Tabulation Datasets for Study PC201708 (SEND-IG 3.0)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	Trial Design	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	Trial Design	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt	
TS	Trial Summary	Trial Design	One record per Trial Summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt	
TX	Trial Sets	Trial Design	One record per Trial Set parameter per Trial Set	Tabulation	STUDYID, SETCD, TXPARMCD	tx.xpt	
CO	Comments	Special Purpose	One record per comment	Tabulation	STUDYID, COSEQ	co.xpt	
DM	Demographics	Special Purpose	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	
SE	Subject Elements	Special Purpose	One record per element experienced per subject	Tabulation	STUDYID, USUBJID, ETCD, SESTDTC	se.xpt	
EX	Exposure	Interventions	One record per constant dosing interval per treatment per subject or pool	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	ex.xpt	
DS	Disposition	Events	One record per subject	Tabulation	STUDYID, USUBJID	ds.xpt	
BG	Body Weight Gains	Findings	One record per test per interval per subject	Tabulation	STUDYID, USUBJID, BGTESTCD, BGDTC, BGENDTC	bg.xpt	
BW	Body Weights	Findings	One record per test per observation time per subject	Tabulation	STUDYID, USUBJID, BWTESTCD, BWDTC	bw.xpt	
CL	Clinical Observations	Findings	One record per finding per observation time per subject or pool	Tabulation	STUDYID, USUBJID, CLTESTCD, CLCAT, CLORRES, CLLOC, CLDTC	cl.xpt	
DD	Death Diagnosis	Findings	One record per diagnosis per subject (for unscheduled deaths only)	Tabulation	STUDYID, USUBJID	dd.xpt	
EG	ECG Test Results	Findings	One record per test per observation time per subject	Tabulation	STUDYID, USUBJID, EGTESTCD, EGDTC	eg.xpt	
FW	Food and Water Consumption	Findings	One record per test per interval per subject or pool	Tabulation	STUDYID, USUBJID, FWTESTCD, FWDTC, FWENDTC	fw.xpt	
LB	Laboratory Test Results	Findings	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID, LBTESTCD, LBSPEC, LBDTC	lb.xpt	
MA	Macroscopic Findings	Findings	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MATESTCD, MASTRESC, MASPEC, MAANTREG, MALAT	ma.xpt	
MI	Microscopic Findings	Findings	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MITESTCD, MISTRESC, MISPEC, MIANTREG, MILAT, MIDIR	mi.xpt	
OM	Organ Measurements	Findings	One record per test per specimen per subject	Tabulation	STUDYID, USUBJID, OMTESTCD, OMSPEC	om.xpt	
PC	Pharmacokinetics Concentrations	Findings	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID, PCTESTCD, PCSPEC, PCDTC	pc.xpt	
PM	Palpable Masses	Findings	One record per test per palpable mass per observation time per subject	Tabulation	STUDYID, USUBJID, PMTESTCD, PMSPID, PMDTC	pm.xpt	
PP	Pharmacokinetics	Findings	One record per test per	Tabulation	STUDYID, USUBJID,	pp.xpt	

	Parameters		timeconcentration profile per specimen per subject or pool		PPTESTCD, PPCAT, PPSPEC, PPRFTDTC		
SC	Subject Characteristics	Findings	One record per characteristic per subject	Tabulation	STUDYID, USUBJID, SCTESTCD	sc.xpt	
TF	Tumor Findings	Findings	One record per tumor per specimen per subject	Tabulation	STUDYID, USUBJID, TFTESTCD, TFORRES, TFSPEC	tf.xpt	
VS	Vital Signs	Findings	One record per measurement per observation time per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VSDTC	vs.xpt	
RELREC	Related Records	Relationship	One record per related record, related group of records (e.g., --GRPID), or related dataset	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELID	relrec.xpt	
SUPPMA	Supplemental Qualifiers for MA	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppma.xpt	
SUPPMI	Supplemental Qualifiers for MI	Relationship	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppmi.xpt	

Trial Arms (TA) [Location: ta.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
ARMCD	Planned Arm Code	2	text	2		Other	Short name of a specific ARM (may be up to 20 characters) used for sorting and programming. Should be populated in Demographics when Arms have been defined in this domain.
ARM	Description of Planned Arm		text	30		Other	Descriptive name given to a specific Trial Arm (e.g., Low Dose, Mid Dose, 10 mg/kg/day dose, 3rd Arm) to which subject was assigned.
TAETORD	Order of Element within Arm	3	integer	8		Other	Number that provides the order of the planned Element within the Arm. This value should be an integer.
ETCD	Element Code		text	5		Other	Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. Maximum 8 characters. The values of ETCD used in the Trial Arms dataset must match values for the same Element in the Trial Elements dataset.
ELEMENT	Description of Element		text	28		Other	The name of the Element. The same Element may occur more than once within an Arm.
TABRANCH	Branch		text	21		Other	Conditions animals meet, occurring at the end of an Element, which cause an Arm to branch off from other Arms (e.g., randomization to control group).
EPOCH	Trial Epoch		text	9		Other	Name of the study Epoch with which this Element of the Arm is associated (e.g., Treatment, Screen). Equivalent to 'Phase' or 'Period.'

Trial Elements (TE) [Location: te.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.

ETCD	Element Code	2	text	5		Other	Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. Maximum 8 characters.
ELEMENT	Description of Element		text	28		Other	The description of the Element. The same Element may occur more than once within an Arm.
TESTRL	Rule for Start of Element		text	41		Other	Expresses rule for beginning Element.
TEENRL	Rule for End of Element		text	31		Other	Expresses rule for ending Element. Either TEENRL or TEDUR must be present for each Element.
TEDUR	Planned Duration of Element		text	4	ISO8601	Other	Planned duration of Element in ISO 8601 format. Use when an Element represents a fixed duration.

Trial Summary (TS) [Location: ts.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain most relevant to the observation.
TSSEQ	Sequence Number	3	integer	8		Derived	Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same TSPARMCD, and can be used to join related records. Sequence of numbers within a set of records
TSGRPID	Group Identifier		text	1		Other	Used to tie together a group of related records. This is not the sponsor-defined protocol group number.
TSPARMCD	Trial Summary Parameter Short Name	2	text	8		Other	Short character value for the trial design characteristic described in TSPARM. Value must be 8 characters or less.
TSPARM	Trial Summary Parameter		text	37	SEND Trial Summary Parameter Test Name	Other	Term for the trial parameter. Value must be 40 characters or less.
TSVAL	Parameter Value		text	52		Other	Value of the TS parameter (e.g., "FDA" when TSPARM is GLP Type). The values for some parameters may be subject to controlled terminology. See the Controlled Terms, Codelist, or Format column in Section 7.6.3 that lists all defined parameters. TSVAL cannot be null – a value is required for the record to be valid.

Trial Sets (TX) [Location: tx.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
SETCD	Set Code	2	text	3		Other	Short name of a specific Trial Set, as defined by the sponsor. Maximum 8 characters. This represents the Trial Set for which parameters are being submitted.
SET	Set Description		text	37		Other	Long description of a specific Trial Set, as defined by the sponsor.
TXSEQ	Sequence Number		integer	8		Derived	Unique number for this record within this dataset. (This sequence should be unique within the entire dataset because there is no USUBJID.)

							Sequence of numbers within a set of records
TXPARMCD	Trial Set Parameter Short Name	3	text	8		Other	Short character value for the Trial Set parameter described in TXPARM. Maximum 8 characters.
TXPARM	Trial Set Parameter		text	33	SEND Trial Summary Parameter Test Name	Other	Term for the Trial Set parameter. Maximum 40 characters.
TXVAL	Trial Set Parameter Value		text	32		Other	Value of the Trial Set parameter (e.g., Fed ad libitum or Restricted Feeding when TXPARM is FEEDREG). Some parameters may be subject to controlled terminology. See the Controlled Terms, Codelist, or Format column in Section 7.4.2 that lists all defined Trial Set parameters.

Comments (CO) [Location: co.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
RDOMAIN	Related Domain Abbreviation		text	2		Other	Domain abbreviation of the parent record(s). Null for comments collected as a general comment or additional information.
USUBJID	Unique Subject Identifier		text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
COSEQ	Sequence Number	2	integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
IDVAR	Identifying Variable		text	5		Other	Identifying variable in the parent dataset that identifies the record(s) to which the comment applies. Examples: BWSEQ or CLGRPID. Used only when individual comments are related to domain records.
IDVARVAL	Identifying Variable Value		text	2		Other	Value of identifying variable of the parent record(s). Used only when individual comments are related to domain records. Cannot be populated if IDVAR is null.
COVAL	Comment		text	33		Collected	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn. See Assumption 4 in Section 5.2.1.1.
CODTC	Date/Time of Comment		datetime		ISO8601	Collected	Date/time of the comment, in ISO 8601 format. Should be null if this is a child record of another domain or if comment date was not collected.

Demographics (DM) [Location: dm.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
SUBJID	Subject Identifier for the		text	4		Other	Subject (i.e., Animal) identifier used within the study.

	Study						
RFSTDTC	Subject Reference Start Date/Time		datetime		ISO8601	Collected	Reference start date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Study day calculation (the --DY variable) in all domains will be based on this date. The sponsor must define what collected date is used to populate RFSTDTC in the data definition file.
RFENDTC	Subject Reference End Date/Time		datetime		ISO8601	Collected	Reference end date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when the subject was determined to have left the study. The sponsor must define what collected date is used to populate RFENDTC in the data definition file.
AGETXT	Age Range		text	3		Other	Used when the age is a range and the exact birthdate is not known. This variable is a character field for the purposes of defining age ranges, e.g., if the information available for the age of the subject is 6-8 and AGEU is WEEKS. Populate only when BRTHDTC or AGE are not specified. The format for AGETXT is "number-number" (e.g., 6-8).
AGEU	Age Unit		text	5	["WEEKS"] <Age Unit>	Other	Units associated with either AGE or AGETXT.
SEX	Sex		text	1	["M", "F"] <Sex>	Other	The sex of the subject.
ARMCD	Planned Arm Code		text	2		Other	Short name for ARM (may be up to 20 characters) used for sorting and programming. Should be populated when Arms have been defined in the TA domain.
ARM	Description of Planned Arm		text	30		Other	Descriptive name given to a specific Trial Arm (e.g., Low Dose, Mid Dose, 10 mg/kg/day dose, Third Arm) to which subject was assigned.
SETCD	Set Code		text	3		Other	Short name of a specific Trial Set, as defined by the sponsor. Maximum of 8 characters. This represents the Trial Set for which parameters are being submitted.

Subject Elements (SE) [Location: se.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
SESEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a USUBJID within a domain. May be any valid number. Sequence of numbers within a Subject ID
ETCD	Element Code	3	text	5		Other	Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. If an encountered Element differs from the planned Element to the point that it is considered a new Element, then use UNPLAN as the value for ETCD to represent this Element. The value in ETCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid).
ELEMENT	Description of Element		text	28		Other	The name of the Element. The same Element may occur more than once within an Arm. If ETCD has the value of UNPLAN, then ELEMENT should be blank.
SESTDTC	Start Date/Time of	4	datetime		ISO8601	Collected	Start date/time for an Element for each subject.

	Element						
SEENDTC	End Date/Time of Element		datetime		ISO8601	Collected	End date/time for an Element for each subject.

Exposure (EX) [Location: ex.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
EXSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
EXTRT	Name of Actual Treatment	3	text	6		Collected	Name of the treatment. Usually the verbatim name of the investigational treatment given during the dosing period for the observation.
EXDOSE	Dose per Administration		float	8		Collected	Amount of treatment administered.
EXDOSU	Dose Units		text	5	Unit	Other	Units for EXDOSE. Examples: ng, mg, or mg/kg.
EXDOSFRM	Dose Form		text	8	["SOLUTION"] <Pharmaceutical Dosage Form>	Collected	Dose form for EXTRT. Examples: TABLET, LOTION.
EXDOSFRQ	Dosing Frequency Per Interval		text	3	["QID"] <Frequency>	Collected	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period. Examples: QD (once daily), BID (2x daily), BIS (2x a week).
EXROUTE	Route of Administration		text	11	["ORAL GAVAGE"] <Route of Administration>	Collected	Route of administration for EXTRT. Examples: ORAL GAVAGE, DERMAL, INTRAVENOUS, BOLUS.
EXLOT	Lot Number		text	6		Collected	Lot Number(s) or Batch Number(s) of the EXTRT test article. If mixed lots of the test article are administered during the same constant dosing interval, this should be represented as "Lot A;Lot B". Mixed lots are produced by the mixing of Lots A and B of the test article into one solution, suspension, or dietary food concentration. If no test article was administered, EXLOT should be null.
EXTRTV	Treatment Vehicle		text	6		Collected	Describes vehicle used for treatment. Example: SALINE.
EXSTDTC	Start Date/Time of Treatment	4	datetime		ISO8601	Collected	Date/Time when administration of the treatment indicated by EXTRT and EXDOSE began, in ISO 8601 format.
EXENDTC	End Date/Time of Treatment		datetime		ISO8601	Collected	Date/Time when administration of the treatment indicated by EXTRT and EXDOSE ended, in ISO 8601 format.
EXSTDY	Study Day of Start of Treatment		integer	8		Derived	Study day when administration of the treatment began, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain EXSTDY = EXSTDTC-RFSTDTC+1 if EXSTDTC is on or after RFTSDTC. EXSTDTC - RFSTDTC if EXSTDTC precedes RFSTDTC.
EXENDY	Study Day of		integer	8		Derived	Study day when administration of the treatment ended, in integer days.

	End of Treatment						The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. EXENDY = EXENDTC-RFSTDTC+1 if EXENDTC is on or after RFSTDTC. EXENDTC - RFSTDTC if EXENDTC precedes RFSTDTC.

Disposition (DS) [Location: ds.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
DSSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
DSTERM	Reported Term for the Disposition Event		text	13		Collected	DSTERM is the original term recorded for animal disposition. DSTERM is not under controlled terminology, but should be mapped to DSDECOD.
DSDECOD	Standardized Disposition Term		text	18	["MORIBUND SACRIFICE", "TERMINAL SACRIFICE", "RECOVERY SACRIFICE"] <Standardized Disposition Term>	Other	Contains the result in a standard format.
VISITDY	Planned Study Day of Disposition		integer	8		Other	Planned study day of the disposition event. Should be an integer. VISITDY should be populated only when DSTERM represents a scheduled activity.
DSSTDTC	Date/Time of Disposition		datetime		ISO8601	Collected	Date/time of the disposition event in ISO 8601 format.
DSSTDY	Study Day of Disposition		integer	8		Derived	Study day of the disposition event, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. DSSTDY = DSSTDTC-RFSTDTC+1 if DSSTDTC is on or after RFTSDTC. DSSTDTC - RFSTDTC if DSSTDTC precedes RFSTDTC.

Body Weight Gains (BG) [Location: bg.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
BGSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID

BGTESTCD	Test Short Name	3	text	6	["BWGAIN"] <Body Weight Gain Test Code>	Other	Short name of the measurement, test, or examination described in BGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BGTESTCD cannot contain characters other than letters, numbers, or underscores.
BGTEST	Test Name		text	16	["Body Weight Gain"] <Body Weight Gain Test Name>	Other	Long name for BGTESTCD. The value in BGTEST cannot be longer than 40 characters.
BGORRES	Result or Findings as Collected		text	3		Other	Result of the measurement or finding as originally recorded.
BGORRESU	Unit of the Original Result		text	1	Unit	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
BGSTRESC	Standardized Result in Character Format		text	3		Other	Contains the result value for all findings or derived from BGORRES in a standard format or standard units. BGSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in BGSTRESN.
BGSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for results or findings in standard format; contains the numeric form of BGSTRESC. BGSTRESN should store all numeric test results or findings.
BGSTRESU	Unit of the Standardized Result		text	1	Unit	Other	Standardized unit used for BGSTRESC or BGSTRESN.
BGDTC	Date/Time Animal Weighed	4	datetime		ISO8601	Collected	Date/time of the start of the weight interval in ISO 8601 format. This must be populated when BGTESTCD is BWGAINA.
BGENDTC	End Date/Time Animal Weighed	5	datetime		ISO8601	Collected	Date/time of the end of the weight interval in ISO 8601 format. This must be populated when BGTESTCD is BWGAINA.
BGDY	Study Day Animal Weighed		integer	8		Derived	Study day of the start of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. BGDY = BGDTC-RFSTDTC+1 if BGDTC is on or after RFTSDTC. BGDTC - RFSTDTC if BGDTC precedes RFSTDTC
BGENDY	Study Day of End of Weight Interval		integer	8		Derived	Study day of the end of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. BGENDY = BGENDTC-RFSTDTC+1 if BGENDTC is on or after RFSTDTC. BGENDTC - RFSTDTC if BGENDTC precedes RFSTDTC.

Body Weights (BW) [Location: bw.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
BWSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.

							Sequence of numbers within a Subject ID
BWTESTCD	Test Short Name	3	text	6	["BW", "TERMBW"] <Body Weight Test Code>	Other	Short name of the measurement, test, or examination described in BWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BWTESTCD cannot contain characters other than letters, numbers, or underscores.
BWTEST	Test Name		text	20	["Body Weight", "Terminal Body Weight"] <Body Weight Test Name>	Other	Long name for BWTESTCD. The value in BWTEST cannot be longer than 40 characters.
BWORRES	Result or Findings as Collected		text	5		Collected	Result of the measurement or finding as originally received or collected.
BWORRESU	Unit of the Original Result		text	1	Unit	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
BWSTRESC	Standardized Result in Character Format		text	5		Other	Contains the result value for all findings or derived from BWORRES in a standard format or standard units. BWSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in BWSTRESN.
BWSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for results or findings in standard format; contains the numeric format of BWSTRESC. BWSTRESN should store all numeric test results or findings.
BWSTRESU	Unit of the Standardized Result		text	1	Unit	Other	Standardized unit used for BWSTRESC and BWSTRESN.
BWBLFL	Baseline Flag		text	1	["N", "Y"] <No Yes Response>	Other	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
VISITDY	Planned Study Day of Collection		integer	8		Other	This is the planned study day of collection.
BWDTC	Date/Time Animal Weighed	4	datetime		ISO8601	Collected	Date/time of body weight collection in ISO 8601 format. This is the date/time of the collection of the observation. If the observation is for a period, this is the start of the period.
BWDY	Study Day Animal Weighed		integer	8		Derived	Study day of body weight collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. BWDY = BWDTC-RFSTDTC+1 if BWDTC is on or after RFTSDTC. BWDTC - RFSTDTC if BWDTC precedes RFSTDTC.

Clinical Observations (CL) [Location: cl.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
CLSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.

							Sequence of numbers within a Subject ID
CLTESTCD	Test Short Name	3	text	2		Other	Short name of the measurement, test, or examination described in CLTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in CLTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). CLTESTCD cannot contain characters other than letters, numbers, or underscores.
CLTEST	Test Name		text	13		Other	Long name for CLTESTCD. The value in CLTEST cannot be longer than 40 characters.
CLCAT	Category for Clinical Observations	4	text	14	["CLINICAL SIGNS", "OPHTHALMOLOGY"] <Category for Clinical Observation>	Other	Used to define a category of the clinical observation.
CLORRES	Result or Findings as Collected	5	text	37		Collected	Text description of the finding as originally received or collected. If the examination was not performed on a particular body system, or at the subject level, then the value should be null, and NOT DONE should appear in CLSTAT.
CLSTRESC	Standardized Result in Character Format		text	11		Other	The base finding from CLORRES without modifiers. If the examination was completed and there were no abnormal findings, the value must be NORMAL.
CLLOC	Location of a Finding	6	text	20		Other	Can be used to specify where a clinical sign occurred. Example: LEFT EAR for skin rash.
VISITDY	Planned Study Day of Collection		integer	8		Other	This is the planned study day of collection.
CLDTC	Start Date/Time of Observation	7	datetime		ISO8601	Collected	Date/time of the clinical observation in ISO 8601 format.
CLDY	Study Day of Observation		integer	8		Derived	Study day of the clinical observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. CLDY = CLDTC-RFSTDTC+1 if CLDTC is on or after RFTSDTC. CLDTC - RFSTDTC if CLDTC precedes RFSTDTC.

Death Diagnosis (DD) [Location: dd.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
DDSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
DDTESTCD	Death Diagnosis Short Name		text	6	["DEATHD"] <Death Diagnosis Test Code>	Other	Short name of the measurement, test, or examination described in DDTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DDTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). DDTESTCD cannot contain characters other than letters, numbers, or underscores. In this domain the value should always be DEATHD.

DDTEST	Death Diagnosis Name		text	15	["Death Diagnosis"] <Death Diagnosis Test Name>	Other	Long name for DDTESTCD. The value in DDTEST cannot be longer than 40 characters. In this domain, the value should always be "Death Diagnosis".
DDORRES	Result or Findings as Collected		text	24		Collected	Result of the diagnosis of the subject's cause of death, as originally received or collected.
DDSTRESC	Standardized Result in Character Format		text	24		Other	Contains the diagnosis information, copied or derived from DDORRES in a standard format. Examples: UNKNOWN, GAVAGE ERROR.
DDRESCAT	Result Category		text	12		Other	Used to categorize the result of a finding. Examples: TREATMENT RELATED, NONTREATMENT RELATED, UNDETERMINED, ACCIDENTAL, etc.
DDDY	Study Day of Diagnosis		integer	8		Derived	Study day of the diagnosis, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC - RFSTDTC if --DTC precedes RFSTDTC

ECG Test Results (EG) [Location: eg.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
EGSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
EGTESTCD	ECG Test or Examination Short Name	3	text	6		Other	Short name of the measurement, test, or examination described in EGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in EGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). EGTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: HRMEAN, QRSDUR
EGTEST	ECG Test or Examination Name		text	24	["PR Interval, Aggregate", "QTcB Interval, Aggregate", "RR Interval, Aggregate"] <ECG Test Name>	Other	Long name for EGTESTCD. The value in EGTEST cannot be longer than 40 characters. Examples: Summary (Mean) Heart Rate, Summary (Mean) QRS Duration.
EGPOS	ECG Position of Subject		text	5	["PRONE"] <Position>	Other	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING, UNCONSTRAINED
EGORRES	Result or Findings as Collected		text	3		Collected	Result of the ECG measurement or interval as originally received or collected.
EGORRESU	Unit of the Original Result		text	4	Unit	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
EGSTRESC	Standardized Result in		text	3	ECG Result	Other	Contains the result value for all findings, copied or derived from EGORRES, in a standard format or standard units. EGSTRESC should

	Character Format						store all results or findings in character format; if results are numeric, they should also be stored in numeric format in EGSTRESN. For example, if a test has results of NONE, NEG, and NEGATIVE in EGORRES and these results effectively have the same meaning, they could be represented in standard format in EGSTRESC as NEGATIVE. For other examples, see general assumptions. Additional examples of result data: SINUS BRADYCARDIA, ATRIAL FLUTTER, ATRIAL FIBRILLATION.
EGSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for continuous or numeric results or findings in standard format; copied in numeric format from EGSTRESC. EGSTRESN should store all numeric test results or findings.
EGSTRESU	Unit of the Standardized Result		text	4	Unit	Other	Standardized unit used for EGSTRESC or EGSTRESN. Preferably SI units.
EGLEAD	Location Used for Measurement		text	7	["LEAD II"] <ECG Lead>	Other	Lead identified to capture the measurement.
EGMETHOD	Method of ECG Test		text	1		Other	Method of the ECG test. Examples: 12 LEAD STANDARD, 6 LEAD STANDARD.
EGCSTATE	Consciousness State		text	9	["CONSCIOUS"] <Consciousness State>	Other	Consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS
EGBLFL	Baseline Flag		text	1	["N", "Y"] <No Yes Response>	Other	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
VISITDY	Planned Study Day of Collection		integer	8		Other	This is the planned study day of collection.
EGDTC	Date/Time of ECG	4	datetime		ISO8601	Collected	Date/time of ECG data collection, in ISO 8601 format. For indicating measurement over a continuous period, DTC should be used to indicate start date/time of collection.
EGDY	Study Day of ECG Collection		integer	8		Derived	Study day of the ECG measurement collection, ininteger days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. EGDY = EGDTC-RFSTDTC+1 if EGDTC is on or after RFTSDTC. EGDTC - RFSTDTC if EGDTC precedes RFSTDTC.

Food and Water Consumption (FW) [Location: fw.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
FWSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
FWTESTCD	Food /Water Consumption Short Name	3	text	2	["FC"] <Food and Water Consumption Test Code>	Other	Short name of the measurement, test, or examination described in FWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). FWTESTCD cannot contain characters other than letters,

							numbers, or underscores. Extensible controlled values are FC, FCRELBW, WC, and WCRELBW.
FWTEST	Food /Water Consumption Name		text	16	["Food Consumption"] <Food and Water Consumption Test Name>	Other	Long name for FWTESTCD. The value in FWTEST cannot be longer than 40 characters. Extensible controlled values are Food Consumption, Food Consumption Relative to Body Wt, Water Consumption, Water Consumption Relative to Body Wt.
FWORRES	Result or Findings as Collected		text	3		Collected	Result of the measurement or finding as originally received or collected.
FWORRESU	Unit of the Original Result		text	5	Unit	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
FWSTRESC	Standardized Result in Character Format		text	3		Other	Contains the result value for all findings, copied or derived from FWORRES in a standard format or standard units.
FWSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for numeric results or findings in standard format; contains the numeric form of FWSTRESC. FWSTRESN should store all numeric test results or findings.
FWSTRESU	Unit of the Standardized Result		text	5	Unit	Other	Standardized unit used for FWSTRESC or FWSTRESN.
FWDTC	Date/Time of Observation	4	datetime		ISO8601	Collected	Date/time of the start of theobservation in IS0 8601 character format.
FWENDTC	End Date/Time of Observation	5	datetime		ISO8601	Collected	Date/time of the end of theobservation in IS0 8601 character format.
FWDY	Study Day of Observation		integer	8		Derived	Study day of the start of the observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC - RFSTDTC if --DTC precedes RFSTDTC
FWENDY	Study Day of End of Observation		integer	8		Derived	Study day of the end of the observation, measured as integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --ENDY = --ENDTC-RFSTDTC+1 if --ENDTC is on or after RFSTDTC. --ENDTC - RFSTDTC if --ENDTC precedes RFSTDTC.

Laboratory Test Results (LB) [Location: lb.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
LBSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
LBTESTCD	Lab Test or Examination Short Name	3	text	7		Other	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters,

							nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ALT, LDH.
LBTEST	Lab Test or Examination Name		text	39	Laboratory Test Name	Other	Long name for LBTESTCD. The value in LBTEST cannot be longer than 40 characters. Examples: Alanine Aminotransferase, Lactate Dehydrogenase.
LBCAT	Category for Lab Test		text	18		Other	Used to define a category of related records across subjects. Examples: URINALYSIS, CLINICAL CHEMISTRY, HEMATOLOGY, etc.
LBORRES	Result or Findings as Collected		text	11		Collected	Result of the measurement or finding as originally received or collected.
LBORRESU	Unit of the Original Result		text	7	Unit	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
LBSTRESC	Standardized Result in Character Format		text	11		Other	Contains the result value for all findings or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as NEGATIVE. For other examples, see general assumptions.
LBSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for continuous or numeric results or findings in standard format; contains the numeric form of LBSTRESC. LBSTRESN should store all numeric test results or findings.
LBSTRESU	Unit of the Standardized Result		text	7	Unit	Other	Standardized unit used for LBSTRESC or LBSTRESN. Preferably SI units.
LBSTAT	Completion Status		text	8	["NOT DONE"] <Not Done>	Other	Used to indicate when a test is not done or result is missing. Should be null if a results exists in LBORRES.
LBREASND	Reason Not Done		text	14		Other	Describes why LBSTAT is NOT DONE, such as BROKEN EQUIPMENT or SPECIMEN LOST.
LBSPEC	Specimen Type	4	text	11	Specimen	Other	Defines the type of specimen used for a measurement. Examples: WHOLE BLOOD, SERUM, URINE, LIVER, HEART.
LBMETHOD	Method of Test or Examination		text	14		Other	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
LBBLFL	Baseline Flag		text	1	["N", "Y"] <No Yes Response>	Other	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
VISITDY	Planned Study Day of Collection		integer	8		Other	This is the planned study day of collection.
LBDTC	Date/Time of Specimen Collection	5	datetime		ISO8601	Collected	Date/time of specimen collection or observation in IS0 8601 format.
LBDY	Study Day of Specimen Collection		integer	8		Derived	Study day of specimen collection or observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. LBDY = LBDTC-RFSTDTC+1 if LBDTC is on or after RFTSDTC. LBDTC - RFSTDTC if LBDTC precedes RFSTDTC.

Macroscopic Findings (MA) [Location: ma.xpt]

Variable	Label	Key	Type	Length	Controlled	Origin	Derivation/Comment

					Terms or Format		
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character code for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
MASEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
MASPID	Mass Identifier		text	1		Other	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
MATESTCD	Macroscopic Examination Short Name	3	text	8	["GROSPATH"] <Macroscopic Findings Test Code>	Other	Short name of the measurement, test, or examination described in MATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MATESTCD cannot contain characters other than letters, numbers, or underscores.
MATEST	Macroscopic Examination Name		text	30	["Gross Pathological Examination"] <Macroscopic Findings Test Name>	Other	Long name for MATESTCD. The value in MATEST cannot be longer than 40 characters. Extensible controlled values are Gross Pathological Examination, Clinical Signs Follow-up.
MAORRES	Result or Findings as Collected		text	75		Collected	Text description of the findings as originally received or collected, including the base gross pathological observation and any modifiers, such as severity, origin, classification, size, color, etc.
MASTRESC	Standardized Result in Character Format	4	text	18		Other	Contains only the base gross pathological observation (e.g., ENLARGED) from MAORRES without any modifiers. Or, if the examination was completed and there were no findings, the value must be NORMAL.
MASPEC	Specimen Material Type	5	text	25	Specimen	Other	Defines the type of tissue, organ, or fluid specimen used as the object for the finding. Examples: GLAND, ADRENAL; KIDNEY; VESSEL, LYMPHATIC. See also Assumption 4.b.
MAANTREG	Anatomical Region of Specimen	6	text	1		Other	Defines the specific anatomical or biological region of a tissue, organ specimen or the region from which the specimen was obtained, such as a section or part of what is defined in the --SPEC variable. If the anatomical region is not included in the specimen description --SPEC, it may be included in this variable. This field can be a combination of terms where needed. This field can be null if not applicable. Examples: CORTEX, MEDULLA, MUCOSA, SEROSA, ISLET, ZONA FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.
MALAT	Specimen Laterality within Subject	7	text	9	["BILATERAL", "LEFT", "RIGHT"] <Laterality>	Other	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.
MASEV	Severity		text	8	["MILD", "MINIMAL", "MODERATE", "MARKED"] <Severity>	Other	Describes the severity or intensity of a particular finding. Examples: MILD, MODERATE, SEVERE.
MADY	Study Day of Specimen		integer	8		Derived	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the

	Collection						Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC - RFSTDTC if --DTC precedes RFSTDTC
Related dataset: Supplemental Qualifiers for MA (SUPPMA)							

Microscopic Findings (MI) [Location: mi.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
MISEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
MISPID	Mass Identifier		text	1		Other	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
MITESTCD	Microscopic Examination Short Name	3	text	6	["MIEXAM"] <Microscopic Findings Test Code>	Other	Short name of the measurement, test, or examination described in MITEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MITESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MITESTCD cannot contain characters other than letters, numbers, or underscores. Extensible controlled value is MIEXAM.
MITEST	Microscopic Examination Name		text	23	["Microscopic Examination"] <Microscopic Findings Test Name>	Other	Long name for MITESTCD. The value in MITEST cannot be longer than 40 characters. Extensible controlled value is Microscopic Examination.
MIORRES	Result or Findings as Collected		text	65		Collected	Text description of the findings as originally received or collected, including the base pathological process and any modifiers.
MISTRESC	Standardized Result in Character Format	4	text	29		Other	Contains only the base pathological process (e.g., NECROSIS) from MIORRES without any modifiers such as severity, distribution, frequency, grade, etc. Or, if the examination was completed and there were no findings, the value must be NORMAL. Tumors must be populated using TFSTRESC controlled list. MISTRESC is not currently controlled for non-neoplastic/non-tumor findings.
MIRESCAT	Result Category		text	9	["BENIGN", "MALIGNANT"] <Microscopic Histopathology Result Category>	Other	Used to categorize the result of a finding. Example: MALIGNANT for tumor findings. Histopathological findings may be categorized as NON-NEOPLASTIC.
MISTAT	Completion Status		text	8	["NOT DONE"] <Not Done>	Other	Used to indicate examination not done or result is missing. Should be null if a result exists in MIORRES.
MIREASND	Reason Not Done		text	18		Other	Describes why MISTAT is NOT DONE, such as SAMPLE AUTOLYZED or SPECIMEN LOST.
MISPEC	Specimen Material Type	5	text	30	Specimen	Other	Subject of the observation. Defines the type of specimen used for a measurement. Examples: LIVER, HEART, BONE MARROW.

MIANTREG	Anatomical Region of Specimen	6	text	6		Other	Example: Cortex, Medulla, or Femur (if the MISPEC is, for example, BONE MARROW).
MISPCCND	Specimen Condition		text	9		Other	Free or standardized text describing the condition of the specimen. Example: AUTOLYZED.
MISPCUFL	Specimen Usability for the Test		text	1	["N", "Y"] <No Yes Response>	Other	Describes the usability of the specimen for the test. Example: N = the specimen is not usable; otherwise null.
MILAT	Specimen Laterality within Subject	7	text	5	["BILATERAL", "LEFT", "RIGHT"] <Laterality>	Other	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.
MIDIR	Specimen Directionality within Subject	8	text	7	["CRANIAL", "CAUDAL"] <Directionality>	Other	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.
MISEV	Severity		text	8	["MILD", "MINIMAL", "MODERATE", "MARKED"] <Severity>	Other	Describes the severity of a particular finding.
MIDTHREL	Relationship to Death		text	1	["N", "Y"] <No Yes Response>	Other	Describes the relationship of a particular finding to the death of a subject (Y=caused death, N=did not cause death, U=unknown). May be left null if not available.
MIDY	Study Day of Specimen Collection		integer	8		Derived	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC - RFSTDTC if --DTC precedes RFSTDTC
Related dataset: Supplemental Qualifiers for MI (SUPPMI)							

Organ Measurements (OM) [Location: om.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
OMSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
OMTESTCD	Test Short Name	3	text	6	["WEIGHT"] <Organ Measurement Test Code>	Other	Short name of the measurement, test, or examination described in OMTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in OMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). OMTESTCD cannot contain characters other than letters, numbers, or underscores.
OMTEST	Test Name		text	6	["Weight"] <Organ Measurement Test Name>	Other	Long name for OMTESTCD. The value in OMTEST cannot be longer than 40 characters.

OMORRES	Result or Findings as Collected		text	14		Collected	Result of the measurement or finding as originally received or collected.
OMORRESU	Unit of the Original Result		text	1	Unit	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
OMSTRESC	Standardized Result in Character Format		text	14		Other	Contains the result value for all findings or derived from OMORRES in a standard format or standard units. OMSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in OMSTRESN.
OMSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for results or findings in standard format; contains the numeric form of OMSTRESC. OMSTRESN should store all numeric test results or findings.
OMSTRESU	Unit of the Standardized Result		text	1	Unit	Other	Standardized unit used for OMSTRESC or OMSTRESN. Example, if the original units were oz for ounces, the standard unit might be g for grams.
OMSPEC	Specimen Material Type	4	text	16	Specimen	Other	Defines the type of tissue, organ, or fluid specimen used as the object for the finding. Examples: GLAND, ADRENAL; KIDNEY; VESSEL, LYMPHATIC.
OMDTC	Date/Time Organ Weighed		datetime		ISO8601	Collected	Date/time of specimen/tissue weighing in ISO 8601 format.
OMDY	Study Day of Weighing		integer	8		Derived	Study day of specimen/tissue weighting, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC -RFSTDTC if --DTC precedes RFSTDTC

Pharmacokinetics Concentrations (PC) [Location: pc.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
PCSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record. Sequence of numbers within a Subject ID
PCTESTCD	Test Short Name	3	text	7		Other	Short name of the measurement, test, or examination described in PCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PCTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ASA, VOL, SPG.
PCTEST	Test Name		text	20		Other	Long name for PCTESTCD, such as the name of the analyte or specimen characteristic. The value in PCTEST cannot be longer than 40 characters. Examples: Acetylsalicyclic Acid, Volume, Specific Gravity.
PCORRES	Result or Findings as Collected		text	5		Collected	Result of the measurement or finding as originally received or collected.
PCORRESU	Unit of the Original Result		text	5	["ng/mL", "h*ng/mL",	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.

					"h"] <PK Parameter Units of Measure>		
PCSTRESC	Standardized Result in Character Format		text	5		Other	Contains the result value for all findings or derived from PCORRES in a standard format or standard units. PCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PCSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in PCORRES and these results effectively have the same meaning, they could be represented in standard format in PCSTRESC as NEGATIVE. For other examples, see general assumptions.
PCSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for continuous or numeric results or findings in standard format; contains the numeric form of PCSTRESC. PCSTRESN should store all numeric test results or findings. For results beyond limits of quantification, this variable should be left null (for example, if PCSTRESC is "<2", PCSTRESN would be null).
PCSTRESU	Unit of the Standardized Result		text	5	["ng/mL", "h*ng/mL", "h"] <PK Parameter Units of Measure>	Other	Standardized unit used for PCSTRESC and PCSTRESN.
PCSPEC	Specimen Material Type	4	text	6	Specimen	Other	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.
PCMETHOD	Method of Test or Examination		text	4		Other	Method of the test or examination. Examples include HPLC/MS, ELISA. This should contain sufficient information and granularity to allow differentiation of various methods that might have been used within a study.
PCBLFL	Baseline Flag		text	1	["N", "Y"] <No Yes Response>	Other	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
PCLLOQ	Lower Limit of Quantitation		float	8		Other	Indicates the lower limit of quantitation for an assay. Units should be those used in PCSTRESU.
VISITDY	Visit Day		integer	8		Other	This is the planned day of collection.
PCDTC	Date/Time of Specimen Collection	5	datetime		ISO8601	Collected	Date/time of specimen collection, in ISO 8601 format. If there is no end time, then this will be the collection time.
PCDY	Study Day of Specimen Collection		integer	8		Derived	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics (DM) domain. PCDY = PCDTC-RFSTDTC+1 if PCDTC is on or after RFTSDTC. PCDTC - RFSTDTC if PCDTC precedes RFSTDTC.
PCTPT	Planned Time Point Name		text	7		Other	Text description of time when specimen should be taken. Note: This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See PCTPTNUM and PCTPTREF. Examples: Start, 5 min post.
PCTPTNUM	Planned Time Point Number		integer	8		Other	Numerical version of PCTPT to aid in sorting.
PCELTM	Planned Elapsed Time from Time Point Ref		text	6		Other	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (PCTPTREF) such as PREVIOUS DOSE or PREVIOUS MEAL. This variable is useful where there are repetitive measures. Not a clock time or a date time variable.

PCTPTREF	Time Point Reference		text	11		Other	Name of the fixed reference point used as a basis for PCTPT, PCTPTNUM, and PCELTM. Example: Most Recent Dose.
PCRFTDTC	Date/Time of Reference Point		datetime		ISO8601	Collected	Date/time of the reference time point described by PCTPTREF.

Palpable Masses (PM) [Location: pm.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
PMSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
PMSPID	Mass Identifier	4	text	1		Other	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
PMTESTCD	Test Short Name	3	text	5	["DESCR"] <Physical Properties Test Code>	Other	Short name of the measurement, test, or examination described in PMTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PMTESTCD cannot contain characters other than letters, numbers, or underscores.
PMTEST	Test Name		text	11	["Description"] <Physical Properties Test Name>	Other	Long name for PMTESTCD. The value in PMTEST cannot be longer than 40 characters.
PMORRES	Result or Findings as Collected		text	23		Collected	Text description of findings as originally recorded. If the examination was not performed, then the value should be null, and NOT DONE should appear in PMSTAT.
PMORRESU	Unit of the Original Result		text	1	Unit	Other	Units for PMORRES if available (e.g., for length, width, or depth findings). Examples: mm, cm.
PMSTRESC	Standardized Result in Character Format		text	10		Other	If there are findings for a body system, then either the dictionary preferred term (if findings are coded using a dictionary) or PMORRES (if findings are not coded) should appear here. If PMORRES is null, PMSTRESC should be null. PMSTRESC should only contain the finding, without the location modifier.
PMSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for numeric results or findings in standard format; contains the numeric form of PMSTRESC. PMSTRESN should store all numeric test results or findings.
PMSTRESU	Unit of the Standardized Result		text	1	Unit	Other	Standardized unit used for PMSTRESC or PMSTRESN.
PMLOC	Location of a Finding		text	13		Other	Specifies the location of the palpable mass finding. Example: LEFT SHOULDER.
VISITDY	Planned Study Day of Collection		integer	8		Other	This is the planned study day of collection.

PMDTC	Start Date/Time of Observation	5	datetime		ISO8601	Collected	Date/time of the observation in ISO 8601 format.
PMDY	Study Day of Observation		integer	8		Derived	Study day of the observation, measured as integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC -RFSTDTC if --DTC precedes RFSTDTC

Pharmacokinetics Parameters (PP) [Location: pp.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
PPSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
PPTESTCD	Parameter Short Name	3	text	6	PK Parameters Code	Other	Short name of the measurement, test, or examination described in PPTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PPTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PPTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: AUCINT, TMAX, CMAX.
PPTEST	Parameter Name		text	25	PK Parameters	Other	Long name for PPTESTCD. The value in PPTEST cannot be longer than 40 characters. Examples: AUCINT, Time of CMAX Observation, Max Conc.
PPCAT	Parameter Category	4	text	6		Other	Used to define a category of related records. For PP, this should be the name of the analyte in PPTEST whose profile the parameter is associated with.
PPORRES	Result or Findings as Collected		text	8		Other	Result of the measurement or finding as originally received or collected.
PPORRESU	Unit of the Original Result		text	7	["ng/mL", "h*ng/mL", "h"] <PK Parameter Units of Measure>	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
PPSTRESC	Standardized Result in Character Format		text	8		Other	Contains the result value for all findings derived from PPORRES in a standard format or standard units. PPSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PPSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in PPORRES and these results effectively have the same meaning, they could be represented in standard format in PPSTRESC as NEGATIVE. For other examples, see general assumptions.
PPSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for continuous or numeric results or findings in standard format; contains the numeric form of PPSTRESC. PPSTRESN should store all numeric test results or findings.
PPSTRESU	Unit of the Standardized Result		text	7	["ng/mL", "h*ng/mL", "h"]	Other	Standardized unit used for PPSTRESC and PPSTRESN.

					<PK Parameter Units of Measure>		
PPSTAT	Completion Status		text	8	["NOT DONE"] <Not Done>	Other	Used to indicate that a parameter was not calculated. Should be null if a result exists in PPORRES.
PPREASND	Reason Not Done		text	14		Other	Describes why a parameter was not performed, such as INSUFFICIENT DATA. Used in conjunction with PPSTAT when value is NOT DONE.
PPSPEC	Specimen Material Type	5	text	6	Specimen	Other	Defines the type of specimen used for a measurement. If multiple specimen types are used for a calculation (e.g., serum and urine for creatinine clearance), then this field should be left blank. Examples: SERUM, PLASMA, URINE.
VISITDY	Planned Study Day of Collection		integer	8		Other	It is the planned study day for the time point reference of the time-concentration profile.
PPRFTDTC	Date/Time of Reference Point	6	datetime		ISO8601	Collected	Date/time of the reference time point from the PC records used to calculate a parameter record. The values in PPRFTDTC should be the same as that in PCRFTDTC for related records.

Subject Characteristics (SC) [Location: sc.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
SCSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
SCTESTCD	Subject Characteristic Short Name	3	text	5		Other	Short name of the measurement, test, or examination described in SCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). SCTESTCD cannot contain characters other than letters, numbers, or underscores. Some extensible controlled values are: SPLRNAM, SPLRLOC, HAIRCOLR.
SCTEST	Subject Characteristic		text	20	["Alternate Identifier"] <SEND Subject Characteristics Test Name>	Other	Long name for SCTESTCD. The value in SCTEST cannot be longer than 40 characters. Examples: Test Subject Supplier, Test Subject Supplier Site, and Hair Coat Color.
SCORRES	Result or Findings as Collected		text	6		Collected	Result of the subject characteristic as originally received or collected.
SCSTRESC	Standardized Result in Character Format		text	6		Other	Contains the result value for all findings derived from SCORRES in a standard format or standard units. SCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SCSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in SCORRES, these results effectively have the same meaning. In this case, they could be represented in standard format in SCSTRESC with a single term NEGATIVE.

SCDY	Study Day of Collection		integer	8		Derived	Study day of collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC - RFSTDTC if --DTC precedes RFSTDTC

Tumor Findings (TF) [Location: tf.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
TFSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
TFSPID	Mass Number		text	1		Other	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
TFTESTCD	Tumor Examination Short Name	3	text	5	["TUMEX"] <Tumor Findings Test Code>	Other	Short name of the measurement, test, or examination described in TFTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in TFTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). TFTESTCD cannot contain characters other than letters, numbers, or underscores. Example: TUMEX.
TFTEST	Tumor Examination		text	17	["Tumor Examination"] <Tumor Findings Test Name>	Other	Long name for TFTESTCD. The value in TFTEST cannot be longer than 40 characters. Example: Tumor Examination.
TFORRES	Result or Findings as Collected	4	text	31		Collected	Result of the histopathological examination as originally received or collected.
TFSTRESC	Standardized Result in Character Format		text	36	["LEIOMYOMA, BENIGN", "CARCINOMA, HEPATOCELLULAR, MALIGNANT", "ADENOMA, HEPATOCELLULAR, BENIGN"] <Neoplasm Type>	Other	Contains the tumor name mapped from TFORRES into a standard format from the controlled terms list.
TFRESCAT	Tumor Malignancy Status		text	9	["BENIGN", "MALIGNANT"] <Neoplastic Status>	Other	Used to record the malignancy of the tumor as determined by the pathologist. It may be copied or derived from a description in TFORRES. Examples: BENIGN, MALIGNANT, METASTATIC, and UNDETERMINED.
TFSPEC	Specimen Material Type	5	text	6	Specimen	Other	Subject of the observation. Defines the type of specimen used for a measurement. Examples: LIVER, HEART.
TFDTHREL	Relationship to Death		text	1	["N", "Y"] <No Yes Response>	Other	Describes the relationship of a particular finding to the death of a subject. Example: Y if the tumor was the cause of death, N if the tumor was not the cause of death, or U for Unknown. Null cannot be used because the variable is required.
TFDY	Study Day of Collection		integer	8		Derived	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. --DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC

							- RFSTDTC if --DTC precedes RFSTDTC
TFDETECT	Time in Days to Detection of Tumor		integer	8		Other	The number of days from the start of dosing to the earliest detection of the tumor in the experimental phase. This variable must be populated for every tumor discovered during the experimental phase.

Vital Signs (VS) [Location: vs.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	Other	Two-character abbreviation for the domain.
USUBJID	Unique Subject Identifier	2	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
VSSEQ	Sequence Number		integer	8		Derived	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. Sequence of numbers within a Subject ID
VSTESTCD	Vital Signs Test Short Name	3	text	2		Other	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: SYSBP, DIABP.
VSTEST	Vital Signs Test Name		text	10	["Heart Rate"] <Vital Signs Test Name>	Other	Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 40 characters. Examples: Systolic Blood Pressure, Diastolic Blood Pressure.
VSORRES	Result or Findings as Collected		text	3		Collected	Result of the vital signs measurement as originally received or collected.
VSORRESU	Unit of the Original Result		text	9	["beats/min"] <Units for Vital Signs Results>	Other	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
VSSTRESC	Standardized Result in Character Format		text	3		Other	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard units. VSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in VSSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in VSORRES and these results effectively have the same meaning, they could be represented in standard format in VSSTRESC as NEGATIVE.
VSSTRESN	Standardized Result in Numeric Format		float	8		Other	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESN should store all numeric test results or findings.
VSSTRESU	Unit of the Standardized Result		text	9	["beats/min"] <Units for Vital Signs Results>	Other	Standardized unit used for VSSTRESC or VSSTRESN.
VSBLFL	Baseline Flag		text	1	["N", "Y"] <No Yes Response>	Other	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
VISITDY	Planned Study Day of Collection		integer	8		Other	This is the planned day of collection.

VSDTC	Date/Time of Measurement	4	datetime		ISO8601	Collected	Date/time of the vital sign measurement collection, in ISO 8601 format. For indicating measurement over a period, DTC should be populated with the start date/time of collection.
VSDY	Study Day of Vital Signs Measurement		integer	8		Derived	Study day of vital signs measurements collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain. VSDY = VSDTC-RFSTDTC+1 if VSDTC is on or after RFTSDTC. VSDTC - RFSTDTC if VSDTC precedes RFSTDTC.

Related Records (RELREC) [Location: relrec.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
RDOMAIN	Related Domain Abbreviation	2	text	2		Other	Two-character abbreviation for the domain of the parent record(s).
USUBJID	Unique Subject Identifier	3	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
IDVAR	Identifying Variable	4	text	5		Other	Name of the identifying variable in the general-observation-class dataset that identifies the related record(s). Examples include --SEQ and --GRPID.
IDVARVAL	Identifying Variable Value	5	text	2		Other	Value of identifying variable described in IDVAR. If --SEQ is the variable being used to describe this record, then the value of --SEQ would be entered here.
RELTYPE	Relationship Type		text	1		Other	Identifies the hierarchical level of the records in the relationship. Values should be either ONE or MANY, only when --SPID is used. However, values are only necessary when identifying a relationship between datasets (as described in Section 8.4).
RELID	Relationship Identifier	6	text	2		Other	Unique value within USUBJID that identifies the relationship. All records for the same USUBJID that have the same RELID are considered "related/associated." "RELID" can be any value the sponsor chooses and is only meaningful within the RELREC dataset to identify the related/associated Domain records.

Supplemental Qualifiers for MA (SUPPMA) [Location: suppma.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
RDOMAIN	Related Domain Abbreviation	2	text	2		Other	
USUBJID	Unique Subject Identifier	3	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
IDVAR	Identifying Variable	4	text	5		Other	
IDVARVAL	Identifying Variable Value	5	text	1		Other	
QNAM	Qualifier Variable Name	6	text	8		Other	
QLABEL	Qualifier Variable Label		text	16		Other	
QVAL	Data Value		text	57		Other	
QORIG	Origin		text	9		Other	
QEVAL	Evaluator		text	1		Other	

Related dataset: Macroscopic Findings (MA)

Supplemental Qualifiers for MI (SUPPMI) [Location: suppmi.xpt]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	8		Other	Unique identifier for a study.
RDOMAIN	Related Domain Abbreviation	2	text	2		Other	
USUBJID	Unique Subject Identifier	3	text	13		Other	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
IDVAR	Identifying Variable	4	text	5		Other	
IDVARVAL	Identifying Variable Value	5	text	2		Other	
QNAM	Qualifier Variable Name	6	text	8		Other	
QLABEL	Qualifier Variable Label		text	16		Other	
QVAL	Data Value		text	43		Other	
QORIG	Origin		text	9		Other	
QEVAL	Evaluator		text	1		Other	

Related dataset: Microscopic Findings (MI)

Controlled Terms

Age Unit [CL.AGEU.7639]

Permitted Value (Code)
WEEKS

Body Weight Gain Test Code [CL.BGTESTCD.7641]

Permitted Value (Code)
BWGAIN

Body Weight Gain Test Name [CL.BGTEST.7641]

Permitted Value (Code)
Body Weight Gain

Body Weight Test Code [CL.BWTESTCD.7642]

Permitted Value (Code)
BW
TERMBW

Body Weight Test Name [CL.BWTEST.7642]

Permitted Value (Code)
Body Weight
Terminal Body Weight

Category for Clinical Observation [CL.CLCAT.7643]

Permitted Value (Code)
CLINICAL SIGNS
OPHTHALMOLOGY

Consciousness State [CL.CSTATE.7644]

Permitted Value (Code)
CONSCIOUS

Death Diagnosis Test Code [CL.DDTESTCD.7646]

Permitted Value (Code)
DEATHD

Death Diagnosis Test Name [CL.DDTEST.7646]

Permitted Value (Code)
Death Diagnosis

Directionality [CL.DIR.7647]

Permitted Value (Code)
CRANIAL
CAUDAL

ECG Lead [CL.EGLEAD.7649]

Permitted Value (Code)
LEAD II

ECG Result [CL.EGSTRESC.7650]

Permitted Value (Code)
68 [*]
157 [*]
243 [*]
69 [*]

158 [*]
167 [*]
55 [*]
145 [*]
201 [*]
44 [*]
164 [*]
217 [*]
48 [*]
166 [*]
238 [*]
59 [*]
165 [*]
141 [*]
45 [*]
153 [*]
228 [*]
58 [*]
156 [*]
246 [*]
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209 [*]
148 [*]
232 [*]
130 [*]
126 [*]
150 [*]
70 [*]
144 [*]
204 [*]
194 [*]
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63 [*]
183 [*]
216 [*]
133 [*]
123 [*]
235 [*]
186 [*]
128 [*]
118 [*]
214 [*]

169 [*]
189 [*]
190 [*]
223 [*]
212 [*]

* Extended Value

ECG Test Name [CL.EGTEST.7653]

Permitted Value (Code)
PR Interval, Aggregate
QTcB Interval, Aggregate
RR Interval, Aggregate

Food and Water Consumption Test Code [CL.FWTESTCD.7654]

Permitted Value (Code)
FC

Food and Water Consumption Test Name [CL.FWTEST.7654]

Permitted Value (Code)
Food Consumption

Frequency [CL.FREQ.7655]

Permitted Value (Code)
QID

Laboratory Test Name [CL.LBTEST.7657]

Permitted Value (Code)
Albumin
Albumin/Globulin
Alkaline Phosphatase
Alanine Aminotransferase
Activated Partial Thromboplastin Time
Aspartate Aminotransferase
Basophils
Bilirubin
Calcium
Cholesterol
Chloride

Creatinine
Eosinophils
Fibrinogen
Gamma Glutamyl Transferase
Globulin
Glucose
Hematocrit
Hemoglobin
Potassium
Large Unstained Cells
Lymphocytes
Ery. Mean Corpuscular Hemoglobin
Ery. Mean Corpuscular HGB Concentration
Ery. Mean Corpuscular Volume
Monocytes
Neutrophils
Phosphate
Platelets
Protein
Prothrombin Time
Erythrocytes
Erythrocytes Distribution Width
Reticulocytes
Sodium
Triglycerides
Urea Nitrogen
Leukocytes
Clarity
Color
Ketones
Occult Blood
pH
Specific Gravity
Volume

Laterality [CL.LAT.7658]

Permitted Value (Code)
BILATERAL
LEFT

RIGHT

Macroscopic Findings Test Code [CL.MATESTCD.7659]

Permitted Value (Code)
GROSPATH

Macroscopic Findings Test Name [CL.MATEST.7659]

Permitted Value (Code)
Gross Pathological Examination

Microscopic Findings Test Code [CL.MITESTCD.7661]

Permitted Value (Code)
MIEXAM

Microscopic Findings Test Name [CL.MITEST.7661]

Permitted Value (Code)
Microscopic Examination

Microscopic Histopathology Result Category [CL.MIRESCAT.7662]

Permitted Value (Code)
BENIGN
MALIGNANT

Neoplasm Type [CL.NEOPLASM.7663]

Permitted Value (Code)
LEIOMYOMA, BENIGN
CARCINOMA, HEPATOCELLULAR, MALIGNANT
ADENOMA, HEPATOCELLULAR, BENIGN

Neoplastic Status [CL.NEOSTAT.7664]

Permitted Value (Code)
BENIGN
MALIGNANT

No Yes Response [CL.NY.7665]

Permitted Value (Code)
N
Y

Not Done [CL.ND.7666]

Permitted Value (Code)
NOT DONE

Organ Measurement Test Code [CL.OMTESTCD.7667]

Permitted Value (Code)
WEIGHT

Organ Measurement Test Name [CL.OMTEST.7667]

Permitted Value (Code)
Weight

PK Parameter Units of Measure [CL.PKUNIT.7670]

Permitted Value (Code)
ng/mL
h*ng/mL
h

PK Parameters [CL.PKPARM.7671]

Permitted Value (Code)
AUC Infinity Obs
AUC to Last Nonzero Conc
Max Conc
Time of Last Nonzero Conc
Time of CMAX
AUC Over Dosing Interval

PK Parameters Code [CL.PKPARMCD.7671]

Permitted Value (Code)
AUCIFO
AUCLST
CMAX
TLST
TMAX
AUCTAU

Pharmaceutical Dosage Form [CL.FRM.7668]

Permitted Value (Code)
SOLUTION

Physical Properties Test Code [CL.PHSPRPCD.7669]

Permitted Value (Code)
DESCR

Physical Properties Test Name [CL.PHSPRP.7669]

Permitted Value (Code)
Description

Position [CL.POSITION.7673]

Permitted Value (Code)
PRONE

Route of Administration [CL.ROUTE.7675]

Permitted Value (Code)
ORAL GAVAGE

SEND Domain Abbreviation [CL.SDOMAIN.7648]

Permitted Value (Code)
BG
BW
CL
CO
DD
DM
DS
EG
EX
FW
LB
MA
MI
OM
PC
PM
PP
SC

SE
TA
TE
TF
TS
TX
VS

SEND Subject Characteristics Test Name [CL.SBCSND.7679]

Permitted Value (Code)
Alternate Identifier

SEND Trial Summary Parameter Test Name [CL.STSPRM.7681]

Permitted Value (Code)
Age Text
Age Unit
Basal Diet
Dosing Duration
Environmental Temperature
Environmental Temperature Units
Experimental End Date
Experimental Start Date
Good Laboratory Practice Type
Housing Group
Housing Type
Housing Humidity
Housing Humidity Units
Method of Identification
Light Cycle
Lot Number [*]
Method of Termination
Planned Number of Female Subjects
Planned Number of Male Subjects
Quality Assurance type [*]
Recovery Period
Route of Administration
Study Design
Sex of Participants
SEND Controlled Terminology Version

SEND Implementation Guide Version
Species
Planned Number of Subjects
Test Subject Supplier
Sponsor's Reference ID
Study Is Randomized
Sponsoring Organization
Study Type
Study Category
Study Director
Study Title
Strain/Substrain
Study Start Date
Test Facility Country
Time to Terminal Sacrifice
Investigational Therapy or Treatment
Primary Treatment CAS Registry Number
Percent Purity of Compound [*]
Treatment Vehicle
Test Site Country
Test Site Location
Test Site Name
Test Facility Location
Test Facility Name
Drinking Water
Arm Code
Group Label
Set Label
Sponsor-Defined Group Code
Control Type
Toxicokinetic Description
Dose Level
Dose Units

* Extended Value

Severity [CL.SEV.7682]

Permitted Value (Code)
MILD
MINIMAL

MODERATE
MARKED

Sex [CL.SEX.7683]

Permitted Value (Code)
M
F

Specimen [CL.SPEC.7686]

Permitted Value (Code)
SERUM
PLASMA
WHOLE BLOOD
URINE
ESOPHAGUS
GLAND, ADRENAL
ALL TISSUES
HINDLIMB
TESTIS
THYMUS
EPIDIDYMIS
GLAND, COAGULATING
GLAND, SEMINAL VESICLE
LYMPH NODE, MESENTERIC
GLAND, THYROID
STOMACH
LARGE INTESTINE, CECUM
LARGE INTESTINE, COLON
LARGE INTESTINE, RECTUM
SKIN
SPLEEN
UTERUS
LUNG
LIVER
KIDNEY
SMALL INTESTINE, ILEUM
SMALL INTESTINE, JEJUNUM
URINARY BLADDER
SMALL INTESTINE, DUODENUM

BODY CAVITY, CRANIAL
BONE MARROW, FEMUR
GLAND, PROSTATE
ARTERY, AORTA
BONE MARROW, STERNUM
BONE, STERNUM
BRAIN
EYE
GLAND, HARDERIAN
GLAND, MAMMARY
GLAND, PARATHYROID
GLAND, PITUITARY
GLAND, SALIVARY, PAROTID
GLAND, SALIVARY, SUBLINGUAL
GLAND, SALIVARY, SUBMANDIBULAR
HEART
JOINT, HIP
LARYNX
LYMPH NODE, POPLITEAL
MUSCLE, QUADRICEPS FEMORIS
NERVE, OPTIC
NERVE, SCIATIC
PANCREAS
PEYER'S PATCH
SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR
SPINAL CORD, THORACIC
TONGUE
TRACHEA
URETER
OVARY

Standardized Disposition Term [CL.DSDECOD.7687]

Permitted Value (Code)
MORIBUND SACRIFICE
TERMINAL SACRIFICE
RECOVERY SACRIFICE

Tumor Findings Test Code [CL.TFTESTCD.7692]

Permitted Value (Code)
TUMEX

Tumor Findings Test Name [CL.TFTEST.7692]

Permitted Value (Code)
Tumor Examination

Unit [CL.UNIT.7693]

Permitted Value (Code)
g
msec
mg/kg
g/day
g/dL
U/L
sec
10^9/L
mg/dL
mmol/L
%
pg
fL
10^12/L
mL
C

Units for Vital Signs Results [CL.VSRESU.7694]

Permitted Value (Code)
beats/min

Vital Signs Test Name [CL.VSTEST.7696]

Permitted Value (Code)
Heart Rate

Computational Algorithms

Method	Type	Description
Algorithm to derive --DY	Computation	--DY = -DTC-RFSTDTC+1 if --DTC is on or after RFTSDTC. --DTC - RFSTDTC if --DTC precedes RFSTDTC
Algorithm to derive --SEQ	Computation	Sequence of numbers within a Subject ID

Algorithm to derive --ENDY	Computation	--ENDY = --ENDTC-RFSTDTC+1 if --ENDTC is on or after RFSTDTC. --ENDTC - RFSTDTC if --ENDTC precedes RFSTDTC.
Algorithm to derive BGSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive TXSEQ	Computation	Sequence of numbers within a set of records
Algorithm to derive TSSEQ	Computation	Sequence of numbers within a set of records
Algorithm to derive VSSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive SESEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive PPSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive PCSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive LBSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive EXSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive EGSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive DSSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive CLSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive BWSEQ	Computation	Sequence of numbers within a Subject ID
Algorithm to derive BGDY	Computation	BGDY = BGDTC-RFSTDTC+1 if BGDTC is on or after RFTSDTC. BGDTC - RFSTDTC if BGDTC precedes RFSTDTC
Algorithm to derive BWDY	Computation	BWDY = BWDTC-RFSTDTC+1 if BWDTC is on or after RFTSDTC. BWDTC - RFSTDTC if BWDTC precedes RFSTDTC.
Algorithm to derive CLDY	Computation	CLDY = CLDTC-RFSTDTC+1 if CLDTC is on or after RFTSDTC. CLDTC - RFSTDTC if CLDTC precedes RFSTDTC.
Algorithm to derive DSSTDY	Computation	DSSTDY = DSSTDTC-RFSTDTC+1 if DSSTDTC is on or after RFTSDTC. DSSTDTC - RFSTDTC if DSSTDTC precedes RFSTDTC.
Algorithm to derive EGDY	Computation	EGDY = EGDTC-RFSTDTC+1 if EGDTC is on or after RFTSDTC. EGDTC - RFSTDTC if EGDTC precedes RFSTDTC.
Algorithm to derive EXSTDY	Computation	EXSTDY = EXSTDTC-RFSTDTC+1 if EXSTDTC is on or after RFTSDTC. EXSTDTC - RFSTDTC if EXSTDTC precedes RFSTDTC.
Algorithm to derive LBDY	Computation	LBDY = LBDTC-RFSTDTC+1 if LBDTC is on or after RFTSDTC. LBDTC - RFSTDTC if LBDTC precedes RFSTDTC.
Algorithm to derive PCDY	Computation	PCDY = PCDTC-RFSTDTC+1 if PCDTC is on or after RFTSDTC. PCDTC - RFSTDTC if PCDTC precedes RFSTDTC.
Algorithm to derive VSDY	Computation	VSDY = VSDTC-RFSTDTC+1 if VSDTC is on or after RFTSDTC. VSDTC - RFSTDTC if VSDTC precedes RFSTDTC.
Algorithm to derive EXENDY	Computation	EXENDY = EXENDTC-RFSTDTC+1 if EXENDTC is on or after RFSTDTC. EXENDTC - RFSTDTC if EXENDTC precedes RFSTDTC.
Algorithm to derive BGENDY	Computation	BGENDY = BGENDTC-RFSTDTC+1 if BGENDTC is on or after RFSTDTC. BGENDTC - RFSTDTC if BGENDTC precedes RFSTDTC.

Comments

CommentOID	Description
COM.BW.BWBLFL	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
COM.EG.EGBLFL	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
COM.LB.LBBLFL	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
COM.PC.PCBLFL	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
COM.VS.VSBLFL	A baseline indicator may be used to calculate differences or changes from baseline. Value should be Y or null. The baseline flag is sponsor-defined.
COM.EX.EXDOSE	Amount of treatment administered.

COM.CL.CLLOC	Can be used to specify where a clinical sign occurred. Example: LEFT EAR for skin rash.
COM.TA.TABRANCH	Conditions animals meet, occurring at the end of an Element, which cause an Arm to branch off from other Arms (e.g., randomization to control group).
COM.EG.EGCSTATE	Consciousness state of the subject at the time of measurement. Examples: CONSCIOUS, SEMI-CONSCIOUS, UNCONSCIOUS
COM.MA.MASTRESC	Contains only the base gross pathological observation (e.g., ENLARGED) from MAORRES without any modifiers. Or, if the examination was completed and there were no findings, the value must be NORMAL.
COM.MI.MISTRESC	Contains only the base pathological process (e.g., NECROSIS) from MIORRES without any modifiers such as severity, distribution, frequency, grade, etc. Or, if the examination was completed and there were no findings, the value must be NORMAL. Tumors must be populated using TFSTRESC controlled list. MISTRESC is not currently controlled for non-neoplastic/non-tumor findings.
COM.DD.DDSTRESC	Contains the diagnosis information, copied or derived from DDORRES in a standard format. Examples: UNKNOWN, GAVAGE ERROR.
COM.DS.DSDECOD	Contains the result in a standard format.
COM.PP.PPSTRESC	Contains the result value for all findings derived from PPORRES in a standard format or standard units. PPSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PPSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in PPORRES and these results effectively have the same meaning, they could be represented in standard format in PPSTRESC as NEGATIVE. For other examples, see general assumptions.
COM.SC.SCSTRESC	Contains the result value for all findings derived from SCORRES in a standard format or standard units. SCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SCSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in SCORRES, these results effectively have the same meaning. In this case, they could be represented in standard format in SCSTRESC with a single term NEGATIVE.
COM.BG.BGSTRESC	Contains the result value for all findings or derived from BGORRES in a standard format or standard units. BGSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in BGSTRESN.
COM.BW.BWSTRESC	Contains the result value for all findings or derived from BWORRES in a standard format or standard units. BWSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in BWSTRESN.
COM.LB.LBSTRESC	Contains the result value for all findings or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as NEGATIVE. For other examples, see general assumptions.
COM.OM.OMSTRESC	Contains the result value for all findings or derived from OMORRES in a standard format or standard units. OMSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in OMSTRESN.
COM.PC.PCSTRESC	Contains the result value for all findings or derived from PCORRES in a standard format or standard units. PCSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in PCSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in PCORRES and these results effectively have the same meaning, they could be represented in standard format in PCSTRESC as NEGATIVE. For other examples, see general assumptions.
COM.EG.EGSTRESC	Contains the result value for all findings, copied or derived from EGORRES, in a standard format or standard units. EGSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in EGSTRESN. For example, if a test has results of NONE, NEG, and NEGATIVE in EGORRES and these results effectively have the same meaning, they could be represented in standard format in EGSTRESC as NEGATIVE. For other examples, see general assumptions. Additional examples of result data: SINUS BRADYCARDIA, ATRIAL FLUTTER, ATRIAL FIBRILLATION.
COM.FW.FWSTRESC	Contains the result value for all findings, copied or derived from FWORRES in a standard format or standard units.
COM.VS.VSSTRESC	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard units. VSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in VSSTRESN. For example, if a test has results NONE, NEG, and NEGATIVE in VSORRES and these results effectively have the same meaning, they could be represented in standard format in VSSTRESC as NEGATIVE.
COM.TF.TFSTRESC	Contains the tumor name mapped from TFORRES into a standard format from the controlled terms list.
COM.BW.BWDTC	Date/time of body weight collection in ISO 8601 format. This is the date/time of the collection of the observation. If the observation is for a period, this is the start of the period.
COM.EG.EGDTC	Date/time of ECG data collection, in ISO 8601 format. For indicating measurement over a continuous period, DTC should be used to indicate start date/time of collection.
COM.LB.LBDTC	Date/time of specimen collection or observation in IS0 8601 format.
COM.PC.PCDTC	Date/time of specimen collection, in ISO 8601 format. If there is no end time, then this will be the collection time.
COM.OM.OMDTC	Date/time of specimen/tissue weighing in ISO 8601 format.
COM.CL.CLDTC	Date/time of the clinical observation in ISO 8601 format.

COM.CO.CODTC	Date/time of the comment, in ISO 8601 format. Should be null if this is a child record of another domain or if comment date was not collected.
COM.DS.DSSTDTC	Date/time of the disposition event in ISO 8601 format.
COM.BG.BGENDTC	Date/time of the end of the weight interval in ISO 8601 format. This must be populated when BGTESTCD is BWGAINA.
COM.FW.FWENDTC	Date/time of the end of theobservation in IS0 8601 character format.
COM.PM.PMDTC	Date/time of the observation in ISO 8601 format.
COM.PC.PCRFTDTC	Date/time of the reference time point described by PCTPTREF.
COM.PP.PPRFTDTC	Date/time of the reference time point from the PC records used to calculate a parameter record. The values in PPRFTDTC should be the same as that in PCRFTDTC for related records.
COM.BG.BGDTC	Date/time of the start of the weight interval in ISO 8601 format. This must be populated when BGTESTCD is BWGAINA.
COM.FW.FWDTC	Date/time of the start of theobservation in IS0 8601 character format.
COM.VS.VSDTC	Date/time of the vital sign measurement collection, in ISO 8601 format. For indicating measurement over a period, DTC should be populated with the start date/time of collection.
COM.EX.EXSTDTC	Date/Time when administration of the treatment indicated by EXTRT and EXDOSE began, in ISO 8601 format.
COM.EX.EXENDTC	Date/Time when administration of the treatment indicated by EXTRT and EXDOSE ended, in ISO 8601 format.
COM.MA.MAANTREG	Defines the specific anatomical or biological region of a tissue, organ specimen or the region from which the specimen was obtained, such as a section or part of what is defined in the --SPEC variable. If the anatomical region is not included in the specimen description --SPEC, it may be included in this variable. This field can be a combination of terms where needed. This field can be null if not applicable. Examples: CORTEX, MEDULLA, MUCOSA, SEROSA, ISLET, ZONA FASICULATA, ZONA RETICULARIS, CRANIAL, MEDIAN, ACCESSORY, SPINAL, LUMBAR, FRONTAL.
COM.PC.PCSPEC	Defines the type of specimen used for a measurement. Examples: SERUM, PLASMA, URINE.
COM.LB.LBSPEC	Defines the type of specimen used for a measurement. Examples: WHOLE BLOOD, SERUM, URINE, LIVER, HEART.
COM.PP.PPSPEC	Defines the type of specimen used for a measurement. If multiple specimen types are used for a calculation (e.g., serum and urine for creatinine clearance), then this field should be left blank. Examples: SERUM, PLASMA, URINE.
COM.OM.OMSPEC	Defines the type of tissue, organ, or fluid specimen used as the object for the finding. Examples: GLAND, ADRENAL; KIDNEY; VESSEL, LYMPHATIC.
COM.MA.MASPEC	Defines the type of tissue, organ, or fluid specimen used as the object for the finding. Examples: GLAND, ADRENAL; KIDNEY; VESSEL, LYMPHATIC. See also Assumption 4.b.
COM.MI.MIDTHREL	Describes the relationship of a particular finding to the death of a subject (Y=caused death, N=did not cause death, U=unknown). May be left null if not available.
COM.TF.TFDTHREL	Describes the relationship of a particular finding to the death of a subject. Example: Y if the tumor was the cause of death, N if the tumor was not the cause of death, or U for Unknown. Null cannot be used because the variable is required.
COM.MI.MISEV	Describes the severity of a particular finding.
COM.MA.MASEV	Describes the severity or intensity of a particular finding. Examples: MILD, MODERATE, SEVERE.
COM.MI.MISPCUFL	Describes the usability of the specimen for the test. Example: N = the specimen is not usable; otherwise null.
COM.EX.EXTRTV	Describes vehicle used for treatment. Example: SALINE.
COM.PP.PPREASND	Describes why a parameter was not performed, such as INSUFFICIENT DATA. Used in conjunction with PPSTAT when value is NOT DONE.
COM.LB.LBREASND	Describes why LBSTAT is NOT DONE, such as BROKEN EQUIPMENT or SPECIMEN LOST.
COM.MI.MIREASND	Describes why MISTAT is NOT DONE, such as SAMPLE AUTOLYZED or SPECIMEN LOST.
COM.TA.ARM	Descriptive name given to a specific Trial Arm (e.g., Low Dose, Mid Dose, 10 mg/kg/day dose, 3rd Arm) to which subject was assigned.
COM.DM.ARM	Descriptive name given to a specific Trial Arm (e.g., Low Dose, Mid Dose, 10 mg/kg/day dose, Third Arm) to which subject was assigned.
COM.CO.RDOMAIN	Domain abbreviation of the parent record(s). Null for comments collected as a general comment or additional information.
COM.EX.EXDOSFRM	Dose form for EXTRT. Examples: TABLET, LOTION.
COM.DS.DSTERM	DSTERM is the original term recorded for animal disposition. DSTERM is not under controlled terminology, but should be mapped to DSDECOD.
COM.SE.SEENDTC	End date/time for an Element for each subject.
COM.MI.MIANTREG	Example: Cortex, Medulla, or Femur (if the MISPEC is, for example, BONE MARROW).

COM.TE.TESTRL	Expresses rule for beginning Element.
COM.TE.TEENRL	Expresses rule for ending Element. Either TEENRL or TEDUR must be present for each Element.
COM.MI.MISPCCND	Free or standardized text describing the condition of the specimen. Example: AUTOLYZED.
COM.USUBJID	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
COM.RELREC.RELTYPE	Identifies the hierarchical level of the records in the relationship. Values should be either ONE or MANY, only when --SPID is used. However, values are only necessary when identifying a relationship between datasets (as described in Section 8.4).
COM.CO.IDVAR	Identifying variable in the parent dataset that identifies the record(s) to which the comment applies. Examples: BWSEQ or CLGRPID. Used only when individual comments are related to domain records.
COM.PM.PMSTRESC	If there are findings for a body system, then either the dictionary preferred term (if findings are coded using a dictionary) or PMORRES (if findings are not coded) should appear here. If PMORRES is null, PMSTRESC should be null. PMSTRESC should only contain the finding, without the location modifier.
COM.PC.PCLLOQ	Indicates the lower limit of quantitation for an assay. Units should be those used in PCSTRESU.
COM.PP.VISITDY	It is the planned study day for the time point reference of the time-concentration profile.
COM.EG.EGLEAD	Lead identified to capture the measurement.
COM.TX.SET	Long description of a specific Trial Set, as defined by the sponsor.
COM.BG.BGTEST	Long name for BGTESTCD. The value in BGTEST cannot be longer than 40 characters.
COM.BW.BWTEST	Long name for BWTESTCD. The value in BWTEST cannot be longer than 40 characters.
COM.CL.CLTEST	Long name for CLTESTCD. The value in CLTEST cannot be longer than 40 characters.
COM.DD.DDTEST	Long name for DDTESTCD. The value in DDTEST cannot be longer than 40 characters. In this domain, the value should always be "Death Diagnosis".
COM.EG.EGTEST	Long name for EGTESTCD. The value in EGTEST cannot be longer than 40 characters. Examples: Summary (Mean) Heart Rate, Summary (Mean) QRS Duration.
COM.FW.FWTEST	Long name for FWTESTCD. The value in FWTEST cannot be longer than 40 characters. Extensible controlled values are Food Consumption, Food Consumption Relative to Body Wt, Water Consumption, Water Consumption Relative to Body Wt.
COM.LB.LBTEST	Long name for LBTESTCD. The value in LBTEST cannot be longer than 40 characters. Examples: Alanine Aminotransferase, Lactate Dehydrogenase.
COM.MA.MATEST	Long name for MATESTCD. The value in MATEST cannot be longer than 40 characters. Extensible controlled values are Gross Pathological Examination, Clinical Signs Follow-up.
COM.MI.MITEST	Long name for MITESTCD. The value in MITEST cannot be longer than 40 characters. Extensible controlled value is Microscopic Examination.
COM.OM.OMTEST	Long name for OMTESTCD. The value in OMTEST cannot be longer than 40 characters.
COM.PC.PCTEST	Long name for PCTESTCD, such as the name of the analyte or specimen characteristic. The value in PCTEST cannot be longer than 40 characters. Examples: Acetylsalicyclic Acid, Volume, Specific Gravity.
COM.PM.PMTEST	Long name for PMTESTCD. The value in PMTEST cannot be longer than 40 characters.
COM.PP.PPTEST	Long name for PPTESTCD. The value in PPTEST cannot be longer than 40 characters. Examples: AUCINT, Time of CMAX Observation, Max Conc.
COM.SC.SCTEST	Long name for SCTESTCD. The value in SCTEST cannot be longer than 40 characters. Examples: Test Subject Supplier, Test Subject Supplier Site, and Hair Coat Color.
COM.TF.TFTEST	Long name for TFTESTCD. The value in TFTEST cannot be longer than 40 characters. Example: Tumor Examination.
COM.EX.EXLOT	Lot Number(s) or Batch Number(s) of the EXTRT test article. If mixed lots of the test article are administered during the same constant dosing interval, this should be represented as "Lot A;Lot B". Mixed lots are produced by the mixing of Lots A and B of the test article into one solution, suspension, or dietary food concentration. If no test article was administered, EXLOT should be null.
COM.MA.MASPID	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
COM.MI.MISPID	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
COM.PM.PMSPID	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.

COM.TF.TFSPID	Mass identifier such as MASS 1 or MASS A. Used when the mass was discovered during the in-life phase or during pathology and assigned a mass identifier. The mass identification should be unique within the subject, regardless of mass location.
COM.EG.EGMETHOD	Method of the ECG test. Examples: 12 LEAD STANDARD, 6 LEAD STANDARD.
COM.PC.PCMETHOD	Method of the test or examination. Examples include HPLC/MS, ELISA. This should contain sufficient information and granularity to allow differentiation of various methods that might have been used within a study.
COM.LB.LBMETHOD	Method of the test or examination. Examples: EIA (Enzyme Immunoassay), ELECTROPHORESIS, DIPSTICK.
COM.PC.PCTPTREF	Name of the fixed reference point used as a basis for PCTPT, PCTPTNUM, and PCELTM. Example: Most Recent Dose.
COM.RELREC.IDVAR	Name of the identifying variable in the general-observation-class dataset that identifies the related record(s). Examples include --SEQ and --GRPID.
COM.TA.EPOCH	Name of the study Epoch with which this Element of the Arm is associated (e.g., Treatment, Screen). Equivalent to 'Phase' or 'Period.'
COM.EX.EXTRT	Name of the treatment. Usually the verbatim name of the investigational treatment given during the dosing period for the observation.
COM.TA.TAETORD	Number that provides the order of the planned Element within the Arm. This value should be an integer.
COM.PC.PCTPTNUM	Numerical version of PCTPT to aid in sorting.
COM.TE.TEDUR	Planned duration of Element in ISO 8601 format. Use when an Element represents a fixed duration.
COM.PC.PCELTM	Planned elapsed time (in ISO 8601) relative to a planned fixed reference (PCTPTREF) such as PREVIOUS DOSE or PREVIOUS MEAL. This variable is useful where there are repetitive measures. Not a clock time or a date time variable.
COM.DS.VISITDY	Planned study day of the disposition event. Should be an integer. VISITDY should be populated only when DSTERM represents a scheduled activity.
COM.EG.EGPOS	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING, UNCONSTRAINED
COM.MI.MIDIR	Qualifier for directionality of the specimen within the subject. Examples: DORSAL, PROXIMAL.
COM.MA.MALAT	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.
COM.MI.MILAT	Qualifier for laterality of the specimen within the subject for paired specimens. Examples: LEFT, RIGHT, BILATERAL.
COM.DM.RFENDTC	Reference end date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when the subject was determined to have left the study. The sponsor must define what collected date is used to populate RFENDTC in the data definition file.
COM.DM.RFSTDTC	Reference start date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Study day calculation (the --DY variable) in all domains will be based on this date. The sponsor must define what collected date is used to populate RFSTDTC in the data definition file.
COM.DD.DDORRES	Result of the diagnosis of the subject's cause of death, as originally received or collected.
COM.EG.EGORRES	Result of the ECG measurement or interval as originally received or collected.
COM.TF.TFORRES	Result of the histopathological examination as originally received or collected.
COM.BW.BWORRES	Result of the measurement or finding as originally received or collected.
COM.FW.FWORRES	Result of the measurement or finding as originally received or collected.
COM.LB.LBORRES	Result of the measurement or finding as originally received or collected.
COM.OM.OMORRES	Result of the measurement or finding as originally received or collected.
COM.PC.PCORRES	Result of the measurement or finding as originally received or collected.
COM.PP.PPORRES	Result of the measurement or finding as originally received or collected.
COM.BG.BGORRES	Result of the measurement or finding as originally recorded.
COM.SC.SCORRES	Result of the subject characteristic as originally received or collected.
COM.VS.VSORRES	Result of the vital signs measurement as originally received or collected.
COM.EX.EXROUTE	Route of administration for EXTRT. Examples: ORAL GAVAGE, DERMAL, INTRAVENOUS, BOLUS.
COM.CO.COSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.EX.EXSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.DS.DSSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.

COM.BG.BGSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.BW.BWSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.CL.CLSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.DD.DDSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.EG.EGSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.FW.FWSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.LB.LBSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.MA.MASEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.MI.MISEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.OM.OMSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.PM.PMSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.PP.PPSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.SC.SCSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.TF.TFSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.VS.VSSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.
COM.PC.PCSEQ	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. The sequence number must be unique for each record within a USUBJID or POOLID, whichever applies for the record.
COM.SE.SESEQ	Sequence number given to ensure uniqueness of subject records within a USUBJID within a domain. May be any valid number.
COM.TS.TSSEQ	Sequence number given to ensure uniqueness within a dataset. Allows inclusion of multiple records for the same TSPARMCD, and can be used to join related records.
COM.TS.TSPARMCD	Short character value for the trial design characteristic described in TSPARM. Value must be 8 characters or less.
COM.TX.TXPARMCD	Short character value for the Trial Set parameter described in TXPARM. Maximum 8 characters.
COM.DM.ARMCD	Short name for ARM (may be up to 20 characters) used for sorting and programming. Should be populated when Arms have been defined in the TA domain.
COM.TA.ARMCD	Short name of a specific ARM (may be up to 20 characters) used for sorting and programming. Should be populated in Demographics when Arms have been defined in this domain.
COM.TX.SETCD	Short name of a specific Trial Set, as defined by the sponsor. Maximum 8 characters. This represents the Trial Set for which parameters are being submitted.
COM.DM.SETCD	Short name of a specific Trial Set, as defined by the sponsor. Maximum of 8 characters. This represents the Trial Set for which parameters are being submitted.
COM.SE.ETCD	Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. If an encountered Element differs from the planned Element to the point that it is considered a new Element, then use UNPLAN as the value for ETCD to represent this Element. The value in ETCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid).
COM.TE.ETCD	Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. Maximum 8 characters.
COM.TA.ETCD	Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. Maximum 8 characters. The values of ETCD used in the Trial Arms dataset must match values for the same Element in the Trial Elements dataset.
COM.BG.BGTESTCD	Short name of the measurement, test, or examination described in BGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BGTESTCD cannot contain characters other than letters, numbers, or underscores.
COM.BW.BWTESTCD	Short name of the measurement, test, or examination described in BWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in BWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). BWTESTCD cannot contain characters other than letters, numbers, or underscores.
COM.CL.CLTESTCD	Short name of the measurement, test, or examination described in CLTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in CLTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). CLTESTCD cannot contain characters other than letters, numbers, or underscores.

COM.DD.DDTESTCD	Short name of the measurement, test, or examination described in DDTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in DDTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). DDTESTCD cannot contain characters other than letters, numbers, or underscores. In this domain the value should always be DEATHD.
COM.EG.EGTESTCD	Short name of the measurement, test, or examination described in EGTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in EGTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). EGTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: HRMEAN, QRSDUR
COM.FW.FWTESTCD	Short name of the measurement, test, or examination described in FWTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FWTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). FWTESTCD cannot contain characters other than letters, numbers, or underscores. Extensible controlled values are FC, FCRELBW, WC, and WCRELBW.
COM.LB.LBTESTCD	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ALT, LDH.
COM.MA.MATESTCD	Short name of the measurement, test, or examination described in MATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MATESTCD cannot contain characters other than letters, numbers, or underscores.
COM.MI.MITESTCD	Short name of the measurement, test, or examination described in MITEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in MITESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). MITESTCD cannot contain characters other than letters, numbers, or underscores. Extensible controlled value is MIEXAM.
COM.OM.OMTESTCD	Short name of the measurement, test, or examination described in OMTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in OMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). OMTESTCD cannot contain characters other than letters, numbers, or underscores.
COM.PC.PCTESTCD	Short name of the measurement, test, or examination described in PCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PCTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: ASA, VOL, SPG.
COM.PM.PMTESTCD	Short name of the measurement, test, or examination described in PMTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PMTESTCD cannot contain characters other than letters, numbers, or underscores.
COM.PP.PPTESTCD	Short name of the measurement, test, or examination described in PPTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PPTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). PPTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: AUCINT, TMAX, CMAX.
COM.SC.SCTESTCD	Short name of the measurement, test, or examination described in SCTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SCTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). SCTESTCD cannot contain characters other than letters, numbers, or underscores. Some extensible controlled values are: SPLRNAM, SPLRLOC, HAIRCOLR.
COM.TF.TFTESTCD	Short name of the measurement, test, or examination described in TFTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in TFTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). TFTESTCD cannot contain characters other than letters, numbers, or underscores. Example: TUMEX.
COM.VS.VSTESTCD	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: SYSBP, DIABP.
COM.PM.PMLOC	Specifies the location of the palpable mass finding. Example: LEFT SHOULDER.
COM.BG.BGSTRESU	Standardized unit used for BGSTRESC or BGSTRESN.
COM.BW.BWSTRESU	Standardized unit used for BWSTRESC and BWSTRESN.
COM.EG.EGSTRESU	Standardized unit used for EGSTRESC or EGSTRESN. Preferably SI units.
COM.FW.FWSTRESU	Standardized unit used for FWSTRESC or FWSTRESN.
COM.LB.LBSTRESU	Standardized unit used for LBSTRESC or LBSTRESN. Preferably SI units.
COM.OM.OMSTRESU	Standardized unit used for OMSTRESC or OMSTRESN. Example, if the original units were oz for ounces, the standard unit might be g for grams.
COM.PC.PCSTRESU	Standardized unit used for PCSTRESC and PCSTRESN.
COM.PM.PMSTRESU	Standardized unit used for PMSTRESC or PMSTRESN.

COM.PP.PPSTRESU	Standardized unit used for PPSTRESC and PPSTRESN.
COM.VS.VSSTRESU	Standardized unit used for VSSTRESC or VSSTRESN.
COM.SE.SESTDTC	Start date/time for an Element for each subject.
COM.BW.BWDY	Study day of body weight collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.SC.SCDY	Study day of collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the
COM.LB.LBDY	Study day of specimen collection or observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.PC.PCDY	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics (DM) domain.
COM.MA.MADY	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.MI.MIDY	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.TF.TFDY	Study day of specimen collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.OM.OMDY	Study day of specimen/tissue weighting, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.CL.CLDY	Study day of the clinical observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.DD.DDDY	Study day of the diagnosis, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.DS.DSSTDY	Study day of the disposition event, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.EG.EGDY	Study day of the ECG measurement collection, ininteger days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.FW.FWENDY	Study day of the end of the observation, measured as integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.BG.BGENDY	Study day of the end of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.PM.PMDY	Study day of the observation, measured as integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.FW.FWDY	Study day of the start of the observation, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.BG.BGDY	Study day of the start of the weight interval, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.VS.VSDY	Study day of vital signs measurements collection, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.EX.EXSTDY	Study day when administration of the treatment began, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain
COM.EX.EXENDY	Study day when administration of the treatment ended, in integer days. The algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in the Demographics (DM) domain.
COM.SUBJID	Subject (i.e., Animal) identifier used within the study.
COM.MI.MISPEC	Subject of the observation. Defines the type of specimen used for a measurement. Examples: LIVER, HEART, BONE MARROW.
COM.TF.TFSPEC	Subject of the observation. Defines the type of specimen used for a measurement. Examples: LIVER, HEART.
COM.TS.TSPARM	Term for the trial parameter. Value must be 40 characters or less.
COM.TX.TXPARM	Term for the Trial Set parameter. Maximum 40 characters.
COM.PM.PMORRES	Text description of findings as originally recorded. If the examination was not performed, then the value should be null, and NOT DONE should

	appear in PMSTAT.
COM.CL.CLORRES	Text description of the finding as originally received or collected. If the examination was not performed on a particular body system, or at the subject level, then the value should be null, and NOT DONE should appear in CLSTAT.
COM.MA.MAORRES	Text description of the findings as originally received or collected, including the base gross pathological observation and any modifiers, such as severity, origin, classification, size, color, etc.
COM.MI.MIORRES	Text description of the findings as originally received or collected, including the base pathological process and any modifiers.
COM.PC.PCTPT	Text description of time when specimen should be taken. Note: This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See PCTPTNUM and PCTPTREF. Examples: Start, 5 min post.
COM.CL.CLSTRESC	The base finding from CLORRES without modifiers. If the examination was completed and there were no abnormal findings, the value must be NORMAL.
COM.TE.ELEMENT	The description of the Element. The same Element may occur more than once within an Arm.
COM.TA.ELEMENT	The name of the Element. The same Element may occur more than once within an Arm.
COM.SE.ELEMENT	The name of the Element. The same Element may occur more than once within an Arm. If ETCD has the value of UNPLAN, then ELEMENT should be blank.
COM.TF.TFDETECT	The number of days from the start of dosing to the earliest detection of the tumor in the experimental phase. This variable must be populated for every tumor discovered during the experimental phase.
COM.DM.SEX	The sex of the subject.
COM.CO.COVAL	The text of the comment. Text over 200 characters can be added to additional columns COVAL1-COVALn. See Assumption 4 in Section 5.2.1.1.
COM.BG.BGORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.BW.BWORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.EG.EGORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.FW.FWORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.LB.LBORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.OM.OMORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.PC.PCORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.PP.PPORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.VS.VSORRESU	The unit for the original result. The unit of the original result should be mapped to a synonymous unit on the Controlled Terminology list.
COM.PC.VISITDY	This is the planned day of collection.
COM.VS.VISITDY	This is the planned day of collection.
COM.BW.VISITDY	This is the planned study day of collection.
COM.CL.VISITDY	This is the planned study day of collection.
COM.EG.VISITDY	This is the planned study day of collection.
COM.LB.VISITDY	This is the planned study day of collection.
COM.PM.VISITDY	This is the planned study day of collection.
COM.TS.DOMAIN	Two-character abbreviation for the domain most relevant to the observation.
COM.RELREC.RDOMAIN	Two-character abbreviation for the domain of the parent record(s).
COM.TA.DOMAIN	Two-character abbreviation for the domain.
COM.TE.DOMAIN	Two-character abbreviation for the domain.
COM.TX.DOMAIN	Two-character abbreviation for the domain.
COM.CO.DOMAIN	Two-character abbreviation for the domain.
COM.DM.DOMAIN	Two-character abbreviation for the domain.
COM.SE.DOMAIN	Two-character abbreviation for the domain.

COM.EX.DOMAIN	Two-character abbreviation for the domain.
COM.DS.DOMAIN	Two-character abbreviation for the domain.
COM.BG.DOMAIN	Two-character abbreviation for the domain.
COM.BW.DOMAIN	Two-character abbreviation for the domain.
COM.CL.DOMAIN	Two-character abbreviation for the domain.
COM.DD.DOMAIN	Two-character abbreviation for the domain.
COM.EG.DOMAIN	Two-character abbreviation for the domain.
COM.FW.DOMAIN	Two-character abbreviation for the domain.
COM.LB.DOMAIN	Two-character abbreviation for the domain.
COM.MI.DOMAIN	Two-character abbreviation for the domain.
COM.OM.DOMAIN	Two-character abbreviation for the domain.
COM.PC.DOMAIN	Two-character abbreviation for the domain.
COM.PM.DOMAIN	Two-character abbreviation for the domain.
COM.PP.DOMAIN	Two-character abbreviation for the domain.
COM.SC.DOMAIN	Two-character abbreviation for the domain.
COM.TF.DOMAIN	Two-character abbreviation for the domain.
COM.VS.DOMAIN	Two-character abbreviation for the domain.
COM.MA.DOMAIN	Two-character code for the domain.
COM.STUDYID	Unique identifier for a study.
COM.TX.TXSEQ	Unique number for this record within this dataset. (This sequence should be unique within the entire dataset because there is no USUBJID.)
COM.RELREC.RELID	Unique value within USUBJID that identifies the relationship. All records for the same USUBJID that have the same RELID are considered "related/associated." "RELID" can be any value the sponsor chooses and is only meaningful within the RELREC dataset to identify the related/associated Domain records.
COM.DM.AGEU	Units associated with either AGE or AGETXT.
COM.EX.EXDOSU	Units for EXDOSE. Examples: ng, mg, or mg/kg.
COM.PM.PMORRESU	Units for PMORRES if available (e.g., for length, width, or depth findings). Examples: mm, cm.
COM.LB.LBSTRESN	Used for continuous or numeric results or findings in standard format; contains the numeric form of LBSTRESC. LBSTRESN should store all numeric test results or findings.
COM.PC.PCSTRESN	Used for continuous or numeric results or findings in standard format; contains the numeric form of PCSTRESC. PCSTRESN should store all numeric test results or findings. For results beyond limits of quantification, this variable should be left null (for example, if PCSTRESC is "<2", PCSTRESN would be null).
COM.PP.PPSTRESN	Used for continuous or numeric results or findings in standard format; contains the numeric form of PPSTRESC. PPSTRESN should store all numeric test results or findings.
COM.EG.EGSTRESN	Used for continuous or numeric results or findings in standard format; copied in numeric format from EGSTRESC. EGSTRESN should store all numeric test results or findings.
COM.VS.VSSTRESN	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESN should store all numeric test results or findings.
COM.FW.FWSTRESN	Used for numeric results or findings in standard format; contains the numeric form of FWSTRESC. FWSTRESN should store all numeric test results or findings.
COM.PM.PMSTRESN	Used for numeric results or findings in standard format; contains the numeric form of PMSTRESC. PMSTRESN should store all numeric test results or findings.
COM.BG.BGSTRESN	Used for results or findings in standard format; contains the numeric form of BGSTRESC. BGSTRESN should store all numeric test results or findings.
COM.OM.OMSTRESN	Used for results or findings in standard format; contains the numeric form of OMSTRESC. OMSTRESN should store all numeric test results or findings.

COM.BW.BWSTRESN	Used for results or findings in standard format; contains the numeric format of BWSTRESC. BWSTRESN should store all numeric test results or findings.
COM.MI.MIRESCAT	Used to categorize the result of a finding. Example: MALIGNANT for tumor findings. Histopathological findings may be categorized as NON-NEOPLASTIC.
COM.DD.DDRESCAT	Used to categorize the result of a finding. Examples: TREATMENT RELATED, NONTREATMENT RELATED, UNDETERMINED, ACCIDENTAL, etc.
COM.LB.LBCAT	Used to define a category of related records across subjects. Examples: URINALYSIS, CLINICAL CHEMISTRY, HEMATOLOGY, etc.
COM.PP.PPCAT	Used to define a category of related records. For PP, this should be the name of the analyte in PPTEST whose profile the parameter is associated with.
COM.CL.CLCAT	Used to define a category of the clinical observation.
COM.MI.MISTAT	Used to indicate examination not done or result is missing. Should be null if a result exists in MIORRES.
COM.PP.PPSTAT	Used to indicate that a parameter was not calculated. Should be null if a result exists in PPORRES.
COM.LB.LBSTAT	Used to indicate when a test is not done or result is missing. Should be null if a results exists in LBORRES.
COM.TF.TFRESCAT	Used to record the malignancy of the tumor as determined by the pathologist. It may be copied or derived from a description in TFORRES. Examples: BENIGN, MALIGNANT, METASTATIC, and UNDETERMINED.
COM.TS.TSGRPID	Used to tie together a group of related records. This is not the sponsor-defined protocol group number.
COM.DM.AGETXT	Used when the age is a range and the exact birthdate is not known. This variable is a character field for the purposes of defining age ranges, e.g., if the information available for the age of the subject is 6-8 and AGEU is WEEKS. Populate only when BRTHDTC or AGE are not specified. The format for AGETXT is "number-number" (e.g., 6-8).
COM.EX.EXDOSFRQ	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period. Examples: QD (once daily), BID (2x daily), BIS (2x a week).
COM.RELREC.IDVARVAL	Value of identifying variable described in IDVAR. If --SEQ is the variable being used to describe this record, then the value of --SEQ would be entered here.
COM.CO.IDVARVAL	Value of identifying variable of the parent record(s). Used only when individual comments are related to domain records. Cannot be populated if IDVAR is null.
COM.TX.TXVAL	Value of the Trial Set parameter (e.g., Fed ad libitum or Restricted Feeding when TXPARM is FEEDREG). Some parameters may be subject to controlled terminology. See the Controlled Terms, Codelist, or Format column in Section 7.4.2 that lists all defined Trial Set parameters.
COM.TS.TSVAL	Value of the TS parameter (e.g., "FDA" when TSPARM is GLP Type). The values for some parameters may be subject to controlled terminology. See the Controlled Terms, Codelist, or Format column in Section 7.6.3 that lists all defined parameters. TSVAL cannot be null – a value is required for the record to be valid.
COM.VS.VSTEST	Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 40 characters. Examples: Systolic Blood Pressure, Diastolic Blood Pressure.