Identification of Medicinal Products (IDMP)

What is necessary in order to be compliant in 2016 and beyond?

February 2015
New ISO standards have been developed addressing the demand for the unique global identification of medicinal products throughout the life cycle of a product.

Through controlled vocabularies, IDMP will enable consistent documentation, coding and exchange of product information between global regulators, manufacturers, suppliers and distributors.

The industry is required to be compliant by July 2016 and the work to become IDMP ready should not be underestimated.

IDMP compliance requires a cross-functional, corporate-wide effort aligning on standards, master data management, data governance and identification of authoritative source systems. This will involve data to be consolidated across the entire lifecycle of a product pulling data from regulatory affairs, product supply, pharmacovigilance and clinical development.
Identification of Medicinal Products

**IDMP overview**

There are five ISO IDMP standards, which together with the existing ISO standard “ISO 21090” form the definition of all elements used in the model of IDMP.

Together they allow for the definition, characterization and unique identification of regulated pharmaceutical products during their life cycle. IDMP standards are intended to support applications and processes where it is necessary to reliably identify and trace the use of medicinal products.

![Diagram showing the six ISO standards forming the IDMP framework](image)

The elements touched by IDMP come from various functions and domains within a pharmaceutical company such as regulatory affairs, manufacturing and product supply, pharmacovigilance and clinical development. IDMP therefore requires a broad approach to capturing, transforming, aligning, governing, and reporting data of:

- Medicinal Product;
- Investigational Medicinal Product;
- Pharmaceutical Product;
- Clinical Particulars;
- Substance Information;
- Packaging;
- Manufacturing;
- Marketing Authorization; and
- Clinical Trial Authorization.

ISO IDMP is global in scope and provides an internationally accepted framework for consistent documentation, coding and exchange of product information between global regulators, manufacturers, suppliers and distributors.

The scope of product information consolidated and submitted is significant and does not only include Authorized Products but also Investigational Medicinal Products. It will require data integration from numerous systems across an organization and data will need to be converted into the new format.
Legislative change (IDMP in Europe)

Over the past few decades the innovative and technological advances within medicinal science have given rise to the development of a great number of new novel molecules and compounds, which has led to lives being saved, an improved quality of life and populations living longer. However, the inherent detrimental facet is that medicines have associated side effects or adverse drug reactions (“ADRs”).

It was highlighted that the current pan-European systems and processes for reporting and tracking ADRs were deemed sub-optimal, overly complex, duplicative and inefficient and detrimental to public health.

Regulatory drivers to improve this situation are:

• Increase patient safety through better pharmacovigilance reporting.

• Enable regulatory agencies worldwide to make faster decisions based on accurate data.

• Support regulatory agencies to have oversight of the development, registration and life cycle management of medicinal products as well as safety and risk management.

• Facilitate the reliable exchange of medicinal product information in a robust and reliable manner for all industry players:
  – **Regulator to regulator** e.g. European Medicines Agency to the US Food and Drug Administration (“FDA”) or vice versa.
  – **Marketing authorization holder to regulator** e.g. Pharmaceutical Company A to Health Canada.
  – **Sponsor of clinical trial to regulator** e.g. Global biotech company X to Austrian Medicines Agency.
  – **Regulator to other stakeholders** e.g. UK Medicines Health Regulatory Agency (“MHRA”) to National Health System (“NHS”).
  – **Interaction of regulator with worldwide-maintained data sources** e.g. Pharmaceutical and Medical Device Agency (“PMDA”) and the assignment of a new substance identifier.


In general the new legislation broadly seeks to strengthen the safety monitoring of drugs, clarify roles and responsibilities, increase the use of studies, improve transparency and generally strengthens the capability to further protect public health. The view is that longer term improved harmonization and efficiencies will be realized.

The European Medicines Agency (“EMA”) has taken a four-phased approach to meeting the legislation:

Figure 2. EMA four-phased approach to IDMP

Currently we are in phase three where data is validated and submitted in XEVMPD format. The next step will be the adoption of the IDMP standards to be in compliance with the EMA guidelines. Legislation exists today to mandate change as of July 1, 2016.
The IDMP rollout by multiple agencies like EMA, FDA and others will have a regional flavor with implementation guidelines currently under development. With future adoption and critical mass, more regulatory use cases throughout the product lifecycle are expected to evolve.

Global IDMP adoption
Currently the existing EU Legislation, coupled with FDA and other Health Authority efforts are aimed to roll out the IDMP standards. The EMA is working towards implementation of IDMP in July 2016 and the FDA is considering working towards the same date for non-mandatory submission of IDMP. The initial foundational changes which are adopting the Product Registration (XEVMPD → IDMP Registry) will leverage a sub-set of IDMP data to comply with the Individual Case Safety Reporting (ICSR (R3)).

Health Authorities are developing IDMP Implementation guides to align with their priorities and goals, so timing of adoption will vary from agency to agency.

In the future we expect the use cases for leveraging IDMP information by Health Authorities and Industry to expand the scope of IDMP adoption in terms of products, processes and geographies.

The IDMP rollout by multiple agencies like EMA, FDA and others will have regional requirements. It is continuing to evolve to meet more regulatory use cases throughout the product lifecycle.

The following overview shows a potential mid term scenario.

Figure 3. Possible extension of the IDMP usage based on three dimensions

<table>
<thead>
<tr>
<th>Extension by geography</th>
<th>EMA (EU)</th>
<th>FDA (USA)</th>
<th>Rest of the World</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extension by product</td>
<td>Authorized Products</td>
<td>Investigational Products</td>
<td></td>
</tr>
<tr>
<td>Extension by use case</td>
<td>Product Registration</td>
<td>Individual Case Safety Report – ICSR (R3)</td>
<td>Other use cases including Investigational Products, Clinical Trial and Post Market</td>
</tr>
<tr>
<td></td>
<td>• Tracking formulation/dose changes throughout the investigational process</td>
<td>• Clinical Trial registration process</td>
<td>• Product-Establishment relationship – Supply chain/counterfeiting</td>
</tr>
<tr>
<td></td>
<td>• Clinical Trial registration process</td>
<td>• Submissions review New Drug Application/Biologics License Application</td>
<td>• Import/Export</td>
</tr>
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<td></td>
<td>• Pre approval inspections</td>
<td>• Pre approval inspections</td>
<td>• Voluntary recalls</td>
</tr>
</tbody>
</table>

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Learnings from XEVMPD implementation
With IDMP approaching, we should consider the learnings from the implementation of XEVMPD. The following factors should be taken into account for the implementation of IDMP:

Impact
• Scale of the XEVMPD initiative was much greater than anticipated. There was a significant impact on budgets and resources during the implementation.

Guidance
• The guidance was subject to interpretation and lead to confusion. This was caused by a lack of well-defined scenarios.

Technologies
• Commercial-off-the-shelf (COTS) vendors adapting to the changes to provide compliant systems. Many companies leveraged the manual data entry process using the web interface EVWEB.

Project Management and Oversight
• Implementation required the use of project management methodologies and capabilities to provide the needed oversight to drive the program through uncertainties.

Timeframe
• The limited available time put significant pressure on the implementation of the requirements.

Master Data Management
• An important aspect of the implementation was the availability of data, identifying the data sources, data cleaning, data preparation and data submission.

Quality
• Initial sample reviews of data submitted for XEVMPD showed poor quality of accuracy, integrity and completeness.

Looking forward to the implementation of IDMP, it is clear that data requirements will be much more complex for IDMP compared to XEVMPD. The industry considers the efforts needed for IDMP to be 3 to 5 times higher than for XEVMPD. This will require the development and preparation of a robust adaptive strategy, roadmap and business case to be able to adapt to future changes as IDMP will not be the last standard enhancement.

IDMP planning and preparation is key
Many companies have begun to prepare for the IDMP standard and have analyzed the impact of the changes and what it means for the organization and the related processes.

As the nature of the change is quite substantial, we propose a structured approach to the topic with the following elements based on our strategy framework:

• Start early to assess readiness and understand magnitude.

• Create awareness and alignment with executive stakeholders.

• Secure funding, executive sponsorship and resourcing.

• Understand the evolving regulations, implementation guidelines and timelines and consequences of not meeting the regulations.
• Prepare for reliable data:
  – Authorities are holding sponsors accountable for data quality.
  – Get alignment with internal and external control vocabularies and effective integration with existing and future systems.
  – Significant unstructured information can be in paper or electronic format (e.g. PDF).
• Have a business case and holistic strategy in place:
  – Business Strategy: See IDMP as a chance to improve and not as another necessary evil.
  – Master Data Strategy: Look at the Master data Management (MDM) needs and align them with the different functions within the company.
  – Governance Strategy: Define who is going to manage which portion of the data within their operational processes.
  – Process Organization and Ownership Strategy: Define the processes touched by IDMP and define the ownership accordingly, restructuring where it makes sense.
  – Technology Strategy: Define which technology can support the IDMP program best and consider minimal invasive strategy to implement the change.
  – Implementation Strategy: Build a roadmap which tackles the gaps in the current organization and prioritizes the projects needed.

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Additional considerations for IDMP
Planning for IDMP implementation should additionally include:

Change management
- The IDMP program will need an extensive set of change management.
- Align with stakeholders and communicate the change that is going to happen as soon as possible.
- Prepare for the question: "Why should we do this?".

Technology assessment
- Understand the current system landscape and the different data silos, which have to provide data to the IDMP data model.
- Consider Master Data Management (MDM) technology capabilities that support IDMP and related business processes, develop auto-loading capabilities with vendor or in-house solutions.
- Understand vendor space and timelines for emerging solutions and underlying assumptions e.g. data feeds to their solutions.

Database re-structuring
- Understand ISO IDMP impacts and integrations to existing master data stores e.g. Company Drug Dictionary (CDD) and WHO drug dictionary databases, Regulatory Information Management (RIM) and Product Lifecycle Management (PLM).
- Prepare to receive and maintain external reference standards and vocabularies including the use of identifiers to be delivered by maintenance organizations.

Data collation and governance
- Collect data (initial focus on master data/IDMP Data), identify gaps, align vocabularies and cleanse data.
- Build on current XEVMPD experience and learnings to apply to IDMP.
- Build a governance model around data stakeholders and owners.

Possible IDMP architecture approaches
The new standard will mandate to gather and hold data from multiple functions in an extended way. One of the common questions relates to the possible architecture approaches to store the cross-functional/ divisional data and how this could be done in the existing landscape. There is no simple answer to this question and it needs to reflect the individual circumstances.

Compared to the majority of the current regulatory standards, the data sources for IDMP will contain a significant amount of information that is "hidden" in unstructured documents (e.g. PDF reports, office documents, archived ZIP files). This information has to be made accessible and translated into a structured format, which will prove to be an additional challenge.

Examples of possible data sources for structured and unstructured data are:
- Regulatory Information Management System (RIMS);
- Submission Dossier Management System;
- Enterprise Resource Planning System (ERP);
- Master Data Management System (MDMS);
- Electronic Document Management System (EDMS);
• Information Governance and Archiving Systems;
• Product Information System; and
• Artworks System.

There are different possible models currently discussed in the industry:

1. Leverage existing RIMS solution and extend it to store additional regulated IDMP data.

2. Use a tailored and dedicated solution for IDMP, which interacts with RIMS and other systems.

3. Introduce a new virtual data layer and service that gathers and stores all relevant IDMP data and provides existing applications with the relevant data needed.

The feasibility of options needs to be evaluated in the context of each company’s unique circumstance. Looking into the future, the number of communications with regulators will presumably require improved standards and product identifiers supporting better communication and response times from the agencies.

Due to the variety of IDMP data that needs to be collected across the various functions within the company, a master data management driven approach is recommended, which can be enabled via a new data layer. This layer would gather in scope IDMP data via pull mechanisms, or receive updates via push mechanisms, from different authoritative sources. This would enable a tailored approach to control the data and measure its quality in a central place. If data quality issues or gaps exist, workflows could be started to take measures to correct either the source or send the corrected data back to the source after correction.

Despite the approach chosen for the implementation of IDMP, readiness and preparation begins with relevant functions within a company aligning their data and identifying gaps. It will be a tremendous challenge and should be started as soon as possible to meet the required deadlines.
Deloitte approach: how we can help

A cross-functional group of specialists from Deloitte’s Regulatory, Supply Chain, Master Data and IT practice have defined a standard approach to help our clients prepare for the upcoming challenges with IDMP. The approach contains a fit-gap analysis to identify the individual data gaps and defines important data elements and structures, which help to plan the needed changes in the organization in order to become IDMP compliant.

In addition to regulatory advisory we assist our clients with defining data models, which reflect the current state and help to define the mandatory and desired future state. This involves workshops with the business and bridges the derived information to the current situation across involved systems.

Using our innovative accelerator tools, we can leverage the fit-gap analysis to a minimum. This allows us to focus on the changes required to design and implement a solution.

Figure 5. Deloitte accelerators for IDMP

**Accelerator 1: DeltaMap**

The implementation of XEVMPD was recent and is an on-going enhancement activity for pharmaceutical companies active in the European market. This is why the documentation of the XEVMPD implementation can be reused for a delta mapping exercise against the currently defined ISO IDMP data model. We have created a mapping tool that takes the data elements used in XEVMPD and maps it to the future ISO IDMP data model with the advantage that the existing data gaps are known at a conceptual level.

**Accelerator 2: IDMP DataScout**

The IDMP DataScout is a structured tool-based approach to define the “as-is” state and to execute a fit-gap analysis. It provides a holistic perspective of the IDMP regulations and facilitates the alignment of the different business units.

The outcome of the IDMP DataScout will be:

- High-level fit-gap assessment.
- Prioritization of gaps according to expected regulatory needs.
- Analysis of data needs depicting structured versus unstructured data.
- Alignment of the required actions for IDMP with other MDM/data initiatives.
- Assessment of data management practices of key data elements against our Deloitte MDM Framework.
**Accelerator 3: DataScout Analytics**

To leverage analyzing the current situation, we built, in addition to the DataScout, a platform that enables a pharmaceutical company to enter the prepared data definitions into a preconfigured application.

The tool can store:

- Data element definitions.
- Data hierarchies.
- Data relevant contact information.
- Investigational questionnaires for data definition.
- Gap classification and priorities.

The platform provides analytical capabilities, which enables our client to perform any reporting requirements on the previously mentioned data sets. In addition it delivers standard reports, covering the general needs of progress and data definition reporting.

**IDMP Program Management**

In order to become IDMP compliant, we design for our clients a holistic IDMP program based on our deep expertise covering the following areas:

- Current state assessment and implementation strategy.
- IDMP roadmap creation.
- Regulatory guidance and advisory.
- Business process design and alignment.
- Project management.
- Change management and business transformation.
- Independent technology selection and implementation covering RIMS, ERP, EDMS, MDMS and Artworks

As discussed in this paper it is crucial to prepare for IDMP proactively and to consider the various challenges that the new standards will bring for your organization. Currently we are on a short timeline to become compliant in July 2016. EMA is holding onto this milestone and organizations have to start working on the topic as early as possible.

The amount of business alignments and changes that need to be implemented must not be underestimated but at the same time represent a great opportunity to create value beyond IDMP.

Deloitte is proud to accompany the pharmaceutical industry on this important initiative to increase patient safety.

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