Multi-Stakeholder Utilization of a Clinical Domain Analysis Model

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Abstract
Development of consensus clinical data standards requires communication methods that clearly convey semantic and technical requirements to clinicians and technologists with disparate perspectives and interests. An annotated clinical domain analysis model (DAM) offers a scalable and extensible solution by integrating clinical definitions, controlled terminology, data transmission formats and clinician-readable representations of specifications. This work illustrates the semantic components of the DAM and relationships among use cases via a single UML-based product. Foundational requirements enable diverse stakeholders to use the DAM from their individual perspectives and understand their representation within the context of others.

Methods
As previously reported2 a multi-disciplinary, cross functional project team utilized a proven standards development methodology3 to create the cardiovascular HL7 DAM (DAM Release 2, which is now an Informative Standard) and a DAM for cardiology. The DAM includes use cases, activity diagrams, and an UML-based CDE library containing precisely defined clinical data elements and permissible values, and robust, broadly applicable metadata specifications.4 A graphical representation of the relationships between semantic components of the DAM was created in the current phase of work to illustrate and clearly communicate the interdependencies across stakeholder perspectives.

Results
The CV DAM R2 includes more than 300 data elements related to the diagnosis, treatment and management of patients with ischemic heart disease and heart failure. These data elements are organized into 166 classes in 4 sub-domains within cardiology. Linkages to controlled terminologies and HL7 RIM mappings were applied using tagged values. CDISC SDTM mappings were captured and are being described in a CDISC SDTM CV implementation Guide. Annotations in the DAM’s UML model make it a viable single source for metadata specification and technical representation of data elements across many use cases. The ability to explicitly capture in a single work product the interrelated metadata and illustrate that complexity of relationships has proven successful. Time required to engage new stakeholders in understanding the complexity and functionality of the model has decreased, and new stakeholders are actively extending the DAM with an additional 500 data elements related to cardiac imaging and cardiovascular clinical endpoints.

Discussion
The semantic content and related use-case driven metadata included in the DAM create a cross-product from which interoperable implementation standards across a wide variety of use cases can be derived. Illustrating data elements within multiple use cases greatly enhances the ability of disparate stakeholders to understand and elucidate the existing interdependence on common data definitions. Improved stakeholder comprehension of these interdependencies reduces the communication burden of a complex technical solution and broadens community support for the DAM.

Conclusion
This shared resource illustrating the relationships among clinical definitions, metadata and various implementation designs is a valuable tool that can be used to engage disparate stakeholders in initial development and extend clinical data standards.

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References

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