Company Name: Example Sponsor Inc.
Protocol: GLP003
Study: GLP003

Study description: XYZ-12345 One-Month Oral Toxicity Study in Rats with a Two-Week Recovery

## Datasets for Study: GLP003

| 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 |
| DD | DEATH DIAGNOSIS | Findings | One record per diagnosis per subject (for unscheduled deaths only) | Tabulation | STUDYID, USUBJID, DDORRES | dd.xpt |
| FW | FOOD AND WATER CONSUMPTION | Findings | One record per test per interval per subject or pool | Tabulation | STUDYID, USUBJID, POOLID, FWTESTCD, FWDTC, FWENDTC | fw.xpt |
| LB | LABORATORY TEST RESULTS | Findings | One record per test per specimen per observation time per subject or pool | Tabulation | STUDYID, USUBJID, POOLID, LBTESTCD, LBSPEC, LBMETHOD, LBSTRESU, LBDTC, LBENDTC, LBTPTNUM | lb.xpt |

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| Dataset | Description | Class | Structure | Purpose | Keys | Location |
|---|---|---|---|---|---|---|
| MA | MACROSCOPIC FINDINGS | Findings | One record per finding per specimen per subject | Tabulation | STUDYID, USUBJID, MATESTCD, MASPEC, MAANTREG, MALAT, MADIR, MAPORTOT, MASTRESC | ma.xpt |
| 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 |
| TF | TUMOR FINDINGS | Findings | One record per tumor per specimen per subject | Tabulation | STUDYID, USUBJID, TFTESTCD, TFSPEC, TFANTREG, TFLAT, TFDIR, TFSTRESC, TFMETHOD | tf.xpt |
| POOLDEF | POOLED DEFINITION | Relationship | One record per subject per pool | Tabulation | STUDYID, USUBJID, POOLID | pooldef.xpt |
| RELREC | RELATED RECORDS | Relationship | One record per related record, related group of records, or related dataset | Tabulation | STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, RELID | relrec.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 |

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## 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 | |
| TABRANCH | Branch | text | | OTHER | Rule | Not populated |
| TATRANS | Transition Rule | text | | OTHER | Rule | Not populated |
| EPOCH | Trial Epoch | text | | OTHER | Timing | |

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## 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 | |

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## TRIAL SUMMARY Dataset (TS)[ts.xpt](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 | |

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## 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 | |

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## 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 |
| POOLID | Pool Identifier | text | | OTHER | | |
| 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 | |
| COREF | Comment Reference | text | | OTHER | Record Qualifier | Not populated |
| COVAL | Comment | text | | COLLECTED | Topic | |
| COEVAL | Evaluator | text | | OTHER | Record Qualifier | Not populated |
| CODTC | Date/Time of Comment | datetime | ISO8601 | COLLECTED | Timing | |
| CODY | Study Day of Comment | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |

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## DEMOGRAPHICS Dataset (DM)[dm.xpt](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 | datetime | 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 |
| AGETXT | Age Range | text | | OTHER | Record Qualifier | This is populated only if an age range rather than a specific age or birth date is recorded for the study animals |
| AGEU | Age Unit | text | AGEU | OTHER | Variable Qualifier | |
| SEX | Sex | text | SEX | COLLECTED | Record Qualifier | |
| SPECIES | Species | text | SPECIES | OTHER | Record Qualifier | If not populated, see the TS domain entry. |
| STRAIN | Strain/Substrain | text | STRAIN | OTHER | Record Qualifier | If not populated, see the TS domain entry. |
| SBSTRAIN | Strain/Substrain Details | text | | OTHER | Record Qualifier | Not populated |
| ARMCD | Planned Arm Code | text | | OTHER | Record Qualifier | |
| ARM | Description of Planned Arm | text | | OTHER | Synonym Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|----------|-------|------|---------------------------|--------|------|---------|
| SETCD | Set Code | text | | OTHER | Record Qualifier | |

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## 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 | |
| SEUPDES | Description of Unplanned Element | text | | OTHER | Synonym Qualifier | |

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## EXPOSURE Dataset (EX)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 |
| POOLID | Pool Identifier | text | | OTHER | Identifier | Not populated |
| 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 |
| EXDOSTXT | Dose Description | text | | OTHER | Record Qualifier | Not Populated |
| EXDOSU | Dose Units | text | UNIT | COLLECTED | Variable Qualifier | |
| EXDOSFRM | Dose Form | text | FRM | 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 | |
| EXLOC | Location of Dose Administration | text | | COLLECTED | Record Qualifier | |
| EXMETHOD | Method of Administration | text | | OTHER | Record Qualifier | Not populated |
| EXTRTV | Treatment Vehicle | text | | OTHER | Record Qualifier | |
| EXVAMT | Amount Administered | integer | | COLLECTED | Variable Qualifier | |
| EXVAMTU | Amount Administered Units | text | UNIT | COLLECTED | Variable Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| EXADJ | Reason for Dose Adjustment | text | | COLLECTED | Record Qualifier | |
| EXSTDTC | Start Date/Time of Treatment | date | ISO8601 | COLLECTED | Timing | |
| EXENDTC | End Date/Time of Treatment | date | ISO8601 | COLLECTED | Timing | |
| EXSTDY | Study Day of Start of Treatment | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPSTDY |
| EXENDY | Study Day of End of Treatment | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPENDY |
| EXDUR | Duration of Treatment | text | ISO8601 | OTHER | Timing | |
| EXTPT | Planned Time Point Name | text | | COLLECTED | Timing | |
| EXTPTNUM | Planned Time Point Number | integer | | OTHER | Timing | See Computational Method: COMPMETHOD.COMPTPTNUM |
| EXELTM | Planned Elapsed Time from Time Point Ref | text | | OTHER | Timing | Not populated |
| EXTPTREF | Time Point Reference | text | | OTHER | Timing | Not populated |
| EXRFTDTC | Date/Time of Reference Time Point | datetime | ISO8601 | OTHER | Timing | Not populated |

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## DISPOSITION Dataset (DS)[ds.xpt](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 |

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## 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 | integer | | DERIVED | Result Qualifier | See Computational Method: COMPMETHOD.COMPSTRESN |
| BGSTRESU | Unit of the Standardized Result | text | UNIT | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPSTRESU |
| BGSTAT | Examination Status | text | ND | OTHER | Record Qualifier | Not populated |
| BGREASND | Reason Not Done | text | | OTHER | Record Qualifier | Not populated |
| BGEXCLFL | Exclusion Flag | text | NY | COLLECTED | Record Qualifier | |
| BGREASEX | Reason for Exclusion | text | | COLLECTED | Record Qualifier | |
| BGDTC | Date/Time Animal Weighed | date | ISO8601 | COLLECTED | Timing | |
| BGENDTC | End Date/Time Animal Weighed | date | ISO8601 | COLLECTED | Timing | |
| BGDY | Study Day Animal Weighed | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| 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 |
| BGTPTREF | Time Point Reference | text | | OTHER | Timing | Not populated |
| BGRFTDTC | Date/Time of Reference Time Point | datetime | ISO8601 | OTHER | Timing | Not populated |

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## 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 |
| BWSTAT | Examination Status | text | ND | COLLECTED | Record Qualifier | |
| BWREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| BWBLFL | Baseline Flag | text | NY | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPBLFL |
| BWFAST | Fasting Status | text | NY | COLLECTED | Record Qualifier | |
| BWEXCLFL | Exclusion Flag | text | NY | COLLECTED | Record Qualifier | |
| BWREASEX | Reason for Exclusion | text | | COLLECTED | Record Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| 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 |

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## CLINICAL OBSERVATIONS Dataset (CL)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 |
| POOLID | Pool Identifier | text | | OTHER | Identifier | Not populated |
| CLSEQ | Sequence Number | integer | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPSEQ |
| CLGRPID | Group Identifier | text | | OTHER | Identifier | Not populated |
| CLSPID | Mass Identifier | text | | OTHER | Identifier | |
| 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 |
| CLBODSYS | Body System or Organ Class | text | | OTHER | Record Qualifier | |
| 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 | |
| CLRESCAT | Result Category | text | | OTHER | Variable Qualifier | Not populated |
| CLSTAT | Examination Status | text | ND | COLLECTED | Record Qualifier | |
| CLREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| CLLOC | Location of a Finding | text | | COLLECTED | Record Qualifier | |
| CLEVAL | Evaluator | text | | OTHER | Record Qualifier | Not populated |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| CLSEV | Severity | text | | COLLECTED | Record Qualifier | |
| CLEXCLFL | Exclusion Flag | text | NY | OTHER | Record Qualifier | Not populated |
| CLREASEX | Reason for Exclusion | text | | OTHER | Record Qualifier | Not populated |
| 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 |
| CLELTM | Planned Elapsed Time from Time Point Ref | text | | OTHER | Timing | Not populated |
| CLTPTREF | Time Point Reference | text | | OTHER | Timing | Not populated |
| CLRFTDTC | Date/Time of Reference Time Point | datetime | ISO8601 | OTHER | Timing | Not populated |

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## DEATH DIAGNOSIS Dataset (DD)dd.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 |
| DDSEQ | Sequence Number | integer | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPSEQ |
| DDTESTCD | Death Diagnosis Short Name | text | DDTESTCD | DERIVED | Topic | Mapped from test name used during data collection |
| DDTEST | Death Diagnosis Name | text | DDTEST | OTHER | Synonym Qualifier | |
| DDORRES | Result or Findings as Collected | text | | COLLECTED | Result Qualifier | |
| DDSTRESC | Standardized Result in Character Format | text | | DERIVED | Result Qualifier | See Computational Method: COMPMETHOD.COMPSTRESC |
| DDRESCAT | Result Category | text | | OTHER | Variable Qualifier | |
| DDEVAL | Evaluator | text | | OTHER | Record Qualifier | Not populated |
| DDDTC | Date/time of Diagnosis | datetime | ISO8601 | COLLECTED | Timing | |
| DDDY | Study Day of Diagnosis | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |

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Study: GLP003

## FOOD AND WATER CONSUMPTION Dataset (FW)[fw.xpt](fw.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 |
| POOLID | Pool Identifier | text | | OTHER | Identifier | |
| FWSEQ | Sequence Number | integer | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPSEQ |
| FWGRPID | Group Identifier | text | | OTHER | Identifier | Not populated |
| FWTESTCD | Food /Water Consumption Short Name | text | FWTESTCD | DERIVED | Topic | Mapped from test name used during data collection |
| FWTEST | Food /Water Consumption Name | text | FWTEST | OTHER | Synonym Qualifier | |
| FWORRES | Result or Findings as Collected | text | | COLLECTED | Result Qualifier | |
| FWORRESU | Unit of the Original Result | text | UNIT | COLLECTED | Variable Qualifier | |
| FWSTRESC | Standardized Result in Character Format | text | | DERIVED | Result Qualifier | See Computational Method: COMPMETHOD.COMPFWPERDAY |
| FWSTRESN | Standardized Result in Numeric Format | float | | DERIVED | Result Qualifier | See Computational Method: COMPMETHOD.COMPSTRESN |
| FWSTRESU | Unit of the Standardized Result | text | UNIT | OTHER | Variable Qualifier | FWORRESU/animal/day |
| FWSTAT | Completion Status | text | ND | COLLECTED | Record Qualifier | |
| FWREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| FWEXCLFL | Exclusion Flag | text | NY | COLLECTED | Record Qualifier | |
| FWREASEX | Reason for Exclusion | text | | COLLECTED | Record Qualifier | |
| FWDTC | Date/Time of Observation | datetime | ISO8601 | COLLECTED | Timing | |
| FWENDTC | End Date/Time of Observation | datetime | ISO8601 | COLLECTED | Timing | |

Company Name: Example Sponsor Inc.
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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| FWDY | Study Day of Observation | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |
| FWENDY | Study Day of End of Observation | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPENDY |

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## LABORATORY TEST RESULTS Dataset (LB)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 |
| POOLID | Pool Identifier | text | | OTHER | Identifier | Not populated |
| 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 | |
| LBSPID | Sponsor-Defined Identifier | text | | OTHER | Identifier | Not populated |
| 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 | |
| LBORNRLO | Reference Range Lower Limit-Orig Unit | text | | OTHER | Variable Qualifier | Not populated |
| LBORNRHI | Reference Range Upper Limit-Orig Unit | text | | OTHER | Variable Qualifier | Not populated |
| 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 |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| LBSTNRLO | Reference Range Lower Limit-Std Unit | integer | | OTHER | Variable Qualifier | Not populated |
| LBSTNRHI | Reference Range Upper Limit-Std Unit | integer | | OTHER | Variable Qualifier | Not populated |
| LBSTNRC | Reference Range for Char Rslt-Std Unit | text | | OTHER | Variable Qualifier | Not populated |
| LBNRIND | Reference Range Indicator | text | | OTHER | Variable Qualifier | Not populated |
| LBSTAT | Completion Status | text | ND | COLLECTED | Record Qualifier | |
| LBREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| LBNAM | Vendor Name | text | | OTHER | Record Qualifier | Not populated |
| LBSPEC | Specimen Type | text | SPEC | DERIVED | Record Qualifier | Derived from the test name used during sample collection |
| LBANTREG | Anatomical Region of Specimen | text | | OTHER | Variable Qualifier | Not populated |
| LBSPCCND | Specimen Condition | text | | OTHER | Variable Qualifier | |
| LBSPCUFL | Specimen Usability for the Test | text | NY | OTHER | Variable Qualifier | |
| LBLOC | Specimen Collection Location | text | | OTHER | Record Qualifier | |
| LBLAT | Specimen Laterality within Subject | text | LAT | OTHER | Variable Qualifier | Not populated |
| LBDIR | Specimen Directionality within Subject | text | | OTHER | Variable Qualifier | Not populated |
| LBPORTOT | Portion or Totality | text | | OTHER | Variable Qualifier | Not populated |
| LBMETHOD | Method of Test or Examination | text | | OTHER | Record Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| LBBLFL | Baseline Flag | text | NY | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPBLFL |
| LBFAST | Fasting Status | text | NY | COLLECTED | Record Qualifier | |
| LBDRVFL | Derived Flag | text | NY | OTHER | Record Qualifier | |
| LBTOX | Toxicity | text | | OTHER | Variable Qualifier | Not populated |
| LBTOXGR | Standard Toxicity Grade | text | | OTHER | Variable Qualifier | Not populated |
| LBEXCLFL | Exclusion Flag | text | NY | COLLECTED | Record Qualifier | |
| LBREASEX | Reason for Exclusion | text | | COLLECTED | Record Qualifier | |
| VISITDY | Planned Study Day of Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPVISITDY |
| LBDTC | Date/Time of Specimen Collection | datetime | ISO8601 | COLLECTED | Timing | |
| LBENDTC | End Date/Time of Specimen Collection | datetime | ISO8601 | COLLECTED | Timing | |
| LBDY | Study Day of Specimen Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |
| LBENDY | Study Day of End of Specimen Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPENDY |
| LBTPT | Planned Time Point Name | text | | COLLECTED | Timing | |
| LBTPTNUM | Planned Time Point Number | integer | | OTHER | Timing | See Computational Method: COMPMETHOD.COMPTPTNUM |
| LBELTM | Planned Elapsed Time from Time Point Ref | text | | OTHER | Timing | Not populated |
| LBTPTREF | Time Point Reference | text | | OTHER | Timing | |
| LBRFTDTC | Date/Time of Reference Time Point | datetime | ISO8601 | OTHER | Timing | Not populated |

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## 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 |
| MASPID | Mass Identifier | text | | COLLECTED | Identifier | |
| 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 | |
| MABODSYS | Body System or Organ Class | text | | OTHER | Record 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 | |
| MASTAT | Examination Status | text | ND | COLLECTED | Record Qualifier | |
| MAREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| MANAM | Laboratory Name | text | | OTHER | Record Qualifier | Not populated |
| 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 |
| MASPCCND | Specimen Condition | text | | OTHER | Variable Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| MASPCUFL | Specimen Usability for the Test | text | NY | OTHER | Variable Qualifier | |
| MALAT | Specimen Laterality within Subject | text | LAT | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| MADIR | Specimen Directionality within Subject | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| MAPORTOT | Portion or Totality | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| MAEVAL | Evaluator | text | | OTHER | Record Qualifier | Not populated |
| MASEV | Severity | text | SEV | COLLECTED | Record Qualifier | |
| MADTHREL | Relationship to Death | text | NY | COLLECTED | Record Qualifier | |
| MADTC | Date/Time of Collection | date | ISO8601 | COLLECTED | Timing | |
| MADY | Study Day of Specimen Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |
| Supplemental Qualifier Dataset (SUPPMA) | | | | | | |

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## 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 |
| MISPID | Mass Identifier | text | | COLLECTED | Identifier | |
| 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 | |
| MIBODSYS | Body System or Organ Class | text | | OTHER | Record 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 | NEOPLASM | COLLECTED | Result Qualifier | |
| MIRESCAT | Result Category | text | | COLLECTED | Variable Qualifier | |
| MISTAT | Completion Status | text | ND | COLLECTED | Record Qualifier | |
| MIREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| MINAM | Laboratory Name | text | | OTHER | Record Qualifier | Not populated |
| MISPEC | Specimen Material Type | text | SPEC | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| MIANTREG | Anatomical Region of Specimen | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| MISPCCND | Specimen Condition | text | | OTHER | Variable Qualifier | |
| MISPCUFL | Specimen Usability for the Test | text | NY | OTHER | Variable Qualifier | |
| MIMETHOD | Method of Test or Examination | text | | OTHER | Record Qualifier | |
| MILAT | Specimen Laterality within Subject | text | LAT | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| MIDIR | Specimen Directionality within Subject | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| MIEVAL | Evaluator | text | | OTHER | Record Qualifier | Not populated |
| MISEV | Severity | text | SEV | COLLECTED | Record Qualifier | |
| MIDTHREL | Relationship to Death | text | NY | COLLECTED | Record Qualifier | |
| MIDTC | Date/Time of Specimen Collection | date | ISO8601 | COLLECTED | Timing | |
| MIDY | Study Day of Specimen Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |
| Supplemental Qualifier Dataset (SUPPMI) | | | | | | |

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## 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 |
| OMSTAT | Finding Status | text | ND | COLLECTED | Record Qualifier | |
| OMREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| OMSPEC | Specimen Material Type | text | SPEC | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| OMANTREG | Anatomical Region of Specimen | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| OMSPCCND | Specimen Condition | text | | OTHER | Variable Qualifier | |
| OMSPCUFL | Specimen Usability for the Test | text | NY | OTHER | Variable Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| OMLAT | Specimen Laterality within Subject | text | LAT | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| OMDIR | Specimen Directionality within Subject | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| OMPORTOT | Portion or Totality | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| OMEXCLFL | Exclusion Flag | text | NY | COLLECTED | Record Qualifier | |
| OMREASEX | Reason for Exclusion | text | | COLLECTED | Record Qualifier | |
| OMDTC | Date/Time Organ Weighed | date | ISO8601 | COLLECTED | Timing | |
| OMDY | Study Day of Weighing | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |

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# 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 |
| POOLID | Pool Identifier | text | | OTHER | Identifier | |
| PCSEQ | Sequence Number | integer | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPSEQ |
| PCGRPID | Group Identifier | text | | OTHER | Identifier | Not populated |
| PCREFID | Sample Identifier | text | | OTHER | Identifier | |
| PCSPID | Sponsor Identifier | text | | OTHER | Identifier | |
| PCTESTCD | Test Short Name | text | | DERIVED | Topic | Mapped from test name used during data collection |
| PCTEST | Test Name | text | | OTHER | Synonym Qualifier | |
| PCCAT | Test Category | text | | OTHER | Grouping Qualifier | |
| PCSCAT | Test Subcategory | text | | OTHER | Grouping Qualifier | Not populated |
| 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 | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| PCNAM | Vendor Name | text | | OTHER | Record Qualifier | Not populated |
| PCSPEC | Specimen Material Type | text | SPEC | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| PCSPCCND | Specimen Condition | text | | COLLECTED | Variable Qualifier | |
| PCMETHOD | Method of Test or Examination | text | | OTHER | Record Qualifier | |
| PCBLFL | Baseline Flag | text | NY | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPBLFL |
| PCFAST | Fasting Status | text | NY | COLLECTED | Record Qualifier | |
| PCDRVFL | Derived Flag | text | NY | OTHER | Record Qualifier | |
| PCLLOQ | Lower Limit of Quantitation | integer | | OTHER | Variable Qualifier | |
| PCEXCLFL | Exclusion Flag | text | NY | COLLECTED | Record Qualifier | |
| PCREASEX | Reason for Exclusion | text | | COLLECTED | Record Qualifier | |
| VISITDY | Visit Day | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPVISITDY |
| PCDTC | Date/Time of Specimen Collection | date | ISO8601 | COLLECTED | Timing | |
| PCENDTC | End Date/Time of Specimen Collection | datetime | ISO8601 | COLLECTED | Timing | |
| PCDY | Study Day of Specimen Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |
| PCENDY | Study Day of End of Specimen Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPENDY |
| PCTPT | Planned Time Point Name | text | | COLLECTED | Timing | |
| PCTPTNUM | Planned Time Point Number | float | | OTHER | Timing | See Computational Method: COMPMETHOD.COMPTPTNUM |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| PCELTM | Planned Elapsed Time from Time Point Ref | text | | DERIVED | Timing | |
| PCTPTREF | Time Point Reference | text | | OTHER | Timing | |
| PCRFTDTC | Date/Time of Reference Point | date | ISO8601 | COLLECTED | Timing | |
| PCEVLINT | Evaluation Interval | text | | OTHER | Timing | |

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## 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 |
| POOLID | Pool Identifier | text | | OTHER | Identifier | |
| PPSEQ | Sequence Number | integer | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPSEQ |
| PPGRPID | Group Identifier | text | | OTHER | Identifier | Not populated |
| 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 | |
| PPSCAT | Parameter Subcategory | 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 | integer | | 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 |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| 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 | date | ISO8601 | COLLECTED | Timing | |
| PPSTINT | Start of Evaluation Interval | text | | OTHER | Timing | |
| PPENINT | End of Evaluation Interval | text | | OTHER | Timing | |

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# TUMOR FINDINGS Dataset (TF)tf.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 |
| TFSEQ | Sequence Number | integer | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPSEQ |
| TFGRPID | Group Identifier | text | | OTHER | Identifier | Not populated |
| TFREFID | Specimen Identifier | text | | OTHER | Identifier | Not populated |
| TFSPID | Mass Number | text | | COLLECTED | Identifier | |
| TFTESTCD | Tumor Examination Short Name | text | TFTESTCD | DERIVED | Topic | Mapped from test name used during data collection |
| TFTEST | Tumor Examination | text | TFTEST | OTHER | Synonym Qualifier | |
| TFORRES | Result or Findings as Collected | text | | DERIVED | Result Qualifier | A concatenation of the individual observation components collected |
| TFSTRESC | Standardized Result in Character Format | text | NEOPLASM | COLLECTED | Result Qualifier | |
| TFRESCAT | Tumor Malignancy Status | text | NEOSTAT | COLLECTED | Variable Qualifier | |
| TFSTAT | Completion Status | text | ND | COLLECTED | Record Qualifier | |
| TFREASND | Reason Not Done | text | | COLLECTED | Record Qualifier | |
| TFNAM | Laboratory Name | text | | OTHER | Record Qualifier | Not populated |
| TFSPEC | Specimen Material Type | text | SPEC | DERIVED | Record Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| TFANTREG | Anatomical Region of Specimen | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| TFSPCCND | Specimen Condition | text | | OTHER | Variable Qualifier | |
| TFMETHOD | Method of Test or Examination | text | | OTHER | Record Qualifier | |

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| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| TFLAT | Specimen Laterality within Subject | text | LAT | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| TFDIR | Specimen Directionality within Subject | text | | DERIVED | Variable Qualifier | See Computational Method: COMPMETHOD.COMPTISSUE |
| TFEVAL | Evaluator | text | | OTHER | Record Qualifier | Not populated |
| TFDTHREL | Relationship to Death | text | NY | COLLECTED | Record Qualifier | |
| TFDTC | Date/Time of Collection | date | ISO8601 | COLLECTED | Timing | |
| TFDY | Study Day of Collection | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPDY |
| TFDETECT | Time in Days to Detection of Tumor | integer | | DERIVED | Timing | See Computational Method: COMPMETHOD.COMPTFDETECT |

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## POOLED DEFINITION Dataset (POOLDEF)[pooldef.xpt](pooldef.xpt)

| 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 | See Computational Method: COMPMETHOD.COMPUSUBJID |

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## RELATED RECORDS Dataset (RELREC)relrec.xpt

| Variable | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|
| STUDYID | Study Identifier | text | | OTHER | Identifier | |
| RDOMAIN | Related Domain Abbreviation | text | DOMAIN | OTHER | | |
| USUBJID | Unique Subject Identifier | text | | OTHER | Identifier | See Computational Method: COMPMETHOD.COMPUSUBJID |
| POOLID | Pool Identifier | text | | OTHER | | |
| IDVAR | Identifying Variable | text | | OTHER | | |
| IDVARVAL | Identifying Variable Value | text | | OTHER | | |
| RELTYPE | Relationship Type | text | RELTYPE | OTHER | | Not populated |
| RELID | Relationship Identifier | text | | OTHER | | |

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## SUPPLEMENTAL QUALIFIERS FOR MA Dataset (SUPPMA)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 |
| POOLID | Pool Identifier | text | | OTHER | | |
| 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 | Not populated |
| QEVAL | Evaluator | text | | OTHER | Synonym Qualifier | Not populated |

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## 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 |
| POOLID | Pool Identifier | text | | OTHER | | |
| 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 | Not populated |
| QEVAL | Evaluator | text | | OTHER | Synonym Qualifier | Not populated |

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## 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 | |

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## 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 | |

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## 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 | OPHTHALMOLOGY | OPHTHALMOLOGY | text | | OTHER | Grouping Qualifier | |
| CLCAT | PHYSICAL EXAM | PHYSICAL EXAM | text | | OTHER | Grouping Qualifier | |

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

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| CLTESTCD | CO | Clinical Observation | text | | DERIVED | Topic | |
| CLTESTCD | UVBS | Unscheduled Vet Exams | text | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.CL.CLCAT.OPHTHALMOLOGY.CLTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| CLTESTCD | EOBS | Ophthalmologic Examinations | text | | DERIVED | Topic | |

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

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| CLTESTCD | VOBS | Veterinary Examinations | text | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.DD.DDTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| DDTESTCD | DEATHD | Death Diagnosis | text | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.FW.FWTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| FWTESTCD | FC | Food Consumption | float | | DERIVED | Topic | |
| FWTESTCD | WC | Water Consumption | float | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.LB.LBCAT)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| LBCAT | COAGULATION | COAGULATION | float | | OTHER | Grouping Qualifier | |
| LBCAT | HEMATOLOGY | HEMATOLOGY | text | | OTHER | Grouping Qualifier | |
| LBCAT | SERUM CHEMISTRY | SERUM CHEMISTRY | float | | OTHER | Grouping Qualifier | |
| LBCAT | URINALYSIS | URINALYSIS | text | | OTHER | Grouping Qualifier | |

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## 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 | |

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## Value Level Metadata ( ValueList.LB.LBCAT.HEMATOLOGY.LBTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| LBTESTCD | ANISO | Anisocytes | text | | DERIVED | Topic | |
| LBTESTCD | BASO | Basophils | float | | DERIVED | Topic | |
| LBTESTCD | EOS | Eosinophils | float | | DERIVED | Topic | |
| LBTESTCD | HCT | Hematocrit | float | | DERIVED | Topic | |
| LBTESTCD | HGB | Hemoglobin | float | | DERIVED | Topic | |
| LBTESTCD | LGUNSCE | Large Unstained Cells | float | | DERIVED | Topic | |
| LBTESTCD | LYM | Lymphocytes | float | | DERIVED | Topic | |
| LBTESTCD | MCH | Ery. Mean Corpuscular Hemoglobin | float | | DERIVED | Topic | |
| LBTESTCD | MCHC | Ery. Mean Corpuscular HGB Concentration | float | | DERIVED | Topic | |
| LBTESTCD | MCV | Ery. Mean Corpuscular Volume | float | | DERIVED | Topic | |
| LBTESTCD | MONO | Monocytes | float | | DERIVED | Topic | |
| LBTESTCD | NEUT | Neutrophils | float | | DERIVED | Topic | |
| LBTESTCD | PLAT | Platelets | integer | | DERIVED | Topic | |
| LBTESTCD | PLATM | Platelet Morphology | text | | DERIVED | Topic | |
| LBTESTCD | POIKILO | Poikilocytes | text | | DERIVED | Topic | |
| LBTESTCD | POLYCHR | Polychromasia | text | | DERIVED | Topic | |
| LBTESTCD | RBC | Erythrocytes | float | | DERIVED | Topic | |
| LBTESTCD | RBCINCL | RBC Inclusions | text | | DERIVED | Topic | |
| LBTESTCD | RBCMORPH | Erythrocyte Cell Morphology | text | | DERIVED | Topic | |
| LBTESTCD | RDW | Erythrocytes Distribution Width | float | | DERIVED | Topic | |

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| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| LBTESTCD | RETI | Reticulocytes | float | | DERIVED | Topic | |
| LBTESTCD | RETIRBC | Reticulocytes/ Erythrocytes | float | | DERIVED | Topic | |
| LBTESTCD | WBC | Leukocytes | float | | DERIVED | Topic | |
| LBTESTCD | WBCMORPH | Leukocyte Cell Morphology | text | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.LB.LBCAT.SERUM 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 | CL | Chloride | integer | | DERIVED | Topic | |
| LBTESTCD | CREAT | Creatinine | float | | 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 | |

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## Value Level Metadata ( ValueList.LB.LBCAT.URINALYSIS.LBTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| LBTESTCD | BACT | Bacteria | text | | DERIVED | Topic | |
| LBTESTCD | BILI | Bilirubin | text | | DERIVED | Topic | |
| LBTESTCD | CASTS | Casts | text | | DERIVED | Topic | |
| LBTESTCD | CLARITY | Clarity | text | | DERIVED | Topic | |
| LBTESTCD | COLOR | Color | text | | DERIVED | Topic | |
| LBTESTCD | CRYOTHER | Other Crystals | text | | DERIVED | Topic | |
| LBTESTCD | CYAMORPH | Amorphous Crystals | text | | DERIVED | Topic | |
| LBTESTCD | CYCACAR | Calcium Carbonate Crystals | text | | DERIVED | Topic | |
| LBTESTCD | CYCAOXA | Calcium Oxalate Crystals | text | | DERIVED | Topic | |
| LBTESTCD | CYTRPHOS | Triple Phosphate Crystals | text | | DERIVED | Topic | |
| LBTESTCD | EPIC | Epithelial Cells | text | | DERIVED | Topic | |
| LBTESTCD | GLUC | Glucose | text | | DERIVED | Topic | |
| LBTESTCD | KETONES | Ketones | text | | DERIVED | Topic | |
| LBTESTCD | MISC | Miscellaneous Cell Types | text | | DERIVED | Topic | |
| LBTESTCD | OCCBLD | Occult Blood | text | | DERIVED | Topic | |
| LBTESTCD | PH | pH | float | | DERIVED | Topic | |
| LBTESTCD | PROT | Protein | integer | | DERIVED | Topic | |
| LBTESTCD | RBC | Erythrocytes | text | | DERIVED | Topic | |
| LBTESTCD | SPERM | Spermatozoa | text | | DERIVED | Topic | |
| LBTESTCD | SPGRAV | Specific Gravity | float | | DERIVED | Topic | |
| LBTESTCD | UROBIL | Urobilinogen | float | | DERIVED | Topic | |
| LBTESTCD | VOLUME | Volume | integer | | DERIVED | Topic | |
| LBTESTCD | WBC | Leukocytes | text | | DERIVED | Topic | |

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## 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 | |

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## 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 | |

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## Value Level Metadata ( ValueList.OM.OMTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| OMTESTCD | WEIGHT | Weight | float | | DERIVED | Topic | See Computational Method: COMPMETHOD.COMPSTRESC |

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## Value Level Metadata ( ValueList.PC.PCCAT)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| PCCAT | ANALYTE | ANALYTE | text | | OTHER | Grouping Qualifier | |

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## Value Level Metadata ( ValueList.PC.PCCAT.ANALYTE.PCTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| PCTESTCD | XYZ12345 | XYZ-12345 | text | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.PP.PPCAT)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| PPCAT | XYZ-12345 | XYZ-12345 | integer | | OTHER | Grouping Qualifier | |

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## Value Level Metadata ( ValueList.PP.PPCAT.XYZ-12345.PPTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| PPTESTCD | AUCALL | AUC All | integer | | DERIVED | Topic | |
| PPTESTCD | CMAX | Max Conc | integer | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.SUPPMA.QNAM)

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

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## 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) | | | | | | | |

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## Value Level Metadata ( ValueList.TF.TFTESTCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| TFTESTCD | TUMEX | Tumor Examination | text | | DERIVED | Topic | |

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## Value Level Metadata ( ValueList.TS.TSPARMCD)

| Source Variable | Value | Label | Type | Controlled Terms or Format | Origin | Role | Comment |
|---|---|---|---|---|---|---|---|
| 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 | ROUTE | Route of Administration | text | ROUTE | OTHER | Topic | |
| TSPARMCD | SDESIGN | Study Design | text | DESIGN | OTHER | Topic | |
| TSPARMCD | SLENGTH | Study Length | text | | 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 | SPLANSUB | Planned Number of Subjects | integer | | 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 | |

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| 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 | TSTFLOC | Test Facility Location | text | | OTHER | Topic | |
| TSPARMCD | TSTFNAM | Test Facility Name | text | | OTHER | Topic | |

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## 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 | |

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## 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.COMPFWPERDAY | The total amount of food consumed during the interval divided by the number of animals in the cage * number of cage days in the interval |
| 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.COMPTFDETECT | Earliest day of any study finding that is correlated to the tumor finding |
| 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. |

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

| Code Value | Code Text |
|------------|-----------|
| DAYS | Day |
| WEEKS | Week |

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

| Code Value | Code Text |
| --- | --- |
| Body Weight Gain | Body Weight Gain |

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

| Code Value | Code Text |
|---|---|
| BWGAIN | Body Weight Gain |

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

| Code Value | Code Text |
|---|---|
| Body Weight | Body Weight |
| Terminal Body Weight | Terminal Body Weight |

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

| Code Value | Code Text |
|---|---|
| BW | Body Weight |
| TERMBW | Terminal Body Weight |

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

| Code Value | Code Text |
|---|---|
| CLINICAL SIGNS | Clinical Signs |
| OPHTHALMOLOGY | Ophthalmology |
| PHYSICAL EXAM | Physical Exam |

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

| Code Value | Code Text |
|------------|-----------|
| USA | UNITED STATES |

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## Controlled Terminology (Code Lists) Section
DDTEST, Reference Name (DDTEST)

| Code Value | Code Text |
|---|---|
| Death Diagnosis | Death Diagnosis |

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## Controlled Terminology (Code Lists) Section
DDTESTCD, Reference Name (DDTESTCD)

| Code Value | Code Text |
|------------|-----------|
| DEATHD | Death Diagnosis |

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

| Code Value | Code Text |
|---|---|
| PARALLEL | PARALLEL |

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

| Code Value | Code Text |
|---|---|
| BG | BODY WEIGHT GAIN |
| BW | BODY WEIGHT |
| CL | CLINICAL OBSERVATIONS |
| CO | COMMENTS |
| DD | DEATH DIAGNOSIS |
| DM | DEMOGRAPHICS |
| DS | DISPOSITION |
| EX | EXPOSURE |
| FW | FOOD AND WATER CONSUMPTION |
| LB | LABORATORY TEST RESULTS |
| MA | MACROSCOPIC FINDINGS |
| MI | MICROSCOPIC FINDINGS |
| OM | ORGAN MEASUREMENTS |
| PC | PHARMACOKINETICS CONCENTRATIONS |
| POOLDEF | POOLED DEFINITION |
| PP | PHARMACOKINETICS PARAMETERS |
| RELREC | RELATED RECORDS |
| SE | SUBJECT ELEMENTS |
| SUPPMA | SUPPLEMENTAL QUALIFIERS FOR MA |
| SUPPMI | SUPPLEMENTAL QUALIFIERS FOR MI |
| TA | TRIAL ARMS |
| TE | TRIAL ELEMENTS |
| TF | TUMOR FINDINGS |
| TS | TRIAL SUMMARY |
| TX | TRIAL SETS |

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

| Code Value | Code Text |
|---|---|
| MORIBUND SACRIFICE | MORIBUND SACRIFICE |
| RECOVERY SACRIFICE | Planned Recovery Sacrifice |
| TERMINAL SACRIFICE | Planned Terminal Sacrifice |

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

| Code Value | Code Text |
|---|---|
| QD | Daily; Per Day |

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## Controlled Terminology (Code Lists) Section
FRM, Reference Name (FRM)

| Code Value | Code Text |
|---|---|
| SUSPENSION | susp |

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## Controlled Terminology (Code Lists) Section
FWTEST, Reference Name (FWTEST)

| Code Value | Code Text |
|---|---|
| Food Consumption | Food Consumption |
| Water Consumption | Water Consumption |

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## Controlled Terminology (Code Lists) Section
FWTESTCD, Reference Name (FWTESTCD)

| Code Value | Code Text |
|---|---|
| FC | Food Consumption |
| WC | Water Consumption |

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## Controlled Terminology (Code Lists) Section
LAT, Reference Name (LAT)

| Code Value | Code Text |
|---|---|
| BILATERAL | BILATERAL |

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

| Code Value | Code Text |
|---|---|
| Glucose | Glucose |
| Cholesterol | Cholesterol; Total Cholesterol |
| Platelet Morphology | Platelet Morphology |
| Bilirubin | Bilirubin; Total Bilirubin |
| Activated Partial Thromboplastin Time | Activated Partial Thromboplastin Time |
| pH | pH |
| Erythrocytes | Erythrocytes; Red Blood Cells |
| Reticulocytes | Reticulocytes |
| Leukocytes | Leukocytes; White Blood Cells |
| Lymphocytes | Lymphocytes |
| Platelets | Platelets |
| Blood Urea Nitrogen | Blood Urea Nitrogen |
| Prothrombin Time | Prothrombin Time |
| Neutrophils | Neutrophils |
| Albumin | Albumin; Microalbumin |
| Alkaline Phosphatase | Alkaline Phosphatase |
| Alanine Aminotransferase | Alanine Aminotransferase; SGPT |
| Aspartate Aminotransferase | Aspartate Aminotransferase; SGOT |
| Bacteria | Bacteria |
| Basophils | Basophils |
| Calcium | Calcium |
| Chloride | Chloride |
| Color | Color |
| Creatinine | Creatinine |
| Eosinophils | Eosinophils |
| Epithelial Cells | Epithelial Cells |
| Fibrinogen | Fibrinogen |
| Hematocrit | EVF; Erythrocyte Volume Fraction; Hematocrit; PCV; Packed Cell Volume |

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| Code Value | Code Text |
|---|---|
| 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 Mean Corpuscular Volume; RBC Mean Corpuscular Volume |
| Erythrocytes Distribution Width | Erythrocytes Distribution Width; Red Blood Cell Distribution Width |
| Polychromasia | Polychromasia |
| Sodium | Sodium |
| Triglycerides | Triglycerides |
| Urobilinogen | Urobilinogen |
| Monocytes | Monocytes |
| Reticulocytes/Erythrocytes | Reticulocytes/Erythrocytes |
| Specific Gravity | Specific Gravity |
| Hemoglobin | Hemoglobin |
| Potassium | Potassium |
| Ketones | Ketones |
| Phosphate | Inorganic Phosphate; Phosphate; Phosphorus |
| Protein | Protein |
| Large Unstained Cells | Large Unstained Cells |
| Spermatozoa | Spermatozoa |
| Amorphous Crystals | Amorphous Crystals |
| Bicarbonate | Bicarbonate; HCO3 |
| Calcium Carbonate Crystals | Calcium Carbonate Crystals |
| Calcium Oxalate Crystals | Calcium Oxalate Crystals |
| Occult Blood | Occult Blood |
| Volume | Volume |
| Globulin | Globulin |
| Triple Phosphate Crystals | Triple Phosphate Crystals |
| Casts | Casts |
| Anisocytes | Anisocytes |
| Albumin/Globulin | Albumin/Globulin |
| Poikilocytes | Poikilocytes |

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| Code Value | Code Text |
| --- | --- |
| Erythrocyte Cell Morphology | Erythrocyte Cell Morphology; RBC Morphology; Red Blood Cell Morphology |
| Leukocyte Cell Morphology | Leukocyte Cell Morphology; WBC Morphology; White Blood Cell Morphology |
| Clarity | Clarity |
| Miscellaneous Cell Types | Miscellaneous Cell Types |
| Other Crystals | Other Crystals |
| RBC Inclusions | RBC Inclusions |

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

| Code Value | Code Text |
|---|---|
| GLUC | Glucose |
| CHOL | Cholesterol; Total Cholesterol |
| BILI | Bilirubin; Total Bilirubin |
| APTT | Activated Partial Thromboplastin Time |
| PH | pH |
| RBC | Erythrocytes; Red Blood Cells |
| RETI | Reticulocytes |
| WBC | Leukocytes; White Blood Cells |
| LYM | Lymphocytes |
| PLAT | Platelets |
| BUN | Blood Urea Nitrogen |
| PT | Prothrombin Time |
| NEUT | Neutrophils |
| ALB | Albumin; Microalbumin |
| ALP | Alkaline Phosphatase |
| ALT | Alanine Aminotransferase; SGPT |
| AST | Aspartate Aminotransferase; SGOT |
| BACT | Bacteria |
| BASO | Basophils |
| CA | Calcium |
| CL | Chloride |
| COLOR | Color |
| CREAT | Creatinine |
| EOS | Eosinophils |
| EPIC | Epithelial Cells |
| FIBRINO | Fibrinogen |
| HCT | EVF; Erythrocyte Volume Fraction; Hematocrit; PCV; Packed Cell Volume |
| MCH | Ery. Mean Corpuscular Hemoglobin |

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| Code Value | Code Text |
|---|---|
| MCHC | Ery. Mean Corpuscular HGB Concentration |
| MCV | Ery. Mean Corpuscular Volume; Erythrocytes Mean Corpuscular Volume; RBC Mean Corpuscular Volume |
| RDW | Erythrocytes Distribution Width; Red Blood Cell Distribution Width |
| POLYCHR | Polychromasia |
| SODIUM | Sodium |
| TRIG | Triglycerides |
| UROBIL | Urobilinogen |
| MONO | Monocytes |
| RETIRBC | Reticulocytes/Erythrocytes |
| SPGRAV | Specific Gravity |
| HGB | Hemoglobin |
| K | Potassium |
| KETONES | Ketones |
| PHOS | Inorganic Phosphate; Phosphate; Phosphorus |
| PROT | Protein |
| LGUNSCE | Large Unstained Cells |
| SPERM | Spermatozoa |
| CYAMORPH | Amorphous Crystals |
| BICARB | Bicarbonate; HCO3 |
| CYCACAR | Calcium Carbonate Crystals |
| CYCAOXA | Calcium Oxalate Crystals |
| OCCBLD | Occult Blood |
| VOLUME | Volume |
| GLOBUL | Globulin |
| CYTRPHOS | Triple Phosphate Crystals |
| CASTS | Casts |
| ANISO | Anisocytes |
| ALBGLOB | Albumin/Globulin |
| POIKILO | Poikilocytes |
| RBCMORPH | Erythrocyte Cell Morphology; RBC Morphology; Red Blood Cell Morphology |

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| Code Value | Code Text |
|---|---|
| WBCMORPH | Leukocyte Cell Morphology; WBC Morphology; White Blood Cell Morphology |
| CLARITY | Clarity |
| CRYOTHER | Other Crystals |
| MISC | Miscellaneous Cell Types |
| PLATM | Platelet Morphology |
| RBCINCL | RBC Inclusions |

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

| Code Value | Code Text |
|---|---|
| Gross Pathological Examination | Gross Pathological Examination |

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

| Code Value | Code Text |
|---|---|
| GROSPATH | Gross Pathological Examination |

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

| Code Value | Code Text |
|---|---|
| Microscopic Examination | Microscopic Examination |

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

| Code Value | Code Text |
|---|---|
| MIEXAM | Microscopic Examination |

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## Controlled Terminology (Code Lists) Section

ND, Reference Name (ND)

| Code Value | Code Text |
| --- | --- |
| NOT DONE | NOT DONE |

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## Controlled Terminology (Code Lists) Section
NEOPLASM, Reference Name (NEOPLASM)

| Code Value | Code Text |
|---|---|
| LYMPHOMA, MALIGNANT | LYMPHOMA (HODGKIN AND NON-HODGKIN); LYMPHOMA (HODGKIN'S AND NON-HODGKIN'S); MALIGNANT LYMPHOMA |
| Angiectasis | Angiectasis |
| Cyst | Cyst |
| Degeneration | Degeneration |
| Dilatation | Dilatation |
| Hematopoiesis | Hematopoiesis |
| Hemorrhage | Hemorrhage |
| Histiocytosis | Histiocytosis |
| Hyperplasia | Hyperplasia |
| Hypertrophy | Hypertrophy |
| Hypoplasia | Hypoplasia |
| Infiltration | Infiltration |
| Infiltration: | Infiltration: |
| Inflammation | Inflammation |
| Mineralization | Mineralization |
| NORMAL | NORMAL |
| Necrosis | Necrosis |
| Nephropathy | Nephropathy |
| Regeneration | Regeneration |
| Ulcer | Ulcer |
| Ulceration/scab | Ulceration/scab |
| Vacuol | Vacuol |
| Vacuolation | Vacuolation |

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## Controlled Terminology (Code Lists) Section
NEOSTAT, Reference Name (NEOSTAT)

| Code Value | Code Text |
|---|---|
| MALIGNANT | Malignant |

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## Controlled Terminology (Code Lists) Section
NY, Reference Name (NY)

| Code Value | Code Text |
|---|---|
| Y | Yes |

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

| Code Value | Code Text |
|---|---|
| Weight | Weight |

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

| Code Value | Code Text |
|------------|-----------|
| WEIGHT | Weight |

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

| Code Value | Code Text |
|---|---|
| Max Conc | Max Conc |
| AUC All | AUC All |

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

| Code Value | Code Text |
|------------|-----------|
| CMAX | Max Conc |
| AUCALL | AUC All |

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

| Code Value | Code Text |
|---|---|
| ng/mL | Microgram per Liter; Milligram per Cubic Meter; Nanogram per Milliliter; mcg/L; mg/m3; ng/mL; ug/L |
| h*ng/mL | h*ng/mL |

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## Controlled Terminology (Code Lists) Section
RELTYPE, Reference Name (RELTYPE)

| Code Value | Code Text |
|---|---|
| MANY | Many; Several |

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## 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 |

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

| Code Value | Code Text |
|---|---|
| ORAL GAVAGE | ORAL GAVAGE |

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

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

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

| Code Value | Code Text |
|---|---|
| F | Female |
| M | Male |

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

| Code Value | Code Text |
|---|---|
| SENDIG V3.0 | SENDIG V3.0 |

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

| Code Value | Code Text |
|---|---|
| GLAND, SALIVARY, SUBMANDIBULAR | Gland, Salivary, Mandibular; Submaxillary Gland |
| SMALL INTESTINE, DUODENUM | SMALL INTESTINE, DUODENUM |
| CERVIX | Cervix Uteri; Uterine Cervix |
| EPIDIDYMIS | EPIDIDYMIS |
| GLAND, MAMMARY | GLAND, MAMMARY |
| 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 | Eye; Eyeball |
| OVARY | Ovary |
| UTERUS | Uterus; Womb |
| VAGINA | Vagina |
| TESTIS | Testicle; Testis |
| TONGUE | Tongue |
| TRACHEA | Trachea; Windpipe |
| BRAIN | Brain; Nervous System, Brain |
| SPINAL CORD | Medulla Spinalis |
| ADIPOSE TISSUE | Adipose Tissue; Body Fat; Fat Tissue |
| ARTERY, AORTA | Aorta |
| MUSCLE, DIAPHRAGM | MUSCLE, DIAPHRAGM |
| BONE, FEMUR | Bone, Femoral; Femur |
| HEART | Cardiac; Heart |
| NERVE, OPTIC | Optic Nerve |
| GLAND, SEMINAL VESICLE | Seminal Sacs |
| BONE, STERNUM | Sterna; Sternum |

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| Code Value | Code Text |
|---|---|
| URINE | URINE |
| SERUM | Sera |
| PLASMA | PLASMA |
| GLAND, ADRENAL | GLAND, ADRENAL |
| URINARY BLADDER | Bladder; Urinary System, Bladder |
| ADIPOSE TISSUE, BROWN | BAT; Brown Fat |
| ESOPHAGUS | ESOPHAGUS |
| STOMACH | STOMACH |
| LIVER | LIVER |
| LUNG | LUNG |
| GLAND, PARATHYROID | GLAND, PARATHYROID |
| GLAND, PROSTATE | GLAND, PROSTATE |
| MUSCLE, QUADRICEPS FEMORIS | Muscle, Quadriceps; Muscle, Thigh |
| KIDNEY | KIDNEY |
| GLAND, THYROID | GLAND, THYROID |
| THYMUS | THYMUS |
| SPLEEN | SPLEEN |
| WHOLE BLOOD | WHOLE BLOOD |
| NERVE, SCIATIC | Sciatic Nerve |
| BONE MARROW SMEAR | BONE MARROW SMEAR |
| GLAND, HARDERIAN | GLAND, HARDERIAN |
| LYMPH NODE, MESENTERIC | LYMPH NODE, MESENTERIC |
| WHOLE ANIMAL | Carcass |
| BONE MARROW, FEMUR | Bone Marrow, Femoral |
| BONE MARROW, STERNUM | Bone Marrow, Sternal |
| ALL TISSUES | ALL TISSUES |
| SKIN/SUBCUTIS | SKIN/SUBCUTIS |
| LYMPH NODE, SUBMANDIBULAR | LYMPH NODE, SUBMANDIBULAR |
| SYSTEMIC NEOPLASMS | SYSTEMIC NEOPLASMS |

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

| Code Value | Code Text |
|------------|-----------|
| RAT | RAT |

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

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

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

| Code Value | Code Text |
|---|---|
| TOX | Toxicology |

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

| Code Value | Code Text |
|---|---|
| SPRAGUE-DAWLEY | SD |

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## Controlled Terminology (Code Lists) Section
TFTEST, Reference Name (TFTEST)

| Code Value | Code Text |
|---|---|
| Tumor Examination | Tumor Examination |

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## Controlled Terminology (Code Lists) Section
TFTESTCD, Reference Name (TFTESTCD)

| Code Value | Code Text |
|---|---|
| TUMEX | Tumor Examination |

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

| Code Value | Code Text |
|---|---|
| % | Percentage |
| mL | Milliliter; cm3 |
| sec | Second |
| RATIO | RATIO |
| g | Gram |
| mmol/L | Micromole per Milliliter; Millimole per Liter; Mole per Cubic Meter; mcmol/mL; mmol/L; mol/m3; nmol/uL; umol/mL |
| pg | Picogram |
| fL | Cubic Micrometer; Cubic Micron; Femtoliter; um3 |
| g/dL | Gram per Deciliter; g% |
| mg/dL | Milligram per Deciliter; mg% |
| 10^9/L | 10^3/mm3; 10^3/uL; 10^6/mL; G/L; Giga per Liter |
| 10^12/L | 10^6/mm3; 10^6/uL; T/L; Tera/L |
| mg/kg | Milligram per Kilogram |
| U/L | Unit per Liter; mU/mL |
| mEq/L | Milliequivalent Per Liter; Millivalent per Liter; mval/L |
| g/animal/day | Gram per Animal per Day |
| pH | pH |

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

| External Dictionary | Dictionary Version |
|---|---|
| No Dictionaries used | |

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