

Converge or Be Purged: IDMP Product Standardisation Deadline Looms

The Identification of Medicinal Products (IDMP) is a set of standards defined by the International Organization for Standardization (ISO). The initiative has enjoyed cross-border support, with the regulatory authorities of the US, Canada, and Switzerland all publicly committing to adoption at some point in the future, and Japan, Australia, Russia, and Iran all expressing at least some level of interest. Europe is the first major region to officially adopt IDMP. The European Medicines Agency (EMA) has mandated that all life sciences organisations in Europe and those selling products in Europe demonstrate compliance by July 1, 2016, and has created a task force to regulate the standards.

Specifically, IDMP requires that life sciences companies assemble data that is sourced from multiple systems and produce a single output file for submission. The emergence of IDMP and other cross-disciplinary standards is driving interoperability, and pushing life sciences companies to find ways to coordinate across multiple systems, multiple departments, and multiple companies, including external service providers. These standards, like so many others, will ultimately benefit life sciences companies by compelling them to align their business processes and supporting systems in ways that lead to dramatic improvements in efficiency. Unfortunately, the efficiencies to be gained from systems that work together hasn't yet been enough to drive widespread changeover, but with new regulations, there's no more waiting it out.

The time to converge is now. Indeed, it's now imperative for IT and business groups to begin formulating a strategy to not just comply with IDMP, but to embrace it as an impetus for change within the organisation.

As is so common with change, the process of getting there will require significant preparation. One of the main challenges in complying with the new IDMP requirement lies in the fragmented landscape of technology systems that house a company's data today. Information is generated and managed in departmental systems within safety, regulatory, manufacturing, and other departments. In order to aggregate the necessary information, the IDMP system needs to talk to each of the other systems. This requires more than just technical integrations. For example, vocabularies and definitions in use today need to be mapped within the IDMP standard. Systems need to actually converge, too. While a challenge, herein lies the big opportunity: the process of establishing a consistent nomenclature and an authoritative source for each data point will naturally compel significant process improvements.

Cross-functional Efficiencies

The purpose of IDMP is to improve the accuracy of safety reporting by standardising how drug products are identified globally. But following its standards will yield value beyond simply regulatory compliance. Standardisation requires that life sciences companies establish an authoritative source for all product data – a big job, but one that will generate incredible efficiencies across a number of functional areas, including regulatory, manufacturing, supply chain management, and even marketing. With standard product nomenclature and a mechanism to unify related data about registrations, regulatory groups can manage product and label changes more effectively. Manufacturing teams can better assess and manage the impact of product changes, and product marketing teams can dramatically reduce the manual churn associated with gathering data including local trade names, indications, and dosage strengths for promotional materials.

In order to comply with IDMP, companies need to focus on interoperability – easier said than done in today's grossly fragmented technology landscape. Information is locked in disparate systems, each supporting a different functional group, with additional systems at work to manage data for all local affiliates. Worse still, data lives in unstructured file sources, such as investigator brochures, SmPCs, 3.2.S/3.2.P sections of dossiers, and protocols. In order to aggregate data from these disconnected domains, life sciences companies need to develop consistent interfaces that use the same vocabulary and data definitions, which gets to the very heart of IDMP compliance. Here's how to get there.

Systems Side of Interoperability

Since data required for IDMP is housed in a variety of source applications and unstructured content files, companies must first determine where the 'golden' records reside. This assessment requires identifying source applications and content that will generate the data, while recognising that there will likely be regional differences. Data will be sourced from multiple global systems (e.g. manufacturing / ERP, RIM, CTMS, and safety). In addition, there are likely to be region instances of these applications, each housing regional-specific data (i.e. labelling, submissions, contract manufacturer data).

With the data sources identified, the next step is to determine the best path for aggregation. This likely involves an 'extract, transform, load' strategy, where programmatic integrations extract the identified source data from each transactional system. There are other extraction methods, but it's important to consider that point-in-time extractions introduce risks around data discrepancies as the systems get out of sync. Integrations



that provide continuous updates to accommodate the frequent changes within source systems may, therefore, prove a much better option.

Once the source data is identified, quality issues must be addressed. To cleanse the data, check for errors and inconsistencies using rules and logic that govern terminology mapping and data matching. Robust data governance processes are needed to properly monitor changes to data, as business logic can be complex regarding how authoritative data is generated (i.e. concatenation of data elements from multiple systems). Finally, the clean data can be brought into your IDMP system of record. RIM systems managing product and registration information already house a substantive portion of the data required by IDMP, and are in many ways the ideal gateway to delivering IDMP data to health authorities and to pharmacovigilance teams that generate individual case safety reports (ICSRs).

Data and Process Side of Interoperability

In order for systems to interoperate, the data housed in the systems also needs to interoperate. This semantic interoperability is key to a successful implementation of IDMP. Each functional group (and system) needs to have a joint understanding of the data fields and the values they capture. For example, there can only be one way to describe the therapeutic area for the same product. In addition, organisations need to embrace coded values and controlled vocabularies. Such standardised values make information transfer more automated, and less reliant on cleansing. Thankfully, the IDMP modellers recognised this and responded specifically with the ISO 11239 specification, which provides controlled terms for a variety of IDMP data, including pharmaceutical dose forms, units of presentation, routes of administration, and packaging.

IDMP readiness was one of the greatest concerns debated among industry leaders at the Drug Information Association's recent eRI conference. Discussions about system integration emerged in nearly every roundtable, panel presentation, and expert talk – even those specifically focused on business, rather than technology, needs. Fortunately, many anticipate that the European Medicines Agency will extend the IDMP compliance deadline. Don't let this be an excuse to delay preparations. Take full advantage of any additional time by identifying the right solution rather than a quick fix. The compliance deadline provides an external forcing function for departments to justify the process initiatives and budget needed to implement and align the best solution across departments.

Done right, the data quality improvements and visibility will produce countless efficiency improvements for regulatory, pharmacovigilance, manufacturing, and supply chain management teams. The controlled vocabularies in IDMP will also help companies finally build interoperable systems. In turn, interoperability will automate the exchange and cleansing of data, thereby providing the entire organisation with an authoritative source for product information worldwide. And, while implementing the necessary process and system changes will not be easy, companies will be closer to their goal of truly global operations. Don't wait. Converge or...

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