webMethods OneData MDR
An Enterprise Metadata Registry Solution for the Pharmaceutical and Healthcare Industries

Deepali Khanduja
VP Product Marketing, MDM

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EXECUTIVE SUMMARY

The ISO/IEC 11179 standard promotes common understanding, standardization and reuse of components of data, both within and across organizations. Common understanding in terms of metadata about data elements is stored in a data element registry or a metadata registry (MDR). Data Element registries provide a way to organize the content and representation of data elements so that data descriptions are consistently specified and can be reused.

This white paper describes the webMethods OneData MDR solution, including specific extensions that have been made to the core software product in order to arrive at a better and more cohesive solution for the pharmaceutical and healthcare industries.

SUMMARY OF NEED

Today’s pharmaceutical and healthcare enterprises encounter a variety of information management challenges, as well as opportunities for significantly reducing operational expenses and improving efficiencies.

Business issues and opportunities:

- Cross-trial analyses are only possible if the variables used across protocols are exactly the same. This is rarely the case in most organizations. The ability to reconcile trials becomes difficult in the absence of a semantic reconciliation layer that links similar variables together in a systematic way. Example: The fact that Arm Diastolic Blood Pressure and Upper Arm Blood Pressure are related may not be known. If the results for one trial can be extrapolated from or compared to other trials at any level, companies can save a tremendous amount of money - easily in the millions of dollars - by reducing expensive and redundant trials.

- The ability to easily meet global regulatory guidance and mandates to comply to clinical data standards (CDISC, HL7 and others), as well as the ability to transform to external submission standards from internal disparate systems.

- The need to have a central source for all internal and external data standards, such as LOINC, MedDRA and ICD-9.

Technical challenges:

- Streamline and automate the specification, acquisition, integration, and analysis of clinical data. Provide support for clinical programs, from protocol planning and specification to post-product launch analysis.

- Effective, timely and accurate integration of data in an organization with disparate systems and processes.

- Ability to seamlessly integrate data and metadata standards into the enterprise Service-Oriented Architecture (SOA) layer.

- Build and maintain an architecture that supports future growth and landscape changes without significant overhead and in a cohesive manner.
THE SOLUTION

Considering these requirements, an effective solution will need to have several different components:

• A standard metadata layer that covers the entire life cycle of a clinical program. Without the standard definition and elements defined, there is no central point of reference or a standard layer to map to. This layer should support standard decomposition of observations as needed, as part of the standard.

• The metadata standard created should be linked to both internal and external standards, so that there is an immediate translation available from source to target via the standard. Automated processes to detect linkages from internal or external metadata assets to the standard should also be available.

• A standard data layer with external data domains (such as CDISC domains) used internally by the organization that can then be deployed and/or mapped to within the solution.

• CDISC SDTM elements and usage contexts built into the core solution.

All of these components and capabilities are built into the webMethods OneData MDR solution for the Pharmaceutical and Healthcare industries, within the framework prescribed by the ISO/IEC 11179 metadata registry standard. At the same time, webMethods OneData MDR provides more than just an ISO 11179 registry, as depicted below in Figure 1.

Figure 1. webMethods OneData MDR and how it works
WEBMETHODS ONEDATA MDR

webMethods OneData MDR, a robust enterprise MDR solution for ISO 11179, is developed and marketed by Software AG. OneData MDR provides organizations both a strategic architectural framework as well as a ready-to-use tool to build, manage, and deploy metadata registries compliant with ISO/IEC 11179 standards. OneData MDR includes a repository built on the 11179 data model, extensions to handle industry-specific requirements, as well as the software application that provides the functionality to access and maintain the repository.

The process of managing an MDR involves creating the data model as well as the presentation layer for maintaining the model and data values, stringent security rules, and embedded workflow and registration processes that can be customized according to the organization’s needs within the context of the standards.

While providing an out-of-the-box MDR compliant with the ISO 11179 standard, webMethods OneData is also fully configurable. The underlying metamodel is extendible, and the user interface is configurable.

webMethods OneData MDR comes with a suite of utilities to help manage and browse the Registry:

- **MDR Import**: The MDR Import engine allows files of any layout to be loaded into the Registry without compromising the built-in rules. The engine detects pre-requisites and creates metadata only if the prerequisites are met. Custom imports exist for Permissible Values, Administered Items, Value Meanings and Classification Scheme Items, which are all constructs of the ISO 11179 standard.

- **Data Dictionary Import and Matching Engine**: Import existing technical metadata into the Registry, and perform auto-match or manual match to link to standard elements using the built-in matching engine.

- **Registration Process**: This is part 6 of the ISO 11179 standard embedded in the Registry, dealing with registration and workflow status transition of metadata items. These include rules, privileges and associated commands.

- **Glossary and Terminological Entities**: The ISO 11179 glossary and terminology are embedded in the Registry. The Glossary can be enhanced with organization-specific terms and interpretations of standard terms. Any user with read-only privileges can access the Glossary.
PHARMACEUTICAL & HEALTHCARE EXTENSIONS

webMethods OneData MDR supports the Pharmaceutical and Healthcare industries by incorporating industry-specific extensions to the MDR, both structurally and in terms of the application utilities provided. Some of the key extensions are described in this section.

Pharmaceutical/Healthcare Extension for Semantic Decomposition

Semantic Decompositions are implemented in the MDR by means of extensions to the ISO 11179 standard. Decomposing observation dictionaries into semantic attributes enables analytical reporting by any cross-section of the attributes. In the example below, Figure 2, semantic decomposition provides the ability to analyze Diastolic Blood Pressure measurements independent of position, or specific to a particular position such as Supine.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Position</th>
<th>Location</th>
<th>Iteration</th>
<th>UOM</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>03</td>
<td>Diastolic Blood Pressure</td>
<td></td>
<td></td>
<td></td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>05</td>
<td>Upper Arm Diastolic Blood Pressure</td>
<td></td>
<td>Upper Arm</td>
<td></td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>06</td>
<td>Supine Diastolic Blood Pressure</td>
<td></td>
<td>Supine</td>
<td></td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>45</td>
<td>Standing Diastolic Blood Pressure</td>
<td></td>
<td>Standing</td>
<td></td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>53</td>
<td>Sitting Upper Arm Diastolic Blood Pressure</td>
<td></td>
<td>Sitting</td>
<td>Upper Arm</td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>65</td>
<td>Diastolic Blood Pressure Reading 1</td>
<td></td>
<td></td>
<td>1</td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>56</td>
<td>Diastolic Blood Pressure Reading 2</td>
<td></td>
<td></td>
<td>2</td>
<td>Mm/Hg</td>
<td>DBP</td>
</tr>
<tr>
<td>77</td>
<td>Oral Body Temperature (C)</td>
<td></td>
<td>Oral</td>
<td></td>
<td>Celsius</td>
<td>Body Temp</td>
</tr>
<tr>
<td>33</td>
<td>Oral Body Temperature (F)</td>
<td></td>
<td>Oral</td>
<td></td>
<td>Fahrenheit</td>
<td>Body Temp</td>
</tr>
<tr>
<td>24</td>
<td>Auxiliary Body Temperature (C)</td>
<td></td>
<td>Aux</td>
<td></td>
<td>Celsius</td>
<td>Body Temp</td>
</tr>
<tr>
<td>96</td>
<td>Body Temperature (F)</td>
<td></td>
<td>Aux</td>
<td></td>
<td>Fahrenheit</td>
<td>Body Temp</td>
</tr>
</tbody>
</table>

Figure 2. Example of semantic decomposition
Data Element Concept and its relationships are used to create the “observation concept.” In the example, Blood Pressure and Body Temperature are the Data Element Concepts used to create a “Blood Pressure Concept.” Related Data Element with extensions to include specific value pair became a specific observation instantiation for the “Blood Pressure Concept.” This ensures compliance with the underlying standard with minor deviations.

Alternate approaches to semantic decomposition can also be implemented. Observations are created completely outside ISO 11179 constructs, so as to make the construct simpler or as additional Administered Item Type instead of Data Elements.

Pharmaceutical/Healthcare Extension for CDISC Data Elements
Outlined below is the set of CDISC SDTM data elements created in webMethods OneData MDR. The example in Figure 3 is of “Group Identifier” which is part of most panels in SDTM. There are two ways to create data elements for the group identifier. Option 1 is more in sync with the ISO 11179 definition of a data element, but a downside is redundancy. Option 2 is more concise and easier to map to systems where the concept of panel is most likely not embedded in the structure. We use the Classification Scheme Item construct to create the usage context – in this example the SDTM panels. Both options are available as part of the standard Registry template.

Figure 3. Two options to create data elements for Group Identifier
Pharmaceutical/Healthcare Extension for Canonical Message Formats

Outlined below in Figure 4 is an illustration of how to generate canonical message formats from within the MDR to integrate with the enterprise SOA layer.

Figure 4. How to generate canonical message formats

The Classification Scheme Item construct has been used for the creation of usage contexts that represent message layouts using the standard data elements defined.

Pharmaceutical/Healthcare Extension for Managing Technical Metadata

webMethods OneData MDR extends the ISO 11179 standard to manage technical metadata assets such as models and dictionaries. Pre-built utilities are available to import and schedule data dictionary loads from databases or files.

Figure 5. Extending ISO 11179 to manage technical metadata assets
Auto-matching algorithms supported by an underlying heuristic matching engine attempt to link system table columns to data elements. The process for requesting the creation of new data elements from the system layer is also embedded, which passes the requests through a workflow process for approvals and notifications. See Figure 5.

**Pharmaceutical/Healthcare Standard Data Sets**
OneData MDR has been pre-configured and populated with Standard Data sets relevant to the pharmaceutical and healthcare verticals, including the following:

- LOINC
- FDA/CDER (NDC codes with enhanced information from alternate sources)
- CPT-4 (AMA license required as a pre-requisite)
- MedDRA (MSSO license required as a pre-requisite)
- ICD-9-CM
- ICD-10-PCS

ISO/IEC 11179-based metadata registries (MDR) address the semantics of data, the representation of data, and the registration of the descriptions of that data. It is through these descriptions that an accurate understanding of the semantics and a useful depiction of the data are found.

The purposes of ISO/IEC 11179 are to promote the following:

- Standard description of data; common understanding of data across organizational elements and between organizations.
- Re-use and standardization of data over time, space, and applications.
- Harmonization and standardization of data within an organization and across organizations.
- Management of the components of data; re-use of the components of data.

**ISO/IEC 11179 OVERVIEW**
ISO/IEC 11179 is a six part standard. Each part is devoted to addressing a different aspect of the needs listed above.

Part 1 – Framework – Contains an overview of the standard and describes the basic concepts.
Part 2 – Classification – Describes how to manage a classification scheme in a metadata registry.
Part 3 – Registry metamodel and basic attributes – Provides the basic conceptual model for a metadata registry, including the basic attributes and relationships.
Part 4 – Formulation of data definitions – Rules and guidelines for forming quality definitions for data elements and their components.
Part 5 – Naming and identification principles – Describes how to form conventions for naming data elements and their components.
Part 6 – Registration – Specifies the roles and requirements for the registration process.
webMethods OneData MDR provides the components and capabilities to support the ISO 11179 standard needs of the Pharmaceutical and Healthcare industries. OneData MDR, a robust enterprise metadata registry, promotes the automated sharing of data and better monitoring, compliance, and enforcement of the ISO 11179 standard across your enterprise. OneData MDR fosters common understanding, standardization, and reuse of data components both within and across organizations, helping you organize the content and representation of data elements. In addition, webMethods OneData MDR provides more than just an ISO 11179 registry, as it is built upon webMethods OneData’s enterprise Master Data Management (MDM) framework. Because of this, OneData MDR provides a strategic architectural framework that is easily expanded to support ANY of your future data management needs.
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