PP03

CDISC BIOMEDICAL CONCEPTS AND DATASET SPECIALIZATIONS

Ready to Use Building Blocks for Define-XML and Data Transformation

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Use Case: Building Blocks for SDTM Define-XML

CDISC kicked off the Biomedical Concepts project in 2022, taking a pragmatic, iterative approach to create Biomedical Concepts (BCs) and representing them in the Foundational Standards as Dataset Specializations with Value Level Metadata definitions. SDTM Dataset Specializations can be represented as Value Level Metadata definitions in Define-XML v2.1. These definitions contain detailed metadata, including Controlled Terminology subsets. The SDTM Dataset Specializations can be considered pre-configured building blocks, from which end-users can select and configure to build Value Level Metadata, which is an important part of the metadata for their Define-XML.

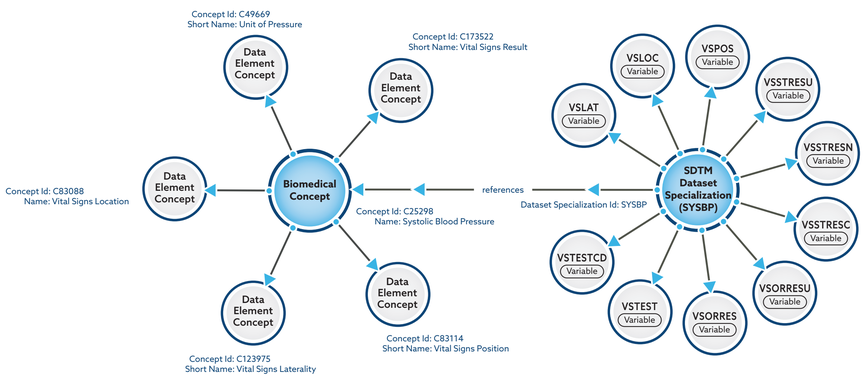
The simplified implementation approach is easy to understand and allows for quick return on investment. SDTM dataset specializations are ready to be used as building blocks for Define-XML. This provides immediate benefits to SDTM programmers and opens the door to efficient programming and automation.

CDISC Biomedical Concepts & Dataset Specializations

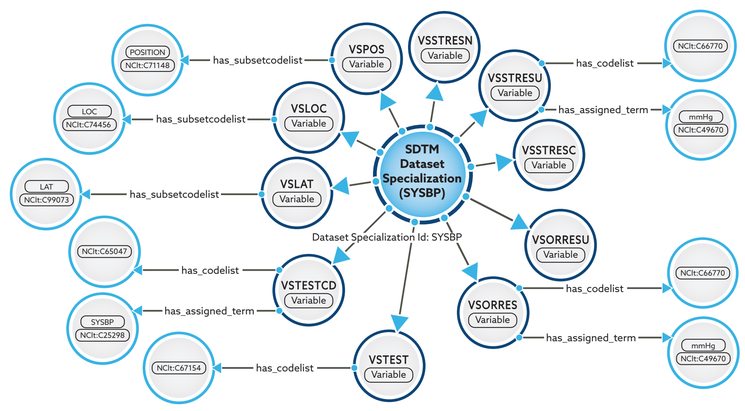
Three Key Pieces

1. Extend foundational standards
   - Add explicit relationships between variables
   - Additional operational metadata, e.g., data type, etc.
2. Conceptual Layer – abstract BC's
   - Provides semantics - aligned with NCI terminology
   - Supports study design, Schedule of Activities (SOA)
3. Implementation Layer - Dataset Specializations with VLM definitions
   - Supports programmers
   - Pre-configured building blocks for Define-XML
   - Tailored to BCs to link with unambiguous semantics & definitions
   - Dataset specializations as an extended dataset structure

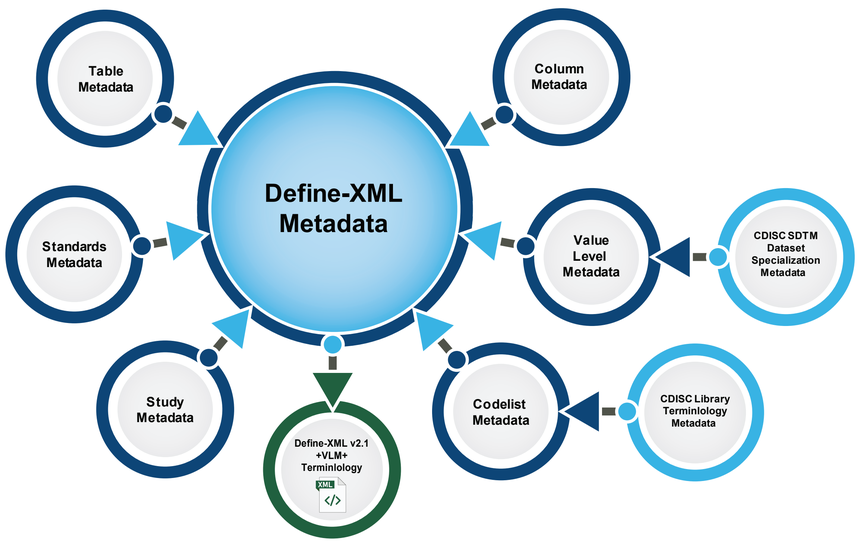
Simplified Data Model Focused on Pragmatic Implementations



SDTM Dataset Specializations



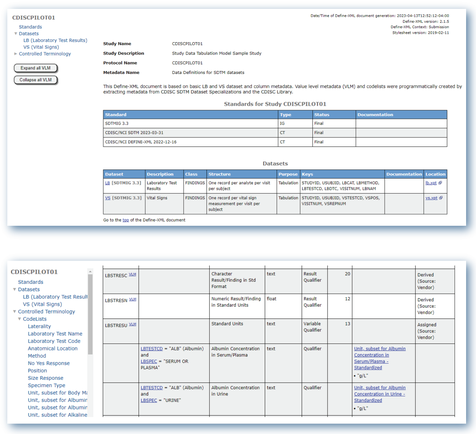
Metadata Flow Using CDISC SDTM Dataset Specialization as Building Blocks for Define-XML 2.1

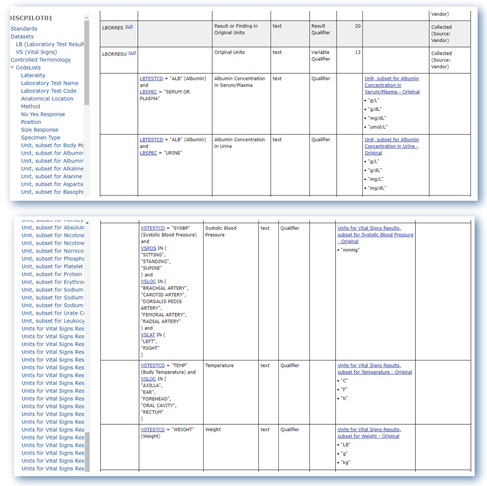


Output: Value Level and Codelist Metadata

Result: Define-XML v2.1 document with complete SDTM Dataset Specialization:

- Controlled Terminology metadata for the LB and VS domains
- Value Level Metadata





Tangible Value for the CDISC Community

Pragmatic Implementation of Biomedical Concepts

Purpose:

- Reduce variability in standards implementations
- Increase metadata-driven automation and efficiency
- Reduce barriers to operational implementation

Provides an iterative approach to creating biomedical concepts with a focus on providing tangible value for the CDISC community

Soon To Come: Dataset Specialization Metadata Informing Data Movement to Facilitate Mapping

A Step Towards Automation of End-To-End Standards

Purpose:

- Dataset Specializations will soon include metadata that informs how data movement occurs in order to facilitate mapping and transformation
- Alignment with OAK-SDTM Automation Project

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More to Come at the 2023 CDISC US Interchange
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