Study -> **PDS2014**

TS

* AGETXT should be 50-56 only 'Days' should be populated as AGEU.
* Both AGE and AGETXT cannot be populated.

DM

* Only one record should be present per animal. DM file has same records as in EX domain.
* AGE variable cannot have the value as 0. Also, AGE should be populated only when BIRTHDTC provided else populate AGETXT and AGEU from TS.

 SE

* Start of treatment element should be one day after the end of Predose element.
* End of treatment element should be populated with the date of animal disposition.

LB

* In LB domain where ORRES = CS and HS, Units should be removed.

MA

* Bilateral should be populated under LAT instead of MAANTREG.
* MASTRESC other than UNREMARKABLE, should be populated in start cases.
* All Lobes should be populated under RESMOD instead of MAANTREG.
* Hepatocellular & Interstitum should be populated under RESMOD instead MIANTREG.
* Where MAORRES is Tissue lost at necropsy & Tissue damaged at necropsy, should be populated in MAREASND instead of STRESC.
* MADTC and MADY should after Disposition date. In DS last set animals killed was Day 58 but in MA it is populated as day 789.

CL

* Values which was populated in CLLOC should be included in CLORRES also.

OM

* In OM domain, few records missing DTC and DY

PC

* in PC domain where STRESC is BQL, PCORRES should be <LLOQ
* PCELTM, PCTPTREF & PCRFTDTC are not populated.
* where TPT 24H,48H,72H NOMDY and NOMLBL should be Day 1 and Day 29. VISITDY is source file is given wrong.

 PP

* PPTPTREF and PPRFTDTC are not populated.

Study -> **STUDY ID**

TS

* AGE or AGETEST should be populated not both.
* GLP type can't be N

TE

* Element should be more descriptive and Length of treatment can be included.
* TESTRL & TEENRL should be descriptive.

 TX

* As Treatment Vehicle is given in TS, it can be removed in TX.
* Toxicokinetic Description, planned number of subjects are missing.
* TCNTRL should be populated only for control group, it should be removed from other trial sets.

DM

* The records in DM should be one record per each subject, where it has duplicates.
* RFSTDTC & RFENDTC can have time component in it.

SE

* The 2 phases can't have same day like the Baseline phase and the treatment phase can't be on the same day.

CL

* CLTEST, CLTESTCD are populated as ‘Normal’, ‘Skin’, ‘General’ etc, instead a proper test name should be populated.
* Where CLSTRESC other than NORMAL, should be populated in Start cases
* STRESC, LOC & SEV values should be in start case.
* Where CLORRES is 'discoloration, injection site (previous day), red', CLSTRESC should be “Discharge” and “red” must be populated under RESMOD.
* CLSEV is wrongly populated with 'small amount' which should be a RESMOD.
* CLTPT & TPTNUM should be removed as it contains only one Timepoint as '1'.
* Body temperature observation wrongly bought under CL which should be bought under VS domain.

LB

* LBBLFL is missing.
* LBTPT can be removed as the day refers to the phase of the study.

PC

* SUPPC domain is missing as there are LLOQ values and where CALCN values should be populated.
* PCTPTNUM is wrongly populated as TPT '0 & 0.17' has same TPTNUM as '0'.

Study -> **GLP0003**

TS

* SEQ should ensure uniqueness and not be in sequential.

TE

* TEENRL is blank – not populated.
* Element should be more descriptive and Length of treatment is missing from descriptions.

TX

* Set descriptions need to be more descriptive and Length of treatment is missing from set descriptions.
* Set Label is not populated.
* Toxicokinetic Description not populated to differentiated TK animals.
* For one SETCD there cannot be 2 different Set Description.

DD

* DD must be populated for all Unscheduled Death subjects.

EX

* EX must Contains one record per animal per dose.

SE

* Start of treatment element should be one day after the end of Predose element.
* End of treatment element should be populated with the date of animal disposition.

CL

* Disposition data are reported as Observations under CL domain, (Unscheduled Euthanasia, Death, End-of-Dose Necropsy, Euthanasia - No Necropsy, Postdose Necropsy) These must only be captured under DS Domain.
* SUPPCL domain missing.
* Where CLORRES is “Discharge, red, Urethral opening” CLSTRESC should be “Discharge” and “red” must be populated under RESMOD.
* Where CLORRES is “Discoloration, Head, Red”, “Discoloration, Ears, both, Red”, “Discoloration, Forelimb, right, Red”, “Discoloration, Neck, Red” -- CLSTRESC should be “Discoloration” and “Red” must be populated under RESMOD.
* Where CLORRES is “Eyelid, partially closed, both” CLSTRESC should be “Partially closed” and CLLOC must be “Eyelid Both”.
* Case Consistency to be maintained when same observation is seen.
* Where CLORRES is “Feces, color, Black” & “Feces, color, Red” – Black & Red must be populated under RESMOD.
* Where CLORRES is “Feces, mucous” CLSTRESC must be “Feces, mucus” – US English
* Where CLORRES is “Scab, multifocal” CLSTRESC must be “Scab” and “Multifocal” must be populated under RESMOD.
* Where CLORRES is “Soiling, perigenital” CLSTRESC must be “Soiling” and “Perigenital” must be populated under CLLOC.
* Where CLORRES is “Swollen, limb, Forelimb, left” CLSTRESC must be “Swollen” and CLLOC must be “Limb, Forelimb, left”.
* Where CLORRES is “Swollen, muzzle” CLSTRESC must be “Swollen” and CLLOC must be “Muzzle”.

LB

* Hematology Morphology data – if decoded values available must be decoded under LBSTRESC.
* When Reason Not Done is “Specimen clotted”, “Platelet clumping”, & “Platelet clumping.  Qualitative estimate = ADEQ”, LBSPCCND & specimen usability flag must be populated as “N’.
* On an assumption that for the Test = Platelet Morphology, “pc” under LBORRES stands for “Platelet clumps” – Specimen condition must be populated.

MA

* Where MAORRES is “SKIN/SUBCUTIS:Alopecia, forelimb, bilateral, corresponds to antemortem observation(s)”  “Bilateral” must be populated under RESMOD and not under MALAT since it is an findings laterality and not specimen laterality.
* Where MAORRES is “GENERAL OBSERVATIONS:clinical observation of soiling present but not collected” – Cannot be an observation – need to verify if this is Reason not done or a general comment related to the animal.

TF

* TF domain need not be submitted/populated unless it is a CARC study.

PC

* PCSTRESC must be populated as “BLQ” when PCORRES is “<LLOQ”.
* PCLLOQ is blank.
* PCSCAT must be PARENT.
* When TPT is post 24h – PCDY and PCDTC must be changed accordingly and be +1 day from that of the reference dose day.