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Industry Brief

Maintaining Compliance: Adapting to Changing Requirements

Beginning with XEVMPD, RIM systems have had to maintain compliance with agency requirements. As the industry continues to move towards structured data, the compliance requirements of RIM systems will only increase. As these standards are new and still developing, it is normal and even expected for them to change in non-trivial ways while they are being developed. This puts increased pressure on vendors to produce solutions that can adapt to the changing requirements as quickly as possible after the agency changes them.

For instance, since February 2021, the EMA has published two versions of the IDMP Implementation Guide (IG): 2.0 and 2.1. Ennov RIM/IDMP is built upon a **flexible platform**, enabling implementation of regulatory updates in a fraction of the time as traditional RIM systems. In fact, for both publications, the changes were analyzed, implemented, and tested in less than two (2) months.

Summary of Changes in IG 2.1

On June 30th, 2021, v2.1 of the IG was published. This was supposed to be a minor update to the chapter on IDMP data, however, there were updates to many of the data elements and even the introduction of new data elements. Some of these changes were expected and others were a surprise. While most of the changes were positive, the result was beyond a minor update from a system point of view. The revision also provided updated, clarified process details (chapter 3). Since chapter 3 will be the focus of the next IG update, we will keep our focus on the impact of the changes to chapter 2, the data.

One new data element worth calling out is the Genetically Modified Organisms (GMO) field. While this element is a small addition, the purpose is to align with the Digital Application Dataset Integration (DADI) project and enable interoperability with the new electronic application forms. This is a positive indication that different groups within the EMA working on digital transformation and standardization projects are working together to ensure consistency across the agency. It's easy to see why these interconnected projects are aligning since DADI manages the data related to the procedure and IDMP manages the data related to the product.

In addition to the above and other new data elements, further clarifications were provided:

- general, editorial, and technical clean-up of the guidance document
- the Provenance, or reason for sending the IDMP message, was clarified, which was greatly anticipated
- MedDRA and ATC codes can now be used directly without the need for an RMS mapped term

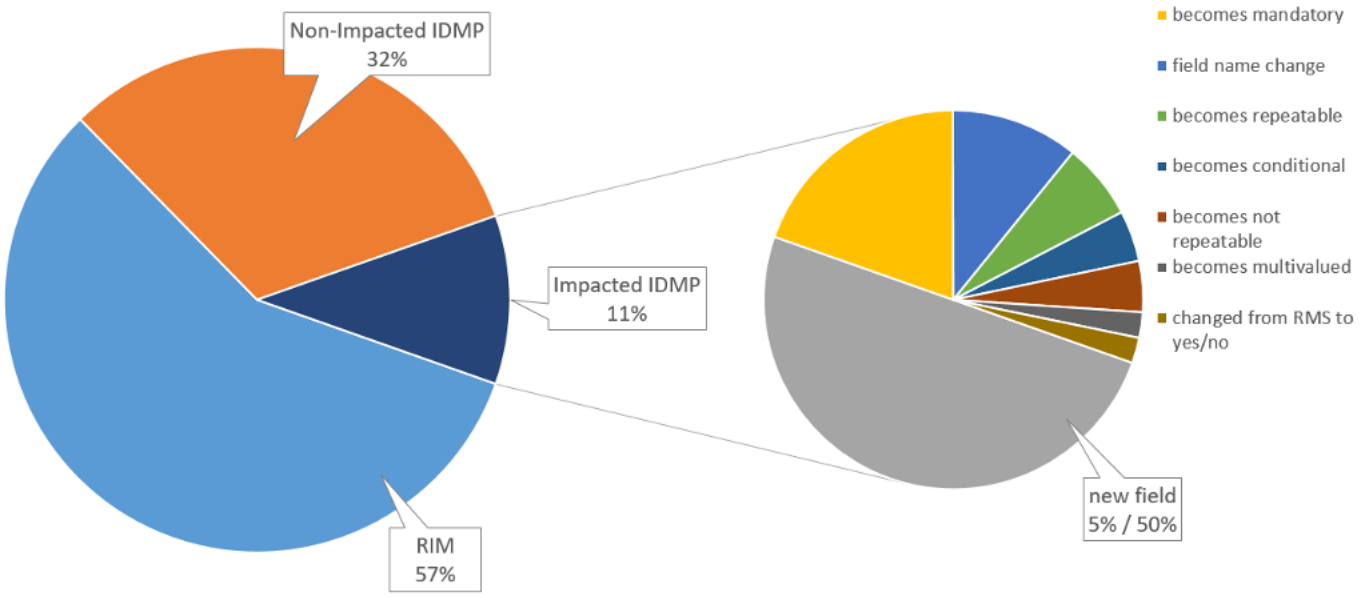
The clean-up explicitly stated things that the prior guidance only implied, provided consistency around the technical details of the data elements and classes, and corrected errors in the prior version.

Analysis of Changes

While changes such as aligning with the DADI project is generally seen as "a good thing", an analysis of all the changes is still needed to truly understand the impact of this minor version update, and put it in context of what it means for Ennov RIM in terms of time to implementation.

Our analysis showed that 12 out of our 18 main data objects were impacted by the IG v2.1 update. The impact wasn't just for registered data but also for master data. Almost all of the main master data and registered data objects were impacted by this update.

It's important to understand that one of the main changes in this update was around general, technical, and editorial clean-up. This means many objects will appear updated even if the modifications were minor. In fact, as the pie chart below indicates, half of all changes were minor clean-up changes and the other half were new fields.



The pie chart on the left represents all of the fields in the Ennov RIM/IDMP product. Roughly 25% of the IDMP fields were impacted by the 2.1 update. This chart clearly shows that half the updates were relatively minor and the other half were new, thus a significant portion of the data model was impacted by this update. The IG v2.1 update was anything but a minor update.

Implementing IG 2.1 in Ennov RIM/IDMP

Prior to IG v2.1 being published on June 30th, 2021, Ennov RIM/IDMP was compliant with IG v2.0. Roughly 30 working days after the v2.1 publication, Ennov RIM/IDMP was compliant with the new v2.1 requirements. That is roughly the same amount of time it took to become compliant with v2.0 as well. In just 30 days, the analysis, implementation, and testing was done for a rather substantial regulatory update. All of the required changes were implemented via configuration. Removing the need to develop or update custom software, resulting in a lighter validation requirement, and more adaptability to fine tune aspects of the implementation for each client.

One measure of how much confidence a sponsor can place in a RIM solution is how quickly it can adapt to the never-ending guidance updates. As the life sciences industry moves more toward structured data, these RIM guidance updates will necessitate the same level of response that the publishing world has needed since the introduction of eCTD. Because Ennov RIM/IDMP is built on our own flexible, expandable, and open platform, our solution easily adapts to the changing regulatory landscape.

It is unknown when the next update will come, how large it will be, or how many updates will follow, but Ennov RIM/IDMP has consistently responded quickly to new guidance updates. While the platform will continue to evolve to be more innovative, Ennov's current track record should establish confidence that clients' needs and timelines are met even when unexpected regulatory updates occur.