Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Study description: Full Title of Report

Datasets for Study: Study ID

Dataset	Description	Class	Structure	Purpose	Keys	Location
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, TXSEQ	tx.xpt
CO	COMMENTS	Special-Purpose	One record per comment	Tabulation	STUDYID, USUBJID, COSEQ	co.xpt
DM	DEMOGRAPHICS	Special-Purpose	One record per subject	Tabulation	STUDYID, DOMAIN, 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, POOLID, EXTRT, EXROUTE, EXTRTV, EXSTDTC	ex.xpt
DS	DISPOSITION	Events	One record per subject	Tabulation	STUDYID, DOMAIN, USUBJID	ds.xpt
BG	BODY WEIGHT GAIN	Findings	One record per test per interval per subject	Tabulation	STUDYID, USUBJID, BGTESTCD, BGDTC, BGENDTC	bg.xpt
BW	BODY WEIGHT	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, POOLID, CLTESTCD, CLCAT, CLORRES, CLDTC, CLTPT	cl.xpt
LB	LABORATORY TEST RESULTS	Findings	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID, POOLID, LBTESTCD, LBSPEC, LBMETHOD, LBSTRESU, LBDTC, LBENDTC, LBTPTNUM	lb.xpt
MA	MACROSCOPIC FINDINGS	Findings	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MATESTCD, MASPEC, MAANTREG, MALAT, MADIR, MAPORTOT, MASTRESC	ma.xpt

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Dataset	Description	Class	Structure	Purpose	Keys	Location
MI	MICROSCOPIC FINDINGS	Findings	One record per finding per specimen per subject	Tabulation	STUDYID, USUBJID, MITESTCD, MISPEC, MIANTREG, MILAT, MIDIR, MISTRESC, MIMETHOD	mi.xpt
OM	ORGAN MEASUREMENTS	Findings	One record per test per specimen per subject	Tabulation	STUDYID, USUBJID, OMTESTCD, OMSPEC, OMANTREG, OMLAT, OMDIR, OMPORTOT	om.xpt
PC	PHARMACOKINETICS CONCENTRATIONS	Findings	One record per test per specimen per observation time per subject or pool	Tabulation	STUDYID, USUBJID, POOLID, PCTESTCD, PCSPEC, PCDTC, PCTPT	pc.xpt
PP	PHARMACOKINETICS PARAMETERS	Findings	One record per test per time-concentration profile per specimen per subject or pool	Tabulation	STUDYID, USUBJID, POOLID, PPTESTCD, PPCAT, PPSPEC, PPRFTDTC	pp.xpt
SUPPBG	SUPPLEMENTAL QUALIFIERS FOR BG	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppbg.xpt
SUPPBW	SUPPLEMENTAL QUALIFIERS FOR BW	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppbw.xpt
SUPPCL	SUPPLEMENTAL QUALIFIERS FOR CL	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppcl.xpt
SUPPDS	SUPPLEMENTAL QUALIFIERS FOR DS	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppds.xpt
SUPPLB	SUPPLEMENTAL QUALIFIERS FOR LB	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	supplb.xpt
SUPPMA	SUPPLEMENTAL QUALIFIERS FOR MA	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppma.xpt
SUPPMI	SUPPLEMENTAL QUALIFIERS FOR MI	Relationship	One record per supplemental qualifier value per original domain record	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	suppmi.xpt

Go to the top

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

TRIAL ARMS Dataset (TA)[ta.xpt](ta.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
ARMCD	Planned Arm Code	text		OTHER	Topic	
ARM	Description of Planned Arm	text		OTHER	Synonym Qualifier	
TAETORD	Order of Element within Arm	integer		OTHER	Identifier	
ETCD	Element Code	text		OTHER	Record Qualifier	
ELEMENT	Description of Element	text		OTHER	Synonym Qualifier	
EPOCH	Trial Epoch	text		OTHER	Timing	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

TRIAL ELEMENTS Dataset (TE)te.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
ETCD	Element Code	text		OTHER	Topic	
ELEMENT	Description of Element	text		OTHER	Synonym Qualifier	
TESTRL	Rule for Start of Element	text		OTHER	Rule	
TEENRL	Rule for End of Element	text		OTHER	Rule	
TEDUR	Planned Duration of Element	text	ISO8601	OTHER	Timing	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

TRIAL SUMMARY Dataset (TS)ts.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
TSSEQ	Sequence Number	integer		OTHER	Identifier	Sequential number identifying records in the domain
TSGRPID	Group Identifier	text		OTHER	Identifier	Not populated
TSPARMCD	Trial Summary Parameter Short Name	text		OTHER	Topic	
TSPARM	Trial Summary Parameter	text		OTHER	Synonym Qualifier	
TSVAL	Parameter Value	text		OTHER	Result Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

TRIAL SETS Dataset (TX)tx.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
SETCD	Set Code	text		OTHER	Identifier	
SET	Set Description	text		OTHER	Synonym Qualifier	
TXSEQ	Sequence Number	integer		OTHER	Identifier	Sequential number identifying records in the domain
TXPARMCD	Trial Set Parameter Short Name	text		OTHER	Topic	
TXPARM	Trial Set Parameter	text		OTHER	Synonym Qualifier	
TXVAL	Trial Set Parameter Value	text		OTHER	Result Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

COMMENTS Dataset (CO)[co.xpt](co.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Record Qualifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
COSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
IDVAR	Identifying Variable	text		OTHER	Record Qualifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Record Qualifier	
COVAL	Comment	text		COLLECTED	Topic	
COVAL1	Comment 1	text			Topic	
CODTC	Date/Time of Comment	datetime	ISO8601	COLLECTED	Timing	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

DEMOGRAPHICS Dataset (DM)dm.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
SUBJID	Subject Identifier for the Study	text		OTHER	Topic	
RFSTDTC	Subject Reference Start Date/Time	date	ISO8601	COLLECTED	Record Qualifier	Animal's start date of the dosing phase
RFENDTC	Subject Reference End Date/Time	date	ISO8601	COLLECTED	Record Qualifier	Animal's date of death on the study. If animal did not die during the study this is the study end date.
SITEID	Study Site Identifier	text		OTHER	Record Qualifier	Not populated
BRTHDTC	Date/Time of Birth	date	ISO8601	COLLECTED	Record Qualifier	
AGE	Age	integer		OTHER	Record Qualifier	See Computational Method: COMPMETHOD.COMPAGE
AGEU	Age Unit	text	AGEU	OTHER	Variable Qualifier	
SEX	Sex	text	SEX	COLLECTED	Record Qualifier	
ARMCD	Planned Arm Code	text		OTHER	Record Qualifier	
ARM	Description of Planned Arm	text		OTHER	Synonym Qualifier	
SETCD	Set Code	text		OTHER	Record Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUBJECT ELEMENTS Dataset (SE)[se.xpt](se.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
SESEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
ETCD	Element Code	text		OTHER	Topic	
ELEMENT	Description of Element	text		OTHER	Synonym Qualifier	
SESTDTC	Start Date/Time of Element	date	ISO8601	COLLECTED	Timing	
SEENDTC	End Date/Time of Element	datetime	ISO8601	COLLECTED	Timing	

[Go to the top](#)

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

EXPOSURE Dataset (EX)[ex.xpt](ex.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
EXSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
EXTRT	Name of Actual Treatment	text		OTHER	Topic	
EXDOSE	Dose per Administration	integer		COLLECTED	Record Qualifier	See Computational Method: COMPMETHOD.COMPDOSE
EXDOSU	Dose Units	text	UNIT	COLLECTED	Variable Qualifier	
EXDOSFRM	Dose Form	text		OTHER	Record Qualifier	
EXDOSFRQ	Dosing Frequency Per Interval	text	FREQ	OTHER	Variable Qualifier	
EXROUTE	Route of Administration	text	ROUTE	OTHER	Variable Qualifier	
EXLOT	Lot Number	text		COLLECTED	Record Qualifier	
EXTRTV	Treatment Vehicle	text		OTHER	Record Qualifier	
EXVAMT	Amount Administered	float		COLLECTED	Variable Qualifier	
EXVAMTU	Amount Administered Units	text	UNIT	COLLECTED	Variable Qualifier	
EXSTDTC	Start Date/Time of Treatment	datetime	ISO8601	COLLECTED	Timing	
EXSTDY	Study Day of Start of Treatment	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPSTDY

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

DISPOSITION Dataset (DS)ds.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
DSSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
DSTERM	Reported Term for the Disposition Event	text		COLLECTED	Topic	
DSDECOD	Standardized Disposition Term	text	DSDECOD	DERIVED	Synonym Qualifier	Translated from collected DSTERM to controlled terminology
VISITDY	Planned Study Day of Disposition	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPVISITDY
DSSTDTC	Date/Time of Disposition	datetime	ISO8601	COLLECTED	Timing	
DSSTDY	Study Day of Disposition	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPSTDY
Supplemental Qualifier Dataset (SUPPDS)						

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

BODY WEIGHT GAIN Dataset (BG)[bg.xpt](bg.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
BGSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
BGTESTCD	Test Short Name	text	BGTESTCD	DERIVED	Topic	Mapped from the test name used to report the calculated gain
BGTEST	Test Name	text	BGTEST	OTHER	Synonym Qualifier	
BGORRES	Result or Findings as Collected	text		DERIVED	Result Qualifier	Difference between values in BWORRES values for interval specified
BGORRESU	Unit of the Original Result	text	UNIT	DERIVED	Variable Qualifier	Unit that body weight was collected in, from BWORRESU
BGSTRESC	Standardized Result in Character Format	text		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESC
BGSTRESN	Standardized Result in Numeric Format	float		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESN
BGSTRESU	Unit of the Standardized Result	text	UNIT	DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPSTRESU
BGDTC	Date/Time Animal Weighed	datetime	ISO8601	COLLECTED	Timing	
BGENDTC	End Date/Time Animal Weighed	datetime	ISO8601	COLLECTED	Timing	
BGDY	Study Day Animal Weighed	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY
BGENDY	Study Day of End of Weight Interval	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPENDY
BGELTM	Planned Elapsed Time from Time Point Ref	text		OTHER	Timing	Not populated
Supplemental Qualifier Dataset (SUPPBG)						

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

BODY WEIGHT Dataset (BW)[bw.xpt](bw.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
BWSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
BWTESTCD	Test Short Name	text	BWTESTCD	DERIVED	Topic	Mapped from test name used during data collection
BWTEST	Test Name	text	BWTEST	OTHER	Synonym Qualifier	
BWORRES	Result or Findings as Collected	text		COLLECTED	Result Qualifier	
BWORRESU	Unit of the Original Result	text	UNIT	COLLECTED	Variable Qualifier	
BWSTRESC	Standardized Result in Character Format	text		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESC
BWSTRESN	Standardized Result in Numeric Format	float		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESN
BWSTRESU	Unit of the Standardized Result	text	UNIT	DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPSTRESU
BWBLFL	Baseline Flag	text		DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPBLFL
VISITDY	Planned Study Day of Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPVISITDY
BWDTC	Date/Time Animal Weighed	datetime	ISO8601	COLLECTED	Timing	
BWDY	Study Day Animal Weighed	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY
Supplemental Qualifier Dataset (SUPPBW)						

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

CLINICAL OBSERVATIONS Dataset (CL)[cl.xpt](cl.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
CLSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
CLGRPID	Group Identifier	text		OTHER	Identifier	Not populated
CLTESTCD	Test Short Name	text		DERIVED	Topic	Mapped from test name used during data collection
CLTEST	Test Name	text		OTHER	Synonym Qualifier	
CLCAT	Category for Clinical Observations	text	CLCAT	OTHER	Grouping Qualifier	Mapped from the collected clinical signs category
CLSCAT	Subcategory for Clinical Observations	text		OTHER	Grouping Qualifier	Not populated
CLORRES	Result or Findings as Collected	text		DERIVED	Result Qualifier	A concatenation of the individual observation components collected
CLSTRESC	Standardized Result in Character Format	text		COLLECTED	Result Qualifier	
CLLOC	Location of a Finding	text		COLLECTED	Record Qualifier	
CLSEV	Severity	text		COLLECTED	Record Qualifier	
VISITDY	Planned Study Day of Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPVISITDY
CLDTC	Start Date/Time of Observation	datetime	ISO8601	COLLECTED	Timing	
CLDY	Study Day of Observation	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY
CLTPT	Planned Time Point Name	text		COLLECTED	Timing	
CLTPTNUM	Planned Time Point Number	integer		OTHER	Timing	See Computational Method: COMPMETHOD.COMPTPTNUM
Supplemental Qualifier Dataset (SUPPCL)						

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

LABORATORY TEST RESULTS Dataset (LB)[lb.xpt](lb.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
LBSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
LBGRPID	Group Identifier	text		OTHER	Identifier	Not populated
LBREFID	Specimen Identifier	text		OTHER	Identifier	
LBTESTCD	Lab Test or Examination Short Name	text	LBTESTCD	DERIVED	Topic	Mapped from test name used during data collection
LBTEST	Lab Test or Examination Name	text	LBTEST	OTHER	Synonym Qualifier	
LBCAT	Category for Lab Test	text		OTHER	Grouping Qualifier	Mapped from the test name used during sample collection
LBSCAT	Subcategory for Lab Test	text		OTHER	Grouping Qualifier	
LBORRES	Result or Findings as Collected	text		COLLECTED	Result Qualifier	
LBORRESU	Unit of the Original Result	text	UNIT	COLLECTED	Variable Qualifier	
LBSTRESC	Standardized Result in Character Format	text		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESC
LBSTRESN	Standardized Result in Numeric Format	float		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESN
LBSTRESU	Unit of the Standardized Result	text	UNIT	DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPSTRESU
LBSPEC	Specimen Type	text	SPEC	DERIVED	Record Qualifier	Derived from the test name used during sample collection
LBMETHOD	Method of Test or Examination	text		OTHER	Record Qualifier	
LBBLFL	Baseline Flag	text		DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPBLFL

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
VISITDY	Planned Study Day of Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPVISITDY
LBDTC	Date/Time of Specimen Collection	datetime	ISO8601	COLLECTED	Timing	
LBDY	Study Day of Specimen Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY
LBTPT	Planned Time Point Name	text		COLLECTED	Timing	
LBTPTNUM	Planned Time Point Number	integer		OTHER	Timing	See Computational Method: COMPMETHOD.COMPTPTNUM
Supplemental Qualifier Dataset (SUPPLB)						

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

MACROSCOPIC FINDINGS Dataset (MA)[ma.xpt](ma.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
MASEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
MAGRPID	Group Identifier	text		OTHER	Identifier	Not populated
MAREFID	Specimen Reference Identifier	text		OTHER	Identifier	Not populated
MATESTCD	Macroscopic Examination Short Name	text	MATESTCD	DERIVED	Topic	Mapped from test name used during data collection
MATEST	Macroscopic Examination Name	text	MATEST	OTHER	Synonym Qualifier	
MAORRES	Result or Findings as Collected	text		DERIVED	Result Qualifier	A concatenation of the individual observation components collected
MASTRESC	Standardized Result in Character Format	text		COLLECTED	Result Qualifier	
MASPEC	Specimen Material Type	text	SPEC	DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPTISSUE
MAANTREG	Anatomical Region of Specimen	text		DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPTISSUE
MASEV	Severity	text	SEV	COLLECTED	Record Qualifier	
MADTC	Date/Time of Collection	datetime	ISO8601	COLLECTED	Timing	
MADY	Study Day of Specimen Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY
Supplemental Qualifier Dataset (SUPPMA)						

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

MICROSCOPIC FINDINGS Dataset (MI)[mi.xpt](mi.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
MISEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
MIGRPID	Group Identifier	text		OTHER	Identifier	Not populated
MIREFID	Specimen Reference Identifier	text		OTHER	Identifier	Not populated
MITESTCD	Microscopic Examination Short Name	text	MITESTCD	DERIVED	Topic	Mapped from test name used during data collection
MITEST	Microscopic Examination Name	text	MITEST	OTHER	Synonym Qualifier	
MIORRES	Result or Findings as Collected	text		DERIVED	Result Qualifier	A concatenation of the individual observation components collected
MISTRESC	Standardized Result in Character Format	text		COLLECTED	Result Qualifier	
MIRESCAT	Result Category	text	MIRESCAT	COLLECTED	Variable Qualifier	
MISTAT	Completion Status	text	ND	COLLECTED	Record Qualifier	
MIREASND	Reason Not Done	text		COLLECTED	Record Qualifier	
MISPEC	Specimen Material Type	text	SPEC	DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPTISSUE
MISPCCND	Specimen Condition	text		OTHER	Variable Qualifier	
MISPCUFL	Specimen Usability for the Test	text		OTHER	Variable Qualifier	
MISEV	Severity	text	SEV	COLLECTED	Record Qualifier	
MIDTC	Date/Time of Specimen Collection	datetime	ISO8601	COLLECTED	Timing	
MIDY	Study Day of Specimen Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
Supplemental Qualifier Dataset (SUPPMI)						

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

ORGAN MEASUREMENTS Dataset (OM)[om.xpt](om.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
OMSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
OMTESTCD	Test Short Name	text	OMTESTCD	DERIVED	Topic	Mapped from test name used during data collection
OMTEST	Test Name	text	OMTEST	OTHER	Synonym Qualifier	
OMORRES	Result or Findings as Collected	text		COLLECTED	Result Qualifier	
OMORRESU	Unit of the Original Result	text	UNIT	COLLECTED	Variable Qualifier	
OMSTRESC	Standardized Result in Character Format	text		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESC
OMSTRESN	Standardized Result in Numeric Format	float		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESN
OMSTRESU	Unit of the Standardized Result	text	UNIT	DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPSTRESU
OMSPEC	Specimen Material Type	text	SPEC	DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPTISSUE
OMDTC	Date/Time Organ Weighed	datetime	ISO8601	COLLECTED	Timing	
OMDY	Study Day of Weighing	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

PHARMACOKINETICS CONCENTRATIONS Dataset (PC)pc.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
PCSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
PCTESTCD	Test Short Name	text		DERIVED	Topic	Mapped from test name used during data collection
PCTEST	Test Name	text		OTHER	Synonym Qualifier	
PCORRES	Result or Findings as Collected	text		COLLECTED	Result Qualifier	
PCORRESU	Unit of the Original Result	text	PKUNIT	COLLECTED	Variable Qualifier	
PCSTRESC	Standardized Result in Character Format	text		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESC
PCSTRESN	Standardized Result in Numeric Format	float		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESN
PCSTRESU	Unit of the Standardized Result	text	PKUNIT	DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPSTRESU
PCSTAT	Completion Status	text	ND	COLLECTED	Record Qualifier	
PCREASND	Reason Not Done	text		COLLECTED	Record Qualifier	
PCNAM	Vendor Name	text		OTHER	Record Qualifier	Not populated
PCSPEC	Specimen Material Type	text	SPEC	DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPTISSUE
PCMETHOD	Method of Test or Examination	text		OTHER	Record Qualifier	
PCBLFL	Baseline Flag	text		DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPBLFL

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PCLLOQ	Lower Limit of Quantitation	float		OTHER	Variable Qualifier	
VISITDY	Visit Day	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPVISITDY
PCDTC	Date/Time of Specimen Collection	datetime	ISO8601	COLLECTED	Timing	
PCDY	Study Day of Specimen Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPDY
PCTPT	Planned Time Point Name	text		COLLECTED	Timing	
PCTPTNUM	Planned Time Point Number	integer		OTHER	Timing	See Computational Method: COMPMETHOD.COMPTPTNUM
PCELTM	Planned Elapsed Time from Time Point Ref	text		DERIVED	Timing	
PCTPTREF	Time Point Reference	text		OTHER	Timing	
PCRFTDTC	Date/Time of Reference Point	datetime	ISO8601	COLLECTED	Timing	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

PHARMACOKINETICS PARAMETERS Dataset (PP)pp.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
DOMAIN	Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
PPSEQ	Sequence Number	integer		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPSEQ
PPTESTCD	Parameter Short Name	text	PKPARMCD	DERIVED	Topic	Mapped from test name used during data collection
PPTEST	Parameter Name	text	PKPARM	OTHER	Synonym Qualifier	
PPCAT	Parameter Category	text		OTHER	Grouping Qualifier	
PPORRES	Result or Findings as Collected	text		COLLECTED	Result Qualifier	
PPORRESU	Unit of the Original Result	text	PKUNIT	COLLECTED	Variable Qualifier	
PPSTRESC	Standardized Result in Character Format	text		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESC
PPSTRESN	Standardized Result in Numeric Format	float		DERIVED	Result Qualifier	See Computational Method: COMPMETHOD.COMPSTRESN
PPSTRESU	Unit of the Standardized Result	text	PKUNIT	DERIVED	Variable Qualifier	See Computational Method: COMPMETHOD.COMPSTRESU
PPSTAT	Completion Status	text	ND	COLLECTED	Record Qualifier	
PPREASND	Reason Not Done	text		COLLECTED	Record Qualifier	
PPSPEC	Specimen Material Type	text	SPEC	DERIVED	Record Qualifier	See Computational Method: COMPMETHOD.COMPTISSUE
VISITDY	Planned Study Day of Collection	integer		DERIVED	Timing	See Computational Method: COMPMETHOD.COMPVISITDY
PPTPTREF	Time Point Reference	text		OTHER	Timing	
PPRFTDTC	Date/Time of Reference Point	datetime	ISO8601	COLLECTED	Timing	
PPSTINT	Start of Evaluation Interval	text		OTHER	Timing	

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPENINT	End of Evaluation Interval	text		OTHER	Timing	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR BG Dataset (SUPPBG)suppbg.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR BW Dataset (SUPPBW)suppbw.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR CL Dataset (SUPPCL)suppcl.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR DS Dataset (SUPPDS)suppds.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR LB Dataset (SUPPLB)supplb.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR MA Dataset (SUPPMA)[suppma.xpt](suppma.xpt)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

SUPPLEMENTAL QUALIFIERS FOR MI Dataset (SUPPMI)suppmi.xpt

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	Identifier	
RDOMAIN	Related Domain Abbreviation	text	DOMAIN	OTHER	Identifier	
USUBJID	Unique Subject Identifier	text		OTHER	Identifier	See Computational Method: COMPMETHOD.COMPUSUBJID
IDVAR	Identifying Variable	text		OTHER	Identifier	
IDVARVAL	Identifying Variable Value	text		OTHER	Identifier	
QNAM	Qualifier Variable Name	text		OTHER	Topic	
QLABEL	Qualifier Variable Label	text		OTHER	Synonym Qualifier	
QVAL	Data Value	text		COLLECTED	Result	
QORIG	Origin	text		OTHER	Synonym Qualifier	
QEVAL	Evaluator	text			Synonym Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata
Value Level Metadata (ValueList.BG.BGTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
BGTESTCD	BWGAIN	Body Weight Gain	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.BW.BWTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
BWTESTCD	BW	Body Weight	float		DERIVED	Topic	
BWTESTCD	TERMBW	Terminal Body Weight	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.CL.CLCAT)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
CLCAT	CLINICAL SIGNS	CLINICAL SIGNS	text		OTHER	Grouping Qualifier	
CLCAT	PHYSICAL EXAM	PHYSICAL EXAM	text		OTHER	Grouping Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.CL.CLCAT.CLINICAL SIGNS.CLTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
CLTESTCD	GEN	General	text		DERIVED	Topic	
CLTESTCD	HA	Hair	text		DERIVED	Topic	
CLTESTCD	IS	Injection Site	text		DERIVED	Topic	
CLTESTCD	N	Normal	text		DERIVED	Topic	
CLTESTCD	SE	Secretion/Excretion	text		DERIVED	Topic	
CLTESTCD	SK	Skin	text		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.CL.CLCAT.PHYSICAL EXAM.CLTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
CLTESTCD	GEN	General	text		DERIVED	Topic	
CLTESTCD	N	Normal	text		DERIVED	Topic	
CLTESTCD	SE	Secretion/Excretion	text		DERIVED	Topic	
CLTESTCD	SK	Skin	text		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.LB.LBCAT)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
LBCAT	Clinical Chemistry	Clinical Chemistry	float		OTHER	Grouping Qualifier	
LBCAT	Coagulation	Coagulation	float		OTHER	Grouping Qualifier	
LBCAT	Hematology	Hematology	text		OTHER	Grouping Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.LB.LBCAT.Clinical Chemistry.LBTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
LBTESTCD	ALB	Albumin	float		DERIVED	Topic	
LBTESTCD	ALBGLOB	Albumin/Globulin	float		DERIVED	Topic	
LBTESTCD	ALP	Alkaline Phosphatase	integer		DERIVED	Topic	
LBTESTCD	ALT	Alanine Aminotransferase	integer		DERIVED	Topic	
LBTESTCD	AST	Aspartate Aminotransferase	integer		DERIVED	Topic	
LBTESTCD	BICARB	Bicarbonate	integer		DERIVED	Topic	
LBTESTCD	BILI	Bilirubin	float		DERIVED	Topic	
LBTESTCD	BUN	Blood Urea Nitrogen	integer		DERIVED	Topic	
LBTESTCD	CA	Calcium	float		DERIVED	Topic	
LBTESTCD	CHOL	Cholesterol	integer		DERIVED	Topic	
LBTESTCD	CK	Creatine Kinase	integer		DERIVED	Topic	
LBTESTCD	CL	Chloride	integer		DERIVED	Topic	
LBTESTCD	CREAT	Creatinine	float		DERIVED	Topic	
LBTESTCD	GGT	Gamma Glutamyl Transferase	integer		DERIVED	Topic	
LBTESTCD	GLOBUL	Globulin	float		DERIVED	Topic	
LBTESTCD	GLUC	Glucose	integer		DERIVED	Topic	
LBTESTCD	K	Potassium	float		DERIVED	Topic	
LBTESTCD	PHOS	Phosphate	float		DERIVED	Topic	
LBTESTCD	PROT	Protein	float		DERIVED	Topic	
LBTESTCD	SODIUM	Sodium	integer		DERIVED	Topic	
LBTESTCD	TRIG	Triglycerides	integer		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.LB.LBCAT.Coagulation.LBTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
LBTESTCD	APTT	Activated Partial Thromboplastin Time	float		DERIVED	Topic	
LBTESTCD	FIBRINO	Fibrinogen	integer		DERIVED	Topic	
LBTESTCD	PT	Prothrombin Time	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.LB.LBCAT.Hematology.LBTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
LBTESTCD	BASO	Basophils	float		DERIVED	Topic	
LBTESTCD	EOS	Eosinophils	float		DERIVED	Topic	
LBTESTCD	HCT	Hematocrit	text		DERIVED	Topic	
LBTESTCD	HGB	Hemoglobin	text		DERIVED	Topic	
LBTESTCD	LYM	Lymphocytes	float		DERIVED	Topic	
LBTESTCD	MCH	Ery. Mean Corpuscular Hemoglobin	text		DERIVED	Topic	
LBTESTCD	MCHC	Ery. Mean Corpuscular HGB Concentration	text		DERIVED	Topic	
LBTESTCD	MCV	Ery. Mean Corpuscular Volume	text		DERIVED	Topic	
LBTESTCD	MONO	Monocytes	float		DERIVED	Topic	
LBTESTCD	MPV	Mean Platelet Volume	float		DERIVED	Topic	
LBTESTCD	NEUT	Neutrophils	float		DERIVED	Topic	
LBTESTCD	PLAT	Platelets	integer		DERIVED	Topic	
LBTESTCD	RBC	Erythrocytes	text		DERIVED	Topic	
LBTESTCD	RDW	Erythrocytes Distribution Width	text		DERIVED	Topic	
LBTESTCD	RETI	Reticulocytes	float		DERIVED	Topic	
LBTESTCD	WBC	Leukocytes	float		DERIVED	Topic	

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.MA.MATESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
MATESTCD	GROSPATH	Gross Pathological Examination	text		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.MI.MIRESCAT)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
MIRESCAT			text		COLLECTED	Variable Qualifier	
MIRESCAT	NON-NEOPLASTIC	NON-NEOPLASTIC	text		COLLECTED	Variable Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Value Level Metadata (ValueList.MI.MITESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
MITESTCD	MIEXAM	Microscopic Examination	text		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.OM.OMTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
OMTESTCD	OWBW	Organ to Body Weight Ratio	float		DERIVED	Topic	See Computational Method: COMPMETHOD.COMPOWBW
OMTESTCD	WEIGHT	Weight	float		DERIVED	Topic	See Computational Method: COMPMETHOD.COMPSTRESC

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.PC.PCTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PCTESTCD	PDAR30AC	Compound_2 ADC Assoc. War. Conc.	text		DERIVED	Topic	
PCTESTCD	PDAR30CC	Compound_2 Conjugated Conc.	text		DERIVED	Topic	
PCTESTCD	PDAR30MC	Compound_2 Free MMAE Conc.	text		DERIVED	Topic	
PCTESTCD	PDAR30TC	Compound_2 Total Concentration	text		DERIVED	Topic	
PCTESTCD	PDAR38AC	Compound_2B ADC Assoc. War. Conc.	float		DERIVED	Topic	
PCTESTCD	PDAR38CC	Compound_2B Conjugated Conc.	text		DERIVED	Topic	
PCTESTCD	PDAR38MC	Compound_2B Free MMAE Conc.	text		DERIVED	Topic	
PCTESTCD	PDAR38TC	Compound_2B Total Concentration	text		DERIVED	Topic	
PCTESTCD	PE2AC	Compound_1 ADC Assoc. Warhead Conc.	float		DERIVED	Topic	
PCTESTCD	PE2CC	Compound_1 Conjugated Conc.	text		DERIVED	Topic	
PCTESTCD	PE2MC	Compound_1 Free MMAE Conc.	text		DERIVED	Topic	
PCTESTCD	PE2TC	Compound_1 Total Concentration	text		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.PP.PPCAT)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPCAT	ADC Associated Warhead Concentration	ADC Associated Warhead Concentration	float		OTHER	Grouping Qualifier	
PPCAT	Conjugated Concentration	Conjugated Concentration	float		OTHER	Grouping Qualifier	
PPCAT	Free MMAE Concentration	Free MMAE Concentration	float		OTHER	Grouping Qualifier	
PPCAT	Total Concentration	Total Concentration	float		OTHER	Grouping Qualifier	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.PP.PPCAT.ADC Associated Warhead Concentration.PPTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPTESTCD	AUCINT	AUC from T1 to T2	float		DERIVED	Topic	
PPTESTCD	AUCINTD	AUC from T1 to T2 Norm by Dose	float		DERIVED	Topic	
PPTESTCD	CONC	Concentration	float		DERIVED	Topic	
PPTESTCD	CONCD	Conc by Dose	float		DERIVED	Topic	
PPTESTCD	LAMZHL	Half-Life Lambda z	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.PP.PPCAT.Conjugated Concentration.PPTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPTESTCD	AUCINT	AUC from T1 to T2	float		DERIVED	Topic	
PPTESTCD	AUCINTD	AUC from T1 to T2 Norm by Dose	float		DERIVED	Topic	
PPTESTCD	CONC	Concentration	float		DERIVED	Topic	
PPTESTCD	CONCD	Conc by Dose	float		DERIVED	Topic	
PPTESTCD	LAMZHL	Half-Life Lambda z	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.PP.PPCAT.Free MMAE Concentration.PPTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPTESTCD	AUCINT	AUC from T1 to T2	float		DERIVED	Topic	
PPTESTCD	AUCINTD	AUC from T1 to T2 Norm by Dose	float		DERIVED	Topic	
PPTESTCD	CMAX	Max Conc	float		DERIVED	Topic	
PPTESTCD	CMAXD	Max Conc Norm by Dose	float		DERIVED	Topic	
PPTESTCD	TMAX	Time of CMAX	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.PP.PPCAT.Total Concentration.PPTESTCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPTESTCD	AUCINT	AUC from T1 to T2	float		DERIVED	Topic	
PPTESTCD	AUCINTD	AUC from T1 to T2 Norm by Dose	float		DERIVED	Topic	
PPTESTCD	CONC	Concentration	float		DERIVED	Topic	
PPTESTCD	CONCD	Conc by Dose	float		DERIVED	Topic	
PPTESTCD	LAMZHL	Half-Life Lambda z	float		DERIVED	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPBG.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	PHSEDAY1	Start Day of Phase	integer		OTHER	Topic	
QNAM	PHSEDAY2	End Day of Phase	integer		OTHER	Topic	
QNAM	PHSNAME1	Start Phase name	text		OTHER	Topic	
QNAM	PHSNAME2	End Phase name	text		OTHER	Topic	
Dataset (BG)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPBW.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	PHASEDAY	Day of Phase	integer		OTHER	Topic	
QNAM	PHSENAME	Phase name	text		OTHER	Topic	
Dataset (BW)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPCL.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	PHASEDAY	Day of Phase	integer		OTHER	Topic	
QNAM	PHSENAME	Phase name	text		OTHER	Topic	
Dataset (CL)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPDS.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	PHASEDAY	Day of Phase	integer		OTHER	Topic	
QNAM	PHSENAME	Phase name	text		OTHER	Topic	
Dataset (DS)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPLB.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	PHASEDAY	Day of Phase	integer		OTHER	Topic	
QNAM	PHSENAME	Phase name	text		OTHER	Topic	
Dataset (LB)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPMA.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	MARESMOD	Result Modifiers	text		OTHER	Topic	
Dataset (MA)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.SUPPMI.QNAM)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QNAM	MIRESMOD	Result Modifiers	text		OTHER	Topic	
Dataset (MI)							

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.TS.TSPARMCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
TSPARMCD	AGE	Age	integer		OTHER	Topic	
TSPARMCD	AGETXT	Age Text	text		OTHER	Topic	
TSPARMCD	AGEU	Age Unit	text	AGEU	OTHER	Topic	
TSPARMCD	DOSDUR	Dosing Duration	text		OTHER	Topic	
TSPARMCD	EXPENDTC	Experimental End Date	date		OTHER	Topic	
TSPARMCD	EXPSTDTC	Experimental Start Date	date		OTHER	Topic	
TSPARMCD	GLPTYP	Good Laboratory Practice Type	text		OTHER	Topic	
TSPARMCD	HOUSETYP	Housing Type	text		OTHER	Topic	
TSPARMCD	ROUTE	Route of Administration	text	ROUTE	OTHER	Topic	
TSPARMCD	SDESIGN	Study Design	text	DESIGN	OTHER	Topic	
TSPARMCD	SNDCTVER	SEND Controlled Terminology Version	text		OTHER	Topic	
TSPARMCD	SNDIGVER	SEND Implementation Guide Version	text	SNDIGVER	OTHER	Topic	
TSPARMCD	SPECIES	Species	text	SPECIES	OTHER	Topic	
TSPARMCD	SPLRNAM	Test Subject Supplier	text		OTHER	Topic	
TSPARMCD	SPREFID	Sponsor's Reference ID	text		OTHER	Topic	
TSPARMCD	SSPONSOR	Sponsoring Organization	text		OTHER	Topic	
TSPARMCD	SSTYP	Study Type	text	SSTYP	OTHER	Topic	
TSPARMCD	STCAT	Study Category	text	STCAT	OTHER	Topic	
TSPARMCD	STDIR	Study Director	text		OTHER	Topic	

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
TSPARMCD	STITLE	Study Title	text		OTHER	Topic	
TSPARMCD	STRAIN	Strain/Substrain	text	STRAIN	OTHER	Topic	
TSPARMCD	STSTDTC	Study Start Date	date		OTHER	Topic	
TSPARMCD	TFCNTRY	Test Facility Country	text	COUNTRY	OTHER	Topic	
TSPARMCD	TRMSAC	Time to Terminal Sacrifice	text		OTHER	Topic	
TSPARMCD	TRT	Investigational Therapy or Treatment	text		OTHER	Topic	
TSPARMCD	TRTCAS	Primary Treatment CAS Registry Number	text		OTHER	Topic	
TSPARMCD	TRTV	Treatment Vehicle	text		OTHER	Topic	
TSPARMCD	TSNAM	Test Site Name	text		OTHER	Topic	
TSPARMCD	TSTFLOC	Test Facility Location	text		OTHER	Topic	
TSPARMCD	TSTFNAM	Test Facility Name	text		OTHER	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Value Level Metadata (ValueList.TX.TXPARMCD)

Source Variable	Value	Label	Type	Controlled Terms or Format	Origin	Role	Comment
TXPARMCD	ARMCD	Arm Code	integer		OTHER	Topic	
TXPARMCD	GRPLBL	Group Label	text		OTHER	Topic	
TXPARMCD	SPGRPCD	Sponsor-Defined Group Code	integer		OTHER	Topic	
TXPARMCD	TCNTRL	Control Type	text		OTHER	Topic	
TXPARMCD	TRTDOS	Dose Level	integer		OTHER	Topic	
TXPARMCD	TRTDOSU	Dose Units	text		OTHER	Topic	
TXPARMCD	TRTV	Treatment Vehicle	text		OTHER	Topic	

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Computational Algorithms Section

Reference Name	Computation Method
COMPMETHOD.COMPAGE	If birth date is collected, this animal's start date on the dosing phase (RFSTDTC) minus Birth date+1, otherwise this is the age of the animal at the start of the study if that is defined in the study protocol.
COMPMETHOD.COMPBLFL	Y for last non missing record on or before the first dose date (RFSTDTC); otherwise Null
COMPMETHOD.COMPDOSE	Actual amount of test article in the dose administered: EXVAMT * Dose concentration
COMPMETHOD.COMPDY	"--DTC minus RFSTDTC plus 1 if --DTC is on or after RFSTDTC. --DTC minus RFSTDTC if --DTC precedes RFSTDTC."
COMPMETHOD.COMPENDY	"--ENDTC minus RFSTDTC plus 1 if --ENDTC is on or after RFSTDTC. --ENDTC minus RFSTDTC if --ENDTC precedes RFSTDTC."
COMPMETHOD.COMPOWBW	Organ weight divided by terminal body weight * 100
COMPMETHOD.COMPSEQ	Sequential number identifying records within a dataset
COMPMETHOD.COMPSTDY	"--STDTC minus RFSTDTC plus 1 if --STDTC is on or after RFSTDTC. --STDTC minus RFSTDTC if --STDTC precedes RFSTDTC"
COMPMETHOD.COMPSTRESC	Copy of --ORRES
COMPMETHOD.COMPSTRESN	When --STRESC contains a numeric result, the numeric equivalent is reported in --STRESN
COMPMETHOD.COMPSTRESU	WHEN --STRESC contains a numeric result, --ORRESU is reported in --STRESU
COMPMETHOD.COMPTISSUE	Derived from the organ/tissue name used during sample collection.
COMPMETHOD.COMPTPTNUM	A value assigned to each unique session name that is reported in --TPT.
COMPMETHOD.COMPUSUBJID	Concatenation of STUDYID-SUBJID
COMPMETHOD.COMPVISITDY	Set equal to associated domain --DY except when activity was performed on a different day than planned or activity was unscheduled.

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section
AGEU, Reference Name (AGEU)

Code Value	Code Text
DAYS	DAYS

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
BGTEST, Reference Name (BGTEST)

Code Value	Code Text
Body Weight Gain	Body Weight Gain

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
BGTESTCD, Reference Name (BGTESTCD)

Code Value	Code Text
BWGAIN	Body Weight Gain

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
BWTEST, Reference Name (BWTEST)

Code Value	Code Text
Body Weight	Body Weight
Terminal Body Weight	Terminal Body Weight

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
BWTESTCD, Reference Name (BWTESTCD)

Code Value	Code Text
BW	Body Weight
TERMBW	Terminal Body Weight

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
CLCAT, Reference Name (CLCAT)

Code Value	Code Text
PHYSICAL EXAM	Physical Exam
CLINICAL SIGNS	Clinical Signs

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section
COUNTRY, Reference Name (COUNTRY)

Code Value	Code Text
USA	UNITED STATES

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section
DESIGN, Reference Name (DESIGN)

Code Value	Code Text
PARALLEL	PARALLEL

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
DOMAIN, Reference Name (DOMAIN)

Code Value	Code Text
CO	COMMENTS
DM	DEMOGRAPHICS
DS	DISPOSITION
EX	EXPOSURE
LB	LABORATORY TEST RESULTS
OM	ORGAN MEASUREMENTS
PC	PHARMACOKINETICS CONCENTRATIONS
PP	PHARMACOKINETICS PARAMETERS
SE	SUBJECT ELEMENTS
TA	TRIAL ARMS
TE	TRIAL ELEMENTS
TS	TRIAL SUMMARY
BG	BODY WEIGHT GAIN
BW	BODY WEIGHT
CL	CLINICAL OBSERVATIONS
MA	MACROSCOPIC FINDINGS
MI	MICROSCOPIC FINDINGS
TX	TRIAL SETS
SUPPBG	SUPPLEMENTAL QUALIFIERS FOR BG
SUPPBW	SUPPLEMENTAL QUALIFIERS FOR BW
SUPPCL	SUPPLEMENTAL QUALIFIERS FOR CL
SUPPDS	SUPPLEMENTAL QUALIFIERS FOR DS
SUPPLB	SUPPLEMENTAL QUALIFIERS FOR LB
SUPPMA	SUPPLEMENTAL QUALIFIERS FOR MA
SUPPMI	SUPPLEMENTAL QUALIFIERS FOR MI

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
DSDECOD, Reference Name (DSDECOD)

Code Value	Code Text
TERMINAL SACRIFICE	TERMINAL SACRIFICE

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
FREQ, Reference Name (FREQ)

Code Value	Code Text
EVERY 3 WEEKS	EVERY 3 WEEKS

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
LBTEST, Reference Name (LBTEST)

Code Value	Code Text
Bilirubin	Bilirubin; Total Bilirubin
Activated Partial Thromboplastin Time	Activated Partial Thromboplastin Time
Glucose	Glucose
Erythrocytes	Erythrocytes; Red Blood Cells
Reticulocytes	Reticulocytes
Leukocytes	Leukocytes; White Blood Cells
Lymphocytes	Lymphocytes
Platelets	Platelets
Blood Urea Nitrogen	Blood Urea Nitrogen
Cholesterol	Cholesterol; Total Cholesterol
Prothrombin Time	Prothrombin Time
Neutrophils	Neutrophils
Albumin	Albumin; Microalbumin
Alkaline Phosphatase	Alkaline Phosphatase
Alanine Aminotransferase	Alanine Aminotransferase; SGPT
Aspartate Aminotransferase	Aspartate Aminotransferase; SGOT
Basophils	Basophils
Calcium	Calcium
Creatine Kinase	Creatine Kinase
Chloride	Chloride
Creatinine	Creatinine
Eosinophils	Eosinophils
Fibrinogen	Fibrinogen
Hematocrit	Hematocrit
Ery. Mean Corpuscular Hemoglobin	Ery. Mean Corpuscular Hemoglobin
Ery. Mean Corpuscular HGB Concentration	Ery. Mean Corpuscular HGB Concentration
Ery. Mean Corpuscular Volume	Ery. Mean Corpuscular Volume
Erythrocytes Distribution Width	Erythrocytes Distribution Width

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Code Value	Code Text
Sodium	Sodium
Triglycerides	Triglycerides
Monocytes	Monocytes
Gamma Glutamyl Transferase	Gamma Glutamyl Transferase
Hemoglobin	Hemoglobin
Potassium	Potassium
Phosphate	Phosphate; Phosphorus; Inorganic Phosphate
Protein	Protein
Bicarbonate	Bicarbonate; HCO3
Mean Platelet Volume	Mean Platelet Volume
Globulin	Globulin
Albumin/Globulin	Albumin/Globulin

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
LBTESTCD, Reference Name (LBTESTCD)

Code Value	Code Text
BILI	Bilirubin; Total Bilirubin
APTT	Activated Partial Thromboplastin Time
GLUC	Glucose
RBC	Erythrocytes; Red Blood Cells
RETI	Reticulocytes
WBC	Leukocytes; White Blood Cells
LYM	Lymphocytes
PLAT	Platelets
BUN	Blood Urea Nitrogen
CHOL	Cholesterol; Total Cholesterol
PT	Prothrombin Time
NEUT	Neutrophils
ALB	Albumin; Microalbumin
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase; SGPT
AST	Aspartate Aminotransferase; SGOT
BASO	Basophils
CA	Calcium
CK	Creatine Kinase
CL	Chloride
CREAT	Creatinine
EOS	Eosinophils
FIBRINO	Fibrinogen
HCT	Hematocrit
MCH	Ery. Mean Corpuscular Hemoglobin
MCHC	Ery. Mean Corpuscular HGB Concentration
MCV	Ery. Mean Corpuscular Volume
RDW	Erythrocytes Distribution Width

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Code Value	Code Text
SODIUM	Sodium
TRIG	Triglycerides
MONO	Monocytes
GGT	Gamma Glutamyl Transferase
HGB	Hemoglobin
K	Potassium
PHOS	Phosphate; Phosphorus; Inorganic Phosphate
PROT	Protein
BICARB	Bicarbonate; HCO3
MPV	Mean Platelet Volume
GLOBUL	Globulin
ALBGLOB	Albumin/Globulin

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
MATEST, Reference Name (MATEST)

Code Value	Code Text
Gross Pathological Examination	Gross Pathological Examination

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
MATESTCD, Reference Name (MATESTCD)

Code Value	Code Text
GROSPATH	Gross Pathological Examination

[Go to the top](#)

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
MIRESCAT, Reference Name (MIRESCAT)

Code Value	Code Text
NON-NEOPLASTIC	Non-neoplastic Disorder

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
MITEST, Reference Name (MITEST)

Code Value	Code Text
Microscopic Examination	Microscopic Examination

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
MITESTCD, Reference Name (MITESTCD)

Code Value	Code Text
MIEXAM	Microscopic Examination

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section

ND, Reference Name (ND)

Code Value	Code Text
NOT DONE	NOT DONE

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
OMTEST, Reference Name (OMTEST)

Code Value	Code Text
Weight	Weight
Organ to Body Weight Ratio	Organ to Body Weight Ratio

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
OMTESTCD, Reference Name (OMTESTCD)

Code Value	Code Text
WEIGHT	Weight
OWBW	Organ to Body Weight Ratio

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
PKPARM, Reference Name (PKPARM)

Code Value	Code Text
Max Conc	Max Conc
AUC from T1 to T2	AUC from T1 to T2
Max Conc Norm by Dose	Max Conc Norm by Dose
Half-Life Lambda z	Half-Life Lambda z
AUC from T1 to T2 Norm by Dose	AUC from T1 to T2 Norm by Dose
Conc by Dose	Conc by Dose
Concentration	Concentration
Time of CMAX	Time of CMAX

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section
PKPARMCD, Reference Name (PKPARMCD)

Code Value	Code Text
CMAX	Max Conc
TMAX	Time of CMAX Observation
AUCINT	AUC from T1 to T2
CMAXD	Max Conc Norm by Dose
LAMZHL	Half-Life Lambda z
AUCINTD	AUC from T1 to T2 Norm by Dose
CONC	Concentration
CONCD	Conc by Dose

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
PKUNIT, Reference Name (PKUNIT)

Code Value	Code Text
ug/mL	g/m3; Gram per Cubic Meter; mg/L; Microgram per Milliliter; Milligram per Liter; mcg/mL; ng/uL; ug/mL
ng/mL	mg/m3; Microgram per Liter; Milligram per Cubic Meter; Nanogram per Milliliter; ug/L; ng/mL; mcg/L
h*mg/mL	mg*h/mL; h*g/L; g*h/L; ug*h/uL; h*ug/uL; h*mg/mL
day	day
h	h
h*mg/mL/(mg/kg)	h*mg/mL/(mg/kg)
ng/mL/(mg/day)	ng/mL/(mg/day)
ug/mL/(mg/kg)	ug/mL/(mg/kg)

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section
ROLECODELIST, Reference Name (ROLECODELIST)

Code Value	Code Text
GROUPING QUALIFIER	GROUPING QUALIFIER
IDENTIFIER	IDENTIFIER
QUALIFIER	QUALIFIER
RECORD QUALIFIER	RECORD QUALIFIER
RESULT	RESULT
RESULT QUALIFIER	RESULT QUALIFIER
RULE	RULE
SYNONYM QUALIFIER	SYNONYM QUALIFIER
TIMING	TIMING
TOPIC	TOPIC
VARIABLE QUALIFIER	VARIABLE QUALIFIER

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
ROUTE, Reference Name (ROUTE)

Code Value	Code Text
INTRAVENOUS	INTRAVENOUS

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
SEV, Reference Name (SEV)

Code Value	Code Text
MINIMAL	Trace
MARKED	MARKED
MODERATE	MODERATE
MILD	Slight
SEVERE	SEVERE

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
SEX, Reference Name (SEX)

Code Value	Code Text
F	Female

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
SNDIGVER, Reference Name (SNDIGVER)

Code Value	Code Text
SEND Implementation Guide Version 3.0	SEND IG Version 3.0

Go to the top

Date of document generation (2016-11-18T17:36:40)

Controlled Terminology (Code Lists) Section
SPEC, Reference Name (SPEC)

Code Value	Code Text
GLAND, SALIVARY, SUBMANDIBULAR	Gland, Salivary, Mandibular; Submaxillary Gland
GLAND, SALIVARY, SUBLINGUAL	GLAND, SALIVARY, SUBLINGUAL
SMALL INTESTINE, DUODENUM	SMALL INTESTINE, DUODENUM
GLAND, MAMMARY	GLAND, MAMMARY
GALLBLADDER	Gallbladder
LARGE INTESTINE, CECUM	Cecal; Cecum
LARGE INTESTINE, COLON	Colon
SMALL INTESTINE, ILEUM	Ileum
SMALL INTESTINE, JEJUNUM	Jejunum
PANCREAS	Pancreas
GLAND, PITUITARY	Hypophysis; Hypophysis Cerebri
EYE	Eyeball; Eye
OVIDUCT	Fallopian Tube
OVARY	Ovary
UTERUS	Womb; Uterus
VAGINA	Vagina
URETER	Ureter
LARYNX	Larynx
TONGUE	Tongue
GLAND, SALIVARY, PAROTID	Parotid Gland
TRACHEA	Trachea; Windpipe
BONE MARROW	BONE MARROW
BRAIN	Brain; Nervous System, Brain
SKIN	Integument; Skin
ARTERY, AORTA	Aorta
HEART	Cardiac; Heart
NERVE, OPTIC	Optic Nerve
NERVE, PERIPHERAL	Peripheral Nerve

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Code Value	Code Text
PEYER'S PATCH	PEYER'S PATCH
SPINAL CORD, CERVICAL	SPINAL CORD, CERVICAL
SPINAL CORD, THORACIC	SPINAL CORD, THORACIC
SPINAL CORD, LUMBAR	SPINAL CORD, LUMBAR
LYMPH NODE, AXILLARY	Axillary Lymph Node
MUSCLE, SKELETAL	Skeletal Muscle Tissue
BONE	BONE
SERUM	Sera
PLASMA	PLASMA
GLAND, ADRENAL	GLAND, ADRENAL
URINARY BLADDER	Urinary System, Bladder; Bladder
ESOPHAGUS	ESOPHAGUS
STOMACH	STOMACH
LIVER	LIVER
LUNG	LUNG
GLAND, PARATHYROID	GLAND, PARATHYROID
KIDNEY	KIDNEY
GLAND, THYROID	GLAND, THYROID
THYMUS	THYMUS
SPLEEN	SPLEEN
WHOLE BLOOD	WHOLE BLOOD
LYMPH NODE, POPLITEAL	LYMPH NODE, POPLITEAL
LYMPH NODE, MESENTERIC	LYMPH NODE, MESENTERIC
LYMPH NODE, TRACHEOBRONCHIAL	LYMPH NODE, TRACHEOBRONCHIAL
SITE, INJECTION	SITE, INJECTION
JOINT, STIFLE	Stifle Joint
LYMPH NODE, MANDIBULAR	LYMPH NODE, MANDIBULAR

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
SPECIES, Reference Name (SPECIES)

Code Value	Code Text
MONKEY	MONKEY

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
SSTYP, Reference Name (SSTYP)

Code Value	Code Text
REPEAT DOSE TOXICITY	FDA RPS Toxicology: Repeat Dose Toxicity

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
STCAT, Reference Name (STCAT)

Code Value	Code Text
TOX	Toxicology

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
STRAIN, Reference Name (STRAIN)

Code Value	Code Text
CYNOMOLGUS	CYNOMOLGUS

Go to the top

Date of document generation (2016-11-18T17:36:40)

Company Name: Company Name
Protocol: Protocol ID
Study: Study ID

Controlled Terminology (Code Lists) Section
UNIT, Reference Name (UNIT)

Code Value	Code Text
%	Percentage
kg	Kilogram
mL	Milliliter; cm3
sec	Second
RATIO	RATIO
g	Gram
mmol/L	Millimole per Liter; umol/mL; Micromole per Milliliter; mol/m3; Mole per Cubic Meter; mcmol/mL; mmol/L; nmol/uL
pg	Picogram
fL	Femtoliter
g/dL	Gram per Deciliter; g%
mg/dL	Milligram per Deciliter; mg%
10^9/L	10^3/uL;10^3/mm3
10^12/L	10^6/uL
IU/L	International Unit per Liter; IU/L; mIU/mL
mg/kg	Milligram per Kilogram

[Go to the top](#)

Date of document generation (2016-11-18T17:36:40)

External Dictionaries

Controlled Terminology (External Dictionaries)
No Dictionaries used, Reference Name (No Dictionaries used)

External Dictionary	Dictionary Version
No Dictionaries used	

Go to the top

Date of document generation (2016-11-18T17:36:40)