

Tabulation Datasets for Study Nimort-01 (SEND-IG3.0)

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, ETC	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	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	DM.xpt	
POOLDEF	Pool Definition	SPECIAL PURPOSE	One record per subject per pool	Tabulation	STUDYID, USUBJID, POOLID	POOLDEF.xpt	
CO	Comments	SPECIAL PURPOSE	One record per comment per Subject	Tabulation	STUDYID, USUBJID, COSEQ	CO.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 disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	DS.xpt	

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
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	
FW	Food and Water Consumption	FINDINGS	One record per test per interval per Poolid	Tabulation	STUDYID, USUBJID, FWTESTCD, FWDTC, FWENDTC	FW.xpt	Data reported by Pool Identifier. Individual subject data for food and water consumption is not available.
LB	Laboratory Tests Results	FINDINGS	One record per test per specimen per observation time per subject	Tabulation	STUDYID, USUBJID, LBTESTCD, LBSPEC, LBDTC	LB.xpt	
MA	Macroscopic Findings	FINDINGS	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MATESTCD, MAORRES, MASPEC, MAANTREG	MA.xpt	

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
MI	Microscopic Findings	FINDINGS	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MITESTCD, MISTRESC, MISPEC	MI.xpt	
OM	Organ Measurements	FINDINGS	One record per test per specimen per subject	Tabulation	STUDYID, USUBJID, OMTESTCD, OMSPEC	OM.xpt	
SUPPEX	Supplemental Qualifiers for EX	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per subject per related domain	Tabulation	STUDYID, USUBJID, IDVAR, IDVARVAL, QNAM	SUPPEX.xpt	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
ARMCD	Planned Arm Code	2	text	4		DERIVED	Coded form of ARM
ARM	Description of Planned Arm		text	9		DERIVED	Decode for ARMCD
TAETORD	Order of Element within Arm	3	integer	8		OTHER	
ETCD	Element Code		text	4		OTHER	
ELEMENT	Description of Element		text	9		OTHER	
TABRANCH	Branch		text	25		OTHER	
TATRANS	Transition Rule		text	1		OTHER	
EPOCH	Trial Epoch		text	9	["FOLLOW-UP", "RUN-IN", "SCREENING", "TREATMENT"] < Other format 1 >	OTHER	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
ETCD	Element Code	2	text	4		OTHER	
ELEMENT	Description of Element		text	9		OTHER	
TESTRL	Rule for Start of Element		text	31		OTHER	
TEENRL	Rule for End of Element		text	68		OTHER	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
TSSEQ	Sequence Number	3	integer	8		OTHER	
TSGRPID	Group Identifier		text	1		OTHER	
TSPARMCD	Trial Summary Parameter Short Name	2	text	8		OTHER	
TSPARM	Trial Summary Parameter		text	36		OTHER	
TSVAL	Parameter Value		text	43		OTHER	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
SETCD	Set Code	2	text	1		COLLECTED	
SET	Set Description		text	43		COLLECTED	
TXSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
TXPARMCD	Trial Set Parameter Short Name	3	text	7	SEND Trial Summary Parameter Test Code	COLLECTED	
TXPARM	Trial Set Parameter		text	26	SEND Trial Summary Parameter Test Name	COLLECTED	
TXVAL	Trial Set Parameter Value		text	18		COLLECTED	

Demographics (DM) [Location: [DM.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Unique Subject ID created by combining study ID & subject ID
SUBJID	Subject Identifier for the Study		text	3		COLLECTED	
RFSTDTC	Subject Reference Start Date/Time		datetime		ISO8601	DERIVED	First dose date
RFENDTC	Subject Reference End Date/Time		datetime		ISO8601	DERIVED	Last dose date
SITEID	Study Site Identifier		text	1		COLLECTED	
AGETXT	Age Range		text	3		COLLECTED	
AGEU	Age Unit		text	5	["WEEKS"] < Age Unit >	COLLECTED	
SEX	Sex		text	1	["F" = "Female", "M" = "Male"] < Sex >	COLLECTED	
SPECIES	Species		text	3	["RAT"] < Species >	COLLECTED	
STRAIN	Strain/Substrain		text	11	["FISCHER 344"] < Strain/Substrain >	COLLECTED	
ARMCD	Planned Arm Code		text	4		COLLECTED	
ARM	Description of Planned Arm		text	9		COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
SETCD	Set Code		text	1		COLLECTE	

Pool Definition (POOLDEF) [Location: [POOLDEF.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
POOLID	Pool Identifier	3	text	3		COLLECTED	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.

Comments (CO) [Location: [CO.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
RDOMAIN	Related Domain Abbreviation		text	2		OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
COSEQ	Sequence Number	3	integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
IDVAR	Identifying Variable		text	5		OTHER	
IDVARVAL	Identifying Variable Value		text	2		OTHER	
COVAL	Comment		text	58		COLLECTED	
CODTC	Date/Time of Comment		date		ISO8601	NOT AVAILABLE	Comment date not available

Exposure (EX) [Location: [EX.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Unique Subject ID created by combining study ID & subject ID
EXSEQ	Sequence Number		integer	8		DERIVED	Record identifier created to identify each record for subject uniquely
EXTRT	Name of Actual Treatment	3	text	9		COLLECTED	
EXDOSE	Dose per Administration		integer	8		OTHER	
EXDOSU	Dose Units		text	9	["mg/kg/day" = "Milligram per Kilogram per Day"] < Exposure Unit >	OTHER	
EXDOSFRM	Dose Form		text	6	["TABLET" = "Tablet Dosage Form"] < Pharmaceutical Dosage Form >	OTHER	
EXDOSFRQ	Dosing Frequency Per Interval		text	2		OTHER	
EXROUTE	Route of Administration		text	4		OTHER	
EXLOT	Lot Number		text	6		OTHER	
EXTRTV	Treatment Vehicle		text	6		OTHER	
EXSTDTC	Start Date/Time of Treatment	4	datetime		ISO8601	COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
EXENDTC	End Date/Time of Treatment		datetime		ISO8601	DERIVED	Exposure start date assigned to exposure end date
EXSTDY	Study Day of Start of Treatment		integer	8		DERIVED	Relative study day calculated using first dose date
EXENDY	Study Day of End of Treatment		integer	8		DERIVED	Relative study day calculated using first dose date
Related dataset: Supplemental Qualifiers for EX (SUPPEX)							

Disposition (DS) [Location: [DS.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
DSSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
DSTERM	Reported Term for the Disposition Event		text	21		COLLECTED	
DSDECOD	Standardized Disposition Term	3	text	18	["ACCIDENTAL DEATH", "FOUND DEAD", "INTERIM SACRIFICE", "TERMINAL SACRIFICE"] < Standardized Disposition Term >	COLLECTED	
VISITDY	Planned Study Day of Disposition		integer	8		DERIVED	Relative study day calculated using first dose date
DSSTDTC	Date/Time of Disposition	4	date		ISO8601	COLLECTED	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
BGSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
BGTESTCD	Test Short Name	3	text	6	["BWGAIN" = "Body Weight Gain"] < Body Weight Gain Test Code >	OTHER	
BGTEST	Test Name		text	16		OTHER	
BGORRES	Result or Findings as Collected		text	5		COLLECTED	
BGORRESU	Unit of the Original Result		text	1		OTHER	
BGSTRESC	Standardized Result in Character Format		text	5		DERIVED	Derived from BGORRES
BGSTRESN	Standardized Result in Numeric Format		float	8		DERIVED	BGSTRESC in numeric format
BGSTRESU	Unit of the Standardized Result		text	1		OTHER	
BGDTC	Date/Time Animal Weighed	4	date		ISO8601	COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
BGENDTC	End Date/Time Animal Weighed	5	date		ISO8601	COLLECTED	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
BWSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
BWTESTCD	Test Short Name	3	text	2	["BW" = "Body Weight"] < Body Weight Test Code >	OTHER	
BWTEST	Test Name		text	11		OTHER	
BWORRES	Result or Findings as Collected		text	7		COLLECTED	
BWORRESU	Unit of the Original Result		text	1	["g" = "Gram", "g/animal/day" = "Gram per Animal per Day", "mL" = "Milliliter", "mL/animal/day" = "Milliliter per Animal per Day"] < Unit >	OTHER	
BWSTRESC	Standardized Result in Character Format		text	7		DERIVED	Derived from BWORRES
BWSTRESN	Standardized Result in Numeric Format		float	8		DERIVED	BWSTRESC in numeric format

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
BWSTRESU	Unit of the Standardized Result		text	1	["g" = "Gram", "g/animal/day" = "Gram per Animal per Day", "mL" = "Milliliter", "mL/animal/day" = "Milliliter per Animal per Day"] <Unit>	OTHER	
BWSTAT	Examination Status		text	8		DERIVED	Set to 'NOT DONE' for records with missing results
BWREASND	Reason Not Done		text	16		COLLECTED	
BWBLFL	Baseline Flag		text	1		DERIVED	Baseline Flag set as 'Y' for first scheduled observation
VISITDY	Planned Study Day of Collection		integer	8		DERIVED	Relative study day calculated using first dose date
BWDTC	Date/Time Animal Weighed	4	date		ISO8601	COLLECTED	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
CLSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
CLTESTCD	Test Short Name	3	text	2	["AC" = "Appearance and Condition", "AG" = "Activity/Gait", "EY" = "Eyes", "GO" = "General Observations"] < CL Test Code >	COLLECTED	
CLTEST	Test Name		text	24		DERIVED	Decode for CLTEST
CLCAT	Category for Clinical Observations	4	text	14	["CLINICAL SIGNS"] < Category for Clinical Observation >	OTHER	
CLORRES	Result or Findings as Collected	5	text	18		COLLECTED	
CLSTRESC	Standardized Result in Character Format		text	18		DERIVED	Derived from CLORRES
CLLOC	Location of a Finding	6	text	1		NOT AVAILABLE	location not collected and left null
CLSEV	Severity		text	8	["MILD", "MODERATE", "SEVERE"] < Severity >	COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
VISITDY	Planned Study Day of Collection		integer	8		DERIVED	Relative study day calculated using first dose date
CLDTC	Start Date/Time of Observation	7	date		ISO8601	COLLECTED	

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	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	1		OTHER	Data pooled and USUBJID left is null
POOLID	Pool Identifier		text	3		COLLECTED	
FWSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
FWTESTCD	Food /Water Consumption Short Name	3	text	2	["FC" = "Food Consumption", "WC" = "Water Consumption"] < Food and Water Consumption Test Code >	COLLECTED	
FWTEST	Food /Water Consumption Name		text	17		COLLECTED	
FWORRES	Result or Findings as Collected		text	3		OTHER	
FWORRESU	Unit of the Original Result		text	2	["g" = "Gram", "g/animal/day" = "Gram per Animal per Day", "mL" = "Milliliter", "mL/animal/day" = "Milliliter per Animal per Day"] < Unit >	COLLECTED	
FWSTRESC	Standardized Result in Character Format		text	1		COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
FWSTRESN	Standardized Result in Numeric Format		integer	8		DERIVED	FWSTRESC in numeric format
FWSTRESU	Unit of the Standardized Result		text	13	["g" = "Gram", "g/animal/day" = "Gram per Animal per Day", "mL" = "Milliliter", "mL/animal/day" = "Milliliter per Animal per Day"] <Unit>	COLLECTED	
FWDTC	Date/Time of Observation	4	date		ISO8601	COLLECTED	
FWENDTC	End Date/Time of Observation	5	date		ISO8601	COLLECTED	

Laboratory Tests Results (LB) [Location: [LB.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Unique Subject ID created by combining study ID & subject ID
LBSEQ	Sequence Number		integer	8		DERIVED	Record identifier created to identify each record for subject uniquely
LBTESTCD	Lab Test or Examination Short Name	3	text	3	["ALB" = "Albumin", "CL" = "Chloride", "K" = "Potassium"] < Laboratory Test Code >	COLLECTED	
LBTEST	Lab Test or Examination Name		text	9		DERIVED	Decode for LBTEST
LBCAT	Category for Lab Test		text	9		COLLECTED	
LBORRES	Result or Findings as Collected		text	3		COLLECTED	
LBORRESU	Unit of the Original Result		text	6	["g/L" = "Kilogram per Cubic Meter", "mmol/L" = "Millimole per Liter"] < Lab Unit >	COLLECTED	
LBORNRL0	Reference Range Lower Limit-Orig Unit		float	8		COLLECTED	
LBORNRI	Reference Range Upper Limit-Orig Unit		float	8		COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
LBSTRESC	Standardized Result in Character Format		text	3		DERIVED	Assigned to LBORRES
LBSTRESN	Standardized Result in Numeric Format		float	8		DERIVED	Assigned to numeric LBORRES
LBSTRESU	Unit of the Standardized Result		text	6	["g/L" = "Kilogram per Cubic Meter", "mmol/L" = "Millimole per Liter"] <Lab Unit>	DERIVED	Assigned to LBORRESU
LBSTNRLO	Reference Range Lower Limit-Std Unit		float	8		DERIVED	Assigned to Original reference range lower limit
LBSTNRHI	Reference Range Upper Limit-Std Unit		float	8		DERIVED	Assigned to Original reference range Upper limit
LBNRIND	Reference Range Indicator		text	1		COLLECTED	All labs in normal range per lab
LBSPEC	Specimen Type	4	text	11		OTHER	
LBMETHOD	Method of Test or Examination		text	1		NOT AVAILABLE	Lab method not available and left as null
LBBLFL	Baseline Flag		text	1	["Y" = "Yes"] <No Yes Response>	DERIVED	Set to 'Y' for screening records
VISITDY	Planned Study Day of Collection		integer	8		DERIVED	Visit Day calculated w.r.t. to first dose date in Demographics
LBDC	Date/Time of Specimen Collection	5	date		ISO8601	COLLECTED	

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
LBTPT	Planned Time Point Name		text	12	["Pre Dose", "4H Post Dose", "8H Post Dose"] < Timepoint (Lab) >	COLLECTED	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
MASEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
MATESTCD	Macroscopic Examination Short Name	3	text	8	["GROSPATH" = "Gross Pathological Examination"] < Macroscopic Findings Test Code >	COLLECTED	
MATEST	Macroscopic Examination Name		text	30		COLLECTED	
MAORRES	Result or Findings as Collected	4	text	55		COLLECTED	
MASTRESC	Standardized Result in Character Format		text	55		DERIVED	Derived from MAORRES
MASPEC	Specimen Material Type	5	text	22	Specimen	COLLECTED	
MAANTREG	Anatomical Region of Specimen	6	text	1		NOT AVAILABLE	Anatomical Region of Specimen no available and left as null
MADTC	Date/Time of Collection		date		ISO8601	COLLECTED	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
MISEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
MITESTCD	Microscopic Examination Short Name	3	text	6	["MIEXAM" = "Microscopic Examination"] < Microscopic Findings Test Code >	COLLECTED	
MITEST	Microscopic Examination Name		text	23		COLLECTED	
MIORRES	Result or Findings as Collected		text	36		COLLECTED	
MISTRESC	Standardized Result in Character Format	4	text	36		DERIVED	Derived from MIORRES
MIRESCAT	Result Category		text	14	["NON-NEOPLASTIC" = "Non-Neoplastic Disorder"] < Microscopic Histopathology Result Category >	COLLECTED	
MISPEC	Specimen Material Type	5	text	17	Specimen	COLLECTED	
MISPCND	Specimen Condition		text	1		NOT AVAILABLE	Specimen Condition not available and left as null

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
MISPCUFL	Specimen Usability for the Test		text	1	["Y" = "Yes"] < No Yes Response >	NOT AVAILABLE	Specimen Usability for the Test not available and left as null
MISEV	Severity		text	8	["MILD", "MODERATE", "SEVERE"] < Severity >	COLLECTED	
MIDTC	Date/Time of Specimen Collection		date		ISO8601	COLLECTED	

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
DOMAIN	Domain Abbreviation		text	2	SEND Domain Abbreviation	OTHER	
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Concat STUDYID and subject ID.
OMSEQ	Sequence Number		integer	8		DERIVED	Numeric sequential identifier to ensure uniqueness of records for each subject
OMTESTCD	Test Short Name	3	text	6	["WEIGHT"] < Organ Measurement Test Code >	COLLECTED	
OMTEST	Test Name		text	6		COLLECTED	
OMORRES	Result or Findings as Collected		text	5		COLLECTED	
OMORRESU	Unit of the Original Result		text	1	["g" = "Gram", "g/animal/day" = "Gram per Animal per Day", "mL" = "Milliliter", "mL/animal/day" = "Milliliter per Animal per Day"] < Unit >	OTHER	
OMSTRESC	Standardized Result in Character Format		text	5		DERIVED	Derived from OMORRES
OMSTRESN	Standardized Result in Numeric Format		float	8		DERIVED	OMSTRESC in numeric format

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
OMSTRESU	Unit of the Standardized Result		text	1	["g" = "Gram", "g/animal/day" = "Gram per Animal per Day", "mL" = "Milliliter", "mL/animal/day" = "Milliliter per Animal per Day"] <Unit>	DERIVED	Derived from OMORRESU
OMSPEC	Specimen Material Type	4	text	5	Specimen	COLLECTED	
OMDTC	Date/Time Organ Weighed		date		ISO8601	COLLECTED	

Supplemental Qualifiers for EX (SUPPEX) [Location: [SUPPEX.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	9		OTHER	
RDOMAIN	Related Domain Abbreviation		text	2		DERIVED	Domain abbreviation from where data originated
USUBJID	Unique Subject Identifier	2	text	13		DERIVED	Obtained from Parent/Source Domain
IDVAR	Identifying Variable	3	text	5		OTHER	
IDVARVAL	Identifying Variable Value	4	text	2		DERIVED	Value of identifying variable of the parent record
QNAM	Qualifier Variable Name	5	text	5		OTHER	
QLABEL	Qualifier Variable Label		text	16		OTHER	
QVAL	Data Value		text	10			
QORIG	Origin		text	9		OTHER	
QEVAL	Evaluator		text	1		OTHER	
Related dataset: Exposure (EX)							

Value Level Metadata

Value Level Metadata - BG [BGORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
BGORRES	BGTESTCD EQ BWGAIN (Body Weight Gain)	float	5		COLLECTED	

Value Level Metadata - BW [BWORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
BWORRES	BWTESTCD EQ BW (Body Weight)	float	7		COLLECTED	

Value Level Metadata - CL [CLORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
CLORES	CLTESTCD EQ AG (Activity/Gait) AND CLCAT EQ CLINICAL SIGNS	text	18		COLLECTED	
CLORES	CLTESTCD EQ AC (Appearance and Condition) AND CLCAT EQ CLINICAL SIGNS	text	4		COLLECTED	

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
CLORES	CLTESTCD EQ EY (Eyes) AND CLCAT EQ CLINICAL SIGNS	text	9		COLLECTED	
CLORES	CLTESTCD EQ GO (General Observations) AND CLCAT EQ CLINICAL SIGNS	text	10		COLLECTED	

Value Level Metadata - FW [FWORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
FWORRES	FWTESTCD EQ FC (Food Consumption)	integer	3		OTHER	
FWORRES	FWTESTCD EQ WC (Water Consumption)	integer	3		OTHER	

Value Level Metadata - LB [LBORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
LBORRES	LBTESTCD EQ ALB (Albumin) AND LBCAT EQ Chemistry	integer	2		COLLECTED	
LBORRES	LBTESTCD EQ CL (Chloride) AND LBCAT EQ Chemistry	integer	3		COLLECTED	

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
LBORRES	LBTESTCD EQ K (Potassium) AND LBCAT EQ Chemistry	float	3		COLLECTED	

Value Level Metadata - MA [MAORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
MAORRES	MATESTCD EQ GROSPATH (Gross Pathological Examination)	text	55		COLLECTED	

Value Level Metadata - MI [MIORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
MIORRES	MITESTCD EQ MIEXAM (Microscopic Examination)	text	36		COLLECTED	

Value Level Metadata - OM [OMORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
OMORRES	OMTESTCD EQ WEIGHT	float	5		COLLECTED	

Value Level Metadata - SUPPEX [QVAL]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
QVAL	QNAM EQ EXTYP (Preparation Type)	text	10		COLLECTED	

Controlled Terms

Age Unit [CL.AGEU, C66781]

Permitted Value (Code)
WEEKS [C29844]

Body Weight Gain Test Code [CL.BGTESTCD, C89960]

Permitted Value (Code)	Display Value (Decode)
BWGAIN [C62754]	Body Weight Gain

Body Weight Test Code [CL.BWTESTCD, C89962]

Permitted Value (Code)	Display Value (Decode)
BW [C81328]	Body Weight

CL Test Code [CL.CLTESTCDF]

Permitted Value (Code)	Display Value (Decode)
AC	Appearance and Condition
AG	Activity/Gait
EY	Eyes
GO	General Observations

Category for Clinical Observation [CL.CLCAT, C89963]

Permitted Value (Code)
CLINICAL SIGNS [C100104]

Exposure Unit [CL.EXUNIT, C71620]

Permitted Value (Code)	Display Value (Decode)
mg/kg/day [C66976]	Milligram per Kilogram per Day

Food and Water Consumption Test Code [CL.FWTESTCD, C89970]

Permitted Value (Code)	Display Value (Decode)
FC [C90384]	Food Consumption
WC [C90484]	Water Consumption

Lab Unit [CL.LBUNIT, C71620]

Permitted Value (Code)	Display Value (Decode)
g/L [C42576]	Kilogram per Cubic Meter
mmol/L [C64387]	Millimole per Liter

Laboratory Test Code [CL.LBTESTCD, C65047]

Permitted Value (Code)	Display Value (Decode)
ALB [C64431]	Albumin
CL [C64495]	Chloride
K [C64853]	Potassium

Macroscopic Findings Test Code [CL.MATESTCD, C89972]

Permitted Value (Code)	Display Value (Decode)
GROSPATH [C90390]	Gross Pathological Examination

Microscopic Findings Test Code [CL.MITESTCD, C89974]

Permitted Value (Code)	Display Value (Decode)
MIEXAM [C90424]	Microscopic Examination

Microscopic Histopathology Result Category [CL.MIRESCAT, C90017]

Permitted Value (Code)	Display Value (Decode)
NON-NEOPLASTIC [C53529]	Non-Neoplastic Disorder

No Yes Response [CL.NY, C66742]

Permitted Value (Code)	Display Value (Decode)
Y [C49488]	Yes

Organ Measurement Test Code [CL.OMTESTCD, C89977]

Permitted Value (Code)
WEIGHT [C25208]

Other format 1 [CL.OTHER01F]

Permitted Value (Code)
FOLLOW-UP
RUN-IN
SCREENING
TREATMENT

Pharmaceutical Dosage Form [CL.FRM, C66726]

Permitted Value (Code)	Display Value (Decode)
TABLET [C42998]	Tablet Dosage Form

SEND Domain Abbreviation [CL.SDOMAIN, C111113]

Permitted Value (Code)	Display Value (Decode)
BG [C95083]	Body Weight Gain Domain
BW [C95085]	Body Weight Domain
CL [C95086]	Clinical Observation Domain
DM [C49572]	Demographics Domain
DS [C49576]	Disposition Domain
EX [C49587]	Exposure Domain
FW [C95090]	Food and Water Consumption Domain
LB [C49592]	Laboratory Data Domain
MA [C95094]	Macroscopic Findings Domain
MI [C95095]	Microscopic Findings Domain

Permitted Value (Code)	Display Value (Decode)
OM [C49605]	Organ Measurement Domain
TA [C49618]	Trial Arms Domain
TE [C49619]	Trial Elements Domain
TS [C53483]	Trial Summary Domain
TX [C95103]	Trial Sets Domain
CO [C49569]	Comment Domain

SEND Trial Summary Parameter Test Code [CL.STSPRMCD, C90009]

Permitted Value (Code)	Display Value (Decode)
ARMCD [C83216]	Planned Arm Code
GRPLBL [C90391]	Group Label
SPGRPCD [C90456]	Sponsor Defined Group Code
TRTDOS [C25488]	Dose
TRTDOSU [C73558]	Dosage Form Unit

SEND Trial Summary Parameter Test Name [CL.STSPRM, C90007]

Permitted Value (Code)
Arm Code [C83216]
Dose Level [C25488]
Dose Units [C73558]
Group Label [C90391]
Sponsor-Defined Group Code [C90456]

Severity [CL.SEV, C90000]

Permitted Value (Code)
MILD [C70666]
MODERATE [C61376]
SEVERE [C70667]

Sex [CL.SEX, C66731]

Permitted Value (Code)	Display Value (Decode)
F [C16576]	Female
M [C20197]	Male

Species [CL.SPECIES, C77808]

Permitted Value (Code)
RAT [C14266]

Specimen [CL.SPEC, C77529]

Permitted Value (Code)
ALL TISSUES [C90476]
GLAND, MAMMARY [C12370]
HEART [C12727]
LARGE INTESTINE, CECUM [C12381]
LARGE INTESTINE, COLON [C12382]
LIVER [C32735]

Permitted Value (Code)
LUNG [C33024]
MUSCLE, SKELETAL [C13050]
TESTIS/EPIDIDYMIS [C77668]
THYMUS [C33952]
UTERUS [C12405]
VAGINA [C12407]

Standardized Disposition Term [CL.DSDECOD, C89968]

Permitted Value (Code)
ACCIDENTAL DEATH [C90351]
FOUND DEAD [C90387]
INTERIM SACRIFICE [C90436]
TERMINAL SACRIFICE [C90465]

Strain/Substrain [CL.STRAIN, C77530]

Permitted Value (Code)
FISCHER 344 [C14401]

Timepoint (Lab) [CL.TPT]

Permitted Value (Code)
Pre Dose
4H Post Dose

Permitted Value (Code)
8H Post Dose

Unit [CL.UNIT, C71620]

Permitted Value (Code)	Display Value (Decode)
g [C48155]	Gram
g/animal/day [C73714]	Gram per Animal per Day
mL [C28254]	Milliliter
mL/animal/day [C73747]	Milliliter per Animal per Day