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White Paper

IDMP Considerations in 2022: Interoperable Structured Data Reporting

Abstract

Interoperable structured data, or the ability to re-use internally generated data for reporting to Regulatory Authorities is increasingly burdensome for pharmaceutical companies. At the same time, as individual territories requirements become more complex, it is more challenging to navigate Standards implemented across the world.

A well-planned Regulatory Information Management (RIM) solution is critical for effective recording and retrieving regulatory data. Simply, translating easily understood, globally applicable internal terms into an extractable structured data message. Those pharmaceutical companies who have strong vendor relationships and have taken the time to future-proof their RIM solution benefit the most as guidance and requirements evolve.

This white paper examines some real examples of interoperable structured data and provides some practical recommendations for reporting and preparing for future changes.

Introduction

Structured data requirements have significantly developed over the last 5 years precipitated by the Identification of Medicinal Products (IDMP, or more accurately ISO IDMP[1]). This internationally-agreed terminology and format facilitates the interoperability of data, improves pharmacovigilance activities, avoids duplication of encoding activities and allows easier information exchange with and between regulatory authorities.

IDMP is enforced through Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26). Those articles mandate the future use of ISO IDMP for the exchange of information on medicinal products across the European Union. ISO IDMP implementation within the EU is through a master data initiative based on four ISO standard domains: Substance, Product, Organization and Referentials, commonly known by the acronym SPOR.

Recent changes to IDMP implementation strategy have resulted in a complex but logical picture developing. Combining existing structured data reporting (xEVMPD[2]) and business processes (eAF[3]) with developed but yet-to-be-implemented reporting (FHIR[4]) into a sensible roadmap for the next few years.

[1] International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)
[2] Extended EudraVigilance Medicinal Product Dictionary
[3] Electronic Application Form
[4] Fast Healthcare Interoperability Resource

The purpose of this document is to provide a general background but also practical examples to ensure that pharmaceutical companies remain appraised of the implications of interoperable structured data reporting.

Modeling Your RIM Data in the Context of Guidance for Structured Data Reporting

Pharmaceutical companies don't live in a world structured into four convenient ISO domains. Although the ISO organization provides a useful reference, this data structure is solely to facilitate the collection and processing of structured data by a regulatory authority. This completely omits business processes, ease of data entry and retrieval, or reviews and approvals by pharmaceutical companies on their data. Fortunately, data can be modelled within a pharmaceutical RIM system to bridge this gap. This is a critical concept to understand for vendors and customers alike. Otherwise there will be gaps and disconnection in data capture or a never-ending implementation.

It may be tempting to match the SPOR data structure from the start. While this may be optimal for the exercise of mapping to IDMP standards, it is generally not practical within the context of a complex pharmaceutical company. It introduces cumbersome routines which do not consider the time and effort of, not only to enter but simply to digest information. RIM system implementations must be more pragmatic and adaptive to internal needs as well as current and future reporting requirements.

RIMS must be independent but compliant with the regulatory guidance constraints in terms of objects, class definition and data relationships (cardinality). This is a technical way of saying that as long as your RIMS is well structured, then the creation of the structured data message for reporting is a simple translation of your internally accepted terms. When guidance changes, your RIM system can accommodate it by simply re-mapping or adding data elements.

Following this train of thought, regulatory guidance will evolve over time but should not be permitted to dictate core RIM data structure. After all, the guidance for structured format and reporting represents data from the Regulatory Authority's point of view, not the sponsor's. For example, xEVMPD does not have a formal definition of a "Product" with each submission being language dependent and the "product" as a combination of Active Pharmaceutical Ingredient (API), Strength and Dosage Form. However, re-using and reporting on a Product is of paramount importance to a pharmaceutical sponsor or MAH.

IDMP currently only has a partial definition as a Pharmaceutical Product Identifier, not yet fully described in the EU Implementation Guidance (IG). Of course, you will want to capture this information in the RIM system regardless of the IG. If and when the guidance catches up, you can re-use or extend your RIM data to support it.

Furthermore, the IDMP guidance messaging data model is generic and therefore must support all existing products. Many companies will never sell a product with a lyophilisate and solvent combination, or co-packaged combination therapies, but they must be contained in IDMP guidance. Implementing overly complex data structures drains time and effort, and may not add any business value. Companies typically have timelines and/or resource limitations, which means that lengthy data entry routines as dictated by IDMP structure will not be appropriate.

Perhaps stating the obvious, but a RIM data model should be driven primarily by internal needs and augmented with structured data reporting. For instance, a company's Master Data Management strategy is company-wide and not just for regulatory purposes. Often regulatory use is an afterthought.

Companies have a clear internal definition of "Product", "Brand" and "Composition", not just for regulatory purposes but for other consumers such as pharmacovigilance (PV) or enterprise resource planning (ERP).

A RIM system should facilitate data entry, reduce duplicate entry and accommodate data sharing such as master product data with other systems. Data retrieval should be a priority for the user experience ensuring that searching is efficient and various means of reporting is streamlined and appropriate for the business purpose, i.e. GXP reporting verses dashboards, or physical reporting from a defined query.

As discussed, the structured data reporting should be a translation of the company vernacular and an important part of aligning business processes and data presentation and retrieval. Items such as primary and secondary packaging or nested packaging items must be captured in a way that is obvious to the consumer of the data. Thus presentation of such complex data is beyond simple vocabulary.

And of course flexibility is key. Even though your company may not have a recombined product or a co-packaged one, it may be developed or acquired during the life of the RIM system. That means that while a current implementation may be simpler, it should ensure that adding additional complexity only requires minimal configuration, not large-scale re-development. RIM data structure should be driven by the company strategy and not guidance implementation choices. RIM systems need to be flexible for local adaption and will evolve over time. After all a RIM system is a global solution and of course guidance are regional, IDMP is an ISO standard, EMA Implementation guides are EU etc.

Controlled Vocabularies

The argument around controlled vocabularies is very similar to the themes presented for RIM data structure. Within a well-structured system, company controlled terms or RIM controlled terms should be mapped to structured data reporting terms and codes. For example, a specific substance will map to a single CAS number which is then used in CMC reporting. The same substance will also map to an xEVMPD EV code which will be submitted to the EMA in the composition. If the same product extends to the United States, the substance should map to the underlying UNII code. IDMP will map the same substance to an SMS code.

In all those cases, it is only a single RIM substance, which is also the company term. RIM users can quickly add the substance familiar to them into the composition, and the system will natively translate the RIM term into the appropriate guidance term.

Such mappings also facilitate a company-specific granularity for terms. For example, when mapping indication codes, a company may have several different terms which map to a single MedDRA term. Each of those terms may map to a separate SNOMED term, allowing for a seamless integration between regions.

What is perhaps more interesting is actively creating RIM terms before they exist in reporting vocabularies. This allows a degree of preparedness and allows cross-regional extraction of RIM data like in the indications example above. Even better, a RIM data can integrate with a Master Data Management system, supporting better governance for term management.

Supporting Message Generation

Mapping between RIM data model and structured data reporting should be managed at three levels. The first, object mapping, followed by field mapping and finally value mapping/controlled vocabularies. This provides the most logical and systematic management of RIM structures and enables multiple layers, as more regulatory authority-driven data reporting processes come on-line.

Today, companies should continue to analyze their ISO IDMP capability and participate in the agency lead testing and development. Companies should also continue to generate, with their vendors FHIR message prototypes as this will be an integral part of data message generation in Europe and potentially globally. In the short term, the Digital Application Dataset Integration (DADI) initiative and the resulting electronic application form (eAF) will include the IDMP dataset in human readable format. This will assist DADI web forms data entry and data verification, thereby supporting the presumed rapid development of the eAF. In the long term more automation is expected dependent on the EMA roadmap and capabilities.

Conclusion

Interoperable structured data reporting is a global reality. The recent EU change in IDMP implementation strategy only enhances the importance of implementing an adaptable RIM system. The global landscape for regulatory guidance is increasingly complex, so any robust RIM system should seamlessly translate company terms and processes to current and future needs. The EMA and EU National Authorities are making unprecedented efforts to share their development, openly court feedback and interaction, and are extremely candid in their expectations and plans. This provides an opportunity to those pharmaceutical companies who have strong vendor relationships and more importantly are willing to take the time to participate in IDMP development. The benefit being that these companies will inevitably make the specific transition to IDMP more smoothly. Globally, those companies which act now developing “a process toolbox” and a robust approach to their interoperable structured data and subsequent RIMs design strategy will ensure future preparedness.