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Challenges in mapping lab data into CDISC

- Understanding the data often requires a basic understanding of medical concepts to assess their validity.
- The use of a variety of lab units by the sites to record the lab results necessitates conversions of lab results into standard units to ease comparing the lab values and prepare the data for analysis.
- Quite a few lab values need to be derived from existing measurements.
- In oncology studies, lab values must be graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) grading standard¹.

Data flow

The data flow from the clinical database to ADLB is shown in Diagram 1. The variable LBLOINC contains the unique controlled terminology code from the Logical Observation Identifiers Names and Codes (LOINC)².

The units used as standard units can be divided into two groups: *Système International* (SI) units³ and conventional units^{4, 5}. The SI units are commonly used as standard units. However, as per the Study Data Technical Conformance Guide of March 2025, the FDA requires to receive the lab data in both SI units (in the LB domain) and conventional units (in a custom domain called LC)⁶.

The variables identifying the lab tests in ADLB are PARAM, PARAMCD and PARCAT1. Unlike LBTEST and LBCAT, the relation between PARAM and PARCAT1 should be a one-to-one relation. Since LBTEST has a many-to-one relation with LBCAT, PARAM should contain a combination of LBTEST, LBSPEC, LBMETHOD and LBSTRESU to make it unique. For Glucose, the result could be like in Table 1.

Table 1: Example of setting PARAMCD and PARAM for blood and urine Glucose

LBCAT	LBTESTCD	LBTEST	LBORRESU	LBSPEC	LBMETHOD	PARAMCD	PARAM	PARCAT1
CHEMISTRY	GLUC	Glucose	mmol/L	SERUM		GLUCSER	Serum Glucose (mmol/L)	CHEMISTRY
URINALYSIS	GLUC	Glucose	mmol/L	URINE		GLUCUR	Urine Glucose (mmol/L)	URINALYSIS
URINALYSIS	GLUC	Glucose	Arbitrary U	URINE	DIPSTICK MEASUREMENT METHOD	GLUCDIP	Urine Glucose (arbitrary U; Dipstick Measurement Method)	URINALYSIS

Abnormal lab results and their clinical significance

The purpose behind capturing lab values is to determine whether they change over time. If they do, it is important to see how much they change and whether the lab values become a health issue. Assessing the latter requires lab reference ranges.

SDTM provides room for only one set of reference ranges, to be mapped in the original and the standard unit. The variable LBNRIND indicates whether the variable is within or outside the reference range.

ADaM provides the possibility to capture additional reference ranges next to the one from SDTM, by means of AyLO, AyHI, AyIND and ByIND. This is useful when the reference ranges in SDTM are the ones from the sites and certain assessments need to be analysed based on one common set of reference ranges.

Baseline variables in ADLB

Diagram 2 shows the process of filling the baseline variables BASE, BASEC, CHG, PCHG, BNRIND and ByIND in ADLB. These variables are not filled for lab values obtained before the baseline values.

Derivations in ADLB

The most common kinds of derivations performed on lab values are calculations of average values and derivations of lab parameters based on already available lab test results.

Deriving a lab value always means that a record is added to the dataset. Two things need to be considered when doing so:

- The variable DTYPE (derivation type) needs to be filled, indicating which kind of derivation was conducted, for example with "AVERAGE" for average records.
- In derived records, the variables coming from SDTM.LB should be emptied. However, keeping VISITNUM and VISIT filled makes it easier to see on which lab values the derived results are based.

CTCAE grading

As mentioned before, CTCAE toxicity grades should be assigned to several lab tests. This is a requirement from the NCI. The NCI CTCAE version 5 documentation¹ provides a list of which lab tests should be graded and how.

Grading lab values is mostly done by determining how far the lab value is outside the reference range, but in some cases by checking absolute values, or by checking how much bigger or smaller a lab value is compared with a baseline value that itself is outside the reference range.

There are six variables containing the toxicity grades, and six variables containing the toxicity grades at baseline. Table 2 lists them all.

Table 2: The variables containing the toxicity grades

Character variable	Numeric variable	Contents of the variables
ATOXGR	ATOXGRN	Toxicity grade assigned.
ATOXGRL	ATOXGRLN	Toxicity grade assigned if AVAL is below the reference range.
ATOXGRH	ATOXGRHN	Toxicity grade assigned if AVAL is above the reference range.
BTOXGR	BTOXGRN	ATOXGR and ATOXGRN from the baseline record (ABLFL="Y").
BTOXGRL	BTOXGRLN	ATOXGRL and ATOXGRLN from the baseline record (ABLFL="Y").
BTOXGRH	BTOXGRHN	ATOXGRH and ATOXGRHN from the baseline record (ABLFL="Y").

Hy's Law and the liver function

Hy's Law is a rule of thumb used for identifying subjects at risk of serious liver damage while they are on study treatment⁸. It consists of three components:

- ALT and/or AST levels elevated to ≥3 times above the upper bound of the reference range.
- When the ALT and/or AST levels is ≥3 times above the upper bound of the reference range, also the Bilirubin values is ≥2 times above the upper bound of the reference range.
- No other reason (like alcohol abuse or hepatitis) can explain these elevated ALT, AST and Bilirubin values.

In ADLB, the subjects fulfilling the Hy's Law criteria regarding the ALT, AST and Bilirubin values need to be flagged. This should be done by checking for the first occurrence of ALT and/or AST values ≥3 times above the upper bound of the reference range, and then checking if there are any records with Bilirubin levels ≥2 times above the upper bound of the reference range chronologically on or after the elevated ALT and AST values. If yes, all the subject's records with ALT, AST and Bilirubin values need to be flagged.

Diagram 1: Data flow from clinical database to ADLB

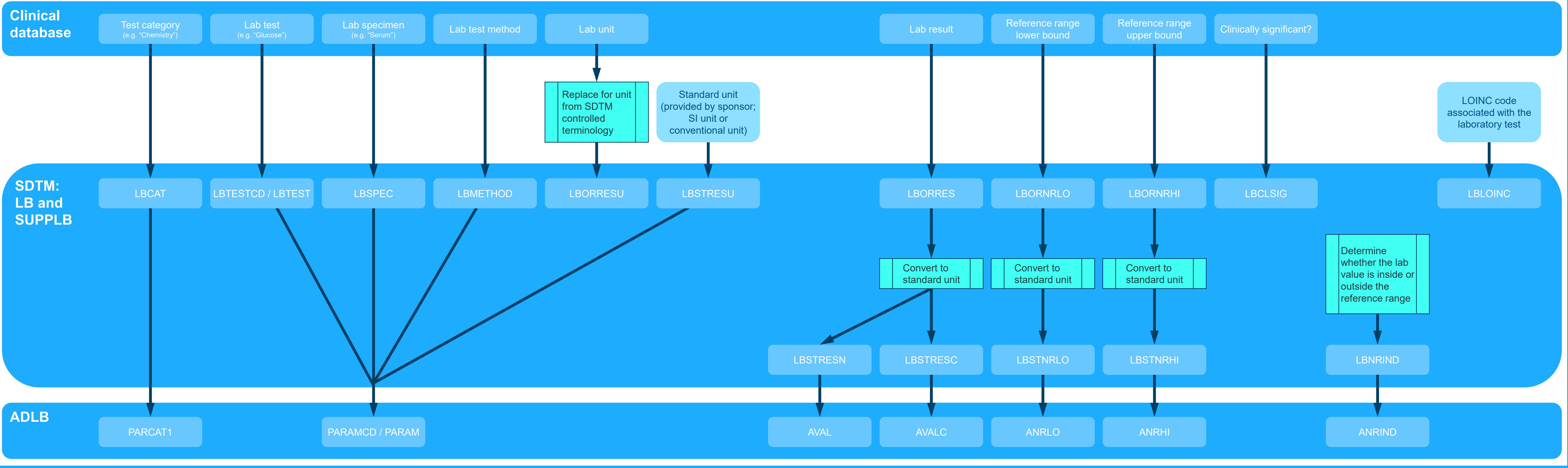
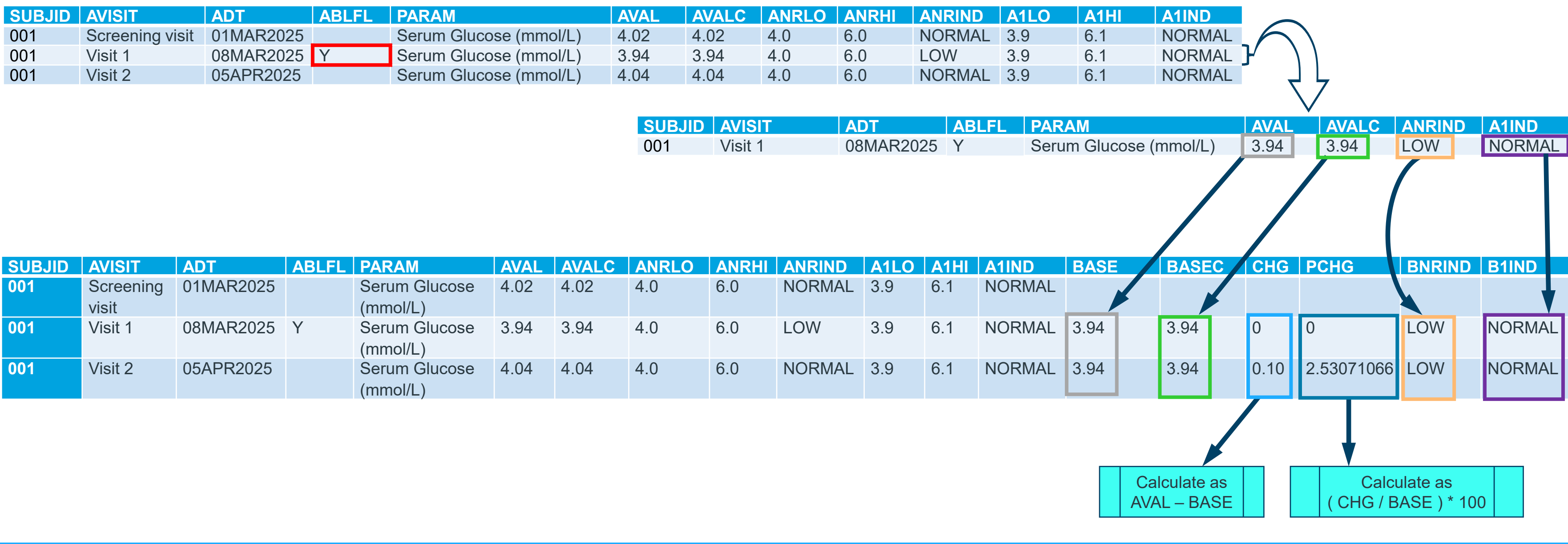


Diagram 2: Baseline and change from baseline



References

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- <https://loinc.org/get-started/>
- <https://www.bipm.org/en/measurement-units/>
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