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Preparing for IDMP:

The Latest Advice on How to Ensure a Smooth Transition

The forthcoming ISO IDMP standards governing pharmaceutical product information recording have far-reaching implications for the way companies capture, collate, organise and report a very wide range of operational data. Master data management as an approach offers an efficient, definitive way to cope with this. But what does this involve in practice and how can companies ensure they derive maximum payback from any new system investments? AMPLEXOR International's Sonia Monahan explains.

As has become only too clear to the life sciences industry, complying with the forthcoming ISO IDMP standards requires much more than additional administrative box-ticking. IDMP increases the range and scope of product-describing data that will need to be submitted as part of regulatory submissions, which the regulators will need to review and approve the data as part of the submission cycle.

This demands a significant rethink of the data gathering and submissions process – and a step change in the amount and depth of data that is needed. Not only that, but the additional data first needs to be identified and found. Even if it has been formally captured somewhere, this doesn't automatically mean it is readily accessible in a submission-friendly format. Or perhaps some of the detail exists, but it is not complete or up to date. Or if it is, there is no easy way to verify this. Even if the quality of the data is assured, companies will need to consider how easy it will be to lift this data and use it in the way that will be needed for IDMP compliance.

So if organisations have been delaying action because of shifting IDMP deadlines, or because they were waiting for the final specifications to be published, they are likely to be working against the clock to get to where they need to be. Although we still don't know exactly when EMA will require data to be submitted for IDMP purposes, we're probably looking at two years from now – with a firm mandate likely by the end of 2019. Although this might sound a way off, the deadline will come round soon enough – and it really isn't long considering that companies need to scope and define their projects, allocate funding, and integrate and test finished solutions.

Securing Management Buy-in

A priority, then, should be commanding management attention for what inevitably will be a very serious and substantial undertaking. A global perspective may help with this. Although IDMP is essentially a European initiative, its reach does not stop at the continent's boundaries. The motivations behind EMA's data intentions (better data quality, better patient safety) are reflected around the world. And, of course, any international pharma business selling into Europe will be affected by IDMP requirements under the same timelines.

But more than that, agencies such as Health Canada and Swissmedic are already looking at how they too improve their own internal data, and what the rigours of IDMP might offer to help them; markets in the Asia Pacific are also considering their options. Certainly regulators far beyond Europe are developing a keen interest in IDMP. Brexit is not expected to have an impact on IDMP, other than the expectation that EMA will relocate its headquarters to mainland Europe, incurring some upheaval as London-based staff reassess their position and operations resettle. Other than that, we can expect the UK to fall in with IDMP so that it is not out of sync with neighbouring markets.

The message consultants have been trying to get across to prompt early action from companies is that, as long as there remains time to do so, organisations have a chance to make their IDMP preparations a means of improving data management for their own benefit – for instance, as a means of facilitating digital transformation and market innovation, perhaps through the adoption of new business models. If they continue to put off IDMP preparations, on the other hand, they are likely to end up doing the minimum – which may mean cutting corners with information preparation and creating more complexity and work for themselves down the line.

Taking stock

So what should companies be doing at this point, to ensure they deliver for EMA and for their own interests?

The first point is that, even where the final detail around IDMP classifications is not yet known, this should not be a barrier to preparation. Just as a housebuilder does not need to know which fixtures and fittings will go where when they're still laying the foundations.

A more pressing concern is identifying where all of the contributing data currently exists in the company, any sources that might be missing, and how the company is going to bring it all together so it can be used for IDMP purposes. Note that a lot of this data will exist across a broad spectrum of sources beyond regulatory affairs. At a minimum, it will span R&D, manufacturing, clinical and pharmacovigilance activities and systems. So firms will need to review the completeness, currency and quality of all of these diverse data sources, if they are to contribute to a definitive record of product reality.

The next aim should be to move things on from initial IDMP data analysis to a broader plan for 'master data management' (MDM) that will set the company in good stead for wider transformation, not least by strengthening transparency across the different business operations.

It is helpful that EMA's own ambition for ISO IDMP is to improve data's quality and integrity, so that its value increases. This means getting the underlying data (the master data) in order, using agreed standards. The reason ISO IDMP has taken so long to materialise as a set of confirmed definitions is that so much groundwork has gone into this to get the detail right; it's also why there are five standards in total, rather than just one. This is intended to be a comprehensive, definitive structure for data management.

Companies can enhance and add to this source data for their own internal purposes: the idea is that building on the right foundations and using agreed terminology will make the fuller data more meaningful and easier to repurpose confidently – whether for publishing, pharma-covigilance, resource planning or artwork preparation. If the underlying data is trusted, next stages can happen much more quickly. Beyond compliance requirements, then, companies should be striving for a 360-degree view of product data: a global, integrated view of product information that supports business processes throughout the lifecycle of a product; a definitive master data set that serves multiple applications. The data doesn't have to be confined to product information either: agreed identifiers can be used to define other core business entities such as customers, patients, partners, suppliers, locations and employees. Ultimately getting master data under control is about changing the foundation for how life sciences firms operate.

Identifying Best Practice

So what might MDM best practice look like? Speaking at AMPLEXOR's recent annual customer conference, Jens Olaf Vanggaard, a senior life sciences R&D consultant at HighPoint Solutions and a member of the ISO IDMP SPOR Task Force Referentials sub-group, provided a useful analysis.

Looking at MDM from an IDMP perspective, he noted that a single, finished product takes three forms: the pharmaceutical product as administered; the authorised medical product; and the packaged product that ships to market. This is just one indication of the complexity systems need to be able to cope with to keep data correct and in sync. Below these higher-level definitions are the more intricate product details.

The set of processes and solutions used to acquire, enhance and share product data across the enterprise are the key tenets of master data management, Vanggaard says.

Further parameters include 'reference data', the set of permissible values to be used by other (master or transaction) data fields. This data is typically non-volatile (slow to change). But managing the processes and solutions used to acquire, manage and share this reference data across the enterprise will become increasingly important with the introduction of IDMP.

Although the scale of the transition could be construed as daunting, Vanggaard believes the journey to master data management should be viewed as an evolutionary one: the important thing being that companies start somewhere and treat developments as a continuum – with people, processes and technology brought on in parallel.

Establishing Control

The starting point should be data governance, Vanggaard says, warning that "without good data governance, [companies] are likely to fail - no matter what technology [they] implement." As long as there might be inconsistent quality and definitions, for example between affiliates and head office, then the value of the system and its potential ROI will be eroded because the data isn't sufficiently dependable.

So it is important to set out early on how quality and consistency will be managed, who owns the data and who is accountable for its quality and integrity. Unless all the right people are on board with this, the endeavour won't deliver all the hoped-for benefits, so it's important to get complete buy-in. "Establishing clear communication channels will enable stakeholders to have a say in the data management process, increasing stakeholder acceptance and ownership of the data across the different functions," Vanggaard advises.

Another early priority must be to set down a data *strategy*, which defines how the company will increase the value, timeliness and reliability of data assets, perhaps by including external data sources which can augment and improve data quality and completeness.

Data policies and processes should then provide the documented guidelines, procedures and tasks to direct data stewards and other stakeholders so they can ensure the integrity, consistency and sharing of enterprise data resources.

Data stewardship will be critical in extracting value from MDM and IDMP investments. This involves pro-active management and oversight of an organisation's data assets. Operationally, the remit can be broken down into a number of clear steps, from initial data profiling/discovery/scoping, and data modelling, to data cleansing, profiling, enriching, matching, consolidating and relating.

Data matching and consolidation stages involve comparing overlapping data across the company to arrive at the 'best version of the truth', keeping full cross-references to enable un-linking if needed. Data relating allows records to be grouped logically for management and analysis.

Mapping the Journey

A checklist of stages companies can expect to go through on the transition to master data management, then, will look something like this:

1. Identify stakeholders (roles and responsibilities)
2. Define data dictionary
3. Define data sources
4. Define target data model
5. Define data quality rules
6. Conduct data pilot
7. Document and communicate pilot learnings
8. Update data dictionary, data sources, data model and data quality rules
9. Prepare business case for implementation phase

Given that life sciences companies will have to do much of this groundwork anyway to fulfil the needs of ISO IDMP, it is strongly in their interests to invest the time in getting this right and deriving the maximum business benefit, while future-proofing any investment because other, new regulatory demands will be much easier to meet once the core data structure is in place.

Irrespective of whether an organisation plans to implement MDM technology to support IDMP or not, IDMP compliance will require solid data governance and use of master data management principles and processes for data stewardship, so much of the above advice will apply anyway.

Ultimately, master data is ISO IDMP's main focus so it makes business sense to harness this for maximum effect. Research by Gens & Associates suggests that companies using a common model for regulatory information management are *3.5 times more likely to realise business benefits, are 18% more efficient and have 2.5 times more confidence in their data quality*. Broaden this approach out to fuller product and operational information, and the potential gains grow exponentially.

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