Behind the Smoke and Mirrors of IDMP Solutions

PEER REVIEWED

Life sciences technology vendors and consultancies are busy promoting Identification of Medicinal Products (IDMP) compliance solutions, which seems odd, given that many details of the final requirements have yet to be published. With a further two years to go until the latest deadline comes around, organisations have every reason to be sceptical of the value of investing now, says Marc Chaillou of Schlafender Hase.

It has been a source of consternation that the European Medicines Agency (EMA) keeps pushing back the deadline for ISO IDMP (Identification of Medicinal Products) compliance. The latest timescales give companies two more years to get their data in order before the authorities formally clamp down and expect full adherence. It does serve everyone's interests that such a definitive international standard for product data exchange is effective, and supports the high quality and reliability that will ensure the data's value. However, the proposed phasing of adoption and now further delays to publication of the fuller requirements, as well as the cut-off for compliance, are sapping any remaining momentum around the initiative and prompting life sciences companies to prioritise spending elsewhere.

This has not stopped the life sciences technology and services industry from promoting IDMP software and solutions, however, which seems odd, given that the finer details of the medicinal dictionary definitions have yet to be set in stone. It would seem that vendors and consultancies are approaching the challenge/opportunity the wrong way round – offering to get manufacturers' databases and submissions systems up to spec even before that spec has been confirmed. Seeing that solutions are available on the market could lull companies into a false sense of security, and worse, encourage them to invest inappropriately – i.e. in the wrong order.

That is not to say that they shouldn't be preparing. On the contrary, life sciences organisations have their work cut out with IDMP. It is such an ambitious project, on such an ambitious scale, that it will take a lot of time to align all the right pieces. And unless companies can deliver the quality and reliability EMA and ISO have in mind, they will compromise not only the payback on their own outlay, but also the intended benefit to patients. After all, it is their safety that IDMP is designed to ensure - by making the target database a robust, definitive, harmonised record of approved and marketed drugs, using agreed definitions and terminology.

As such, IDMP will be central to mass-scale, cross-border pharmacovigilance. Its slowness to get off the ground is down to the ISO's ambitions for the set of standards, which are much grander and more comprehensive than previous attempts at electronic publishing requirements (most recently XEVMPD), under the remit of regulatory affairs. The implications of this are that data preparation will now touch all corners of the organisation, as well as outlying parties including in-country affiliates and supply-chain partners. All have a part to play in ensuring that core systems and applications contain the latest, accurate information. Consistency and reliability are paramount.

The upside of putting in all of the groundwork to get content in order is that life sciences companies stand to gain from this effort in many other ways. By investing in a central, definitive master resource of product data, they are creating new possibilities for the business and its operations, because that data potentially has value in a range of other scenarios, such as portfolio planning and improved operational management.

But that's only if the data is of high quality, and has been robustly tested to ensure this. This is the investment that companies need to be making now, irrespective of whether IDMP filing timelines may shift again, and of the final specifications that have yet to be agreed.

A Stitch in Time

Forward-thinking companies are treating this intervening time as an opportunity to quantify the data preparation task that lies ahead. First, they need to identify all of the source content, the different formats that it is held in, and where it resides within the global organisation. By creating a comprehensive inventory of files and file types, organisations can start to understand the size and scope of the task that lies ahead and begin to work out how they are going to tackle it.

This preliminary process is likely to throw up a number of issues. For example, when there are multiple iterations of a document, which and where is the most up-to-date version? This might be in Regulatory Affairs, Legal or Marketing, for instance. If it is in a document management system, which one? Very few organisations have a single, comprehensive, centralised system for holding content – and in fact, many have a number of systems in use for different departments – so bringing content together or trying to compare one version with another is unlikely to be easy to achieve. So part of the task must be to itemise all the different software platforms and determine what is where. If the company has been subject to mergers and acquisition activity, and/or has amassed different legacy infrastructures over the years, all of this will add to the complexity of content management. Across the wider ecosystem, contract manufacturers, CROs, local representative offices, translation companies and other service providers will also need to be surveyed for contributing product information.

Beyond structured databases and formal document management systems, there are likely to be assets stored on people's desktops, attached to emails, or kept in folders on servers without a common naming convention. If documents are PDFs, and do not contain selectable text (i.e. if they are simply outlines or images), their content will be difficult to extract and re-use – machines will be unable to read it. Use of non-Unicode fonts – those that are displayed differently or incorrectly across software and operating systems – could also interfere with machine readability. Different languages, different spellings and corrupted content could all compromise consistency and accuracy as organisations work towards a definitive record of correct, current product information. Files may have been broken up by regulatory teams too – so that a master product information file running to 30–40 pages of detail on a drug may also exist as a series of separate Word files – e.g. containing the content for labelling, box content, patient literature – intended for the graphic design team. If these have been copied and pasted manually, and updated/corrected separately, the scope for variation will multiply.

Given all of this complexity, it is surprising that so many life sciences companies continue to put off their preparations until they have the final IDMP specifications. Other than among some of the very large players, who have understood the broader benefit of getting their product data in order, there is still a wait-and-see mentality.

Beware the Emperor's New Clothes

Companies will undoubtedly need help with all of this, but they need to be careful where they go for this assistance, especially in this intervening period where full IDMP solutions cannot possibly be what they claim. How content or data will ultimately be used is purely secondary. The first priority must be to ensure that that data is correct, complete and clean, that it is usable, and that it is of value to the organisation. Without that sure footing, companies will be progressing on shaky ground. Whether the later application is IDMP submission or something more operational and internal, the output will only ever be as good as the source content. Put garbage in and you'll get garbage out. If companies are making the investment, they may as well get the most they possibly can out of it – and one of the biggest benefits of IDMP (beyond improved patient safety) is expected to be huge efficiency gains and long-term cost savings for the industry. As long as the directory is of sufficient quality that it can be used confidently, that is.

So how can companies get ahead, and make this work for them? What they cannot do is cut corners; otherwise they will render their efforts worthless. But they can harness automation, if they understand the task and pick the right tools. When it comes to selecting the definitive source documents, checking for updates, aligning languages, fonts and other intricacies, it is possible to very accurately compare files in different formats for the content they contain – as long as the technology can 'read' content at the right level – one that transcends 'noise' such as font or file type. This ability to quickly compare content of similar documents from multiple sources, in large batches, could help save organisations vast amounts of time in this laborious yet inevitable preparatory stage of getting the company's product data assets in order.

For now, the rest is just smoke and mirrors. It is too early to have a magic database that companies can use to submit to the IDMP. In any case, that final-stage task – definition refinement and submission – will be relatively easy compared to the work that needs to happen now.

As long as all documents have been accounted for, cross-referenced and checked, and labelling and other patient content verified as correct and up to scratch, firms will stand themselves in good stead for what's to come. The final step will be comparing pre-compliant content with the new specifications when the time comes – ideally with an ability to filter and flag key words (controlled vocabularies) to ensure that quality checks will be efficient and reliable.

Developing a plan which takes companies on the journey mapped out here, offers their best hope of being ready, and of deriving the maximum benefit from investments in IDMP.

In the meantime, firms would do well to keep checking the EMA website for new updates (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000645.jsp), and join the IRISS Forum (https://iriss-forum.org/). The latter, which costs a nominal fee of around $100 to subscribe to, is a not-for-profit body of pharma companies and technology vendors. It was set up as a single central forum to promote stakeholder discussion around evolving regulatory submissions standards, user requirements and practical global implementation issues for the mutual benefit of industry, government agencies and public health.

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