Datasets for Study: PDS2014

Dataset	Description	Structure	Location
DM	Demographics	One record per subject	dm.xpt
CO	Comments	One record per comment	co.xpt
EX	Exposure	One record per constant dosing interval per treatment per subject or pool	ex.xpt
DS	Disposition	One record per subject	ds.xpt
BW	Body Weight	One record per test per observation time per subject	bw.xpt
BG	Body Weight Gains	One record per test per interval per subject	bg.xpt
CL	Clinical Observations	One record per finding per observation time per subject or pool	cl.xpt
MA	Macroscopic Findings	One record per finding per specimen per subject	ma.xpt
LB	Laboratory	One record per test per specimen per observation time per subject or pool	lb.xpt
OM	Organ Measurements	One record per test per specimen per subject	om.xpt
MI	Microscopic Findings	One record per finding per specimen per subject	mi.xpt
PC	Pharmacokinetic Concentrations	One record per test per specimen per observation time per subject or pool	pc.xpt
PP	Pharmacokinetics Parameters	One record per pharmacokinetic parameter per time-concentration profile per pool	pp.xpt
TS	Trial Summary	One record per Trial Summary parameter value	ts.xpt
SC	Subject Characteristics	One record per characteristic per subject	sc.xpt
POOLDEF	Pooled Definition	One record per subject per pool,	pooldef.xpt
FW	Food and Water Consumption	One record per test per interval per subject or pool	fw.xpt
RELREC	Related Records - RELREC	One record per related record, related group of records (e.g. --GRPID), or related dataset, Tabulation.	relrec.xpt
SUPPMA	Supplemental Qualifiers - MA	One record per IDVAR, IDVARVAL, and QNAM value per subject	suppma.xpt
SUPPMI	Supplemental Qualifiers - MI	One record per IDVAR, IDVARVAL, and QNAM value per subject	suppmi.xpt
SUPPPP	Supplemental Qualifiers - PP	One record per IDVAR, IDVARVAL, and QNAM value per subject	supppp.xpt

Demographics (DM)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
SUBJID	Subject Identifier for the Study	text		OTHER	TOPIC	
RFSTDTC	Subject Reference Start Date/Time	datetime	CL.ISO8601	COLLECTED	QUALIFIER.REC	
RFENDTC	Subject Reference End Date/Time	datetime	CL.ISO8601	COLLECTED	QUALIFIER.REC	
SITEID	Study Site Identifier	text		OTHER	QUALIFIER.REC	not populated
BRTHDTC	Date/Time of Birth	datetime	CL.ISO8601	COLLECTED	QUALIFIER.REC	
AGE	Age	integer		DERIVED	QUALIFIER.REC	
AGETXT	Age Range	text		OTHER	QUALIFIER.REC	
AGEU	Age Unit	text	CL.C66781.AGEU	OTHER	QUALIFIER.VAR	
SEX	Sex	text	CL.C66731.SEX	COLLECTED	QUALIFIER.REC	
SPECIES	Species	text	CL.C77808.SPECIES	COLLECTED	QUALIFIER.REC	
STRAIN	Strain/Substrain	text	CL.C77530.STRAIN	COLLECTED	QUALIFIER.REC	
SBSTRAIN	Strain/Substrain Details	text		OTHER	QUALIFIER.REC	not populated
ARMCD	Planned Arm Code	text		OTHER	QUALIFIER.REC	
ARM	Description of Planned Arm	text		OTHER	QUALIFIER.SYN	
SETCD	Set Code	text		OTHER	QUALIFIER.REC	

Comments (CO)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	QUALIFIER.REC	
USUBJID	Unique Subject Identifier	text		COLLECTED	IDENTIFIER	
COSEQ	Sequence Number	float		OTHER	IDENTIFIER	
IDVAR	Identifying Variable	text		OTHER	QUALIFIER.REC	
IDVARVAL	Identifying Variable Value	text		OTHER	QUALIFIER.REC	
COREF	Comment Reference	text		OTHER	QUALIFIER.REC	not populated
COVAL	Comment	text		COLLECTED	TOPIC	
COEVAL	Evaluator	text		OTHER	QUALIFIER.REC	
CODTC	Date/Time of Comment	datetime	CL.ISO8601	COLLECTED	TIMING	not populated

Comments (CO)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
CODY	Study Day of Comment	integer		OTHER	TIMING	Computational Algorithm: CM.DY

Exposure (EX)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
EXSEQ	Sequence Number	float		OTHER	IDENTIFIER	
EXTRT	Name of Actual Treatment	text		COLLECTED	TOPIC	
EXDOSE	Dose per Administration	float		COLLECTED	QUALIFIER.REC	
EXDOSTXT	Dose Description	text		OTHER	QUALIFIER.REC	not populated
EXDOSU	Dose Units	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
EXDOSFRM	Dose Form	text	CL.C66726.FRM	COLLECTED	QUALIFIER.REC	not populated
EXDOSFRQ	Dosing Frequency Per Interval	text	CL.C71113.FREQ	COLLECTED	QUALIFIER.VAR	
EXROUTE	Route of Administration	text	CL.C66729.ROUTE	COLLECTED	QUALIFIER.VAR	
EXLOT	Lot Number	text		COLLECTED	QUALIFIER.REC	not populated
EXLOC	Location of Dose Administration	text		OTHER	QUALIFIER.REC	not populated
EXMETHOD	Method of Administration	text		OTHER	QUALIFIER.REC	not populated
EXTRTV	Treatment Vehicle	text		COLLECTED	QUALIFIER.REC	
EXVAMT	Amount Administered	float		OTHER	QUALIFIER.REC	
EXVAMTU	Amount Administered Units	text	CL.C71620.UNIT	OTHER	QUALIFIER.VAR	
EXADJ	Reason for Dose Adjustment	text		OTHER	QUALIFIER.REC	not populated
EXSTDTC	Start Date/Time of Treatment	datetime	CL.ISO8601	COLLECTED	TIMING	
EXENDTC	End Date/Time of Treatment	datetime	CL.ISO8601	COLLECTED	TIMING	not populated
EXSTDY	Study Day of Start of Treatment	integer		OTHER	TIMING	Computational Algorithm: CM.DY
EXENDY	Study Day of End of Treatment	integer		OTHER	TIMING	not populated Computational Algorithm: CM.DY
EXDUR	Duration of Treatment	text	CL.ISO8601	OTHER	TIMING	not populated
EXTPT	Planned Time Point Name	text		OTHER	TIMING	
EXTPTNUM	Planned Time Point Number	float		OTHER	TIMING	
EXELTM	Planned Elapsed Time from Time Point Ref	text	CL.ISO8601	OTHER	TIMING	not populated
EXTPTREF	Time Point Reference	text		OTHER	TIMING	not populated
EXRFTDTC	Date/Time of Reference Time Point	datetime	CL.ISO8601	OTHER	TIMING	not populated

Disposition (DS)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		COLLECTED	IDENTIFIER	
DSSEQ	Sequence Number	float		OTHER	IDENTIFIER	
DSTERM	Reported Term for the Disposition Event	text		COLLECTED	TOPIC	
DSDECOD	Standardized Disposition Term	text	CL.C89968.DSDECOD	DERIVED	QUALIFIER.SYN	
VISITDY	Planned Study Day of Disposition	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
DSSTDTC	Date/Time of Disposition	datetime	CL.ISO8601	COLLECTED	TIMING	
DSSTDY	Study Day of Disposition	integer		DERIVED	TIMING	Computational Algorithm: CM.DY

Body Weight (BW)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
BWSEQ	Sequence Number	float		OTHER	IDENTIFIER	
BWTESTCD	Test Short Name	text	CL.C89962.BWTESTCD	OTHER	TOPIC	

Body Weight (BW)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
BWTEST	Test Name	text	CL.C89961.BWTEST	OTHER	QUALIFIER.SYN	
BWORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
BWORRESU	Unit of the Original Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
BWSTRESC	Standardized Result in Character Format	text		COLLECTED	QUALIFIER.RES	
BWSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
BWSTRESU	Unit of the Standardized Result	text	CL.C71620.UNIT	DERIVED	QUALIFIER.VAR	
BWSTAT	Examination Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
BWREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
BWBLFL	Baseline Flag	text	CL.C66742.NY	DERIVED	QUALIFIER.REC	not populated
BWFAST	Fasting Status	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	not populated
BWEXCLFL	Exclusion Flag	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	
BWREASEX	Reason for Exclusion	text		COLLECTED	QUALIFIER.REC	
VISITDY	Planned Study Day of Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
BWDTC	Date/Time Animal Weighed	datetime	CL.ISO8601	COLLECTED	TIMING	
BWDY	Study Day Animal Weighed	integer		DERIVED	TIMING	Computational Algorithm: CM.DY

Body Weight Gains (BG)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
BGSEQ	Sequence Number	float		OTHER	IDENTIFIER	
BGTESTCD	Test Short Name	text	CL.C89960.BGTESTCD	OTHER	TOPIC	
BGTEST	Test Name	text	CL.C89959.BGTEST	OTHER	QUALIFIER.SYN	
BGORRES	Result or Findings as Collected	text		DERIVED	QUALIFIER.RES	computed from BWORRES values for interval specified
BGORRESU	Unit of the Original Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
BGSTRESC	Standardized Result in Character Format	text		COLLECTED	QUALIFIER.RES	
BGSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
BGSTRESU	Unit of the Standardized Result	text	CL.C71620.UNIT	DERIVED	QUALIFIER.VAR	
BGSTAT	Examination Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
BGREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
BGEXCLFL	Exclusion Flag	text	CL.C66742.NY	OTHER	QUALIFIER.REC	
BGREASEX	Reason for Exclusion	text		OTHER	QUALIFIER.REC	
BGDTC	Date/Time Animal Weighed	datetime	CL.ISO8601	COLLECTED	TIMING	
BGENDTC	End Date/Time Animal Weighed	datetime	CL.ISO8601	COLLECTED	TIMING	
BGDY	Study Day Animal Weighed	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
BGENDY	Study Day of End of Weight Interval	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
BGELTM	Planned Elapsed Time from Time Point Ref	text	CL.ISO8601	OTHER	TIMING	not populated
BGTPTREF	Time Point Reference	text		OTHER	TIMING	not populated
BGRFTDTC	Date/Time of Reference Time Point	datetime	CL.ISO8601	OTHER	TIMING	not populated

Clinical Observations (CL)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	
CLSEQ	Sequence Number	float		OTHER	IDENTIFIER	
CLGRPID	Group Identifier	text		OTHER	IDENTIFIER	not populated
CLREFID	Reference ID	text		OTHER	IDENTIFIER	
CLSPID	Mass Identifier	text		OTHER	IDENTIFIER	not populated
CLTESTCD	Test Short Name	text		OTHER	TOPIC	

Clinical Observations (CL)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
CLTEST	Test Name	text		OTHER	QUALIFIER.SYN	
CLCAT	Category for Clinical Observations	text	CL.C89963.CLCAT	OTHER	QUALIFIER.GRP	
CLSCAT	Subcategory for Clinical Observations	text		OTHER	QUALIFIER.GRP	not populated
CLBODSYS	Body System or Organ Class	text		OTHER	QUALIFIER.REC	not populated
CLORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
CLSTRESC	Standardized Result in Character Format	text		DERIVED	QUALIFIER.RES	
CLRESCAT	Result Category	text		OTHER	QUALIFIER.VAR	not populated
CLSTAT	Examination Status	text	CL.C66789.ND	OTHER	QUALIFIER.REC	not populated
CLREASND	Reason Not Done	text		OTHER	QUALIFIER.REC	not populated
CLLOC	Location of a Finding	text		DERIVED	QUALIFIER.REC	not populated
CLEVAL	Evaluator	text		OTHER	QUALIFIER.REC	
CLSEV	Severity	text		COLLECTED	QUALIFIER.REC	not populated
CLEXCLFL	Exclusion Flag	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	not populated
CLREASEX	Reason for Exclusion	text		COLLECTED	QUALIFIER.REC	not populated
VISITDY	Planned Study Day of Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
CLDTC	Start Date/Time of Observation	datetime	CL.ISO8601	COLLECTED	TIMING	
CLDY	Study Day of Observation	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
CLTPT	Planned Time Point Name	text		COLLECTED	TIMING	not populated
CLTPTNUM	Planned Time Point Number	float		OTHER	TIMING	not populated
CLELTM	Planned Elapsed Time from Time Point Ref	text	CL.ISO8601	OTHER	TIMING	not populated
CLTPTREF	Time Point Reference	text		OTHER	TIMING	not populated
CLRFTDTC	Date/Time of Reference Time Point	datetime	CL.ISO8601	OTHER	TIMING	not populated

Macroscopic Findings (MA)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
MASEQ	Sequence Number	float		OTHER	IDENTIFIER	
MAGRPID	Group Identifier	text		OTHER	IDENTIFIER	not populated
MAREFID	Specimen Reference Identifier	text		OTHER	IDENTIFIER	
MASPID	Mass Identifier	text		OTHER	IDENTIFIER	not populated
MATESTCD	Macroscopic Examination Short Name	text	CL.C89972.MATESTCD	OTHER	TOPIC	
MATEST	Macroscopic Examination Name	text	CL.C89971.MATEST	OTHER	QUALIFIER.SYN	
MABODSYS	Body System or Organ Class	text		OTHER	QUALIFIER.REC	not populated
MAORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
MASTRESC	Standardized Result in Character Format	text		DERIVED	QUALIFIER.RES	
MASTAT	Examination Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	not populated
MAREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	not populated
MANAM	Laboratory Name	text		OTHER	QUALIFIER.REC	not populated
MASPEC	Specimen Material Type	text	CL.C77529.SPEC	COLLECTED	QUALIFIER.REC	
MAANTREG	Anatomical Region of Specimen	text		DERIVED	QUALIFIER.VAR	
MASPCCND	Specimen Condition	text		DERIVED	QUALIFIER.VAR	not populated
MASPCUFL	Specimen Usability for the Test	text	CL.C66742.NY	DERIVED	QUALIFIER.VAR	not populated
MALAT	Specimen Laterality within Subject	text	CL.C99073.LAT	DERIVED	QUALIFIER.VAR	not populated
MADIR	Specimen Directionality within Subject	text		OTHER	QUALIFIER.VAR	not populated
MAPORTOT	Portion or Totality	text		OTHER	QUALIFIER.VAR	not populated
MAEVAL	Evaluator	text		OTHER	QUALIFIER.REC	
MASEV	Severity	text	CL.C90000.SEV	DERIVED	QUALIFIER.REC	not populated
MADTHREL	Relationship to Death	text	CL.C66742.NY	DERIVED	QUALIFIER.REC	not populated
MADTC	Date/Time of Collection	datetime	CL.ISO8601	COLLECTED	TIMING	
MADY	Study Day of Specimen Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY

Laboratory (LB)						
Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
LBSEQ	Sequence Number	float		OTHER	IDENTIFIER	
LBGRPID	Group Identifier	text		OTHER	IDENTIFIER	not populated
LBREFID	Specimen Identifier	text		OTHER	IDENTIFIER	not populated
LBSPID	Sponsor-Defined Identifier	text		OTHER	IDENTIFIER	not populated
LBTESTCD	Lab Test or Examination Short Name	text	CL.C65047.LBTESTCD	OTHER	TOPIC	
LBTEST	Lab Test or Examination Name	text	CL.C67154.LBTEST	OTHER	QUALIFIER.SYN	
LBCAT	Category for Lab Test	text		OTHER	QUALIFIER.GRP	
LBSCAT	Subcategory for Lab Test	text		OTHER	QUALIFIER.GRP	not populated
LBORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
LBORRESU	Unit of the Original Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
LBORNRLO	Reference Range Lower Limit-Orig Unit	float		OTHER	QUALIFIER.VAR	not populated
LBORNRHI	Reference Range Upper Limit-Orig Unit	float		OTHER	QUALIFIER.VAR	not populated
LBSTRESC	Standardized Result in Character Format	text		COLLECTED	QUALIFIER.RES	
LBSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
LBSTRESU	Unit of the Standardized Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
LBSTNRLO	Reference Range Lower Limit-Std Unit	float		OTHER	QUALIFIER.VAR	not populated
LBSTNRHI	Reference Range Upper Limit-Std Unit	float		OTHER	QUALIFIER.VAR	not populated
LBSTNRC	Reference Range for Char Rslt-Std Unit	text		OTHER	QUALIFIER.VAR	not populated
LBNRIND	Reference Range Indicator	text		OTHER	QUALIFIER.VAR	not populated
LBSTAT	Completion Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
LBREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
LBNAM	Vendor Name	text		OTHER	QUALIFIER.REC	not populated
LBSPEC	Specimen Type	text	CL.C77529.SPEC	OTHER	QUALIFIER.REC	not populated
LBANTREG	Anatomical Region of Specimen	text		OTHER	QUALIFIER.VAR	not populated
LBSPCCND	Specimen Condition	text		COLLECTED	QUALIFIER.REC	
LBSPCUFL	Specimen Usability for the Test	text	CL.C66742.NY	DERIVED	QUALIFIER.VAR	
LBLOC	Specimen Collection Location	text		OTHER	QUALIFIER.REC	not populated
LBLAT	Specimen Laterality within Subject	text	CL.C99073.LAT	OTHER	QUALIFIER.VAR	not populated
LBDIR	Specimen Directionality within Subject	text		OTHER	QUALIFIER.VAR	not populated
LBPORTOT	Portion or Totality	text		OTHER	QUALIFIER.VAR	not populated
LBMETHOD	Method of Test or Examination	text		OTHER	QUALIFIER.REC	
LBBLFL	Baseline Flag	text	CL.C66742.NY	DERIVED	QUALIFIER.REC	not populated
LBFAST	Fasting Status	text	CL.C66742.NY	OTHER	QUALIFIER.REC	not populated
LBDRVFL	Derived Flag	text	CL.C66742.NY	OTHER	QUALIFIER.REC	
LBTOX	Toxicity	text		OTHER	QUALIFIER.VAR	not populated
LBTOXGR	Standard Toxicity Grade	text		OTHER	QUALIFIER.VAR	not populated
LBEXCLFL	Exclusion Flag	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	
LBREASEX	Reason for Exclusion	text		COLLECTED	QUALIFIER.REC	
VISITDY	Planned Study Day of Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
LBDTC	Date/Time of Specimen Collection	datetime	CL.ISO8601	COLLECTED	TIMING	
LBENDTC	End Date/Time of Specimen Collection	datetime	CL.ISO8601	OTHER	TIMING	not populated
LBDY	Study Day of Specimen Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
LBENDY	Study Day of End of Specimen Collection	integer		OTHER	TIMING	not populated Computational Algorithm: CM.DY
LBTPT	Planned Time Point Name	text		OTHER	TIMING	not populated
LBTPTNUM	Planned Time Point Number	float		OTHER	TIMING	not populated
LBELTM	Planned Elapsed Time from Time Point Ref	text	CL.ISO8601	OTHER	TIMING	not populated
LBTPTREF	Time Point Reference	text		OTHER	TIMING	not populated
LBRFTDTC	Date/Time of Reference Time Point	datetime	CL.ISO8601	OTHER	TIMING	not populated

Organ Measurements (OM)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
OMSEQ	Sequence Number	float		OTHER	IDENTIFIER	
OMTESTCD	Test Short Name	text	CL.C89977.OMTESTCD	OTHER	TOPIC	
OMTEST	Test Name	text	CL.C89976.OMTEST	OTHER	QUALIFIER.SYN	
OMORRES	Result or Findings as Collected	text		MULTIPLE	QUALIFIER.RES	Origin is COLLECTED when OMTESTCD = OW, otherwise DERIVED
OMORRESU	Unit of the Original Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
OMSTRESC	Standardized Result in Character Format	text		MULTIPLE	QUALIFIER.RES	Origin is COLLECTED when OMTESTCD = OW, otherwise DERIVED
OMSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
OMSTRESU	Unit of the Standardized Result	text	CL.C71620.UNIT	DERIVED	QUALIFIER.VAR	
OMSTAT	Finding Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
OMREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
OMSPEC	Specimen Material Type	text	CL.C77529.SPEC	COLLECTED	QUALIFIER.REC	
OMANTREG	Anatomical Region of Specimen	text		OTHER	QUALIFIER.VAR	not populated
OMSPCCND	Specimen Condition	text		OTHER	QUALIFIER.REC	
OMSPCUFL	Specimen Usability for the Test	text	CL.C66742.NY	OTHER	QUALIFIER.VAR	not populated
OMLAT	Specimen Laterality within Subject	text	CL.C99073.LAT	OTHER	QUALIFIER.VAR	
OMDIR	Specimen Directionality within Subject	text		OTHER	QUALIFIER.VAR	not populated
OMPORTOT	Portion or Totality	text		OTHER	QUALIFIER.VAR	not populated
OMEXCLFL	Exclusion Flag	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	
OMREASEX	Reason for Exclusion	text		COLLECTED	QUALIFIER.REC	
OMDTC	Date/Time Organ Weighed	datetime	CL.ISO8601	COLLECTED	TIMING	
OMDY	Study Day of Weighing	integer		DERIVED	TIMING	Computational Algorithm: CM.DY

Microscopic Findings (MI)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
MISEQ	Sequence Number	float		OTHER	IDENTIFIER	
MIGRPID	Group Identifier	text		OTHER	IDENTIFIER	
MIREFID	Specimen Reference Identifier	text		OTHER	IDENTIFIER	
MISPID	Mass Identifier	text		OTHER	IDENTIFIER	not populated
MITESTCD	Microscopic Examination Short Name	text	CL.C89974.MITESTCD	OTHER	TOPIC	
MITEST	Microscopic Examination Name	text	CL.C89973.MITEST	OTHER	QUALIFIER.SYN	
MIBODSYS	Body System or Organ Class	text		OTHER	QUALIFIER.REC	not populated
MIORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
MISTRESC	Standardized Result in Character Format	text		DERIVED	QUALIFIER.RES	
MIRESCAT	Result Category	text	CL.C90017.MIRESCAT	COLLECTED	QUALIFIER.RES	
MISTAT	Completion Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
MIREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
MINAM	Laboratory Name	text		OTHER	QUALIFIER.REC	not populated
MISPEC	Specimen Material Type	text	CL.C77529.SPEC	COLLECTED	QUALIFIER.REC	
MIANTREG	Anatomical Region of Specimen	text		DERIVED	QUALIFIER.VAR	not populated
MISPCCND	Specimen Condition	text		DERIVED	QUALIFIER.VAR	
MISPCUFL	Specimen Usability for the Test	text	CL.C66742.NY	DERIVED	QUALIFIER.VAR	
MIMETHOD	Method of Test or Examination	text		OTHER	QUALIFIER.REC	not populated
MILAT	Specimen Laterality within Subject	text	CL.C99073.LAT	DERIVED	QUALIFIER.VAR	
MIDIR	Specimen Directionality within Subject	text		DERIVED	QUALIFIER.VAR	not populated
MIEVAL	Evaluator	text		OTHER	QUALIFIER.REC	
MISEV	Severity	text	CL.C90000.SEV	COLLECTED	QUALIFIER.VAR	
MIDTHREL	Relationship to Death	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	

Microscopic Findings (MI)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
MIDTC	Date/Time of Specimen Collection	datetime	CL.ISO8601	COLLECTED	TIMING	
MIDY	Study Day of Specimen Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY

Pharmacokinetic Concentrations (PC)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
PCSEQ	Sequence Number	float		OTHER	IDENTIFIER	
PCGRPID	Group Identifier	text		OTHER	IDENTIFIER	
PCREFID	Sample Identifier	text		OTHER	IDENTIFIER	
PCSPID	Sponsor Identifier	text		OTHER	IDENTIFIER	not populated
PCTESTCD	Test Short Name	text		COLLECTED	TOPIC	
PCTEST	Test Name	text		COLLECTED	QUALIFIER.SYN	
PCCAT	Test Category	text		COLLECTED	QUALIFIER.GRP	
PCSCAT	Test Subcategory	text		OTHER	QUALIFIER.GRP	not populated
PCORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
PCORRESU	Unit of the Original Result	text	CL.C85494.PKUNIT	COLLECTED	QUALIFIER.VAR	
PCSTRESC	Standardized Result in Character Format	text		COLLECTED	QUALIFIER.RES	
PCSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
PCSTRESU	Unit of the Standardized Result	text	CL.C85494.PKUNIT	DERIVED	QUALIFIER.VAR	
PCSTAT	Completion Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
PCREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
PCNAM	Vendor Name	text		OTHER	QUALIFIER.REC	not populated
PCSPEC	Specimen Material Type	text	CL.C77529.SPEC	COLLECTED	QUALIFIER.REC	
PCSPCCND	Specimen Condition	text		COLLECTED	QUALIFIER.VAR	
PCMETHOD	Method of Test or Examination	text		OTHER	QUALIFIER.REC	
PCBLFL	Baseline Flag	text	CL.C66742.NY	DERIVED	QUALIFIER.REC	
PCFAST	Fasting Status	text	CL.C66742.NY	OTHER	QUALIFIER.REC	not populated
PCDRVFL	Derived Flag	text	CL.C66742.NY	OTHER	QUALIFIER.REC	
PCLLOQ	Lower Limit of Quantitation	integer		OTHER	QUALIFIER.VAR	
PCEXCLFL	Exclusion Flag	text	CL.C66742.NY	OTHER	QUALIFIER.REC	
PCREASEX	Reason for Exclusion	text		OTHER	QUALIFIER.REC	
VISITDY	Visit Day	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
PCDTC	Date/Time of Specimen Collection	datetime	CL.ISO8601	COLLECTED	TIMING	
PCENDTC	End Date/Time of Specimen Collection	datetime	CL.ISO8601	OTHER	TIMING	not populated
PCDY	Study Day of Specimen Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
PCENDY	Study Day of End of Specimen Collection	integer		DERIVED	TIMING	not populated Computational Algorithm: CM.DY
PCTPT	Planned Time Point Name	text		COLLECTED	TIMING	
PCTPTNUM	Planned Time Point Number	float		DERIVED	TIMING	not populated
PCELTM	Planned Elapsed Time from Time Point Ref	text	CL.ISO8601	OTHER	TIMING	not populated
PCTPTREF	Time Point Reference	text		OTHER	TIMING	not populated
PCRFTDTC	Date/Time of Reference Point	datetime	CL.ISO8601	COLLECTED	TIMING	not populated
PCEVLINT	Evaluation Interval	text	CL.ISO8601	OTHER	TIMING	not populated

Pharmacokinetics Parameters (PP)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
PPSEQ	Sequence Number	float		OTHER	IDENTIFIER	
PPGRPID	Group Identifier	text		OTHER	IDENTIFIER	

Pharmacokinetics Parameters (PP)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
PPTESTCD	Parameter Short Name	text	CL.C85839.PKPARMCD	OTHER	TOPIC	
PPTEST	Parameter Name	text	CL.C85493.PKPARM	OTHER	QUALIFIER.SYN	
PPCAT	Parameter Category	text		COLLECTED	QUALIFIER.GRP	
PPSCAT	Parameter Subcategory	text		OTHER	QUALIFIER.GRP	not populated
PPORRES	Result or Findings as Collected	text		DERIVED	QUALIFIER.RES	
PPORRESU	Unit of the Original Result	text	CL.C85494.PKUNIT	DERIVED	QUALIFIER.VAR	
PPSTRESC	Standardized Result in Character Format	text		DERIVED	QUALIFIER.RES	
PPSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
PPSTRESU	Unit of the Standardized Result	text	CL.C85494.PKUNIT	DERIVED	QUALIFIER.VAR	
PPSTAT	Completion Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	
PPREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	
PPSPEC	Specimen Material Type	text	CL.C77529.SPEC	OTHER	QUALIFIER.REC	
VISITDY	Planned Study Day of Collection	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
PPTPTREF	Time Point Reference	text		COLLECTED	TIMING	not populated
PPRFTDTC	Date/Time of Reference Point	datetime	CL.ISO8601	COLLETED	TIMING	not populated
PPSTINT	Start of Evaluation Interval	text	CL.ISO8601	COLLECTED	TIMING	not populated
PPENINT	End of Evaluation Interval	text	CL.ISO8601	COLLECTED	TIMING	not populated

Trial Summary (TS)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
TSSEQ	Sequence Number	float		OTHER	IDENTIFIER	
TSGRPID	Group Identifier	text		OTHER	IDENTIFIER	not populated
TSPARMCD	Trial Summary Parameter Short Name	text	CL.C90009.STSPRMCD	OTHER	TOPIC	
TSPARM	Trial Summary Parameter	text	CL.C90007.STSPRM	OTHER	QUALIFIER.SYN	
TSVAL	Parameter Value	text		OTHER	QUALIFIER.RES	

Subject Characteristics (SC)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	TOPIC	
SCSEQ	Sequence Number	float		OTHER	QUALIFIER.SYN	
SCGRPID	Group Identifier	text		OTHER	IDENTIFIER	not populated
SCTESTCD	Subject Characteristic Short Name	text	CL.C89981.SBCCDSND	OTHER	TOPIC	
SCTEST	Subject Characteristic	text	CL.C89980.SBCSND	OTHER	QUALIFIER.SYN	
SCORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
SCORRESU	Unit of the Original Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.RES	not populated
SCSTRESC	Standardized Result in Character Format	text		COLLECTED	QUALIFIER.RES	
SCSTRESN	Standardized Result in Numeric Format	float		OTHER	QUALIFIER.RES	not populated
SCSTRESU	Unit of the Standardized Result	text	CL.C71620.UNIT	OTHER	QUALIFIER.REC	not populated
SCDTC	Date/Time of Collection	datetime	CL.ISO8601	COLLECTED	TIMING	not populated
SCDY	Study Day of Collection	integer		DERIVED	TIMING	not populated

Pooled Definition (POOLDEF)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	

Food and Water Consumption (FW)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
DOMAIN	Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	

Food and Water Consumption (FW)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	
FWSEQ	Sequence Number	float		OTHER	IDENTIFIER	
FWGRPID	Group Identifier	text		OTHER	IDENTIFIER	not populated
FWTESTCD	Food /Water Consumption Short Name	text	CL.C89970.FWTESTCD	OTHER	TOPIC	
FWTEST	Food /Water Consumption Name	text	CL.C89969.FWTEST	OTHER	QUALIFIER.SYN	
FWORRES	Result or Findings as Collected	text		COLLECTED	QUALIFIER.RES	
FWORRESU	Unit of the Original Result	text	CL.C71620.UNIT	COLLECTED	QUALIFIER.VAR	
FWSTRESC	Standardized Result in Character Format	text		DERIVED	QUALIFIER.RES	
FWSTRESN	Standardized Result in Numeric Format	float		DERIVED	QUALIFIER.RES	
FWSTRESU	Unit of the Standardized Result	text	CL.C71620.UNIT	DERIVED	QUALIFIER.VAR	
FWSTAT	Completion Status	text	CL.C66789.ND	COLLECTED	QUALIFIER.REC	not populated
FWREASND	Reason Not Done	text		COLLECTED	QUALIFIER.REC	not populated
FWEXCLFL	Exclusion Flag	text	CL.C66742.NY	COLLECTED	QUALIFIER.REC	not populated
FWREASEX	Reason for Exclusion	text		COLLECTED	QUALIFIER.REC	not populated
FWDTC	Date/Time of Observation	datetime	CL.ISO8601	COLLECTED	TIMING	
FWENDTC	End Date/Time of Observation	datetime	CL.ISO8601	COLLECTED	TIMING	
FWDY	Study Day of Observation	integer		DERIVED	TIMING	Computational Algorithm: CM.DY
FWENDY	Study Day of End of Observation	integer		DERIVED	TIMING	Computational Algorithm: CM.DY

Related Records - RELREC (RELREC)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
IDVAR	Identifying Variable	text		OTHER	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		OTHER	IDENTIFIER	
RELTYPE	Relationship Type	text		OTHER	Record Qualifier	not populated
RELID	Relationship Identifier	text		OTHER	IDENTIFIER	

Supplemental Qualifiers - MA (SUPPMA)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
IDVAR	Identifying Variable	text		OTHER	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		OTHER	IDENTIFIER	
QNAM	Qualifier Variable Name	text		OTHER	IDENTIFIER	
QLABEL	Qualifier Variable Label	text		OTHER	QUALIFIER.SYN	
QVAL	Data Value	text		OTHER	QUALIFIER.RES	
QORIG	Origin	text		OTHER	QUALIFIER.REC	
QEVAL	Evaluator	text		OTHER	QUALIFIER.REC	

Supplemental Qualifiers - MI (SUPPMI)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
IDVAR	Identifying Variable	text		OTHER	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		OTHER	IDENTIFIER	
QNAM	Qualifier Variable Name	text		OTHER	IDENTIFIER	
QLABEL	Qualifier Variable Label	text		OTHER	QUALIFIER.SYN	
QVAL	Data Value	text		OTHER	QUALIFIER.RES	

Supplemental Qualifiers - MI (SUPPMI)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
QORIG	Origin	text		OTHER	QUALIFIER.REC	
QEVAL	Evaluator	text		OTHER	QUALIFIER.REC	

Supplemental Qualifiers - PP (SUPPPP)

Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text		OTHER	IDENTIFIER	
RDOMAIN	Related Domain Abbreviation	text	CL.C66734.DOMAIN	OTHER	IDENTIFIER	
USUBJID	Unique Subject Identifier	text		OTHER	IDENTIFIER	
POOLID	Pool Identifier	text		OTHER	IDENTIFIER	not populated
IDVAR	Identifying Variable	text		OTHER	IDENTIFIER	
IDVARVAL	Identifying Variable Value	text		OTHER	IDENTIFIER	
QNAM	Qualifier Variable Name	text		OTHER	IDENTIFIER	
QLABEL	Qualifier Variable Label	text		OTHER	QUALIFIER.SYN	
QVAL	Data Value	text		OTHER	QUALIFIER.RES	
QORIG	Origin	text		OTHER	QUALIFIER.REC	
QEVAL	Evaluator	text		OTHER	QUALIFIER.REC	

Computational Algorithms Section

Reference Name	Computation Method
CM.DY	--DY = (date portion of --DTC) - (date portion of RFSTDTC) + 1 if --DTC is on or after RFSTDTC --DY = (date portion of --DTC) - (date portion of RFSTDTC) if --DTC precedes RFSTDTC

Controlled Terminology (Code Lists) Section

Code Value	Code Text
Roles (CL.ROLES)	
IDENTIFIER	Identifier
TOPIC	Topic
QUALIFIER	Qualifier
QUALIFIER.REC	Record Qualifier
QUALIFIER.RES	Result Qualifier
QUALIFIER.SYN	Synonym Qualifier
QUALIFIER.VAR	Variable Qualifier
QUALIFIER.GRP	Grouping Qualifier
TIMING	Timing
RULE	Rule
ISO 8601 (Dates/Times) (CL.ISO8601)	
ISO 8601	N/A
Category for Clinical Observation (CL.C89963.CLCAT)	
CLINICAL SIGNS	CLINICAL SIGNS
OPHTHALMOLOGY	OPHTHALMOLOGY
Not Done (CL.C66789.ND)	
NOT DONE	NOT DONE
No Yes Response (CL.C66742.NY)	
Y	Y
Age Unit (CL.C66781.AGEU)	
DAYS	DAYS
Sex (CL.C66731.SEX)	
F	F
M	M
Species (CL.C77808.SPECIES)	
RAT	RAT
Strain/Substrain (CL.C77530.STRAIN)	
SPRAGUE-DAWLEY	SPRAGUE-DAWLEY
Unit (CL.C71620.UNIT)	
%	%
/uL	/uL

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
10^12/L	10^12/L
10^9/L	10^9/L
fL	fL
g	g
g/100g	g/100g
g/day	g/day
g/dL	g/dL
mg/dL	mg/dL
mg/kg	mg/kg
mg/kg/day	mg/kg/day
mL	mL
mmol/L	mmol/L
pg	pg
RATIO	RATIO
sec	sec
U/L	U/L
Pharmaceutical Dosage Form (CL.C66726.FRM)	
SUSPENSION	SUSPENSION
Frequency (CL.C71113.FREQ)	
QD	QD
Route of Administration (CL.C66729.ROUTE)	
ORAL GAVAGE	ORAL GAVAGE
Macroscopic Findings Test Code (CL.C89972.MATESTCD)	
GROSPATH	GROSPATH
Macroscopic Findings Test Name (CL.C89971.MATEST)	
Gross Pathological Examination	Gross Pathological Examination
Specimen (CL.C77529.SPEC)	
ALL TISSUES	ALL TISSUES
ARTERY, AORTA	ARTERY, AORTA
BONE MARROW, FEMUR	BONE MARROW, FEMUR
BONE MARROW, STERNUM	BONE MARROW, STERNUM
BONE, STERNUM	BONE, STERNUM
BRAIN	BRAIN
CERVIX	CERVIX
EPIDIDYMIS	EPIDIDYMIS
ESOPHAGUS	ESOPHAGUS
EYE	EYE
GLAND, ADRENAL	GLAND, ADRENAL
GLAND, CLITORAL	GLAND, CLITORAL
GLAND, COAGULATING	GLAND, COAGULATING
GLAND, HARDERIAN	GLAND, HARDERIAN
GLAND, LACRIMAL	GLAND, LACRIMAL
GLAND, MAMMARY	GLAND, MAMMARY
GLAND, PARATHYROID	GLAND, PARATHYROID
GLAND, PITUITARY	GLAND, PITUITARY
GLAND, PREPUTIAL	GLAND, PREPUTIAL
GLAND, PROSTATE	GLAND, PROSTATE
GLAND, SALIVARY, PAROTID	GLAND, SALIVARY, PAROTID
GLAND, SALIVARY, SUBLINGUAL	GLAND, SALIVARY, SUBLINGUAL
GLAND, SALIVARY, SUBMANDIBULAR	GLAND, SALIVARY, SUBMANDIBULAR
GLAND, SEMINAL VESICLE	GLAND, SEMINAL VESICLE
GLAND, THYROID	GLAND, THYROID
HEART	HEART
JOINT, STIFLE	JOINT, STIFLE
KIDNEY	KIDNEY
LARGE INTESTINE, CECUM	LARGE INTESTINE, CECUM
LARGE INTESTINE, COLON	LARGE INTESTINE, COLON
LARGE INTESTINE, RECTUM	LARGE INTESTINE, RECTUM
LARYNX	LARYNX

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
LIVER	LIVER
LUNG	LUNG
LYMPH NODE, MESENTERIC	LYMPH NODE, MESENTERIC
LYMPH NODE, POPLITEAL	LYMPH NODE, POPLITEAL
MUSCLE, QUADRICEPS FEMORIS	MUSCLE, QUADRICEPS FEMORIS
NERVE, OPTIC	NERVE, OPTIC
NERVE, SCIATIC	NERVE, SCIATIC
NOSE	NOSE
OVARY	OVARY
OVIDUCT	OVIDUCT
PANCREAS	PANCREAS
PEYER'S PATCH	PEYER'S PATCH
PLASMA	PLASMA
SERUM	SERUM
SITE, MICROCHIP	SITE, MICROCHIP
SKIN	SKIN
SMALL INTESTINE, DUODENUM	SMALL INTESTINE, DUODENUM
SMALL INTESTINE, ILEUM	SMALL INTESTINE, ILEUM
SMALL INTESTINE, JEJUNUM	SMALL INTESTINE, JEJUNUM
SPINAL CORD, CERVICAL	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, LUMBAR
SPINAL CORD, THORACIC	SPINAL CORD, THORACIC
SPLEEN	SPLEEN
STOMACH	STOMACH
SUBCUTIS	SUBCUTIS
TESTIS	TESTIS
THYMUS	THYMUS
TONGUE	TONGUE
TRACHEA	TRACHEA
URETER	URETER
URINARY BLADDER	URINARY BLADDER
URINE	URINE
UTERUS	UTERUS
VAGINA	VAGINA
WHOLE BLOOD	WHOLE BLOOD
Laterality (CL.C99073.LAT)	
BILATERAL	BILATERAL
UNILATERAL	UNILATERAL
Severity (CL.C90000.SEV)	
MILD	MILD
MODERATE	MODERATE
SEVERE	SEVERE
Study Type (CL.C90003.SSTYP)	
SUBCHRONIC	SUBCHRONIC
Standardized Disposition Term (CL.C89968.DSDECOD)	
FOUND DEAD	FOUND DEAD
TERMINAL SACRIFICE	TERMINAL SACRIFICE
Microscopic Findings Test Code (CL.C89974.MITESTCD)	
MIEXAM	MIEXAM
Microscopic Findings Test Name (CL.C89973.MITEST)	
Microscopic Examination	Microscopic Examination
Microscopic Histopathology Result Category (CL.C90017.MIRESCAT)	
NON-NEOPLASTIC	NON-NEOPLASTIC
Organ Measurement Test Code (CL.C89977.OMTESTCD)	
OWBR	OWBR
OWBW	OWBW
WEIGHT	WEIGHT
Organ Measurement Test Name (CL.C89976.OMTEST)	
Organ to Body Weight Ratio	Organ to Body Weight Ratio

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
Organ to Brain Weight Ratio	Organ to Brain Weight Ratio
Weight	Weight
SEND Subject Characteristics Test Code (CL.C89981.SBCCDSND)	
SPLRNAM	SPLRNAM
SEND Subject Characteristics Test Name (CL.C89980.SBCSND)	
Test Subject Supplier Name	Test Subject Supplier Name
Body Weight Test Code (CL.C89962.BWTESTCD)	
BW	BW
TERMBW	TERMBW
Body Weight Test Name (CL.C89961.BWTEST)	
Body Weight	Body Weight
Terminal Body Weight	Terminal Body Weight
Body Weight Gain Test Code (CL.C89960.BGTESTCD)	
BWGAIN	BWGAIN
BWGAINA	BWGAINA
BWGAINP	BWGAINP
Body Weight Gain Test Name (CL.C89959.BGTEST)	
Average Body Weight Gain	Average Body Weight Gain
Body Weight Gain	Body Weight Gain
Percentage Body Weight Gain	Percentage Body Weight Gain
Laboratory Test Code (CL.C65047.LBTESTCD)	
ALB	ALB
ALBGLOB	ALBGLOB
ALP	ALP
ALT	ALT
AMORPHSD	AMORPHSD
ANISO	ANISO
APTT	APTT
AST	AST
BACT	BACT
BASO	BASO
BASOCE	BASOCE
BILI	BILI
BLAST	BLAST
BLASTLE	BLASTLE
BLSTNMCE	BLSTNMCE
BUN	BUN
CA	CA
CASULPH	CASULPH
CHOL	CHOL
CL	CL
CLARITY	CLARITY
COLOR	COLOR
CREAT	CREAT
CSEPI	CSEPI
CSFAT	CSFAT
CSGRAN	CSGRAN
CSHYAL	CSHYAL
CSRBC	CSRBC
CSWAX	CSWAX
CSWBC	CSWBC
CYBILI	CYBILI
CYCACAR	CYCACAR
CYCAOXA	CYCAOXA
CYCAPHOS	CYCAPHOS
CYCHOL	CYCHOL
CYCYSTIN	CYCYSTIN
CYSTARCH	CYSTARCH
CYTRPHOS	CYTRPHOS
CYTYRO	CYTYRO

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
CYURIAC	CYURIAC
EOS	EOS
EOSCE	EOSCE
EPIC	EPIC
EPISQCE	EPISQCE
EPITUCE	EPITUCE
FATACFR	FATACFR
FATDROP	FATDROP
FIBRINO	FIBRINO
GGT	GGT
GLOBUL	GLOBUL
GLUC	GLUC
HCT	HCT
HGB	HGB
HPOCROM	HPOCROM
HYPERCHR	HYPERCHR
K	K
KETONES	KETONES
LGLUCLE	LGLUCLE
LGUNSCE	LGUNSCE
LYM	LYM
LYMAT	LYMAT
LYMATLE	LYMATLE
LYMCE	LYMCE
MACROCY	MACROCY
MCH	MCH
MCHC	MCHC
MCV	MCV
METAMY	METAMY
METAMYCE	METAMYCE
MICROCY	MICROCY
MONO	MONO
MONOCE	MONOCE
MYCY	MYCY
MYCYCE	MYCYCE
NEUT	NEUT
NEUTCE	NEUTCE
OCCBLD	OCCBLD
PH	PH
PHOS	PHOS
PLAT	PLAT
PLATCLMP	PLATCLMP
PLATLRG	PLATLRG
PROMY	PROMY
PROMYCE	PROMYCE
PROT	PROT
PT	PT
RBC	RBC
RBCNUCLE	RBCNUCLE
RDW	RDW
RETI	RETI
RETIRBC	RETIRBC
SODIUM	SODIUM
SPERM	SPERM
SPGRAV	SPGRAV
TRIG	TRIG
VOLUME	VOLUME
WBC	WBC
YEAST	YEAST
Laboratory Test Name (CL.C67154.LBTEST)	

Controlled Terminology (Code Lists) Section

Code Value	Code Text
Activated Partial Thromboplastin Time	Activated Partial Thromboplastin Time
Alanine Aminotransferase	Alanine Aminotransferase
Albumin	Albumin
Albumin/Globulin	Albumin/Globulin
Alkaline Phosphatase	Alkaline Phosphatase
Amorphous Sediment	Amorphous Sediment
Anisocytes	Anisocytes
Aspartate Aminotransferase	Aspartate Aminotransferase
Bacteria	Bacteria
Basophils	Basophils
Basophils/Total Cells	Basophils/Total Cells
Bilirubin	Bilirubin
Bilirubin Crystals	Bilirubin Crystals
Blasts	Blasts
Blasts/Leukocytes	Blasts/Leukocytes
Blood Urea Nitrogen	Blood Urea Nitrogen
Calcium	Calcium
Calcium Carbonate Crystals	Calcium Carbonate Crystals
Calcium Oxalate Crystals	Calcium Oxalate Crystals
Calcium Phosphate Crystals	Calcium Phosphate Crystals
Calcium Sulphate	Calcium Sulphate
Chloride	Chloride
Cholesterol	Cholesterol
Cholesterol Crystals	Cholesterol Crystals
Clarity	Clarity
Color	Color
Creatinine	Creatinine
Cystine Crystals	Cystine Crystals
Eosinophils	Eosinophils
Eosinophils/Total Cells	Eosinophils/Total Cells
Epithelial Casts	Epithelial Casts
Epithelial Cells	Epithelial Cells
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	Erythrocytes
Erythrocytes Distribution Width	Erythrocytes Distribution Width
Fat Droplet	Fat Droplet
Fatty Casts	Fatty Casts
Fibrinogen	Fibrinogen
Free Fatty Acid	Free Fatty Acid
Gamma Glutamyl Transferase	Gamma Glutamyl Transferase
Globulin	Globulin
Glucose	Glucose
Granular Casts	Granular Casts
Hematocrit	Hematocrit
Hemoglobin	Hemoglobin
Hyaline Casts	Hyaline Casts
Hyperchromia	Hyperchromia
Hypochromia	Hypochromia
Ketones	Ketones
Large Platelets	Large Platelets
Large Unstained Cells	Large Unstained Cells
Large Unstained Cells/Leukocytes	Large Unstained Cells/Leukocytes
Leukocytes	Leukocytes
Lymphocytes	Lymphocytes
Lymphocytes Atypical	Lymphocytes Atypical
Lymphocytes Atypical/Leukocytes	Lymphocytes Atypical/Leukocytes

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
Lymphocytes/Total Cells	Lymphocytes/Total Cells
Macrocytes	Macrocytes
Metamyelocytes	Metamyelocytes
Metamyelocytes/Total Cells	Metamyelocytes/Total Cells
Microcytes	Microcytes
Monocytes	Monocytes
Monocytes/Total Cells	Monocytes/Total Cells
Myelocytes	Myelocytes
Myelocytes/Total Cells	Myelocytes/Total Cells
Neutrophils	Neutrophils
Neutrophils/Total Cells	Neutrophils/Total Cells
Normoblasts/Total Cells	Normoblasts/Total Cells
Nucleated Erythrocytes/Leukocytes	Nucleated Erythrocytes/Leukocytes
Occult Blood	Occult Blood
pH	pH
Phosphate	Phosphate
Platelet Clumps	Platelet Clumps
Platelets	Platelets
Potassium	Potassium
Promyelocytes	Promyelocytes
Promyelocytes/Total Cells	Promyelocytes/Total Cells
Protein	Protein
Prothrombin Time	Prothrombin Time
RBC Casts	RBC Casts
Reticulocytes	Reticulocytes
Reticulocytes/Erythrocytes	Reticulocytes/Erythrocytes
Sodium	Sodium
Specific Gravity	Specific Gravity
Spermatozoa	Spermatozoa
Squamous Epithelial Cells	Squamous Epithelial Cells
Starch Crystals	Starch Crystals
Triglycerides	Triglycerides
Triple Phosphate Crystals	Triple Phosphate Crystals
Tubular Epithelial Cells	Tubular Epithelial Cells
Tyrosine Crystals	Tyrosine Crystals
Uric Acid Crystals	Uric Acid Crystals
Volume	Volume
Waxy Casts	Waxy Casts
WBC Casts	WBC Casts
Yeast Cells	Yeast Cells
Food and Water Consumption Test Code (CL.C89970.FWTESTCD)	
FC	FC
FCRELBW	FCRELBW
FCRELD	FCRELD
FDEFF	FDEFF
Food and Water Consumption Test Name (CL.C89969.FWTEST)	
Food Consumption	Food Consumption
Food Consumption Relative to Body Wt	Food Consumption Relative to Body Wt
Food Consumption Relative to Day	Food Consumption Relative to Day
Food Utilization Efficiency	Food Utilization Efficiency
PK Parameter Units of Measure (CL.C85494.PKUNIT)	
h	h
h*ng/mL	h*ng/mL
ng/mL	ng/mL
PK Parameters Code (CL.C85839.PKPARMCD)	
AUCIFO	AUCIFO
AUCLST	AUCLST
AUCTAU	AUCTAU
CMAX	CMAX

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
TLST	TLST
TMAX	TMAX
PK Parameters (CL.C85493.PKPARM)	
AUC Infinity Obs	AUC Infinity Obs
AUC Over Dosing Interval	AUC Over Dosing Interval
AUC to Last Nonzero Conc	AUC to Last Nonzero Conc
Max Conc	Max Conc
Time of CMAX	Time of CMAX
Time of Last Nonzero Conc	Time of Last Nonzero Conc
SEND Trial Summary Parameter Test Code (CL.C90009.STSPRMCD)	
AGE	AGE
AGETXT	AGETXT
AGEU	AGEU
ALTSTDID	ALTSTDID
ASOCSTDY	ASOCSTDY
CLASS	CLASS
DOSDUR	DOSDUR
EXPENDTC	EXPENDTC
EXPSTDTC	EXPSTDTC
GLPTYP	GLPTYP
ROUTE	ROUTE
SDESIGN	SDESIGN
SNDCTVER	SNDCTVER
SNDIGVER	SNDIGVER
SPECIES	SPECIES
SPLRNAM	SPLRNAM
SPREFID	SPREFID
SSPONSOR	SSPONSOR
SSTYP	SSTYP
STCAT	STCAT
STDIR	STDIR
STENDTC	STENDTC
STITLE	STITLE
STRAIN	STRAIN
STSTDTC	STSTDTC
TFCNTRY	TFCNTRY
TRMSAC	TRMSAC
TRT	TRT
TRTCAS	TRTCAS
TRTV	TRTV
TSTFLOC	TSTFLOC
SEND Trial Summary Parameter Test Name (CL.C90007.STSPRM)	
Age	Age
Age Text	Age Text
Age Unit	Age Unit
Alternate Study ID	Alternate Study ID
Associated Study	Associated Study
Class Of Compound	Class Of Compound
Dosing Duration	Dosing Duration
Experimental End Date	Experimental End Date
Experimental Start Date	Experimental Start Date
Good Laboratory Practice Type	Good Laboratory Practice Type
Investigational Therapy or Treatment	Investigational Therapy or Treatment
Primary Treatment CAS Registry Number	Primary Treatment CAS Registry Number
Route of Administration	Route of Administration
SEND Controlled Terminology Version	SEND Controlled Terminology Version
SEND Implementation Guide Version	SEND Implementation Guide Version

Controlled Terminology (Code Lists) Section	
Code Value	**Code Text**
Species	Species
Sponsor's Reference ID	Sponsor's Reference ID
Sponsoring Organization	Sponsoring Organization
Strain/Substrain	Strain/Substrain
Study Category	Study Category
Study Design	Study Design
Study Director	Study Director
Study End Date	Study End Date
Study Start Date	Study Start Date
Study Title	Study Title
Study Type	Study Type
Test Facility Country	Test Facility Country
Test Facility Location	Test Facility Location
Test Subject Supplier	Test Subject Supplier
Time to Terminal Sacrifice	Time to Terminal Sacrifice
Treatment Vehicle	Treatment Vehicle
Domain Abbreviation (CL.C66734.DOMAIN)	
BG	BG
BW	BW
CL	CL
CO	CO
DM	DM
DS	DS
EX	EX
FW	FW
LB	LB
MA	MA
MI	MI
OM	OM
PC	PC
PP	PP
SC	SC
TS	TS