Release Notes 0.2.0

GitHub Link

Summary

The IDMP Ontology release 0.2.0 was created as part of the early start of the IDMP-O project mid-November till end of 2022. The changes made during this period fell into several categories:

- Commons ontology revisions – including alignment of those that have been released by the Object Management Group (OMG) with the formal specification and extension of the products and services ontology to incorporate GTINs, UPCs, and SKUs, and add organizations and in particular, government organizations together with jurisdictions for the EU (others will follow in 2023)
- ISO IDMP ontology revisions – addressing some of the issues that came up during meetings in Boston, a very preliminary ontology for SPOR-related controlled vocabularies, the addition of some of the concepts required to answer competency questions related to UC-2, bridging the gap between regulatory and manufacturing, the addition of metadata annotations to enable clearer identification of deviations from the ISO standards in the ontologies, and additional restructuring needed to provide better semantics for substance-related concepts (which deviate from what is in the ISO standards, including new annotations)
- Revision of the UC-1 SPARQL queries to align with the changes made to the ontologies
- Revision of the GSRS transformation scripts to simplify them and align with changes to the ontologies
- New mappings and transformations to support SPOR reference data (OMS and SMS)
- New hygiene tests as a part of the infrastructure to address potential performance issues, including a new report to summarize deviations from the ISO standards using the new metadata annotations
- Governance and Infrastructure configuration updates

Detailed Description

Category: Commons Ontology Library (CMNS)

Summary: This quarter, 11 of the ontologies included in the current CMNS ontologies were published as a formal standard by the Object Management Group (OMG). The current library in use by the IDMP project includes an additional 9 ontologies that we will work on standardizing at OMG in 2023 along with a subset of the jurisdictions that we hope to complete and promote at OMG by the end of this year. Most of them were originally part of the Financial Industry Business Ontology (FIBO), and well tested in that context. They are all quite general useful for many ontology projects in addition to the IDMP effort. We will be revising FIBO and other projects to leverage the same version of these ontologies that we promote at OMG, and will incorporate any new insights that come from the other projects that use them as appropriate.

Changes to the ontologies that are not yet standardized by OMG, incorporated this quarter, include extension of the products and services ontology to incorporate GTINs, UPCs, and SKUs, the addition of small ontologies for organizations and in particular, government organizations, a small locations ontology, and 7 new jurisdiction-specific ontologies covering the EU, United Kingdom, and Western Asia, as some countries in Western Asia are members of the Council of Europe. These jurisdiction-specific ontologies and others that we have yet to generalize from FIBO are needed to represent the various regulatory agencies required for IDMP.

Category: ISO IDMP Ontologies

Summary: Shortly after the initial Phase I release closed, the ontology team met with some of our stakeholders in Boston for workshops after the Pistoia Alliance conference. Several questions came up during those discussions, some of which led to Jira issues that we have addressed since. One of those was that IDMP ontology users were generally confused by the way ingredients were modeled in the ontology, which has been refined with this release.

Another issue was that a number of our stakeholders understood the need to model various concepts differently in the ontology from their more relational representation in the IDMP standards, but wanted a way to highlight those differences and report them back to the ISO working group as potential areas for enhancement in the standards. A new ontology that provides annotations for various ways that an IDMP ontology might differ from the relevant ISO standard was added to the META partition, and we have initiated incorporation of those annotations where they are appropriate. We will perform a comprehensive review in Q1 to ensure that we have annotated all such deviations properly and using a new reporting capability discussed below under hygiene testing can run the report at any time to highlight the deviations for our users and to forward to ISO TC 215 as appropriate.

Yet another issue that was discussed in Boston had to do with the simplistic way jurisdictions were modeled in the Phase I ontology. We initiated work to address this in Q4 for the EU by (1) including EU-specific governments and jurisdictions in Commons as mentioned above, and (2) moving the EU-specific regulatory agencies and registration authorities from the current ISO 11238 Registration Authorities ontology to a couple of new jurisdiction-specific ontologies in a new European Jurisdiction partition of the ISO category. We expect to continue moving and expanding on the number and nature of regulatory agencies and registration authorities for other jurisdictions following a similar pattern over the coming months until we have good coverage for the rest of the planet. Jurisdictions are divided based on the United Nations’ M49 codes for continents and the countries that are located in those continents, as well as based on ISO 3166 countries and country subdivisions.
One of the main areas of work this quarter was the addition of the mapping to SPOR. Most of that work involved the mapping and transformations discussed below, though we added a new, small starting point ontology to capture some of the SPOR-specific controlled vocabularies. More of these will be added over the coming months.

Finally, we initiated work on changes to the ontologies to support our next set of competency questions related to bridging the gap between manufacturing and the regulatory areas of the pharmaceutical industry, as well as continuing a bit of restructuring of substance related concepts to provide more scientifically oriented semantics than is reflected in the ISO standards. The concepts that no longer conform to the standards are annotated using the new metadata annotations defined for that purpose.

Category: Competency Questions (SPARQL Queries)

Summary: The primary changes made over the last several weeks involved streamlining the existing queries and revising them to reflect the latest revisions to the ontologies. Several additional queries were added to better reflect what is needed to answer the questions and to provide examples that the various pharma companies can use as examples for internal query and mapping efforts.

Category: Mappings and Transformations

Summary: This quarter a significant effort was focused on the preliminary integration of the IDMP ontologies with data from the European Commission’s SPOR repository. This includes support for reference data from several SPOR repositories. Some preliminary work to generate content reflecting various SPOR-specific controlled vocabularies was included as a part of this initial effort, which will be aligned with the ontology as the vocabularies are mapped more completely in 2023. In addition to SPOR integration, the GSRS transformation scripts were updated to simplify them and align with changes to the ontologies.

What's Changed - By Pull Request

- IDMP-GitHub-MaturityAlignment - Maturity Levels to About File Contents Alignment by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/220
- Update config by @pattrycjamia in https://github.com/edmcouncil/idmp/pull/221
- IDMP-298 - Rename IngredientRole to Ingredient, including its subclasses by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/223
- IDMP-CMNS-1.0 - Revise the Commons Ontology Library per OMG updates by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/226
- IDMP-356: Simplify GSRS transformation scripts by @aliariff in https://github.com/edmcouncil/idmp/pull/234
- IDMP-326 - Add the concept of a Global Trade Item Number (GTIN) by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/231
- IDMP-235: Fix ChembliDatabase URI by @aliariff in https://github.com/edmcouncil/idmp/pull/235
- Sync GSRS transformation files by @aliariff in https://github.com/edmcouncil/idmp/pull/237
- Fix GSRS script for result generation by @aliariff in https://github.com/edmcouncil/idmp/pull/236
- IDMP-GitHub-228 - Nameless substances by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/242
- Cq updates mvp.01 by @stsilva-osthus in https://github.com/edmcouncil/idmp/pull/218
- IDMP-305 - Update Ontology with jurisdiction concepts as discussed in Boston workshop by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/240
- Update config by @pattrycjamia in https://github.com/edmcouncil/idmp/pull/245
- IDMP-366: Add RIM related IDMP concept: Packaged Medicinal Product by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/247
- IDMP-312: Add SPOR Substances Transformation by @aliariff in https://github.com/edmcouncil/idmp/pull/238
- Remove old GSRS sparql-gen scripts by @aliariff in https://github.com/edmcouncil/idmp/pull/248
- IDMP-Github-249 - Wrong versionIRI in ISO/EuropeanJurisdiction/EuropeanRegistrationAuthorities.rdf by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/250
- New about and metadata files by @mereolog in https://github.com/edmcouncil/idmp/pull/252
- IDMP-GitHub-MaturityAlignment - Maturity Levels to About File Contents Alignment by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/253
- Update MetadatAISO with missing import statements by @mereolog in https://github.com/edmcouncil/idmp/pull/255
- IDMP-380 - Make "isStoichiometric" on chemical substances optional by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/259
- IDMP-357 - Add EMA SPOR SMS 'substance domain' to the Substances ontology by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/257
- IDMP-380 - Make "isStoichiometric" on chemical substances optional (reverse) by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/263
- IDMP-367 - Include SKUs in IDMP-O by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/262
- Adjust transformation for SPOR SMS by @aliariff in https://github.com/edmcouncil/idmp/pull/260
- Performance driven hygiene tests by @mereolog in https://github.com/edmcouncil/idmp/pull/267
- IDMP-390 - Add annotations to suggest changes to definitions that are needed in the IDMP standard by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/272
- IDMP-348 - ISO conformance report as a hygiene test by @mereolog in https://github.com/edmcouncil/idmp/pull/270
- Update catalog-v001.xml to fix an obsolete Locations.rdf resolution by @mereolog in https://github.com/edmcouncil/idmp/pull/275
- IDMP-391 - The relationship between structure and structural representation should be better defined by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/277
- IDMP-367 - Complete the set of terms required to answer UC-2, CQ-1 by @ElisaKendall in https://github.com/edmcouncil/idmp/pull/277

New Contributors

- @aliariff made their first contribution in https://github.com/edmcouncil/idmp/pull/233

Full Changelog: https://github.com/edmcouncil/idmp/compare/master_v0.1.0...master_v0.2.0