# PP09 The First Steps in Laboratory Dataset

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## 1. Motivation

- Early identification of laboratory issues will let you:
  - ensure data quality long before the database lock,
  - increase work efficiency and the quality of results coming from the programming team,
  - prevent data loss due to unmapped or non-standard values,
  - pool data easily and reply to regulatory agencies faster,
  - communicate efficiently across departments/ companies that apply the same standard. One example is cooperation between Programming and Medical Writing.

## 2. Understand the domain

- The laboratory domain (LB) captures laboratory data collected in the CRF or received from a central provider or vendor. CDISC standard has categorised it as **findings** observation class.
- Very often there are only two values analysed per subject and parameter: baseline and maximum on treatment value. Values outside the normal ranges and toxicities as defined per NCI CTCAE are also summarised.
- Sometimes lab test values are analysed per treatment cycle or epoch.
- More complicated outputs include:
  - Analysing abnormalities overlapping with other abnormalities or specific Adverse Events. One example is Hy's Law analysis.
  - CTC grades analysis, including shift tables (see QR code for the CTC Grades derivation).

## 3. Study requirements

- Check the analysis plan and table mocks to determine study needs.
- Verify the sorting key. The CDISC recommendation is that you have one record per lab test, time point, visit and subject. Discuss duplicates with the study team.
- Review available tests, specimen types and categories for potential exclusions (see **table 1** for an example of specimen exclusions for potassium). Exclusions may also be done on the category level (for example: urinalysis) or test level (for example: cholesterol).

## 4. Mapping checks

- Does each test have a unique category? See **table 1** for an example test assigned to multiple categories. It may result in the same test being reported in different tables.
- Are we clear in which table each test belongs? For example, the hematology category may feed into chemistry or be a separate table.
- Do we need to group specimens for reporting? See the example in **figure 1** - arterial blood, blood and venous blood are mapped to blood.
- Do test codes and names map one-to-one, at least within a category? See the example of mapping laboratory test names in **figure 2**.

## 5. Qualitative values

- Not all tests will have continuous numeric results, for example urinalysis tests like ketones, glucose, protein.
- Qualitative values can be mapped:
  - to other qualitative values: N, NEG, NEGATIV, NONE-DETECTED → NEGATIVE
  - to quantitative values:

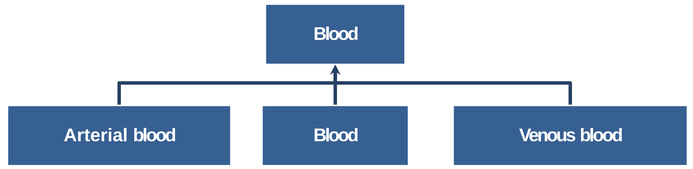
    ++, +++, ++++, +1, 1+, POSITIVE, Positive → 1

    >60 → 60.01
- The fact that there are no units associated with the result does not mean it is qualitative. Example tests with quantitative results and no unit are pH or ratio.

**Table 1. Categories and Specimens Available for Potassium**

| Category for Lab Test | Specimen Type | Lab Test |
|---|---|---|
| CHEMISTRY | ARTERIAL BLOOD | Potassium |
| ~~CHEMISTRY~~ | ~~BILE~~ | ~~Potassium~~ |
| CHEMISTRY | BLOOD | Potassium |
| ~~CHEMISTRY~~ | ~~BONE MARROW~~ | ~~Potassium~~ |
| CHEMISTRY | PLASMA | Potassium |
| CHEMISTRY | SERUM | Potassium |
| CHEMISTRY | VENOUS BLOOD | Potassium |
| HEMATOLOGY | BLOOD | Potassium |
| HEMATOLOGY | VENOUS BLOOD | Potassium |
| SEROLOGY | BLOOD | Potassium |

**Figure 1. Mapping of Specimens**




**QR Code for CTC Grades**

**Figure 2. Mapping of Lab Tests**

| Lab Test Short Name | Lab Test |
|---|---|
| URATE | Urate |
| URATE | Urate; Uric Acid |
| URATE | Uric Acid |

→ Urate

**Table 2. Comparison of Different Unit Standards**

| Lab Test | Conventional Unit (US) | Factor | Client Unit | Factor | SI Unit |
|---|---|---|---|---|---|
| Alanine Aminotransferase | U/L | 1.0 | IU/L | 0.0167 | UKAT/L |
| Erythrocytes | 10^6/UL | 1.0 | 10**6/MM**3 | 1.0 | 10^12/L |
| Leukocytes | 10^3/UL | 1.0 | 10**3/MM**3 | 1.0 | 10^9/L |

**Table 3. Unit Conversion not Dependent on Lab Test**

| Original Unit | Conversion Factor | Reporting Unit |
|---|---|---|
| UG/L | 0.0000001 | G/DL |
| MG/L | 0.0001 | G/DL |
| MG/100ML | 0.001 | G/DL |

**Table 4. Unit Conversion Dependent on Lab Test**

| Original Unit | Conversion Factor | Reporting Unit | Lab Test |
|---|---|---|---|
| UMOL/L | 0.01131 | MG/DL | Creatinine |
| UMOL/L | 0.002433 | MG/DL | Magnesium |
| UMOL/L | 0.0031 | MG/DL | Phosphate |

## 6. Conversion of units

- There are many unit standards; agree on one with your clinical team. Some example standards are: *Système International (SI) unit*, *U.S. Conventional units*, Client-specific standard. See **table 2** for examples.
- Do all units follow the agreed standard? If not, unit conversion should be applied. Conversion of units is done by multiplying the original lab test value by the specified **conversion factor**. If you are missing any conversion factor, talk to the clinical team.
- Conversion may be needed for lower and upper limits of range too.
- Conversion may depend on the lab test – see **table 3** and **table 4**.
- Check outliers in the converted observations – sometimes the initial unit is incorrect and the conversion was not needed.

## 7. Central and local laboratories

- Central laboratories can be identified by the unique lab identifier or name/ address specified in the analysis plan.
- Common issues with data from local laboratories are:
  - missing or not evaluable result ('less than 10', '11-21', '3 Plus', '>=1000'),
  - upper and/ or lower limit ranges not provided,
  - non-standard/ missing units, units concatenated with the result.
- Analyses of central and local laboratories may be different, for example:
  - not including results from local laboratories in the outputs,
  - converting units only for local laboratories,
  - applying different parameters derivations for results obtained from local and central laboratories.

## 8. Assigning the baseline value

- Use SDTM baseline flag on team consent.
- Ask for appropriate baseline definition, otherwise.
- Definition can be:
  - specific visit,
  - last non-missing result prior to 1st dose.
- Point to consider:
  - usage/ imputation of measurement time or time-points,
  - imputation of missing/ incomplete dates,
  - unplanned visit.
- Clarify if subjects with no baseline are expected to be summarised in post-baseline or shift tables.

## 9. Recommendations

- How can you develop the laboratory process within your organisation?
  - use the CDISC validator which will cover many checks described earlier,
  - have a designated laboratory subject matter expert,
  - develop a *Best Programming Practices for Laboratory Domain* document,
  - create a database of mapping decisions from studies that use the same standard or keep one study as a reference for mapping,
  - develop a list of standard QC checks for the laboratory domain,
  - develop standard macros to handle repeated steps, for example: read in and check the specification with the CDISC validator, do the test/ units mapping, read in/ create codelists, convert units, derive baseline.



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