PMS and IDMP: Latest Guidance and What you Need to Do to Prepare

Our recent webinar with Remco Munnik, Director at IPERION, a Deloitte Business, Jack Kelleher, Head of Innovation at Generis, and Karolina Rogowska, Head of Marketing at Generis was a session packed with invaluable insights into the IDMP landscape, and Generis' approach to IDMP-ready Data Management with the CARA Life Sciences Platform.

Below are some of the highlights and key insights from "***PMS and IDMP: Latest Guidance and What you Need to Do to Prepare.***"

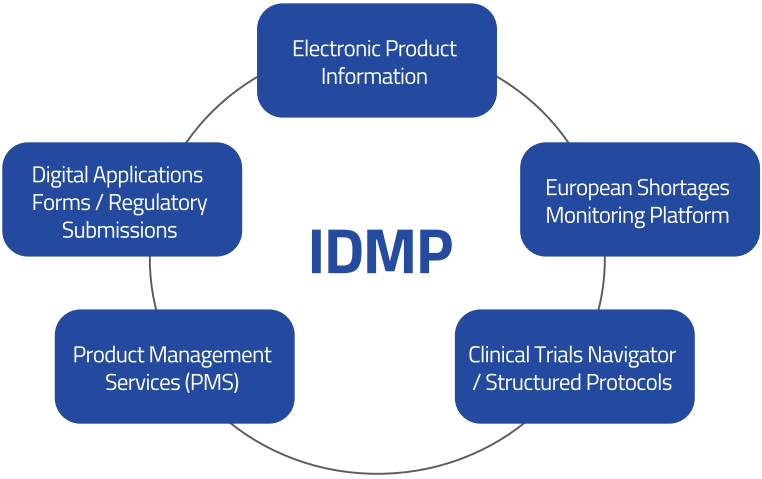
Key updates from the PMS Info Day

Remco began the online session by discussing the key information presented by EMA at the April 16th PMS Info Day.

Remco Munnik: "The 16th of April was a key moment in the ISO IDMP implementation journey because EMA shared that PMS has gone live internally, and also the integration with other systems.

EMA have now related the ISO IDMP implementation with the Master Data Management programme called SPOR; it's important to highlight that IDMP and FHIR messaging are really at the centre of all their key initiatives.

Update on Key Initiatives



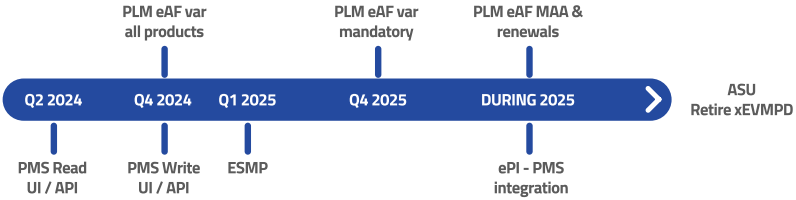
All of the initiatives you see above are built around structured data in IDMP, in the PMS Database, but also with the FHIR data exchange. It's really important to be aware of this."

Remco discussed the progress of IDMP implementation, from implementing xEVMPD in 2012, to announcing an agile implementation methodology in 2021, and finally to the PMS go-live today in 2024:

"Now in 2024, PMS has gone live. This basically means the IDMP data is here, and not only that, but it's also now being integrated with regulatory processes. The PLM electronic Application Form already has optional use of this data for the centralised procedures, but we soon expect it to be mandatory. ESMP, the shortage reporting, is going to happen in February 2025, and ePI, the electronic Product Information, is also coming soon."

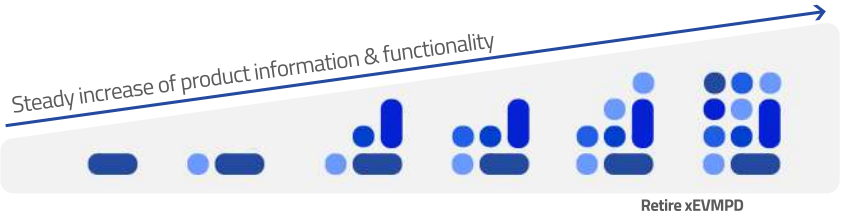
PMS is the Data Backbone for EMA's Systems and Processes

"What EMA shared during the information day is that PMS is really the data backbone for all EMA systems and processes. So, it is really the central point for data upon which regulatory processes are built. This target 'operating model ID' which we had about one-time data submission, assessment of the data during a regulatory procedure where the data is then approved, and for the next submission the data is reused – it's a reality. For the PLM electronic application form, this is now happening."



"In Q2 2024 we will have PMS Read access, then in Q4 2024 there will be PMS Write access either by user interface or by an API, but EMA is tying it in with all kinds of procedural systems. By Q4, it will be possible to make the PLM electronic application forms for variations for all products, and then we expect that by next year it will become mandatory. And then during 2025 EMA will also work on the PLM electronic application form for initial marketing organisations and renewals, so it's really important that you also have a system and processes in place that can capture this data."

EMA's PMS Go-Live: Impact on Industry



To do's

1. Review and set-up processes
2. Create awareness and training
3. Establish Data Governance
4. Review / Implement RIM capabilities
5. Check data availability and accuracy

"What is the impact of all this on industry? I think what you will see is that constantly, in industry, you need to capture more and more product information, but also functionality in your tooling. So I think what is really important here is that you need to review a set of processes. Not only for the PLM application form for ESMP, but also to create awareness and training within your organisation. This is coming – it's not only regulatory data, it's also, for example, for the interaction between regulatory and supply chain.

And then on point 3, 'Establish Data Governance' – who's the owner of a certain data set? What happens with the data set if it is changed due to its lifecycle? How do you maintain this data? From a technology point of view, you would need a technology that's also robust and can cope with these changes. So really look at your RIM capabilities, what do you need now and what will you need in the future? And last but not least, we see that a lot of the data that companies have is captured from documents. So really look at your data viability, is it also correct? The data that EMA has, is that the same as the data that you have internally and with different stakeholders?"

European Shortages Monitoring Platform (ESMP): What you Need to Know

Remco shared some critical information on what you need to do to prepare for the ESMP go-live in February 2025, including latest instructions from EMA.

"For the ESMP go-live in Feb 2025, there are two really important activities that companies need to do. The first is an enrichment of pack sizes needed in PMS, but through XEVMPD. What EMA has now asked is that you start now, at least for the products that are listed on the critical medicines list, they should be enriched on a pack size level. So EMA really wants you to split your XEVMPD data according to pack sizes. For the critical medicines that should be done by February 2025, and for all products by December 2025.

In addition to this, also for the ESMP go-live, is the enrichment of manufacturers – so your operation type and your structured pack sizes – can be enriched in PMS directly, either through the write user interface or API. The deadline for doing this is December 2025. Now we also know that in November of this year, the critical medicines list will be revised by the authorities, so our advice is to really start checking which products are on that list."

Summary and Next Steps

"EMA has successfully kicked off their digital journey successfully, so I think what we see in the market is there are two critical activities right now for RIM capabilities review. One is EMA's requirement for PMS go-live, and it's really linking it to the electronic application form, linking it to shortage reporting and to the electronic product information. You really need to start thinking 'how is my RIM data being used in other systems?' And the other topic that we see a lot is AI and Gen AI. Now we're really seeing the opportunity that it can be used to unlock and optimise business processes. And we at Deloitte can really help with all aspects of this journey."

Deloitte offering

Capabilities

- IDMP Subject Matter Advisor
- Thought leadership (data and processes)
- Regulators relation
- Experience with IDMP implementation
- Technology implementation
- Change Management
- Data Governance
- Program Management
- Global footprint

Regulatory Intelligence

1. We have **unmatched IDMP experience and intelligence**:
   - IRISS ISO IDMP topic group lead
   - Member of several topic groups and IDMP initiatives
   - Key relationships with European Health Authorities
   - Supported in the authoring of European IDMP guides
2. **IDMP experience with big, medium, small pharma & biotech companies**, but also supported tool vendors and regulators in their IDMP journey.

The CARA Life Sciences Platform™ for IDMP

Karolina Rogowska, Head of Marketing at Generis briefly explained the key benefits of the CARA Life Sciences Platform for IDMP Data Management.

Karolina Rogowska: Our unified CARA Life Sciences Platform enables content and data management from its creation to archival on a single, structured information lake that gives users instant access to cross-functional data and enables powerful process optimisation. Looking at Data management, data objects, Master Data Management (MDM), we offer a built-in database, CARA can manage content-less pure data objects, while still applying versioning, security, lifecycles, forms, etc. as with any other object. With all functions available through API, CARA provides an excellent MDM hub for multiple systems. This includes historic names, unique identifiers, source mapping to regulatory authorities and other sources.

Metadata form the backbone of the system. All objects may have associated metadata whether they are content or data objects. That metadata drives navigation, searching, reporting and more. The CARA documents data model uses the DIA Reference Model.

We originally built a template-based mechanism for IDMP and other data exchange, where clients can create templates for generating output content from structured data. This serves any structured content authoring use cases such as labelling and others.

The main benefit of CARA for IDMP is the connectivity. This means that, while there are point solutions available, CARA handles management of the processes around IDMP – not just the data. It also means that we have connections with gateways required for submissions, including handling responses for example. Alongside this there is also:

- **Structured Information Lake** – all of the data in the system is available to Safety, Clinical, and other areas within your company.

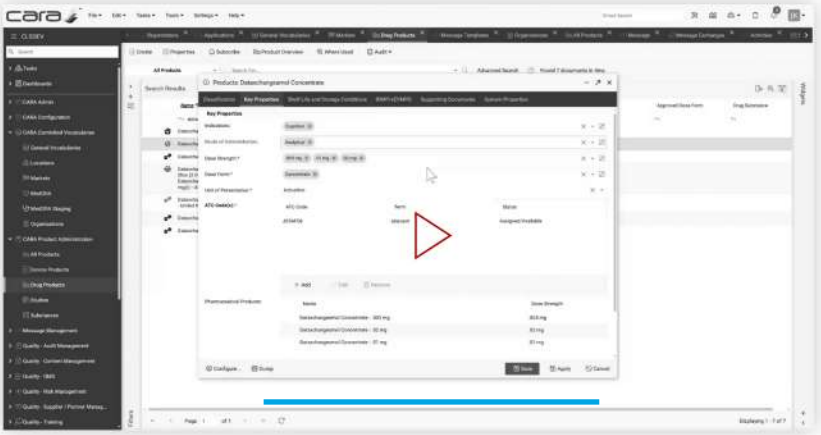
- **Flexible Templates** – Originally built for XEVMPD but extended to cover all other cases of output with other templates; FHIR, ePI, E2B(R3), And now IDMP. Unlike with static solutions, CARA doesn't have to create a new model based on what would be required from these outputs, all of the information is already stored in the system and it only takes a couple of minutes to activate whichever fields are needed with simple end-user configuration.

- **CARA's Underlying Data Management** – CARA captures and stores all possible data, but not in an artificial 'IDMP screen', instead the data already sits in the logical place where data owners can manage that data easily, helping to avoid data governance issues and disputes.

- **Aligned with EMA and More** – Working with partners, industry experts and customers to understand what is really needed for IDMP. EMA's IDMP implementation guide was used to create our IDMP data model.

Demo: IDMP with The CARA Life Sciences Platform™

To end the session, Jack Kelleher provided a live demo of CARA's capabilities for IDMP. You can watch the demo in full by clicking below:



[You can watch the full webinar on demand here.](#)