF Page 41		
PNCD2	If yes, indicate pancreatitis symptoms	text	PNCD2_F	CRF Page 24		
PNCD4	Pancreatic imaging	text	PNCD4_F	CRF Page 24		
PNCRES1	Did the subject have symptoms suggestive	text	YN_F	CRF Page 24		
PNCRES3	Did the subject have confirmed amylase	text	YN_F	CRF Page 24		
PNCRES5	Pancreatic imaging results	text	PNCRES5_F	CRF Page 24		
TRTCMPF	Subject compliant with treatment regimen	text	YN_F	CRF Page 44		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
ALBCREAT	Albumin/Creatinine	text		eDT		
ALP	Alkaline Phosphatase	integer		eDT		
ALT	Alanine Aminotransferase	integer		eDT		
AMYLASE	Amylase	integer		eDT		
AMYLASEP	Amylase, Pancreatic	text		eDT		
ANISO	Anisocytes	integer		eDT		
AST	Aspartate Aminotransferase	integer		eDT		
BACT	Bacteria	integer		eDT		
BASO	Basophils	float		eDT		
BILDIR	Direct Bilirubin	integer		eDT		
BILI	Bilirubin	integer		eDT		
BUN	Blood Urea Nitrogen	float		eDT		
BURRCE	Burr Cells	text		eDT		
C14	UA-Microscopic Exam	text		eDT		
CASTS	Casts	integer		eDT		
CHOL	Cholesterol	float		eDT		
CK	Creatine Kinase	integer		eDT		
CKMB	Creatine Kinase MB	text		CRF Page 28		
CL	Chloride	integer		eDT		
CREAT	Creatinine	integer		eDT		
CREATCLR	Creatinine Clearance	text		eDT		
CRP	C Reactive Protein	float		eDT		
CSGRAN	Granular Casts	integer		eDT		
CSHYAL	Hyaline Casts	integer		eDT		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
CYAMORPH	Amorphous Crystals	text		eDT		
CYAMPURT	Amorphous Urate Crystals	text		eDT		
CYCAOXA	Calcium Oxalate Crystals	integer		eDT		
CYSTARCH	Starch Crystals	text		eDT		
CYTRPHOS	Triple Phosphate Crystals	text		eDT		
CYURIAC	Uric Acid Crystals	integer		eDT		
D58	DNA Extraction/Lysis Date	integer		eDT		
D77	DNA Extraction Concentration	float		eDT		
D95	Patient DNA Sample Received?	text		eDT		
ELLIPCY	Elliptocytes	text		eDT		
EOS	Eosinophils	float		eDT		
EPIC	Epithelial Cells	integer		eDT		
EPITCE	Transitional Epithelial Cells	integer		eDT		
EPITUCE	Tubular Epithelial Cells	integer		eDT		
GADAB	Glutamic Acid Decarboxylase Antibody	text		eDT		
GGT	Gamma Glutamyl Transferase	integer		eDT		
GLUC	Glucose	float		CRF Page 35		
HBA1C	Hemoglobin A1C	float		eDT		
HCG	Choriogonadotropin Beta	text		eDT		
HCT	Hematocrit	float		eDT		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
HDL	HDL Cholesterol	float		eDT		
HG3	Islet Cell Antibody, IGG	text		eDT		
HGB	Hemoglobin	integer		eDT		
HPOCROM	Hypochromia	integer		eDT		
I20	Anti-LY2189265 (GLP-FC)	text		eDT		
I22	Anti-LY2189265 (GLP-FC) Titer	integer		eDT		
INSULIN	Insulin	text		eDT		
INTLK6	Interleukin 6	text		eDT		
INTLK8	Interleukin 8	integer		eDT		
JE9	LY2189265 Neutralizing Antibody	text		eDT		
K	Potassium	text		eDT		
K03	DNA Extraction Volume	float		eDT		
KETONES	Ketones	integer		eDT		
LDL	LDL Cholesterol	text		eDT		
LEUKASE	Leukocyte Esterase	integer		eDT		
LIPASE	Triacylglycerol Lipase	integer		eDT		
LYM	Lymphocytes	float		eDT		
LYMAT	Lymphocytes Atypical	float		eDT		
MACROCY	Macrocytes	integer		eDT		
MCHC	Ery. Mean Corpuscular HGB Concentration	integer		eDT		
MCV	Ery. Mean Corpuscular Volume	integer		eDT		
MICROCY	Microcytes	integer		eDT		
MONO	Monocytes	float		eDT		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
NEUTB	Neutrophils Band Form	float		eDT		
NEUTSG	Neutrophils, Segmented	float		eDT		
NEUTVAC	Vacuolated Neutrophils	text		eDT		
OCCBLD	Occult Blood	integer		eDT		
P22	Serum - Combined Specimen Banking	text		eDT		
P23	Citrated Plasma - Combined Specimen	text		eDT		
PLAT	Platelets	integer		eDT		
PLATLRG	Large Platelets	text		eDT		
POIKILO	Poikilocytes	integer		eDT		
POLYCHR	Polychromasia	integer		eDT		
PROT	Protein	integer		eDT		
RBC	Erythrocytes	float		eDT		
RBCMORPH	Erythrocyte Cell Morphology	text		eDT		
ROULEAUX	Rouleaux Formation	text		eDT		
S79	Non-HDL Cholesterol	float		eDT		
S82	Triglyceride/HDL	float		eDT		
SODIUM	Sodium	integer		eDT		
TEARDCY	Dacryocytes	text		eDT		
TNF	Tumor Necrosis Factor	float		eDT		
TRGTCE	Target Cells	text		eDT		
TRIG	Triglycerides	float		eDT		
TROPONI	Troponin I	text		CRF Page 28		
TROPONT	Troponin T	text		CRF Page 28		



Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
WBC	Leukocytes	float		eDT		
YEAST	Yeast Cells	integer		eDT		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
R39	LY2189265, PLASMA	text		eDT		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
HYPTENFL	Reports HTN; anti-hypertensive meds	text	YN_F	CRF Page 15		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DNAORG61	Primary: Paternal grandmother	text		CRF Page 23		
DNAORG62	Secondary: Paternal grandmother	text		CRF Page 23		
DNAORG63	Tertiary: Paternal grandmother	text		CRF Page 23		
DNAORG71	Primary: Paternal grandfather	text		CRF Page 23		
DNAORG72	Secondary: Paternal grandfather	text		CRF Page 23		
DNAORG73	Tertiary: Paternal grandfather	text		CRF Page 23		
DNAORG81	Primary: Maternal grandmother	text		CRF Page 23		
DNAORG82	Secondary: Maternal grandmother	text		CRF Page 23		
DNAORG83	Tertiary: Maternal grandmother	text		CRF Page 23		
DNAORG91	Primary: Maternal grandfather	text		CRF Page 23		
DNAORG92	Secondary: Maternal grandfather	text		CRF Page 23		
DNAORG93	Tertiary: Maternal grandfather	text		CRF Page 23		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
AECDVER	MedDRA Coding Version	float		Assigned		MedDRA coding version dependent on subject informed consent date. Versions used: 11.0, 12.0
AERPVER	MedDRA Reporting Version	float		Assigned		
AERSTDIS	Relationship to Study Disease	text	Y_F	Assigned		
AERSTPRC	Relationship to Study Procedure	text	Y_F	Assigned		
AETRTEM	Treatment Emergent AE	text	Y_F	DERIVED		Y if AESTDTC > RFXSTDTC. The same determination is used for partial date, using the partial portion of AESTDTC compared to the equivalent partial portion of RFSTDTC.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
CMENREAS	Reason Discontinued	text	CMENREAS_F	CRF Pages 14, 22		
DOSEADJ	Dose Adjustment Type	text	DOSEADJ_F	CRF Page 22		
PTLBL	Protocol Period	text	PTLBL_F	CRF Page 21		
REASADJ	Reason Dose Adjusted	text	REASADJ_F	CRF Page 22		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DALOT	Lot Number	text		eDT		
DAPKDESC	Package Description	text		eDT		
DAPKTPID	Package Type ID	text		eDT		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
RACEEVAL	Race Evaluator	text	RACEEVAL_F	DERIVED		Equivalent to Race Assessor on Demographic CRF page.
RACE_1	White	text		CRF Page 8		When DM_RACE = MULTIPLE and '1' is selected under RACE, then populate with the decoded value according to the race category.
RACE_84	American Indian or Alaska Native	text		CRF Page 8		When DM_RACE = MULTIPLE and '84' is selected under RACE, then populate with the decoded value according to the race category.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DSEVAL	Informed Consent Signer	text	DSEVAL_F	DERIVED		Mapped from Informed Consent CRF page.
ICSTP	Informed Consent Subtype	text	ICSTP_F	DERIVED		Mapped from Informed Consent CRF page. Populate with the decoded value according to informed consent subtype category.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
EGGLSTCD	GLS ECG Test or Examination Code	text		eDT		
EGRESSRC	ECG Result Source	text		DERIVED		Set to 'GLS'.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DOSEDESC	Treatment Dose Description	text	DOSEDESC_F	DERIVED		If DOSEDESC = '1', '2' or '.', or if TRTRMD='93', or if DOSEDESC = '17', then no SUPPQUAL record is created.
TRTDESC	Treatment Description	text		PROTOCOL		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DOSEDESC	Treatment Dose Description	text	DOSEDESC_F	DERIVED		Mapped from Hypoglycemic Events CRF page, If DOSEDESC = '.', no SUPPQUAL record is created. If HYMD= '93', no SUPPQUAL record is created.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
LBGLSTCD	GLS Lab Test or Examination Code	text		Assigned		
LBNRINDO	Original Reference Range Indicator	text		DERIVED		As LBNRIND relates to the standard result, LBNRINDO relates to the original result. Determined the same as LBNRIND but using original information.
LBRESSRC	Lab Result Source	text		DERIVED		For LAB results, set to 'GLS'. For Blood Glucose Monitoring results, set to 'CRF'.
LBSTRLAB	Standard Reference Range Lab	text		DERIVED		For LAB results, set to the GLS dictionary lab code used in the standard reference range look up.

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
MHCDVER	MedDRA Coding Version	float		Assigned		
MHRPVER	MedDRA Reporting Version	float		Assigned		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
PCRESSRC	PK Result Source	text		DERIVED		Set to "GLS".

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
EXC11	Have type 1 diabetes as suggested by positive anti-glutamate decarboxylase (GAD) and/or anti-islet cell antibody, or history of ketoacidosis, or any other type of diabetes, other than type 2.	text		PROTOCOL		
EXC12	Are taking any glucose-lowering oral agents other than metformin within 3 months prior to Visit 1.	text		PROTOCOL		
EXC13	GLP-1 analog or incretin mimetic w/in 6 mon prior to Visit 1, insulin therapy ever for diabetes. if insulin for short-term management of acute conditions > 3 mon prior to visit 1 may participate.	text		PROTOCOL		
EXC14	Are currently taking prescription or over-the-counter medications to promote weight loss.	text		PROTOCOL		
EXC15	Receiving chronic systemic glucocorticoid therapy (excluding topical, intraocular, intranasal, intra-articular, or inhaled preparations) or received such therapy within 4 weeks prior to Visit 1.	text		PROTOCOL		



Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
EXC16	Have a known clinically significant gastric emptying abnormality, have undergone gastric bypass (bariatric) surgery, or chronically take drugs that directly reduce gastrointestinal motility.	text		PROTOCOL		
EXC17	Are currently taking a central nervous system stimulant (for example, Ritalin-SR).	text		PROTOCOL		
EXC18	Any of following <= 6 months prior to Visit 1: ACS, CHD treated by CABG or PCI, heart failure, atrial or ventricular arrhythmia, pacemaker implant, cs signs of ischemic heart disease, tia or stroke.	text		PROTOCOL		
EXC19	Poorly controlled hypertension at Visits 1 or 4, or change antihypertensive meds between Visits 1 and 4, renal artery stenosis, or evidence of labile BP including symptomatic postural hypotension.	text		PROTOCOL		
EXC20	Visit 1 ECG on, relevant for interpretation or indicates cardiac disease (QTc [Bazett] int >450 msec males or >470 msec females); and aberrant, blocked, or impaired propagation (pr int >220 msec).	text		PROTOCOL		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
EXC21	Have obvious clinical signs or symptoms of liver disease, acute or chronic hepatitis, or ALT levels >3.0 times the upper limit of the reference range at Visit 1, determined by central lab.	text		PROTOCOL		
EXC22	Have obvious clinical signs or symptoms of pancreatitis (section 6.2.1.1.1), a history of chronic pancreatitis or acute pancreatitis at Visit 1 , as determined by the investigator.	text		PROTOCOL		
EXC22A	Signs or symptoms of pancreatitis, history of chronic or acute pancreatitis at Visit 1. excluded if amylase >=3 times ULN and/or lipase >=2 times ULN, as determined by the central lab at Visit 1.	text		PROTOCOL		
EXC23	Have a serum creatinine >=1.5 mg/dl for men or >=1.4 mg/dl for women, or a creatinine clearance <60 ml/minute as determined by the central laboratory at Visit 1.	text		PROTOCOL		
EXC24	Have uncontrolled diabetes defined as 2 or more episodes of hyperosmolar state requiring hospitalization in the 6 months prior to Visit 1.	text		PROTOCOL		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
EXC25	Have evidence of a significant active, uncontrolled endocrine or autoimmune abnormality, as judged by the screening investigator.	text		PROTOCOL		
EXC26	Have a history of a transplanted organ (corneal transplants [keratoplasty] allowed).	text		PROTOCOL		
EXC27	Have active or untreated malignancy or in remission from clin sig malignancy other than basal or squamous cell skin cancer, in situ carcinoma of the cervix or in situ prostate cancer < 5 years.	text		PROTOCOL		
EXC28	Have any other condition (such as known drug or alcohol abuse or psychiatric disorder), in the opinion of the investigator, that may preclude the patient from following and completing the protocol.	text		PROTOCOL		
EXC29	Are investigator site personnel directly affiliated with this study and/or their immediate families. immediate family is defined as a spouse, parent, child, or sibling, whether biological or adopted.	text		PROTOCOL		
EXC30	Are Lilly employees.	text		PROTOCOL		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
EXC31	Have received treatment within the last 30 days with a drug that has not received regulatory approval in the respective country for any indication at the time of study entry.	text		PROTOCOL		
EXC32	Have participated in an interventional medical, surgical, or pharmaceutical study (a study in which a medical or surgical treatment was given) within 30 days prior to entry into the study.	text		PROTOCOL		
EXC33	Have previously completed or withdrawn from this study after providing informed consent.	text		PROTOCOL		
INC1	Have type 2 diabetes based on the disease diagnostic criteria (World Health Organization [WHO] classification, protocol attachment GBCK.3).	text		PROTOCOL		
INC10	Have given written informed consent to participate in this study in accordance with local regulations and the ethical review board (ERB) governing the study site.	text		PROTOCOL		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
INC2	Are antihyperglycemic medication-naïve (diet and exercise only) or are taking metformin as monotherapy and are willing to discontinue this medication.	text		PROTOCOL		
INC3	Have completed at least 8 weeks of wash-out prior to randomization (Visit 4), if taking metformin prior to Visit2.	text		PROTOCOL		
INC3A	Have completed at least 8 weeks of wash-out prior to collecting the hba1c sample for randomization (Visit 4), if taking metformin prior to Visit 2.	text		PROTOCOL		
INC4	HbA1c, from central lab, Visit 1 and 4. therapy at Visit 1 HbA1c at Visit 1 HbA1c at Visit 4 diet and exercise $\geq 7.0\%$ to $\leq 9.5\%$ $\geq 7.0\%$ to $\leq 9.5\%$ metformin monotherapy $\geq 6.0\%$ to $\leq 8.5\%$ $\geq 7.0\%$ to $\leq 9.5\%$	text		PROTOCOL		
INC4A	HbA1c, from central lab, Visit 1 and 4. therapy at Visit 1 HbA1c, at Visit 1 HbA1c, at Visit 4 diet and exercise $\geq 7.0\%$ to $\leq 9.5\%$ $\geq 6.5\%$ to $\leq 9.5\%$ metformin monotherapy $\geq 6.5\%$ to $\leq 9.0\%$ $\geq 6.5\%$ to $\leq 9.$	text		PROTOCOL		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
INC5	Men or women who are between the ages of 18 to 75 years, inclusive.	text		PROTOCOL		
INC6	Females of childbearing potential must test negative for pregnancy at Visit 1, agree to use a reliable method of birth control during and 1 month following last dose and not be breastfeeding.	text		PROTOCOL		
INC7	BMI between 23 and 40 kg/m <sup>2</sup> , inclusive, for patients who are native to, and reside in, south and/or east Asia. all other patients must have a BMI between 27 and 40 kg/m <sup>2</sup> , inclusive.	text		PROTOCOL		
INC7A	BMI between 23 and 40 kg/m <sup>2</sup> , inclusive, for patients who are native to, and reside in, south and/or east Asia. all other patients must have a BMI between 25 and 40 kg/m <sup>2</sup> , inclusive.	text		PROTOCOL		

Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
INC8	Have a stable weight during the 3 months prior to Visit 1, in the opinion of the investigator.	text		PROTOCOL		
INC9	Motivated, capable, willing to perform smg testing, self-inject treatment, (if not able to perform the injections must have assistance from persons trained to inject drug) and maintain a study diary.	text		PROTOCOL		

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Value	Label	Type	Controlled Terms or Format	Origin	Role	Comments
DIABP	Diastolic Blood Pressure	integer		CRF Page 12		
HEIGHT	Height	float		CRF Page 10		
PULSE	Pulse Rate	integer		CRF Page 12		
SYSBP	Systolic Blood Pressure	integer		CRF Page 12		
WEIGHT	Weight	float		CRF Page 11		

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Code Value	Code Text
GENERAL ADVERSE EVENTS	GENERAL ADVERSE EVENTS

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<b>Code Value</b>	<b>Code Text</b>
FATAL	FATAL
NOT RECOVERED/NOT RESOLVED	NOT RECOVERED/NOT RESOLVED
RECOVERED/RESOLVED	RECOVERED/RESOLVED
RECOVERED/RESOLVED WITH SEQUELAE	RECOVERED/RESOLVED WITH SEQUELAE
RECOVERING/RESOLVING	RECOVERING/RESOLVING
UNKNOWN	UNKNOWN

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Code Value	Code Text
MILD	MILD
MODERATE	MODERATE
SEVERE	SEVERE

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Code Value	Code Text
YEARS	YEARS

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Code Value	Code Text
ELEVATED ENZYMES	ELEVATED ENZYMES
IMAGING RESULTS	IMAGING RESULTS
SYMPTOMS	SYMPTOMS

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Code Value	Code Text
PANCREATITIS, HEMORRHAGIC	PANCREATITIS, HEMORRHAGIC

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Code Value	Code Text
CHOLELITHIASIS	CHOLELITHIASIS

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Code Value	Code Text
PANCREATITIS, ACUTE	PANCREATITIS, ACUTE

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Code Value	Code Text
SEVERE	SEVERE

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Code Value	Code Text
A-1	TR1_PLACEBO
A-2	TR2_LY2189265-0.1mg
A-3	TR3_LY2189265-0.5mg
A-4	TR4_LY2189265-1.0mg
A-5	TR5_LY2189265-1.5mg
A-6	TR6_LY2189265-3.0mg
NOTASSGN	NOT ASSIGNED
SCRNFAIL	SCREEN FAILURE

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Code Value	Code Text
CONCOMITANT THERAPY	CONCOMITANT THERAPY
PREVIOUS TREATMENT	PREVIOUS TREATMENT

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Code Value	Code Text
mg	milligram

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<b>Code Value</b>	<b>Code Text</b>
CANNOT AFFORD MEDICATION	CANNOT AFFORD MEDICATION
CAREGIVER DECISION	CAREGIVER DECISION
HEALTH INSURANCE CHANGES	HEALTH INSURANCE CHANGES
PRESCRIPTION INCONVENIENCE	PRESCRIPTION INCONVENIENCE
SUBJECT DECISION	SUBJECT DECISION
TO ENTER THIS TRIAL	TO ENTER THIS TRIAL
TREATMENT AVAILABILITY	TREATMENT AVAILABILITY

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<b>Code Value</b>	<b>Code Text</b>
ANTIHYPERGLYCEMICS	ANTIHYPERGLYCEMICS
ANTIHYPERTENSIVE MEDICATIONS	ANTIHYPERTENSIVE MEDICATIONS
GENERAL CONCOMITANT MEDICATIONS	GENERAL CONCOMITANT MEDICATIONS

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Code Value	Code Text
STUDY TREATMENT	STUDY TREATMENT

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Code Value	Code Text
LY2189265	LY2189265
PLACEBO	PLACEBO

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Code Value	Code Text
DOSE INCREASED	DOSE INCREASED
DOSE REDUCED	DOSE REDUCED

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Code Value	Code Text
LAST (PRIOR) DOSE	LAST (PRIOR) DOSE
LAST (PRIOR) DOSE BEFORE PK DRAW	LAST (PRIOR) DOSE BEFORE PK DRAW
NEXT TO LAST DOSE BEFORE PK DRAW	NEXT TO LAST DOSE BEFORE PK DRAW

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Code Value	Code Text
DISPOSITION EVENT	DISPOSITION EVENT
PROTOCOL MILESTONE	PROTOCOL MILESTONE

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Code Value	Code Text
ADVERSE EVENT	ADVERSE EVENT
COMPLETED	COMPLETED
DEATH	DEATH
ENTRY CRITERIA NOT MET	ENTRY CRITERIA NOT MET
INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED
LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
NON-COMPLIANCE WITH STUDY DRUG	NON-COMPLIANCE WITH STUDY DRUG
PHYSICIAN DECISION	PHYSICIAN DECISION
PROTOCOL VIOLATION	PROTOCOL VIOLATION
RANDOMIZED	RANDOMIZED
SPONSOR DECISION	SPONSOR DECISION
WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT

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Code Value	Code Text
STUDY SUBJECT	STUDY SUBJECT

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Code Value	Code Text
STRATIFIED RANDOMIZED BLOCKS	STRATIFIED RANDOMIZED BLOCKS
STUDY	STUDY
SUBJECT SUMMARY	SUBJECT SUMMARY
SUPPLEMENTAL	SUPPLEMENTAL

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Code Value	Code Text
INTERPRETER	INTERPRETER

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Code Value	Code Text
12 LEAD UNSPECIFIED	12 LEAD UNSPECIFIED

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Code Value	Code Text
ABNORMAL	ABNORMAL
NORMAL	NORMAL
UNABLE TO EVALUATE	UNABLE TO EVALUATE

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Code Value	Code Text
AFTER	AFTER
DURING/AFTER	DURING/AFTER

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Code Value	Code Text
TRIAL EARLY DISCONTINUATION	TRIAL EARLY DISCONTINUATION
TRIAL FOLLOW UP	TRIAL FOLLOW UP
TRIAL LEAD-IN	TRIAL LEAD-IN
TRIAL SCREENING	TRIAL SCREENING
TRIAL TREATMENT	TRIAL TREATMENT

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Code Value	Code Text
ED	EARLY DISCONTINUATION
FU	FOLLOW UP
LEAD_IN	LEAD-IN
LY0P1	LY2189265 0.1mg
LY0P5	LY2189265 0.5mg
LY1P0	LY2189265 1.0mg
LY1P5	LY2189265 1.5mg
LY3P0	LY2189265 3.0mg
PL	PLACEBO
SCRN	SCREENING

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Code Value	Code Text
HISPANIC OR LATINO	HISPANIC OR LATINO
NOT HISPANIC OR LATINO	NOT HISPANIC OR LATINO

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Code Value	Code Text
STUDY TREATMENT	STUDY TREATMENT

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Code Value	Code Text
SOLUTION	SOLUTION

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Code Value	Code Text
ONCE	ONCE
QS	EVERY WEEK

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Code Value	Code Text
mg	milligram

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Code Value	Code Text
SUBCUTANEOUS	SUBCUTANEOUS

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Code Value	Code Text
LY2189265	LY2189265
PLACEBO	PLACEBO

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Code Value	Code Text
ADJUDICATION PANCREATIC EVENT	ADJUDICATION PANCREATIC EVENT
HYPOGLYCEMIA - NUMBER OF EVENTS	HYPOGLYCEMIA - NUMBER OF EVENTS
HYPOGLYCEMIC EVENTS	HYPOGLYCEMIC EVENTS
MEDICAL HISTORY - DISEASE CHARACTERISTICS	MEDICAL HISTORY - DISEASE CHARACTERISTICS
PANCREATIC FOLLOW-UP ASSESSMENT	PANCREATIC FOLLOW-UP ASSESSMENT
STUDY TREATMENT COMPLIANCE	STUDY TREATMENT COMPLIANCE

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Code Value	Code Text
SELF-AWARE	SELF-AWARE
UNAWARE	UNAWARE

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Code Value	Code Text
BETWEEN BEDTIME AND BREAKFAST	BETWEEN BEDTIME AND BREAKFAST
BETWEEN BREAKFAST AND BEDTIME	BETWEEN BREAKFAST AND BEDTIME

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Code Value	Code Text
PROLONGED RECOVERY	PROLONGED RECOVERY
PROMPTLY RECOVERED	PROMPTLY RECOVERED

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Code Value	Code Text
NOT SEVERE	NOT SEVERE

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Code Value	Code Text
DRINK	DRINK
FOOD	FOOD

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Code Value	Code Text
PHARMACOGENOMICS - SAMPLE BANKING	PHARMACOGENOMICS - SAMPLE BANKING

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Code Value	Code Text
CHEMISTRY	CHEMISTRY
ENDOCRINE	ENDOCRINE
HEMATOLOGY	HEMATOLOGY
IMMUNOLOGY	IMMUNOLOGY
SAMPLE BANKING	SAMPLE BANKING
URINALYSIS	URINALYSIS

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Code Value	Code Text
1	PRE-MORNING MEAL
2	2 HOURS AFTER MORNING MEAL
3	PRE-MID-DAY MEAL
4	2 HOURS AFTER MID-DAY MEAL
5	PRE-EVENING MEAL
6	2 HOURS AFTER EVENING MEAL
7	NEXT DAY MORNING

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Code Value	Code Text
HISTORICAL ILLNESS	HISTORICAL ILLNESS
PRE-EXISTING CONDITION	PRE-EXISTING CONDITION

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Code Value	Code Text
NOT DONE	NOT DONE

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Code Value	Code Text
ANALYTE	ANALYTE

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Code Value	Code Text
NAUSEA	NAUSEA
PAIN, ABDOMINAL	PAIN, ABDOMINAL
VOMITING	VOMITING

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Code Value	Code Text
COMPUTED TOMOGRAPHY WITH CONTRAST	COMPUTED TOMOGRAPHY WITH CONTRAST
OTHER	OTHER
ULTRASOUND	ULTRASOUND

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Code Value	Code Text
ANOMALY, PANCREAS	ANOMALY, PANCREAS
EDEMA, PANCREATIC	EDEMA, PANCREATIC
NORMAL	NORMAL

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<b>Code Value</b>	<b>Code Text</b>
RESCUE THERAPY (V5-V8)	RESCUE THERAPY (V5-V8)
SAFETY FOLLOW-UP PERIOD (V9)	SAFETY FOLLOW-UP PERIOD (V9)
SCREENING/WASHOUT PERIOD (V1-V4)	SCREENING/WASHOUT PERIOD (V1-V4)

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Code Value	Code Text
CARDIOVASCULAR RISK ASSESSMENT	CARDIOVASCULAR RISK ASSESSMENT

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Code Value	Code Text
STUDY SUBJECT	STUDY SUBJECT

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Code Value	Code Text
AMERICAN INDIAN OR ALASKA NATIVE	AMERICAN INDIAN OR ALASKA NATIVE
ASIAN	ASIAN
BLACK OR AFRICAN AMERICAN	BLACK OR AFRICAN AMERICAN
MULTIPLE	MULTIPLE
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
WHITE	WHITE

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Code Value	Code Text
ADVERSE EVENT	ADVERSE EVENT
INADEQUATE RESPONSE	INADEQUATE RESPONSE
INVESTIGATOR DECISION	INVESTIGATOR DECISION

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Code Value	Code Text
SAMPLE BANKING ORIGIN	SAMPLE BANKING ORIGIN

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Code Value	Code Text
F	FEMALE
M	MALE

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Code Value	Code Text
EXCLUSION	EXCLUSION
INCLUSION	INCLUSION

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Code Value	Code Text
ADDON	Added on to Existing Treatments
AGEMAX	Planned Maximum Age of Subjects
AGEMIN	Planned Minimum Age of Subjects
AGESPAN	Age Span
AGEU	Age Unit
DOSE	Dose per Administration
DOSFRQ	Dosing Frequency
DOSU	Dose Units
INDIC	Trial Indication
LENGTH	Trial Length
OBJPRIM	Trial Primary Objective
OBJSEC	Trial Secondary Objective
PLANSUB	Planned Number of Subjects
RANDOM	Trial is Randomized
ROUTE	Route of Administration
SDTMVER	SDTM VERSION
SEXPOP	Sex of Participants
SPONSOR	Sponsoring Organization
TBLIND	Trial Blinding Schema
TCNTRL	Control Type
TDIGRP	Diagnosis Group
TINDTP	Trial Indication Type
TITLE	Trial Title
TPHASE	Trial Phase Classification
TRT	Reported Name of Test Product
TTYPE	Trial Type

Code Value	Code Text
EARLY DISCONTINUATION	EARLY DISCONTINUATION
VISIT1	VISIT1
VISIT2	VISIT2
VISIT3	VISIT3
VISIT4	VISIT4
VISIT5	VISIT5
VISIT6	VISIT6
VISIT7	VISIT7
VISIT8	VISIT8
VISIT9	VISIT9

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Code Value	Code Text
1000	VISIT1
1001	VISIT2
1002	VISIT3
1003	VISIT4
1004	VISIT5
1005	VISIT6
1006	VISIT7
1007	VISIT8
1998	EARLY DISCONTINUATION
1999	VISIT9

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Code Value	Code Text
PHYSICAL CHARACTERISTICS	PHYSICAL CHARACTERISTICS
VITAL SIGNS	VITAL SIGNS

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Code Value	Code Text
N	NO
Y	YES

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Code Value	Code Text
Y	YES

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Code Value	Code Text
Grouping Qualifier	Grouping Qualifier
Identifier	Identifier
Record Qualifier	Record Qualifier
Result Qualifier	Result Qualifier
Rule	Rule
Synonym Qualifier	Synonym Qualifier
Timing	Timing
Topic	Topic
Variable Qualifier	Variable Qualifier

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External Dictionary	Dictionary Version
ISO8601	
ISO3166	
MedDRA	11.0
WHO Drug	01Jun2008-01Dec2010
MedDRA	11.0

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