

CDISC Conceptual and Operational Standards Metadata Services (COSMoS): Pragmatic Implementation of Biomedical Concepts

Author: Linda Lander, Senior Metadata Consultant, CDISC, llander@cdisc.org

COSMoS Project Overview

PURPOSE

- Reduce variability in standards implementations
- Increase metadata-driven automation
- Reduce barriers to operational implementation
- Improve transparency in data flow
- Fill gaps such as semantics, relationships, value-level metadata in current standards
- Less configuration needed to use standards

OBJECTIVES AND KEY RESULTS

- Abstract BC conceptual layer based on NCI terminology and ontology with links to external coding systems, e.g., LOINC
- Simplified BC implementation layer with pre-coordinated dataset specializations
- Formal data model and schema
- Structured machine-readable format validated with conformance rules
- Retrievable via CDISC Library APIs
- CDISC curation and governance process

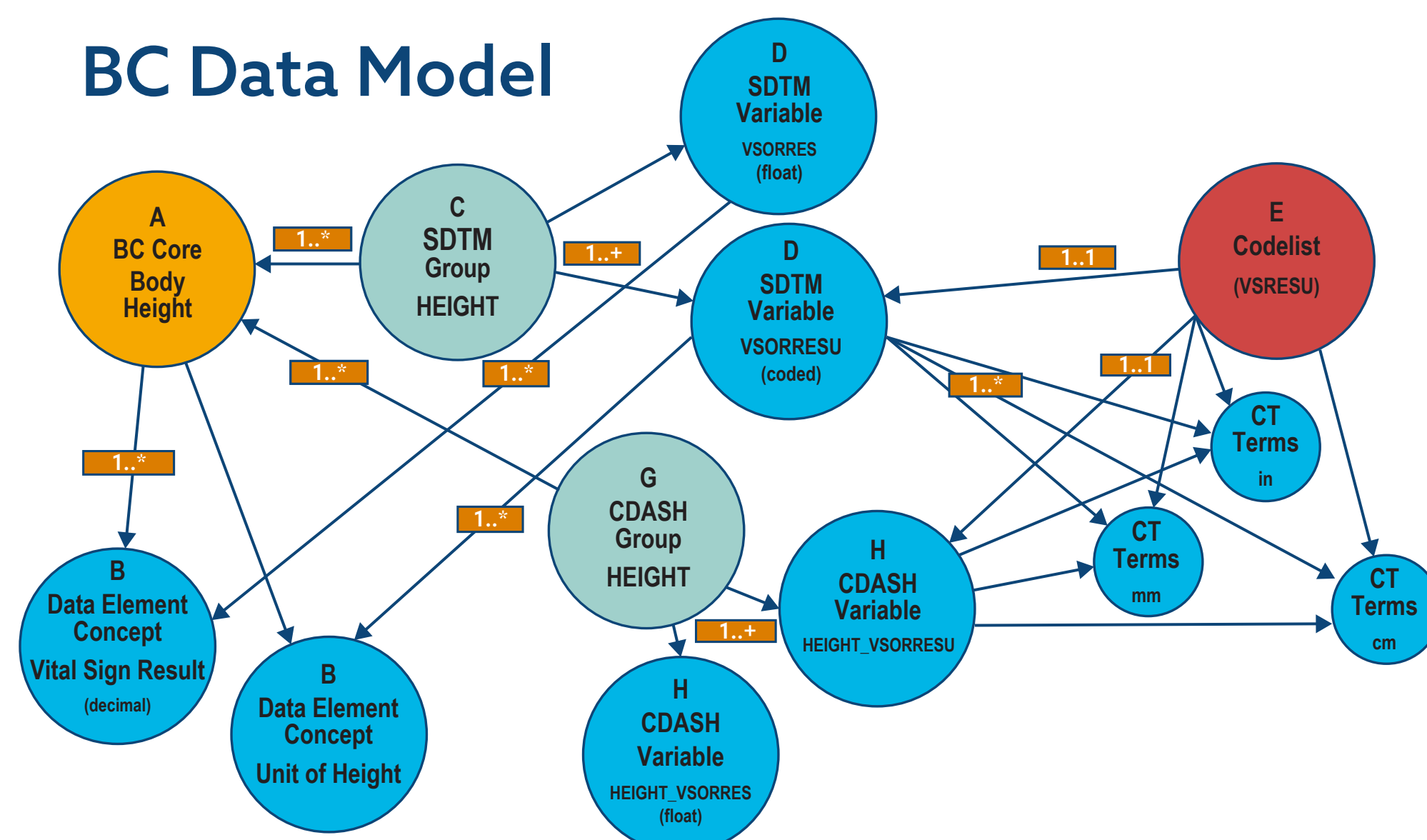
INITIAL USE CASES

- Publish BC content as Define-XML document including Value Level Metadata
- Retrieve a list of assessments for study

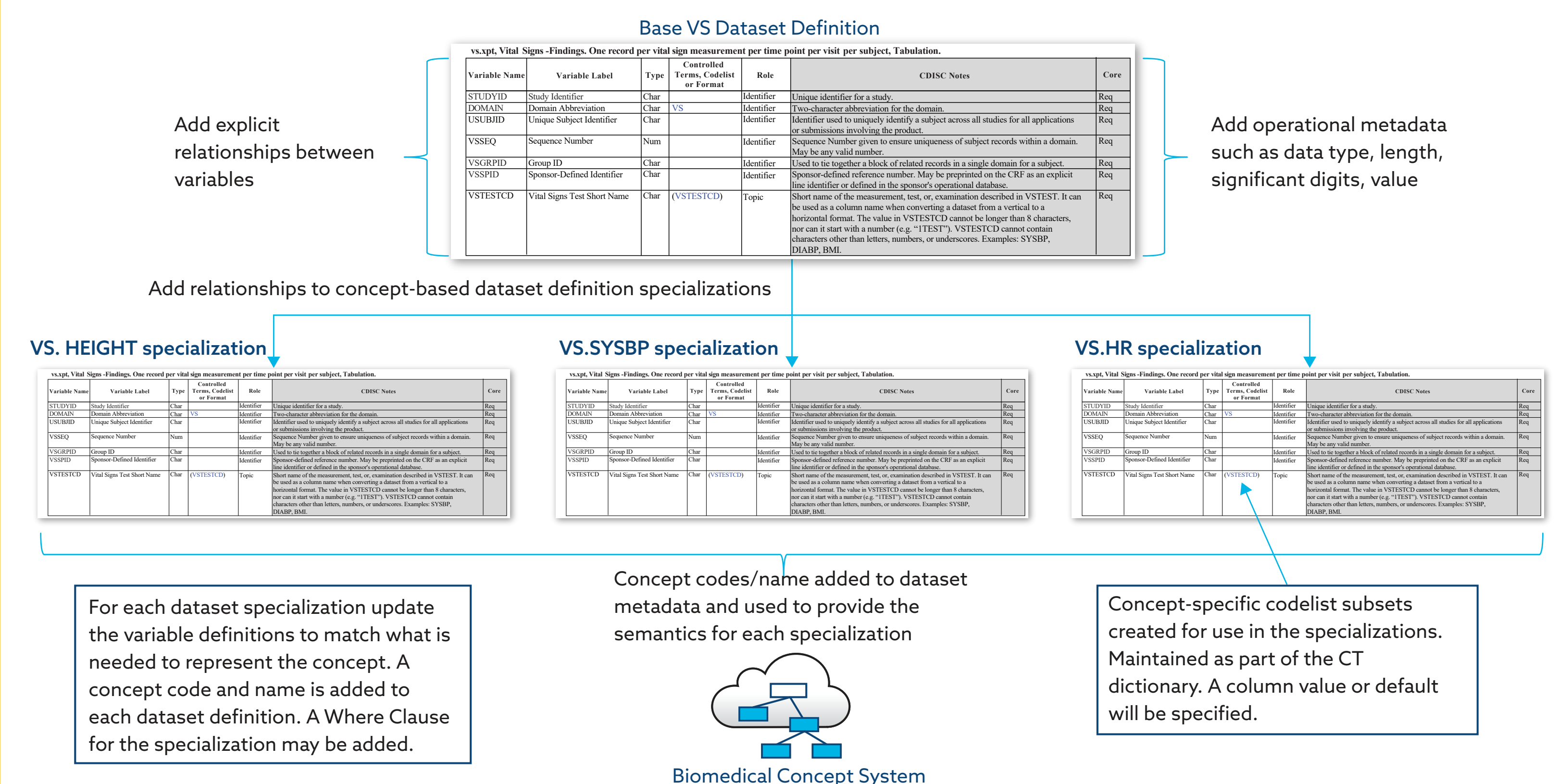
COSMoS BIOMEDICAL CONCEPTS (BC)

- Simplify overall model
- Non-normative standards
- Decouple abstract BC model from implementation model
- SDTM and CDASH dataset specializations are extended dataset structure
- Easier to develop
- Easier to implement, usable out of the box

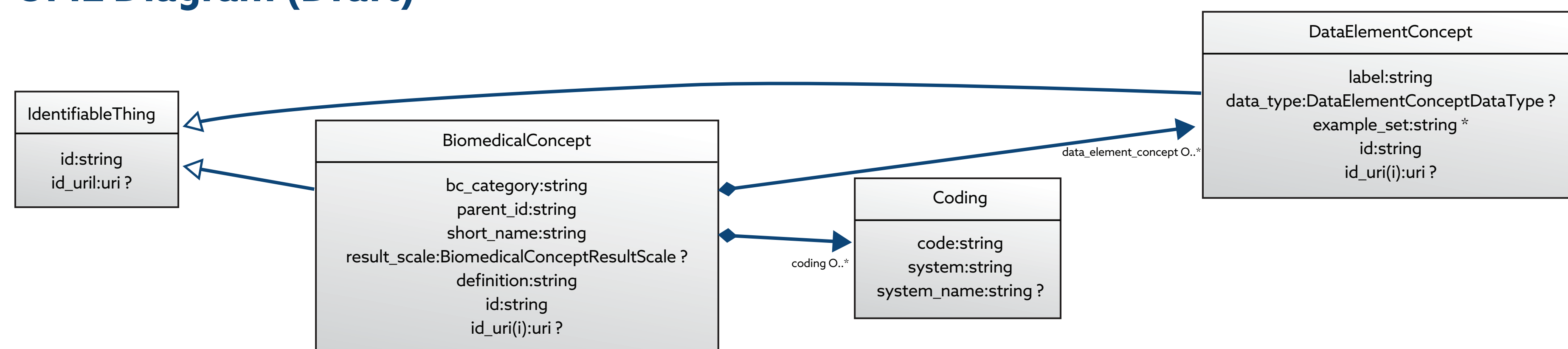
BC Data Model



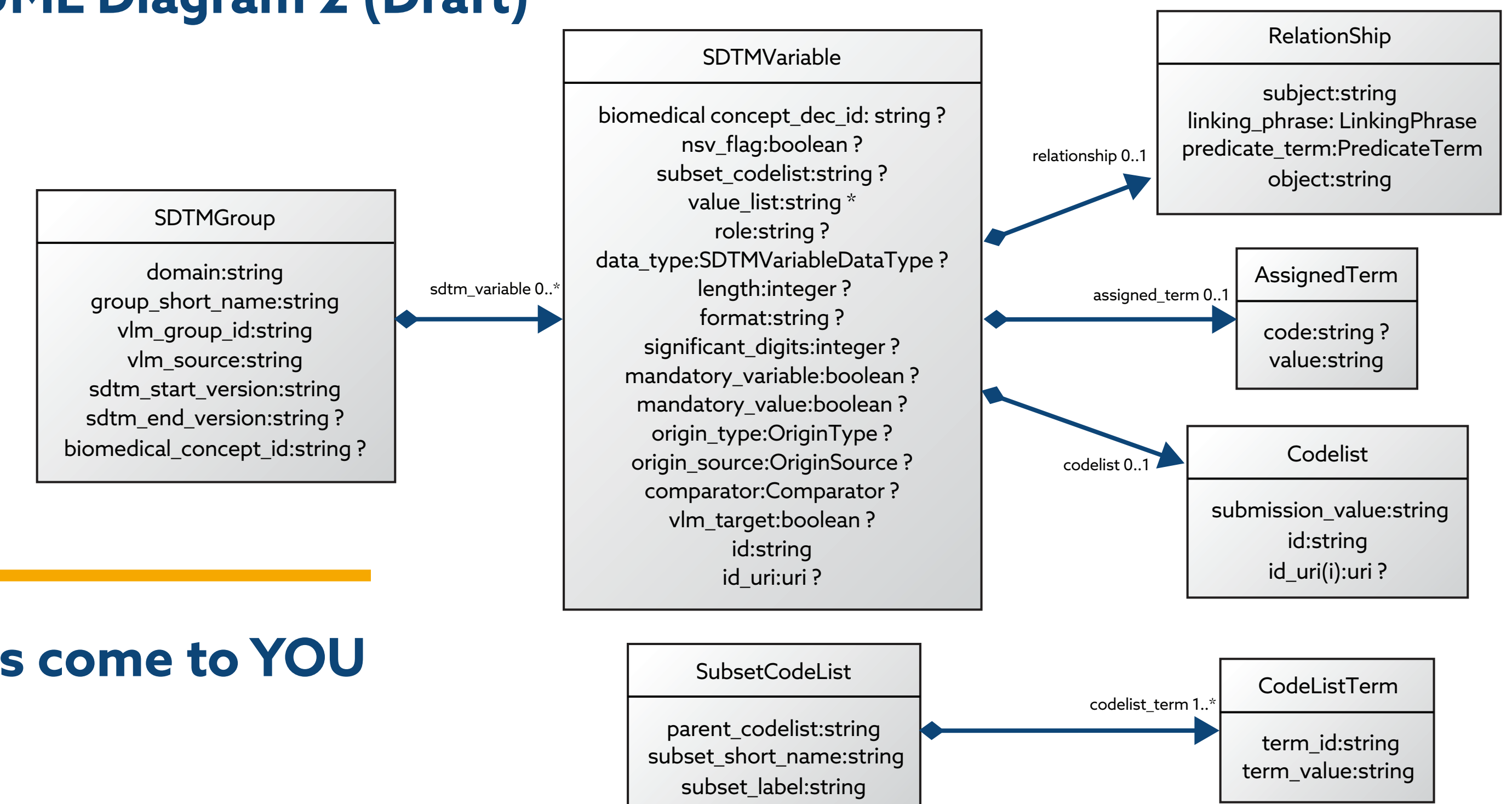
Simplified Model that Separates Concepts and Data Model Metadata



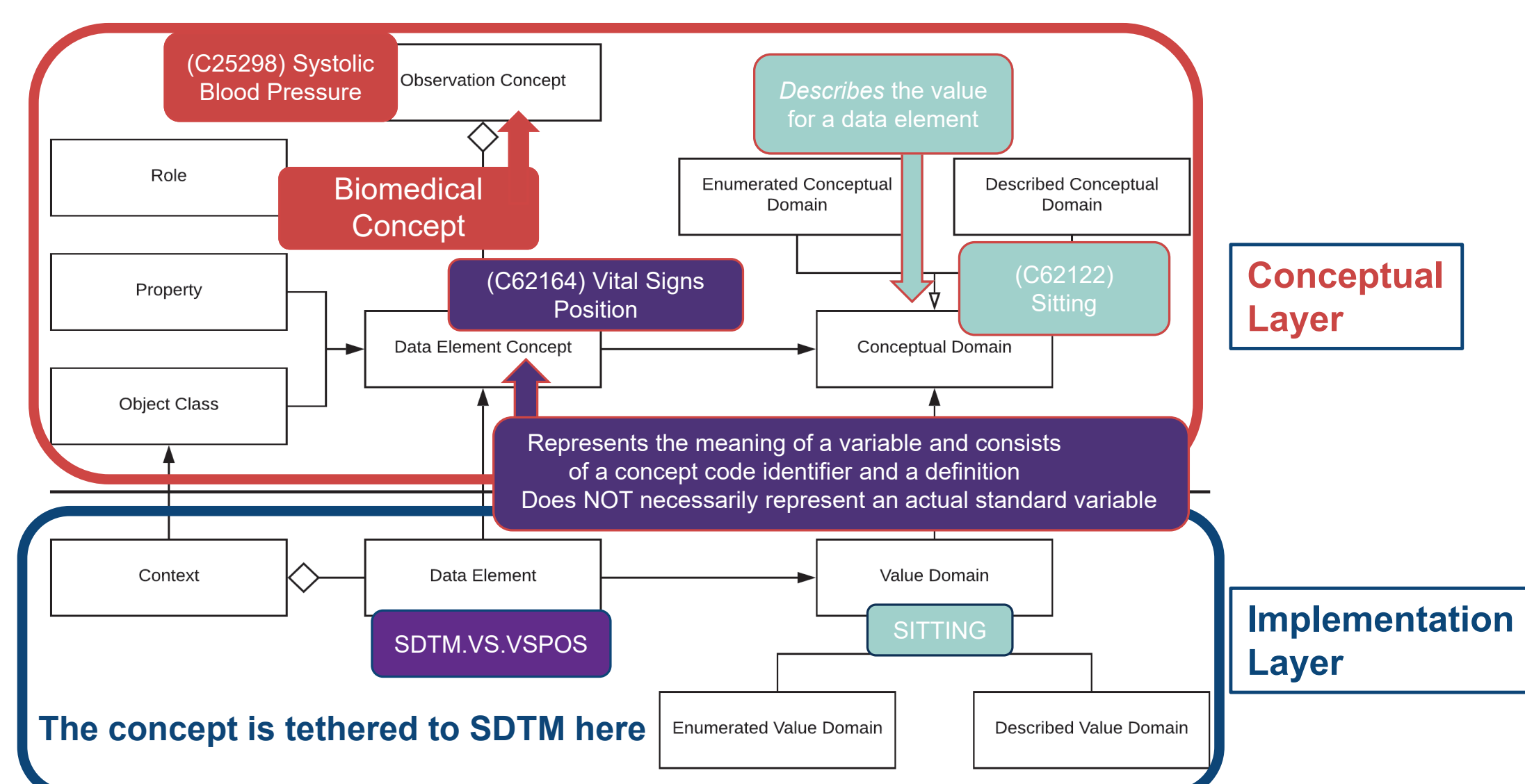
UML Diagram (Draft)



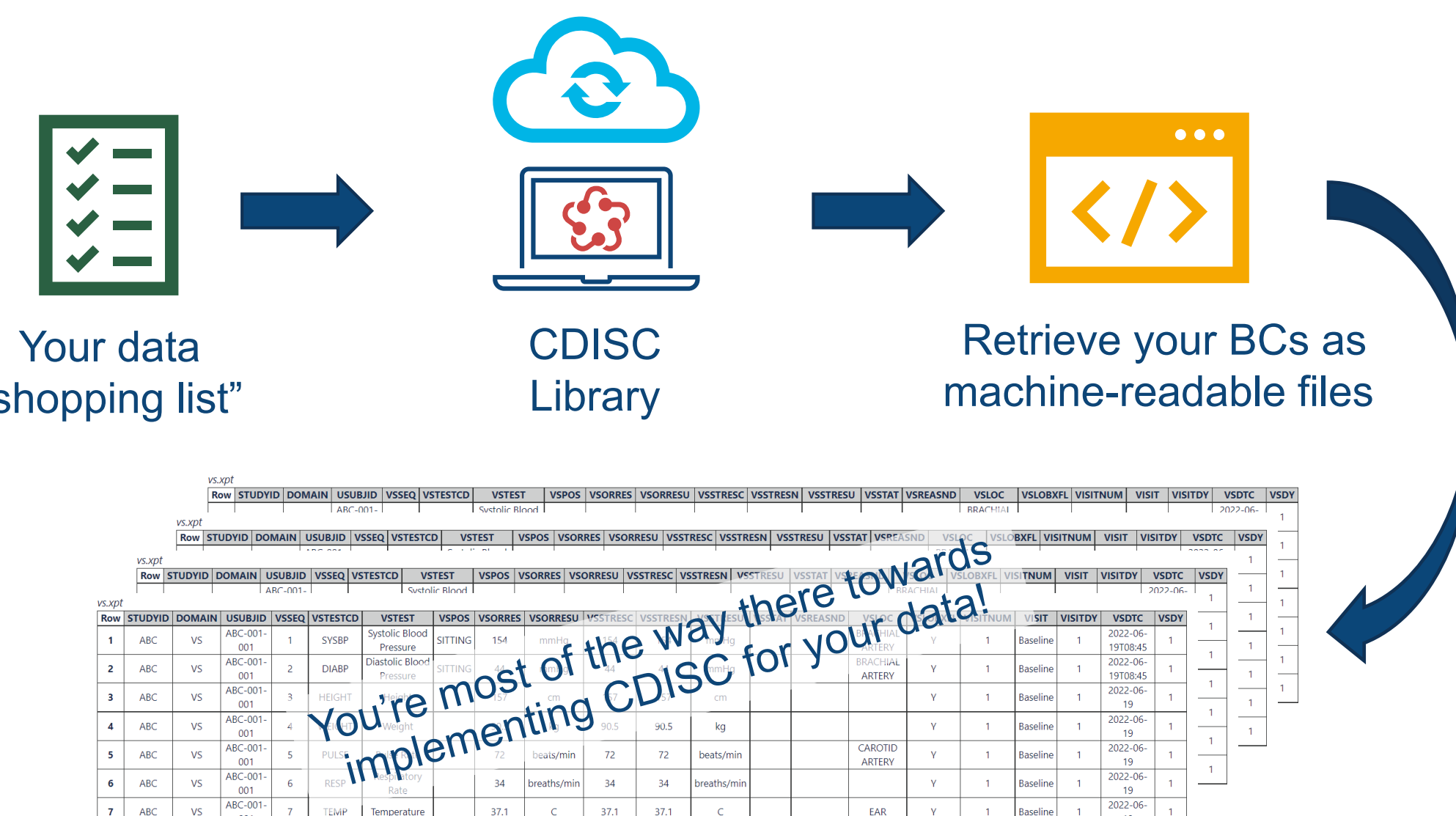
UML Diagram 2 (Draft)



Biomedical Concepts Link to ISO 11179 Model



Focus on your data. Let the standards come to YOU



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2022 CDISC US Interchange
26-27 October | Austin, TX