

Tabulation Datasets for Study RABBITV1 (SEND-IG 3.1)

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, TSSEQ, TSPARMCD	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	
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	FINDINGS	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID, LBTESTCD, LBSPEC, LBDTC, LBPTNUM	lb.xpt	
MA	Macroscopic Findings	FINDINGS	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MATTESTCD, MAORRES, MASPEC, MAANTREG, MALAT, MADIR	ma.xpt	
MI	Microscopic Findings	FINDINGS	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MITESTCD, MISTRES, MISPEC, MIANTREG, MILAT, MIDIR	mi.xpt	
OM	Organ Measurements	FINDINGS	One record per test per specimen per subject	Tabulation	STUDYID, USUBJID, OMTESTCD, OMSPEC, OMANTREG, OMLAT, OMDIR	om.xpt	
TF	Tumor Findings	FINDINGS	One record per tumor per specimen per subject	Tabulation	STUDYID, USUBJID, TFTESTCD, TFORRES, TFSPEC, TFANTREG, TFLAT, TFDIR	tf.xpt	
VS	Vital Signs	FINDINGS	One record per measurement per observation time per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VSDTC, VSTPT	vs.xpt	
POOLDEF	Pool Definition	RELATIONSHIP	One record per subject per pool	Tabulation	STUDYID, POOLID, USUBJID	pooldef.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	
SUPPCL	Supplemental Qualifiers for CL	RELATIONSHIP	One record per supplemental qualifier per related parent domain record(s)	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppcl.xpt	
SUPPLB	Supplemental Qualifiers for LB	RELATIONSHIP	One record per supplemental qualifier per related parent domain record(s)	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	supplb.xpt	
SUPPMA	Supplemental Qualifiers for MA	RELATIONSHIP	One record per supplemental qualifier per related parent domain record(s)	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppma.xpt	
SUPPMI	Supplemental Qualifiers for MI	RELATIONSHIP	One record per supplemental qualifier per related parent domain record(s)	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	200			
DOMAIN	Domain Abbreviation		text	2			
ARMCD	Planned Arm Code	2	text	200			
ARM	Description of Planned Arm		text	200			
TAETORD	Order of Element within Arm	3	integer	50			
ETCD	Element Code		text	200			
ELEMENT	Description of Element		text	200			
TABRANCH	Branch		text	200			
TATRANS	Transition Rule		text	200			
EPOCH	Trial Epoch		text	200			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
ETCD	Element Code	2	text	200			
ELEMENT	Description of Element		text	200			
TESTRL	Rule for Start of Element		text	200			
TEENRL	Rule for End of Element		text	200			
TEDUR	Planned Duration of Element		durationDate-time		ISO8601		

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
TSSEQ	Sequence Number	3	integer	50			
TSGRPID	Group Identifier		text	200			
TSPARMCD	Trial Summary Parameter Short Name	2	text	200			
TSPARM	Trial Summary Parameter		text	200			
TSVAL	Parameter Value		text	200			
TSVALNF	Parameter Null Flavor		text	200			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
SETCD	Set Code	2	text	200			
SET	Set Description		text	200			
TXSEQ	Sequence Number		integer	50			
TXPARMCD	Trial Set Parameter Short Name	3	text	200			
TXPARM	Trial Set Parameter		text	200			
TXVAL	Trial Set Parameter Value		text	200			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
DOMAIN	Domain Abbreviation		text	2			
RDOMAIN	Related Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier		text	200			
POOLID	Pool Identifier		text	200			
COSEQ	Sequence Number	2	integer	50			
IDVAR	Identifying Variable		text	200			
IDVARVAL	Identifying Variable Value		text	200			
COREF	Comment Reference		text	200			
COVAL	Comment		text	200			
COEVAL	Evaluator		text	200			
CODTC	Date/Time of Comment		datetime		ISO8601		
CODY	Study Day of Comment		integer	50			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
SUBJID	Subject Identifier for the Study		text	200			
RFSTDTC	Subject Reference Start Date/Time		datetime		ISO8601		
RFENDTC	Subject Reference End Date/Time		datetime		ISO8601		
RFXSTDTC	Date/Time of First Study Treatment		datetime		ISO8601		
RFXENDTC	Date/Time of Last Study Treatment		datetime		ISO8601		
SITEID	Study Site Identifier		text	200			
BRTHDTC	Date/Time of Birth		datetime		ISO8601		
AGE	Age		integer	8			
AGETXT	Age Range		text	20			
AGEU	Age Unit		text	200			
SEX	Sex		text	200			
SPECIES	Species		text	200			
STRAIN	Strain/Substrain		text	200			
SBSTRAIN	Strain/Substrain Details		text	200			
ARMCD	Planned Arm Code		text	200			
ARM	Description of Planned Arm		text	200			
SETCD	Set Code		text	200			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
SESEQ	Sequence Number		integer	50			
ETCD	Element Code	3	text	200			
ELEMENT	Description of Element		text	200			
SESTDTC	Start Date/Time of Element	4	datetime		ISO8601		

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
SEENDTC	End Date/Time of Element		datetime		ISO8601		
SEUPDES	Description of Unplanned Element		text	200			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
POOLID	Pool Identifier		text	200			
FOCID	Focus of Study-Specific Interest		text	50			
EXSEQ	Sequence Number		integer	50			
EXTRT	Name of Actual Treatment	3	text	200			
EXDOSE	Dose per Administration		float	10			
EXDOSTXT	Dose Description		text	200			
EXDOSU	Dose Units		text	200			
EXDOSFRM	Dose Form		text	200			
EXDOSFRQ	Dosing Frequency Per Interval		text	200			
EXROUTE	Route of Administration		text	200			
EXLOT	Lot Number		text	200			
EXLOC	Location of Dose Administration		text	200			
EXMETHOD	Method of Administration		text	200			
EXTRTV	Treatment Vehicle		text	200			
EXVAMT	Amount Administered		float	10			
EXVAMTU	Amount Administered Units		text	200			
EXADJ	Reason for Dose Adjustment		text	200			
EXSTDTC	Start Date/Time of Treatment	4	datetime		ISO8601		
EXENDTC	End Date/Time of Treatment		datetime		ISO8601		
EXSTDY	Study Day of Start of Treatment		integer	50			
EXENDY	Study Day of End of Treatment		integer	50			
EXDUR	Duration of Treatment		durationDate-time		ISO8601		
EXTPT	Planned Time Point Name		text	200			
EXTPTNUM	Planned Time Point Number		float	10			
EXELTM	Planned Elapsed Time from Time Point Ref		durationDate-time		ISO8601		
EXTPTREF	Time Point Reference		text	200			
EXRFTDTC	Date/Time of Reference Time Point		datetime		ISO8601		

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
DSSEQ	Sequence Number		integer	50			
DSTERM	Reported Term for the Disposition Event		text	200			
DSDECOD	Standardized Disposition Term		text	200			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
DSUSCHFL	Unscheduled Flag		text	1			
VISITDY	Planned Study Day of Disposition		integer	50			
DSSTDTCT	Date/Time of Disposition		datetime		ISO8601		
DSSTDY	Study Day of Disposition		integer	50			
DSNOMDY	Nominal Study Day for Tabulations		integer	50			
DSNOMLBL	Label for Nominal Study Day		text	50			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
BGSEQ	Sequence Number		integer	50			
BGTESTCD	Test Short Name	3	text	8			
BGTEST	Test Name		text	200			
BGORRES	Result or Findings as Collected		text	200			
BGORRESU	Unit of the Original Result		text	200			
BGSTRESC	Standardized Result in Character Format		text	200			
BGSTRESN	Standardized Result in Numeric Format		float	10			
BGSTRESU	Unit of the Standardized Result		text	200			
BGSTAT	Completion Status		text	8			
BGREASND	Reason Not Done		text	200			
BGEXCLFL	Exclusion Flag		text	1			
BGREASEX	Reason for Exclusion		text	200			
BGUSCHFL	Unscheduled Flag		text	1			
BGDTCT	Date/Time Animal Weighed	4	datetime		ISO8601		
BGENDTCT	End Date/Time Animal Weighed	5	datetime		ISO8601		
BGDY	Study Day of Start of Interval		integer	50			
BGENDY	Study Day of End of Weight Interval		integer	50			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
BWSEQ	Sequence Number		integer	50			
BWTESTCD	Test Short Name	3	text	8			
BWTEST	Test Name		text	200			
BWORRES	Result or Findings as Collected		text	200			
BWORRESU	Unit of the Original Result		text	200			
BWSTRESC	Standardized Result in Character Format		text	200			
BWSTRESN	Standardized Result in Numeric Format		float	10			
BWSTRESU	Unit of the Standardized Result		text	200			
BWSTAT	Completion Status		text	8			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
BWREASND	Reason Not Done		text	200			
BWBLFL	Baseline Flag		text	1			
BWFAST	Fasting Status		text	1			
BWEXCLFL	Exclusion Flag		text	1			
BWREASEX	Reason for Exclusion		text	200			
BWUSCHFL	Unscheduled Flag		text	1			
VISITDY	Planned Study Day of Collection		integer	50			
BWDTC	Date/Time Animal Weighed	4	datetime		ISO8601		
BWDY	Study Day Animal Weighed		integer	50			
BWNOMDY	Nominal Study Day for Tabulations		integer	50			
BWNOMLBL	Label for Nominal Study Day		text	50			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
POOLID	Pool Identifier		text	200			
FOCID	Focus of Study-Specific Interest		text	50			
CLSEQ	Sequence Number		integer	50			
CLGRPID	Group Identifier		text	200			
CLSPID	Mass Identifier		text	200			
CLTESTCD	Test Short Name	3	text	8			
CLTEST	Test Name		text	200			
CLCAT	Category for Clinical Observations	4	text	200			
CLSCAT	Subcategory for Clinical Observations		text	200			
CLBODSYS	Body System or Organ Class		text	200			
CLORRES	Result or Findings as Collected	5	text	200			
CLSTRESC	Standardized Result in Character Format		text	200			
CLRESCAT	Result Category		text	200			
CLSTAT	Completion Status		text	8			
CLREASND	Reason Not Done		text	200			
CLLOC	Location of a Finding	6	text	200			
CLEVAL	Evaluator		text	200			
CLSEV	Severity		text	200			
CLEXCLFL	Exclusion Flag		text	1			
CLREASEX	Reason for Exclusion		text	200			
CLUSCHFL	Unscheduled Flag		text	1			
VISITDY	Planned Study Day of Collection		integer	50			
CLDTC	Date/Time of Observation	7	datetime		ISO8601		
CLENDTC	End Date/Time of Observation		datetime		ISO8601		
CLDY	Study Day of Observation		integer	50			
CLENDY	Study Day of End of Observation		integer	50			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
CLNOMDY	Nominal Study Day for Tabulations		integer	50			
CLNOMLBL	Label for Nominal Study Day		text	50			
CLTPT	Planned Time Point Name		text	200			
CLTPTNUM	Planned Time Point Number		float	10			
CLELTM	Planned Elapsed Time from Time Point Ref		durationDate-time		ISO8601		
CLTPTREF	Time Point Reference		text	200			
CLRFTDTC	Date/Time of Reference Time Point		datetime		ISO8601		

Related dataset: Supplemental Qualifiers for CL ([SUPPCL](#))

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	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
POOLID	Pool Identifier		text	200			
FWSEQ	Sequence Number		integer	50			
FWGRPID	Group Identifier		text	200			
FWTESTCD	Food/Water Consumption Short Name	3	text	8			
FWTEST	Food/Water Consumption Name		text	200			
FWORRES	Result or Findings as Collected		text	200			
FWORRESU	Unit of the Original Result		text	200			
FWSTRESC	Standardized Result in Character Format		text	200			
FWSTRESN	Standardized Result in Numeric Format		float	10			
FWSTRESU	Unit of the Standardized Result		text	200			
FWSTAT	Completion Status		text	8			
FWREASND	Reason Not Done		text	200			
FWEXCLFL	Exclusion Flag		text	1			
FWREASEX	Reason for Exclusion		text	200			
FWDTTC	Start Date/Time of Observation	4	datetime		ISO8601		
FWENDTC	End Date/Time of Observation	5	datetime		ISO8601		
FWDY	Study Day of Start of Observation		integer	50			
FWENDY	Study Day of End of Observation		integer	50			

Laboratory (LB) [Location: [lb.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
POOLID	Pool Identifier		text	200			
LBSEQ	Sequence Number		integer	50			
LBGRPID	Group Identifier		text	200			
LBREFID	Specimen Identifier		text	200			
LBSPID	Sponsor-Defined Identifier		text	200			
LBTESTCD	Lab Test or Examination Short Name	3	text	8			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
LBTEST	Lab Test or Examination Name		text	200			
LBCAT	Category for Lab Test		text	200			
LBSCAT	Subcategory for Lab Test		text	200			
LBORRES	Result or Findings as Collected		text	200			
LBORRESU	Unit of the Original Result		text	200			
LBORNRLLO	Reference Range Lower Limit-Orig Unit		text	10			
LBORNRLHI	Reference Range Upper Limit-Orig Unit		text	10			
LBSTRESC	Standardized Result in Character Format		text	200			
LBSTRESN	Standardized Result in Numeric Format		float	10			
LBSTRESU	Unit of the Standardized Result		text	200			
LBSTNRLLO	Reference Range Lower Limit-Std Unit		float	10			
LBSTNRLHI	Reference Range Upper Limit-Std Unit		float	10			
LBSTNRC	Reference Range for Character Result-Std Unit		text	200			
LBNRIND	Reference Range Indicator		text	200			
LBSTAT	Completion Status		text	8			
LBREASND	Reason Not Done		text	200			
LBNAM	Laboratory Name		text	200			
LBSPEC	Specimen Material Type	4	text	200			
LBANTREG	Anatomical Region of Specimen		text	200			
LBSPCCND	Specimen Condition		text	200			
LBSPCUFL	Specimen Usability for the Test		text	1			
LBLOC	Specimen Collection Location		text	200			
LBLAT	Specimen Laterality within Subject		text	200			
LBDIR	Specimen Directionality within Subject		text	200			
LBPORTOT	Portion or Totality		text	200			
LBMETHOD	Method of Test or Examination		text	200			
LBSLFL	Baseline Flag		text	1			
LBFAST	Fasting Status		text	1			
LBDRVFL	Derived Flag		text	1			
LBTOX	Toxicity		text	200			
LBTOXGR	Standard Toxicity Grade		text	200			
LBEXCLFL	Exclusion Flag		text	1			
LBREASEX	Reason for Exclusion		text	200			
LBUSCHFL	Unscheduled Flag		text	1			
VISITDY	Planned Study Day of Collection		integer	50			
LBDTC	Date/Time of Specimen Collection	5	datetime		ISO8601		
LBENDTC	End Date/Time of Specimen Collection		datetime		ISO8601		
LBDY	Study Day of Specimen Collection		integer	50			
LBENDY	Study Day of End of Specimen Collection		integer	50			
LBNOMDY	Nominal Study Day for Tabulations		integer	50			
LBNOMLBL	Label for Nominal Study Day		text	50			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
LBTPT	Planned Time Point Name		text	200			
LBTPTNUM	Planned Time Point Number	6	float	10			
LBELTM	Planned Elapsed Time from Time Point Ref		durationDate-time		ISO8601		
LBTPTREF	Time Point Reference		text	200			
LBRFTDTC	Date/Time of Reference Time Point		datetime		ISO8601		

Related dataset: Supplemental Qualifiers for LB ([SUPPLB](#))

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
FOCID	Focus of Study-Specific Interest		text	50			
MASEQ	Sequence Number		integer	50			
MAGRPID	Group Identifier		text	200			
MAREFID	Specimen Reference Identifier		text	200			
MASPID	Mass Identifier		text	200			
MATESTCD	Macroscopic Examination Short Name	3	text	8			
MATEST	Macroscopic Examination Name		text	200			
MABODSYS	Body System or Organ Class		text	200			
MAORRES	Result or Findings as Collected	4	text	200			
MASTRESC	Standardized Result in Character Format		text	200			
MASTAT	Completion Status		text	8			
MAREASND	Reason Not Done		text	200			
MANAM	Laboratory Name		text	200			
MASPEC	Specimen Material Type	5	text	200			
MAANTREG	Anatomical Region of Specimen	6	text	200			
MASPCCOND	Specimen Condition		text	200			
MASPCUFL	Specimen Usability for the Test		text	1			
MALAT	Specimen Laterality within Subject	7	text	200			
MADIR	Specimen Directionality within Subject	8	text	200			
MAPORTOT	Portion or Totality		text	200			
MAEVAL	Evaluator		text	200			
MASEV	Severity		text	200			
MADTHREL	Relationship to Death		text	1			
MADTC	Date/Time		datetime		ISO8601		
MADY	Study Day		integer	50			

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	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
FOCID	Focus of Study-Specific Interest		text	50			
MISEQ	Sequence Number		integer	50			
MIGRPID	Group Identifier		text	200			
MIREFID	Specimen Reference Identifier		text	200			
MISPID	Mass Identifier		text	200			
MITESTCD	Microscopic Examination Short Name	3	text	8			
MITEST	Microscopic Examination Name		text	200			
MIBODSYS	Body System or Organ Class		text	200			
MIORRES	Result or Findings as Collected		text	200			
MISTRESC	Standardized Result in Character Format	4	text	200			
MIRESCAT	Result Category		text	200			
MICHRON	Chronicity of Finding		text	200			
MIDISTR	Distribution Pattern of Finding		text	200			
MISTAT	Completion Status		text	8			
MIREASND	Reason Not Done		text	200			
MINAM	Laboratory Name		text	200			
MISPEC	Specimen Material Type	5	text	200			
MIANTREG	Anatomical Region of Specimen	6	text	200			
MISPCOND	Specimen Condition		text	200			
MISPCUFL	Specimen Usability for the Test		text	1			
MILAT	Specimen Laterality within Subject	7	text	200			
MIDIR	Specimen Directionality within Subject	8	text	200			
MIMETHOD	Method of Test or Examination		text	200			
MIEVAL	Evaluator		text	200			
MISEV	Severity		text	200			
MIDTHREL	Relationship to Death		text	1			
MIDTC	Date/Time		datetime		ISO8601		
MIDY	Study Day		integer	50			

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	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
OMSEQ	Sequence Number		integer	50			
OMTESTCD	Test Short Name	3	text	8			
OMTEST	Test Name		text	200			
OMORRES	Result or Findings as Collected		text	200			
OMORRESU	Unit of the Original Result		text	200			
OMSTRESC	Standardized Result in Character Format		text	200			
OMSTRESN	Standardized Result in Numeric Format		float	10			
OMSTRESU	Unit of the Standardized Result		text	200			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
OMSTAT	Completion Status		text	8			
OMREASND	Reason Not Done		text	200			
OMSPEC	Specimen Material Type	4	text	200			
OMANTREG	Anatomical Region of Specimen	5	text	200			
OMSPCCND	Specimen Condition		text	200			
OMSPCUFL	Specimen Usability for the Test		text	1			
OMLAT	Specimen Laterality within Subject	6	text	200			
OMDIR	Specimen Directionality within Subject	7	text	200			
OMPORTOT	Portion or Totality		text	200			
OMEXCLFL	Exclusion Flag		text	1			
OMREASEX	Reason for Exclusion		text	200			
OMDTC	Date/Time Organ Measured		datetime		ISO8601		
OMDY	Study Day of Measurement		integer	50			
OMNOMDY	Nominal Study Day for Tabulations		integer	50			
OMNOMLBL	Label for Nominal Study Day		text	50			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
TFSEQ	Sequence Number		integer	50			
TFGRPID	Group Identifier		text	200			
TFREFID	Specimen Identifier		text	200			
TFSPID	Mass Identifier		text	200			
TFTESTCD	Tumor Examination Short Name	3	text	8			
TFTEST	Tumor Examination Name		text	200			
TFORRES	Result or Findings as Collected	4	text	200			
TFSTRESC	Standardized Result in Character Format		text	200			
TFRESCAT	Tumor Malignancy Status		text	200			
TFNAM	Laboratory Name		text	200			
TFSPEC	Specimen Material Type	5	text	200			
TFANTREG	Anatomical Region of Specimen	6	text	200			
TFSPCCND	Specimen Condition		text	200			
TFLAT	Specimen Laterality within Subject	7	text	200			
TFDIR	Specimen Directionality within Subject	8	text	200			
TFMETHOD	Method of Test or Examination		text	200			
TFEVAL	Evaluator		text	200			
TFDTHREL	Relationship to Death		text	1			
TFDTC	Date/Time		datetime		ISO8601		
TFDY	Study Day		integer	50			
TFDETECT	Time in Days to Detection of Tumor		integer	50			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation		text	2			
USUBJID	Unique Subject Identifier	2	text	200			
VSSEQ	Sequence Number		integer	50			
VSGRPID	Group Identifier		text	200			
VSSPID	Sponsor-Defined Identifier		text	200			
VSTESTCD	Vital Signs Test Short Name	3	text	8			
VSTEST	Vital Signs Test Name		text	200			
VSCAT	Category for Vital Signs		text	200			
VSSCAT	Subcategory for Vital Signs		text	200			
VSPOS	Vital Signs Position of Subject		text	200			
VSORRES	Result or Findings as Collected		text	200			
VSORRESU	Unit of the Original Result		text	200			
VSSTRESC	Standardized Result in Character Format		text	200			
VSSTRESN	Standardized Result in Numeric Format		float	10			
VSSTRESU	Unit of the Standardized Result		text	200			
VSSTAT	Completion Status		text	8			
VSREASND	Reason Not Done		text	200			
VSLOC	Location of Vital Signs Measurement		text	200			
VSCSTATE	Consciousness State		text	8			
VSBLFL	Baseline Flag		text	1			
VSDRVFL	Derived Flag		text	1			
VSEXCLFL	Exclusion Flag		text	1			
VSREASEX	Reason for Exclusion		text	200			
VSUSCHFL	Unscheduled Flag		text	1			
VISITDY	Planned Study Day of Collection		integer	50			
VSDTC	Date/Time of Measurement	4	datetime		ISO8601		
VSENDTC	End Date/Time of Measurement		datetime		ISO8601		
VSDY	Study Day of Vital Signs Measurement		integer	50			
VSENDY	Study Day of End of Measurement		integer	50			
VSNOMDY	Nominal Study Day for Tabulations		integer	50			
VSNOMLBL	Label for Nominal Study Day		text	50			
VSTPT	Planned Time Point Name	5	text	200			
VSTPTNUM	Planned Time Point Number		float	10			
VSELTM	Planned Elapsed Time from Time Point Ref		durationDate-time		ISO8601		
VSTPTREF	Time Point Reference		text	200			
VSRFTDTC	Date/Time of Time Point Reference		datetime		ISO8601		

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
POOLID	Pool Identifier	2	text	200			
USUBJID	Unique Subject Identifier	3	text	200			

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

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
RDOMAIN	Related Domain Abbreviation	2	text	2			
USUBJID	Unique Subject Identifier	3	text	200			
POOLID	Pool Identifier		text	200			
IDVAR	Identifying Variable	4	text	200			
IDVARVAL	Identifying Variable Value	5	text	200			
RELTYPE	Relationship Type		text	4			
RELID	Relationship Identifier	6	text	200			

Supplemental Qualifiers for CL (SUPPCL) [Location: [suppcl.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
RDOMAIN	Related Domain Abbreviation	2	text	2			
USUBJID	Unique Subject Identifier	3	text	200			
POOLID	Pool Identifier		text	200			
IDVAR	Identifying Variable	4	text	200			
IDVARVAL	Identifying Variable Value	5	text	200			
QNAM	Qualifier Variable Name	6	text	200			
QLABEL	Qualifier Variable Label		text	200			
QVAL	Data Value		text	200			
QORIG	Origin		text	200			
QEVAL	Evaluator		text	200			

Related dataset: Clinical Observations ([CL](#))

Supplemental Qualifiers for LB (SUPPLB) [Location: [supplb.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
RDOMAIN	Related Domain Abbreviation	2	text	2			
USUBJID	Unique Subject Identifier	3	text	200			
POOLID	Pool Identifier		text	200			
IDVAR	Identifying Variable	4	text	200			
IDVARVAL	Identifying Variable Value	5	text	200			
QNAM	Qualifier Variable Name	6	text	200			
QLABEL	Qualifier Variable Label		text	200			
QVAL	Data Value		text	200			
QORIG	Origin		text	200			
QEVAL	Evaluator		text	200			

Related dataset: Laboratory ([LB](#))

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	200			

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
RDOMAIN	Related Domain Abbreviation	2	text	2			
USUBJID	Unique Subject Identifier	3	text	200			
POOLID	Pool Identifier		text	200			
IDVAR	Identifying Variable	4	text	200			
IDVARVAL	Identifying Variable Value	5	text	200			
QNAM	Qualifier Variable Name	6	text	200			
QLABEL	Qualifier Variable Label		text	200			
QVAL	Data Value		text	200			
QORIG	Origin		text	200			
QEVAL	Evaluator		text	200			

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	200			
RDOMAIN	Related Domain Abbreviation	2	text	2			
USUBJID	Unique Subject Identifier	3	text	200			
POOLID	Pool Identifier		text	200			
IDVAR	Identifying Variable	4	text	200			
IDVARVAL	Identifying Variable Value	5	text	200			
QNAM	Qualifier Variable Name	6	text	200			
QLABEL	Qualifier Variable Label		text	200			
QVAL	Data Value		text	200			
QORIG	Origin		text	200			
QEVAL	Evaluator		text	200			

Related dataset: Microscopic Findings ([MI](#))

Value Level Metadata

Value Level Metadata - MI [MISTRESC]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
MISTRESC	MIRESCAT EQ NON-NEOPLASTIC	text	200			
MISTRESC	MIRESCAT IN ("BENIGN" , "MALIG-NANT" , "METASTATIC")	text	200			

Value Level Metadata - TS [TSVAL]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
TSVAL	TSPARMCD EQ AGEU	text	6			
TSVAL	TSPARMCD EQ SDESIGN	text	200			
TSVAL	TSPARMCD EQ ROUTE	text	200			
TSVAL	TSPARMCD EQ SNDIGVER	text	200			
TSVAL	TSPARMCD EQ SPECIES	text	200			
TSVAL	TSPARMCD EQ STCAT	text	200			
TSVAL	TSPARMCD EQ STRAIN	text	200			
TSVAL	TSPARMCD EQ SSTYP	text	200			
TSVAL	TSPARMCD EQ TFCNTRY	text	200			
TSVAL	TSPARMCD EQ ENVTEMPU	text	1			
TSVAL	TSPARMCD EQ HUMIDTU	text	200			
TSVAL	TSPARMCD EQ MTHTRM	text	200			
TSVAL	TSPARMCD EQ SRANDOM	text	1			
TSVAL	TSPARMCD EQ SEXPOP	text	4			
TSVAL	TSPARMCD EQ TSCNTRY	text	200			
TSVAL	TSPARMCD EQ DOSDUR	durationDatetime		ISO8601		
TSVAL	TSPARMCD EQ EXPENDTC	date		ISO8601		
TSVAL	TSPARMCD EQ EXPSTDTC	date		ISO8601		
TSVAL	TSPARMCD EQ STSTDTC	date		ISO8601		
TSVAL	TSPARMCD EQ TRMSAC	durationDatetime		ISO8601		
TSVAL	TSPARMCD EQ DOSENDTC	datetime		ISO8601		
TSVAL	TSPARMCD EQ DOSSTDTC	datetime		ISO8601		
TSVAL	TSPARMCD EQ INTSAC	durationDatetime		ISO8601		
TSVAL	TSPARMCD EQ SLENGTH	durationDatetime		ISO8601		
TSVAL	TSPARMCD EQ RECSAC	durationDatetime		ISO8601		
TSVAL	TSPARMCD EQ STENDTC	date		ISO8601		
TSVAL	TSPARMCD EQ GLPFL	text	1			
TSVAL	TSPARMCD EQ INTERIM	text	1			
TSVAL	TSPARMCD EQ AGE	integer				

Value Level Metadata - TX [TXVAL]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
TXVAL	TXPARMCD EQ ENVTEMPU	text	1			
TXVAL	TXPARMCD EQ MTHTRM	text	200			
TXVAL	TXPARMCD EQ SPECIES	text	4			
TXVAL	TXPARMCD EQ STRAIN	text	200			

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
TXVAL	TXPARMCD EQ SEXPOP	text	200			
TXVAL	TXPARMCD EQ HUMIDTU	text	200			
TXVAL	TXPARMCD EQ DOSENDTC	datetime		ISO8601		
TXVAL	TXPARMCD EQ DOSSTDTC	datetime		ISO8601		
TXVAL	TXPARMCD EQ TRTDOSU	text	200			
TXVAL	TXPARMCD EQ PLANFSUB	integer				
TXVAL	TXPARMCD EQ PLANMSUB	integer				
TXVAL	TXPARMCD EQ SPLANSUB	integer				