Using an MDR to Manage Lab Test Specifications

Dan Ringenbach
Roopa Kandukuri
Outline

• Lab Specification Scenario
• LOINC Requirement
• Lab Metadata in an MDR
• Benefits of MDR Managed Lab Specs
Lab Specification Scenario
Study Design

We should measure blood sugar levels

Lab Test Name Glucose, Serum

Units mmol/L

LBTEST
Glucose

LBTESTCD
GLUC
Lab Data Received

<table>
<thead>
<tr>
<th>Unique ID</th>
<th>CDISC Test Name</th>
<th>CDISC Test Code</th>
<th>Specimen Material Name</th>
<th>Category</th>
<th>Sub-Category</th>
<th>Method</th>
<th>Conventional Units</th>
<th>SI Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>LABID</td>
<td>LBTEST</td>
<td>LBTESTCD</td>
<td>LBSPEC</td>
<td>LBCAT</td>
<td>LBSCAT</td>
<td>METHOD</td>
<td>CNVU</td>
<td>SIU</td>
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<tr>
<td>10006</td>
<td>Alanine Aminotransferase</td>
<td>ALT</td>
<td>SERUM</td>
<td>LIVER AND KIDNEY FUNCTION</td>
<td>LIVER FUNCTION TESTS</td>
<td>SPECTROPHOTOMETRY</td>
<td>U/L</td>
<td>U/L</td>
</tr>
<tr>
<td>10007</td>
<td>Glucose</td>
<td>GLUC</td>
<td>PLASMA</td>
<td>CHEMISTRY</td>
<td>GLUCOSE TESTS</td>
<td>PHOTOMETRY</td>
<td>U/L</td>
<td>mmol/L</td>
</tr>
<tr>
<td>10008</td>
<td>Glucose</td>
<td>GLUC</td>
<td>URINE</td>
<td>URINALYSIS</td>
<td>URINE CHEMISTRY</td>
<td>DIPSTICK</td>
<td>mg/dL</td>
<td>mmol/L</td>
</tr>
</tbody>
</table>

- Lab ID or Name
- LBTEST
- LBTESTCD
- UNITS
Study Design

What I really mean is……..
Blood sugar level
- With specimen type of Serum
- Using method of photometry
- With units of mmol/L
- Included in a Battery or Panel
- With a Company Lab ID
- Measured at a certain time
- With the patient fasting
- With a lab test name of Glucose, Serum
- Mapped to CDISC LBTEST = Glucose
- Mapped to CDISC LBTESTCD = GLUC
Managing the Lab Test Specs

- Manage the lab tests in a spreadsheet, sometimes in multiple spreadsheets
  - List all the attributes of the lab tests
- Share the spreadsheet on Sharepoint
Spreadsheet Management

- Study teams download the specifications
  - Make a copy and add all the labs needed for the study
- Share with the lab vendor
- Multiple Copies
- Lab vendor has multiple specifications
What’s the problem

• Having multiple copies of a spreadsheet or loose governance of the standards in the spreadsheet can lead to poor quality lab data, or need for rework or investigation to determine the context.

• Governance processes to manage lab standards, adhering to controlled terminology in the lab standards

• Visibility to what lab tests are being used across the sponsor is not known, no impact analysis to changing or new lab specifications

• No audit trail of changes to specifications

• Ability to extend, add new attributes,
  • Addition of LOINC codes are a new requirement coming in 2020.
  • New types of lab tests that require new attributes
LOINC Requirement
FDA LOINC Requirement

• LOINC Requirement
  • The FDA Data Standards Catalog includes the requirement to populate the LBLOINC variable in the LB Domain for study data submitted to the FDA
  • The requirement for LOINC codes begins for studies that start after March 15, 2020 for NDAs, ANDAs and certain BLAs, and on March 15, 2021 for certain INDs.

• With the introduction of LOINC code requirement it is more important than ever to have a set of lab test specifications and an organization and process and tools to support it.

• While it is not until next year, companies will need to come up with a strategy to add, approve and manage LOINC mappings for lab tests
LOINC Mapping

- Mapping LOINC dimensions and lab test specifications may not always be straight-forward

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Description</th>
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<tbody>
<tr>
<td>Component</td>
<td>Glucose</td>
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<tr>
<td>Property</td>
<td>MCnc</td>
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<tr>
<td>Timing</td>
<td>Pt</td>
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<tr>
<td>System</td>
<td>Ser/Plas</td>
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<td>Scale</td>
<td>On</td>
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<td></td>
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Lab Test Name
Glucose, Serum

LOINC 2345-7
Glucose [Mass/volume] in Serum or Plasma

- LBCAT Chemistry
- LBTEST Glucose
- LBSCAT Glucose Tests
- LBTESTCD GLUC
- LBSPEC Serum
- LOINC Code
- Lab ID
- Battery/Panel ID
- Timing
- Units mmol/L
- Fasting Yes/No/UNK
LOINC Working Group

• Sponsors should include LOINC codes for any test where a valid LOINC code exists for new trials’ electronic submissions per the FDA Data Standards Catalog requirement dates.*
  • The most specific LOINC code should always be used without over-specifying details that are not known by the sponsor, such as method or scale.*

• CDISC Lab Working Group has assessed over 2000 common lab tests and assigned LOINC codes*

*Source: Recommendations for the Submission of LOINC Codes in Regulatory Applications to the U.S. Food and Drug Administration, November 2017
Although LOINC mapping tools exist (e.g. Regenstrief LOINC Mapping Assistant pictured), the Working Group recommends that sponsors not attempt to derive a mapping to LOINC as they create the SDTM files. Lab test names are notoriously ambiguous, and making assumptions in the mapping process without confirming with the test performer can lead to serious data quality issues. It is best to work with lab providers, CDISC and Regenstrief.
Lab Metadata in an MDR
# Modeling Lab Metadata

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Each column is a list of controlled terminologies.

Each row is a unique lab test with a set of related items of multiple controlled terminologies.
Modeling Lab Metadata
Extending the Model

Add new attributes without affecting existing lab mappings

Update CT without affecting the existing lab mappings
Benefits of MDR-Managed Lab Specifications
Benefits of Managing Lab Metadata in an MDR

• Accessibility
  • Most MDR’s have web based user interfaces making the lab specifications accessible to global users

• Traceability / Audit Trail
  • Any changes to lab specifications will be captured in an audit trail. Track changes with versioning capabilities in an MDR

• Governance / Control
  • Workflows aid in governance and approval processes as well as in adding new lab model extensions

• Extensibility
  • Update lab specification attributes for changing requirements in the future (e.g. LOINC)
Benefits of Managing Lab Metadata in an MDR

• Impact Analysis
  • Understand the impact of changes to lab specifications, changes to LOINC code status or mappings or changes to CDISC CT.

• Conformance Checking
  • Enable automated lab data conformance checking with programmatic access to the latest lab standards.
Benefits of Lab Metadata in an MDR

- Legacy Lab Tests
- CDISC Lab Tests
- LOINC
- New Lab Metadata

Governance
Traceability
Audit Trail
Metrics

- Lab Test Metadata

- Reports
- Programmatic Access
- User Search & Browse
- Lab Metadata Exports

CDISC CT
Conclusions

• Lab test specifications are a complex set of related attributes. The attributes are subject to controlled terminologies.
  • Lab test specifications are difficult to manage using only a spreadsheet.
  • Managing related sets of metadata is the strength of an MDR.

• Managing lab test specifications as metadata in a metadata repository can provide benefits of increased accessibility to lab standards, and increased governance and control.

• An MDR can provide added benefits of impact analysis, audit trails and improved conformance checking capability.
Questions?