VIEW POINT

IDMP: CROSSING THE PRODUCT DATA CHASM TO IMPLEMENTATION–PART 1

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Executive Summary

Most major life sciences organizations are already in the journey to comply with IDMP requirements. Though there were a series of delays which sapped momentum, the ability of European Medicines Agency (EMA) was never in doubt in delivery of ISO IDMP. The European Union (EU) implementation guide is out for consultation which will be followed by another actionable version by next year. This necessitates the countdown for compliance from life sciences firms. They will have to get everything in order to comply within a year which appears a daunting task.

As industry has been rigorously working in preparing for the change, the SPOR task force has been regularly sharing updates regarding the activities of PMS (Product Management Services), SMS (Substance Management Services) and EU Implementation Guide.

In this whitepaper, we will explore the current status of development in PMS, to adopt the Target Operating Model (TOM) or create a Minimum Viable Product (MVP).

Product Management Services: TOM vs MVP

PMS-TOM aims to optimize the data exchange across applications between regulators and applicants within the regulatory framework. It is designed to gradually increase the overall data quality by checking data within the scope of the procedure.

Article 57 requires all marketing authorization holders in the EU and European Economic Area (EEA) to submit information to EMA on authorized medicines and keep it up-to-date.

A target operating model is advocated to overcome the limitations of Article 57 such that:

1. Administrative burden is minimized.
2. Integrating SPOR.
3. Ensuring that centralized and National Competent Authorities NCA/EMA databases have consistent data

Article 57 process does not provide the data quality and would be intensive to EMA with respect to time and cost to validate the data against the Summary of Product Characteristics (SmPC).

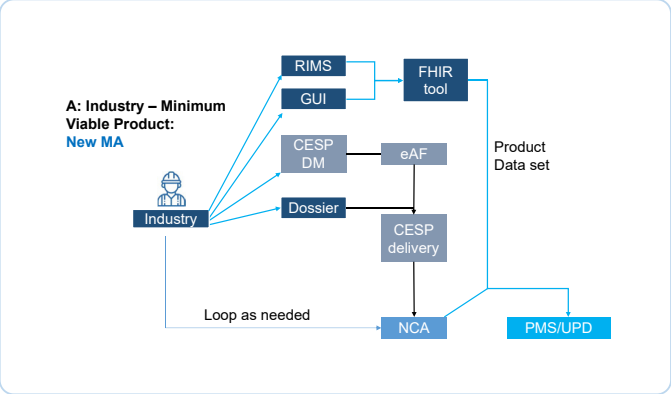
- Unsuitable for e-prescriptions/e-health
- Unsuitable for cross-border product identification
- Unsuitable for regulatory purposes

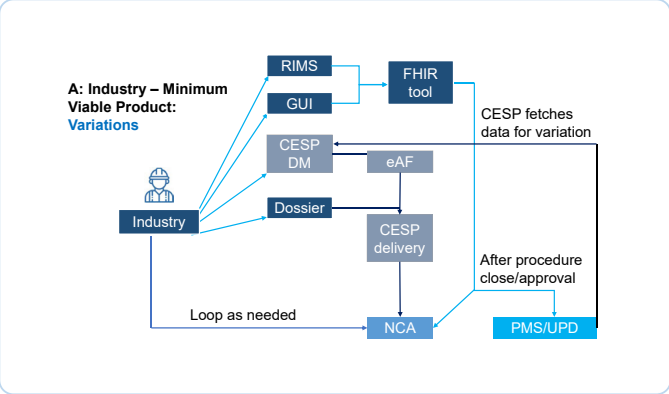
The involvement of NCAs is needed such that an electronic version of the data quality has been checked by NCA.

To ensure and support the purpose of feeding high-quality data in to PMS, the SPOR taskforce received two proposals from industry and NCA.

A. Industry: Proposal for MVP

A separate tool which is Fast Healthcare Interoperability Resources (FHIR) compatible which creates a full iteration 1 dataset and submission of the data to NCAs along with electronic application form (eAF)/ Common European Submission Platform (CESP) dataset.





Advantages:

a. Independent of CESP delivery and timeframe

b. FHIR messaging from the beginning

c. Ability to submit non-regulatory information (sales, availability, Quality Person Responsible for Pharmacovigilance)

Disadvantages:

a. Two product datasets – one in eAF, one from FHIR tool

b. FHIR tool requires multiple datasets (new human, new veterinary, variations, parallel trade/import) to be developed

c. NCAs will need to look at two datasets and compare with quality folder in eCTD

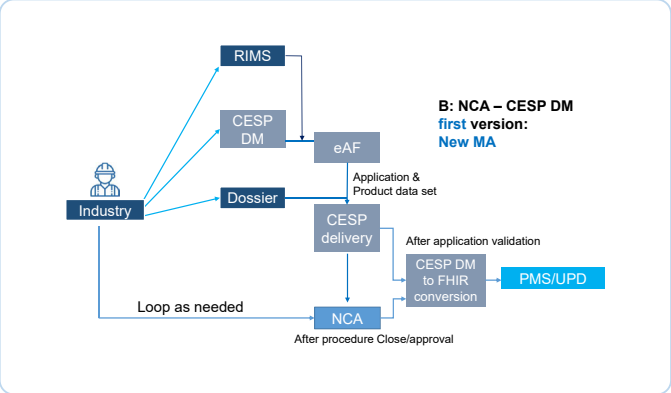
d. NCAs will potentially receive two data deliveries for one application procedure

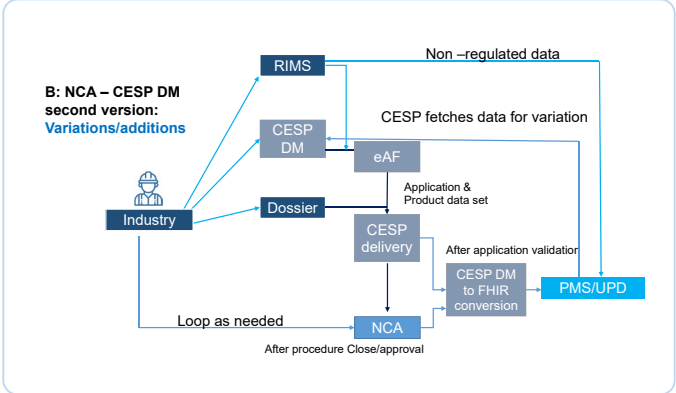
e. Lack of assurance of dataset submitted from FHIR tool is exactly the same as NCA approved

RIMS: Regulatory Information Management System; GUI: Graphical User Interface; FHIR: Fast Healthcare Interoperability Resources (FHIR); CESP: Common European Submission Platform; eAF: electronic Application Form; NCA: National Competent Authority; PMS: Product Management Services; UPD: Union Product Database.

B. NCAs: Proposal for TOM

TOM is proposed to expand the CESP dataset module which is under development supporting these processes





Advantages:

a. The required tool is under development

b. FHIR tool for comparison of two dataset versions already in scope

c. No extra tool to train and maintain

d. NCA will need to compare one dataset to quality folder in eCTD

e. Common process for human and veterinary

Disadvantages:

a. Uncertainty in financing and delivery time frame

b. Data in new XML-format, not FHIR – Health Level 7 standards

c. Dataset incomplete: QC/Article 57 process will be needed for missing data in dataset.

d. No variation form in development yet

e. Variation eAF based on present form has less structured data and new concept form needed

f. Requirement of a tool to submit non-regulated data (sales, availability, etc.)

Irrespective of the approach taken for data quality, either TOM or MVP, it is envisioned that the data quality will be significantly improved and sustained during the life-cycle of a medicinal product.

Implementation of TOM provides significant benefits including the reuse of master data on different processes and validation of product data linked to regulatory procedure. Nevertheless, it is understood that TOM is a complex operating model. Hence, further funding of TOM development for future versions is subject to Heads of Medicine Agencies (HMA)/Telematics governance approval.

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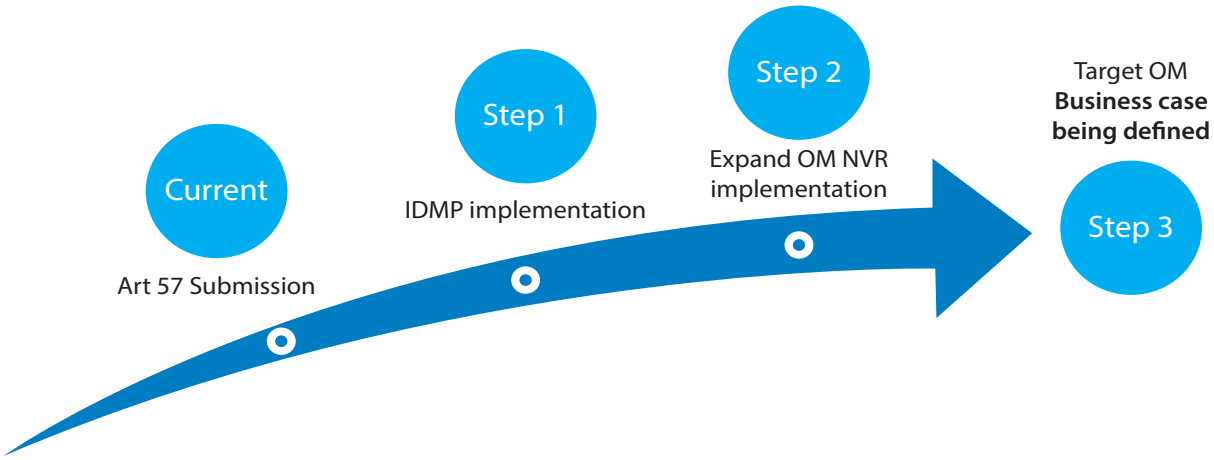
The factors that fit into a TOM phase implementation is represented in the following schematic



Article 57 – Submission	Step 1 – IDMP Implementation	Step 2 – Expand OM Implementation	Step 3 – Target OM
Product data de-coupled from regulatory procedure	Product data submission possibly at anytime of the procedure – optional, likely for Centrally Authorized Products (CAPs)	Submission of Product data linked to regulatory submission	Submission of Product data linked to regulatory submission – full integration
Overall product quality assurance for EMA	Quality assurance of Product Data by EMA after regulatory procedure (validation procedure for CAPs can be explored)	Validation of product data during regulatory procedure by NCAs for National Authorized Products (NAPs) and EMA for CAPs	Validation of product data during regulatory procedure by NCAs for National Authorized Products (NAPs) and EMA for CAPs
Use of SmPC	Use of Module 3 of eCTD/SmPC	Use of Module 3 of eCTD/SmPC	Use of Module 3 of eCTD/SmPC
Submission via xEVPRM	Submission via FHIR	Submission via FHIR	Submission via FHIR
xEVPRM database	Availability of API/EU IG/MDM hub	Basic technology solution (UI) to View/Edit/Create products	Needs of use case to support the change and development
	Business case available	Heads of Medicines Agencies (HMA)/Management Board (MB) approval	HMA/MB approval

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Conclusion:

Pharmaceutical companies may have delayed their investment in IDMP due to possible deferrals in implementation and concerns over the verdict on Brexit. European Commission and the EMA, through efforts of navigating through various systems is continuing to persuade Pharmaceutical companies towards the overall implementation and benefits of the scheme.

IDMP has evolved, from only an alert system across Europe about an adverse reaction from a drug to encompass operation beyond agency, in being repository for volumes of data.

While industry and EMA are clarifying TOM vs MVP as a better approach for PMS, TOM appears to outweigh MVP with certain limitations enabling NCAs in a larger context. For companies and EMA, IDMP provides a transformational program which could provide a master data management and analytics capability to break-down siloes to ensure important information is accessible.

Ultimately, it is realized that the success of IDMP in Europe and elsewhere will depend not only on its improvement of regulatory efficiencies but also of the technology integration and operational efficiencies of pharmaceutical companies.

Thus, effective IT and domain consulting strategies in designing the orchestration of technology towards effective compliance to SPOR requirements is imperative.

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