About the Authors

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Executive Summary

For anyone marketing medicinal products (pharmaceutical, biologics, generics) in Europe, the ISO identification of medicinal products (IDMP) poses a comprehensive and imminent compliance challenge: the IDMP data chasm, which is complex and cross-organizational.

Due to its complexity, the IDMP data chasm can’t be crossed simply by expanding the pharmaceutical companies’ regulatory information management system (RIMS) or eXtended EudraVigilance Medicinal Product Dictionary solutions. Crossing the IDMP data chasm requires comprehensive data management, standardization and dedicated IDMP capabilities.

Though many companies are focused on the key compliance objective of submitting IDMP data to the European Medicines Agency (EMA) by Q4 2018, the IDMP journey is basically just starting. There are interesting business analytics and reporting opportunities for those with a broader perspective. Furthermore, many companies will approach IDMP as a first step on a multiyear master data management (MDM) journey.

Here we define eight key IDMP challenges and follow up with perspectives on each from SAS. At the end of this paper, our perspective on IDMP is presented in an MDM context, as well as the possibilities for using IDMP as the future foundation for new business analytics and insights.

The IDMP Data Chasm

Pharmaceutical companies with European-marketed products are facing a significant data standardization challenge regarding adoption and compliance to IDMP. This data standardization challenge is referred to as the “IDMP data chasm” due to its extensive and challenging nature seen from a data management, cross-organizational and (relatively) limited timeframe perspective.

IDMP is an industry regulation that pharmaceutical companies, biologics and generic companies must comply with in EMA/EU by Q4 2018 (note: based on current regulatory timeline). The main and global objective of IDMP is to provide the basis for a unique identification of medicinal products. EMA is the first competent authority that has mandated a regional deadline, and other regions (including the US and Japan) are expected to provide their deadlines in the near future.

In addition to providing unique identifiers on five different levels of a medicinal product, IDMP requires pharmaceutical companies to exchange specific IDMP standardized data to competent authorities. This standardized data relates to approximately 225-300 mandatory and optional fields provided in the ISO IDMP standards.

Mapping and standardizing source data to these data fields are the core activities of the IDMP data chasm. Data from source systems must be extracted, parsed, standardized, matched against CVs, enriched and transformed to comply with the IDMP standard (an IDMP data/target model).

Let’s explore eight core challenges of the IDMP data chasm and how SAS can help you bridge the chasm.
Introducing IDMP Data Hub From SAS

Before we explain the IDMP data challenges and how each specific challenge can be overcome by the capabilities provided with SAS®, let’s introduce the main components of any IDMP solution.

An IDMP solution consists of the following main components:

1. A submission tool/gateway to exchange information between pharmaceutical sponsor and authorities.
2. A data hub to integrate, cleanse and IDMP-standardize data from multiple data sources, and verify data according to specified CVs.
3. Powerful text extraction capabilities that extract IDMP required information from unstructured sources, such as documents and PDFs.

To manage the data hub, the SAS approach is an IDMP data hub solution,¹ based on extensive data management functionality and enriched with IDMP intellectual property (IP) and logic to accelerate the necessary IDMP standardization tasks. SAS has vast experience with data integration and standardization in the life sciences and other industries. This core competency has always been important to SAS because well-structured, cleansed and standardized data is a precondition for advanced business analytics.

In the pharmaceutical industry, SAS has provided clinical data standardization and data management for life science customers for decades. In the last decade, SAS has shown strong commitment and focused resources on supporting, developing and enabling the adoption of CDISC standards in the industry.²

Figure 1. The complexity of an IDMP solution.

¹ Other technology vendors provide the IDMP Application/Gateway.
² For more information on CDISC, please see cdisc.org.
The Eight Core IDMP Challenges

Based on IDMP consultations with several pharmaceutical companies, we’ve identified eight core challenges that pharmaceutical companies are facing and will need to overcome in order to bridge the IDMP data chasm.

1. Get a Quick Overview of Data and Data Sources

In the initial assessment and analysis phase, it’s critical to identify and understand the main source systems and identify potential and relevant source data for IDMP.

A typical approach is to use spreadsheets and perform a simple mapping of the source system and specific source data fields to be used for a specific data field in the IDMP data/target model. These spreadsheets tend to become rather large, and the relationships between the data entities are difficult to illustrate or visualize. Furthermore, no initial data profiling is done on the source data leaving the sponsor with very limited insights into the quality of the source data in scope.

The SAS Perspective

The IDMP data hub from SAS provides a quick virtual overview of all the data sources involved. The virtual access of each source system can be set up in a matter of hours. Data is cached (but not stored), and performance of the source systems is not affected. Once access to the source systems has been set up, the IDMP data hub can provide one virtual and holistic view of all the source data. It can also do initial data profiling on the source data to provide a good overview of the data quality of the specific source data fields that are to be used for IDMP.

2. Access Data

IDMP is cross-organizational in nature, and the primary business areas that provide source data to IDMP are regulatory affairs, product supply/manufacturing, packaging, product safety, research/CMC and clinical development.

Many pharmaceutical companies operate in departmental silos, store data in these silos, and have strong process and system ownership managing each silo. For this reason, getting access to a good clinical/manufacturing (GxP) solution for a separate business need such as IDMP requires internal approval by system owners. Secondly, once approval is obtained, technical data access must be established to the source system.

Some of the solutions containing relevant source data for IDMP are listed on the following table:
The SAS Perspective

Accessing data is part of the SAS DNA. We are recognized and known for our comprehensive ability to access and integrate data from many systems and databases.

3. Extract Information from Documents and PDFs

Some IDMP data fields require information that resides in unstructured sources like documents and PDFs. This poses a text extraction challenge, and many pharmaceutical companies consider this a difficult task. One of the important data sources for IDMP is the summary of product characteristics (SmPC) that provides information on clinical particulars, i.e., therapeutic indications, contraindications, interactions and undesirable effects.

Let’s look at a specific example. Three of the fields in IDMP are the following:

- Therapeutic indication text (mandatory).
- Indication as disease/symptom/procedure (mandatory).
- Age (Optional).

Section 4.1 of the SmPC contains the therapeutic indication text. Figure 2 shows a copy of the SmPC text from section 4.1 of the pharmaceutical product Lantus:

Except for the header of 4.1, this section is the exact text required for the “Therapeutic indication text” IDMP field. For the “Indication as disease/symptom/procedure,” field, it is

![SmPC text](image)

Figure 2. Source: Lantus SmPC, Pg. 2.

<table>
<thead>
<tr>
<th>Business area</th>
<th>IT system</th>
<th>IDMP relevance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory affairs (RA)</td>
<td>Regulatory information management system (RIMS)</td>
<td>• Medicinal product</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Market authorization information</td>
</tr>
<tr>
<td>Clinical development</td>
<td>Clinical trial management system (CTMS)</td>
<td>• Pharmaceutical particulars</td>
</tr>
<tr>
<td></td>
<td>Clinical data repository/warehouse (CDR/CDW)</td>
<td>• Clinical particulars</td>
</tr>
<tr>
<td>Manufacturing &amp; product supply</td>
<td>Enterprise resource planning (ERP)</td>
<td>• Manufacturing</td>
</tr>
<tr>
<td>Research/CMC</td>
<td>Substance database</td>
<td>• Substances</td>
</tr>
<tr>
<td>Packaging</td>
<td>Labelling system</td>
<td>• Packaging information</td>
</tr>
<tr>
<td>Quality &amp; support</td>
<td>Enterprise document management system (EDMS)</td>
<td>• i.e., SmPC for pharmaceutical particulars and clinical particulars information</td>
</tr>
</tbody>
</table>
necessary to extract the specific indication and conform to the proper term from the controlled vocabulary “indication.” In the example with Lantus, the compliant IDMP value is therefore “diabetes mellitus.” For the “Age” field, three data entries would be required: adults, adolescents, and children aged two years and above, and these values must be identical to the values of the controlled vocabulary “Age.”

The SAS Perspective

Instead of error-prone and manually intensive copy-paste extractions from SmPCs and other documents, SAS provides powerful text extraction capabilities that accelerate the process of extracting relevant IDMP information from unstructured sources like documents and PDFs. Once relevant information has been extracted and stored in a structured format, a qualified expert can ensure that the extraction is correct by comparing the specific section of the PDF/document with the new structured format. Once this is done, this new structured data will be parsed and processed like any other source in the IDMP data hub standardization flow.

4. Interpret and Parse Relevant Source Information

One of the true differentiators for any IDMP data hub solution is the ability to interpret, understand and parse the relevant IDMP content in the source data. It is important to remember that data in source systems is structured for purposes other than IDMP. Some of these source data fields contain IDMP relevant data that is useful for multiple IDMP fields. So being able to extract the contextual meaning of a specific source data field into values that are relevant for IDMP will result in a more efficient, more intelligent and faster standardization process.

Let’s look at an example from a regulatory information management system (RIMS). A relevant source data field could look like this:

<table>
<thead>
<tr>
<th>RIMS data field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gellatin 10,000 units. Powder and solvent for solution for injection</td>
</tr>
<tr>
<td>LXA 10 mg/ml Solution for injection Subcutaneous use Vial (glass)</td>
</tr>
<tr>
<td>Influenzvac 5mg SUSPENSION FOR INJECTION, adults</td>
</tr>
<tr>
<td>Sarlac® hard capsules 110mg</td>
</tr>
<tr>
<td>Sarlac® soft capsules 100 mg for adults</td>
</tr>
<tr>
<td>Quality &amp; support</td>
</tr>
</tbody>
</table>

Being able to interpret, understand and parse this field into the specific contextual elements that are relevant for IDMP is an IDMP challenge that many pharmaceutical companies are facing.

The SAS Perspective

One of the unique and very powerful capabilities SAS offers is the IDMP quality knowledge base (QKB). The IDMP QKB is a central component of our solution and provides life science interpretation logic that supports efficient IDMP data cleansing operations such as parsing, standardization, and match codes to facilitate fuzzy matching. As part of the IDMP QKB logic, the QKB also refers to and uses the many IDMP CVs as reference data.
Applying the IDMP QKB to the RIMS example results in the following decomposition of the RIMS data field into some of the IDMP data fields:

<table>
<thead>
<tr>
<th>Invented Name</th>
<th>Strength</th>
<th>Pharmaceutical Dose Form</th>
<th>Target Pop.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gellatin</td>
<td>10,000 units</td>
<td>POWDER AND SOLVENT FOR SOLUTION FOR INJECTION</td>
<td></td>
</tr>
<tr>
<td>LXA</td>
<td>10 mg/ml</td>
<td>SOLUTION FOR INJECTION</td>
<td></td>
</tr>
<tr>
<td>Influenzavac</td>
<td>5 mg</td>
<td>SUSPENSION FOR INJECTION</td>
<td>Adults</td>
</tr>
<tr>
<td>Sarlac</td>
<td>110 mg</td>
<td>CAPSULE, HARD</td>
<td></td>
</tr>
<tr>
<td>Sarlac</td>
<td>100 mg</td>
<td>CAPSULE, SOFT</td>
<td>Adults</td>
</tr>
</tbody>
</table>

As described above, the IDMP QKB accelerates the IDMP standardization process by conducting it more intelligently and efficiently. The business value of such a capability is faster IDMP implementation, fewer resources required to maintain the IDMP solution, and ultimately a lower total cost of ownership (TCO) for being IDMP compliant.

5. Comply With and Manage Controlled Vocabularies

Many of the data fields in IDMP are controlled and must comply with a designated term from a controlled vocabulary (CV). These CVs are managed by external organizations and evolve over time, i.e. new terms are included in the vocabulary or obsolete terms are deprecated. Some CVs are rather static in nature while others are updated on a frequent basis.

The challenge in an IDMP setting is to ensure that source data is standardized and validated toward the correct and current version of a CV at all times. CVs must therefore be managed and governed whenever they are modified or updated.

The SAS Perspective

CVs are managed and governed as reference data. Each CV is version-controlled, and the user interface provides an easily accessible view of the vocabulary for all interested parties. However, only few individuals are expected to be in charge of managing CVs and will be the only ones having write-access to this part of the solution.

6. Cleanse and Standardize Data to IDMP Compliant Format

The primary purpose of any IDMP solution is to standardize source data into an IDMP compliant format, which is then exchanged with competent authorities. At the heart of the IDMP standardization process is the ability to cleanse and standardize data toward an IDMP target model – also called IDMP data model.

Like any other data model in the life science industry, the IDMP data model is expected to evolve over time. Until EMA finalizes the IDMP implementation guide for Europe, it is unknown which IDMP data fields will be mandatory, conditional and/or optional. Current indications from the IDMP workgroup suggest that the draft is rather mature,
and that approximately 90 percent of the IDMP data fields are fixed and will be included in the final version of the implementation guide.

In the near future, other competent authorities (e.g., the US Food and Drug Administration [FDA] and the Japanese Pharmaceutical and Medical Device Agency [PMDA]) are likely to mandate IDMP for their regions. When this happens, these authorities are expected to demand a slight modification to the IDMP data model in their implementation guides as compared to the EMA. It should be anticipated that sponsors must manage and comply with “none-identical” IDMP data models. This means that a sponsor must be able to manage multiple IDMP data model variations and versions in order to be compliant in different regions, even though IDMP is a global standard.

Data cleansing is an effort that is often underestimated. The industry perception seems to be that the data quality is high because the source systems are GxP validated systems. Practical experience shows that this is simply not the case, and that data quality varies from system to system. This challenge calls for comprehensive data quality functionality with data cleansing being an integrated part of the IDMP standardization flow.

The SAS Perspective

SAS understands that the IDMP data model will evolve over time and that different regions will require different versions of the IDMP data model. That’s why managing and working with several IDMP data models is possible in the SAS solution.

Furthermore, the IDMP data hub from SAS enables sponsors to efficiently identify and cleanse data issues as well as intuitively create data quality rules to avoid any reoccurrence of the same data quality issues.

7. Provide Intuitive Remediation Workflow for Line of Business Users

Due to the cross-organizational nature of IDMP, data comes from many different source systems and line of business (LoB) areas. When data exceptions occur and are identified in the standardization flow, the most qualified resources to remediate the exceptions are thus the LoB employees who know the origin of the source data. Providing efficient and intuitive remediation workflow capabilities for LoB is a key component of any IDMP solution.

For example, if there is a quality issue for a specific data element related to the clinical particulars of a product, the most qualified person to resolve that issue is an employee from clinical development, who has clinical insight and access to the relevant source system (i.e. CTMS or CDW).

The SAS Perspective

SAS can provide intuitive and powerful data remediation functionality as pictured below:

[Figure 3. IDMP data remediation flow.]
When data issues and exceptions are identified in the IDMP standardization flow, this automatically triggers the initiation of a remediation flow. Based on data governance rules, the remediation flow notifies the right LoB personnel. A qualified employee logs in and is presented with an intuitive user interface showing the data issue or exception and what data business rule was triggered. The employee remediates the data issue, and a workflow enabled approval process is initiated.

8. Access Control, Security, Audit Trail and Data Lineage

Due to the well-structured and organized compilation of valuable information about products, IDMP information is sensitive and confidential in nature.

In addition to this, the IDMP solution is classified as a GxP solution and as such needs appropriate functionality to support access control, security, audit trail and data lineage.

The SAS Perspective

The IDMP data hub from SAS is access-controlled and provides cell-level security. Every data activity is audit trailed, and powerful data lineage functionality is available, providing data stewards with the necessary insight to understand relationships and dependencies between specific variables and data points. All this information is displayed in the SAS® Data Governance web interface.

A Closer Look at the IDMP Data Hub From SAS

The next diagram provides a conceptual overview of the SAS solution. The core IDMP data processing is conducted in the IDMP data hub standardization flow, and includes data extraction, parsing and IDMP standardization, enrichment and mapping. Whenever data quality or business rules are violated in the Standardization Flow, an exception is identified and created. The IDMP Data Remediation Flow is triggered, and via data governance and workflow management, the right employees are notified regarding the exception. Necessary correction of data can be done followed by an appropriate approval process – all managed in a web interface.

The specific IDMP logic and functionality (i.e., the IDMP QKB) that are core parts of the SAS solution are pictured at the bottom of the conceptual diagram. Managing and updating controlled vocabularies, the IDMP business rules, the IDMP QKB, data governance, access controls, and the IDMP target model are central administration activities of the solution.

IDMP Accelerator for Reduced TCO

The SAS solution for IDMP consists of two main components: SAS® Data Management and an accelerator with specific IDMP logic. SAS Data Management is a core component that provides the comprehensive data management standard functions required.
In addition, IDMP-specific logic has been configured and built into the solution to specifically address the IDMP challenges. From a SAS perspective, the IDMP built-in logic should be viewed as an IDMP accelerator; it basically accelerates the time and reduces the amount of resources needed to comply with IDMP. For example, the IDMP QKB enables data stewards to build more efficient and smarter IDMP standardization flows – simply because the IDMP QKB understands and is designed to interpret words and concepts relevant in an IDMP context. The way in which CVs are updated and managed, and how they are linked to the IDMP QKB, is an additional example.

Smarter and more efficient IDMP standardization flows and business rules require less resources and time for both the implementation and the maintenance of the SAS solution. This can ultimately lead to a lower total cost of ownership specifically regarding the data hub part of the IDMP solution.

IDMP in the MDM Context

Some companies in the life science industry have not yet adopted master data management (MDM). Many pharmaceutical companies have initiatives to evaluate MDM, and many companies perceive IDMP to be a first step on an MDM journey.
Due to the complexity and very limited timeline for IDMP, organizations may want to focus on implementing IDMP first and then use it as a basis for expanding and adopting MDM.

For those organizations that have already implemented and fully adopted MDM, assessments should be made as to the degree to which their MDM solution can support their IDMP business requirements, and at what total cost of ownership.

SAS provides a powerful and comprehensive MDM solution, and our IDMP data hub solution is based on the same standard software components. This means that an upgrade from the IDMP data hub to an MDM solution is a matter of commercial licensing.

A brief overview of the different approaches to IDMP in an MDM context is provided in Figure 5.

Just IDMP Compliance, or the Foundation for New Business Insights?

Even though most pharmaceutical companies are focused on becoming compliant by Q4 2018 and have a goal of achieving compliance to the absolute “minimum requirements,” there is value and business opportunity when looking beyond just the

Figure 5. Different approaches to IDMP in an MDM context.
compliance aspect. A few visionary pharmaceutical companies recognize the potential business value in well-structured and nicely ordered IDMP data. If this data is combined with pharmaceutical sales, promotional and/or financial data, there is a strong foundation for generating new business insights.

Several pharmaceutical customers use SAS Data Management as a commercial data hub in the sales and marketing division. Establishing a close link between the commercial data hub and the IDMP (or regulatory) data hub is an obvious next step. Some of these visionary companies are also taking initial steps to exploit real-world evidence. Pharmaceutical companies that succeed in establishing the right data foundation across these traditional organizational silos – and apply business analytics to gain new business innovation and insight – will ultimately gain competitive advantages.

Conclusion

The IDMP data chasm is a comprehensive and demanding challenge – but it can be crossed with the right preparation, approach and solution.

This white paper highlights eight IDMP challenges, and how they can be addressed with an IDMP data hub solution from SAS. We have provided a view and recommendation on IDMP in an MDM context, and finally broadened the perspective by looking beyond the approach of solely adopting IDMP for compliance.

From the day SAS was founded four decades ago, our core has always been to provide customers with superior data management and business analytics solutions. This is in our DNA, and it can move your organization beyond the IDMP data chasm.
Appendix 1. List of Controlled Vocabularies in IDMP

The following table provides an overview of controlled vocabularies for IDMP. Please note the list is subject to change.

<table>
<thead>
<tr>
<th>Additional Monitoring Indicator</th>
<th>Country</th>
<th>Interaction Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrable Dose Form</td>
<td>Data Carrier Identifier Code System</td>
<td>Jurisdiction</td>
</tr>
<tr>
<td>Age</td>
<td>Device Alternate Material</td>
<td>Language</td>
</tr>
<tr>
<td>Age Range</td>
<td>Device Material</td>
<td>Legal Status of Supply</td>
</tr>
<tr>
<td>Allergenicity Indicator</td>
<td>Device Type</td>
<td>Location Role</td>
</tr>
<tr>
<td>Alternate Material</td>
<td>Device Usage</td>
<td>Management Actions</td>
</tr>
<tr>
<td>Application Type</td>
<td>Disease Status</td>
<td>Manufactured Dose Form</td>
</tr>
<tr>
<td>Authorization Status</td>
<td>Document Type</td>
<td>Material</td>
</tr>
<tr>
<td>Classification System</td>
<td>Frequency of Occurrence</td>
<td>Medication</td>
</tr>
<tr>
<td>Colour</td>
<td>Gender</td>
<td>Operation Type</td>
</tr>
<tr>
<td>Country</td>
<td>Health Status Specifics</td>
<td>Package Item (Container) Type</td>
</tr>
<tr>
<td>Combined Pharmaceutical Dose Form</td>
<td>Indication</td>
<td>Paediatric Use Indicator</td>
</tr>
<tr>
<td>Co-morbidity</td>
<td>Ingredient Role</td>
<td>Product Classification</td>
</tr>
<tr>
<td>Component Alternate Material</td>
<td>Intended Effect</td>
<td>Procedure Type</td>
</tr>
<tr>
<td>Component Material</td>
<td>Interactant Code System</td>
<td>Race</td>
</tr>
<tr>
<td>Component Type</td>
<td>Interaction Effect</td>
<td>Regulated Document</td>
</tr>
<tr>
<td>Confidentiality Indicator</td>
<td>Interaction Incidence</td>
<td>Role</td>
</tr>
</tbody>
</table>

Appendix 2. What Is ISO IDMP?

ISO identification of medicinal products (IDMP) is a group of five ISO standards which together provide the basis for the unique identification of medicinal products. It is a global standard and will support regulatory activities related to, for example, development, registration, lifecycle management of medicinal products, pharmacovigilance and risk management.

Why ISO IDMP?

ISO IDMP is a response to a worldwide demand for internationally harmonized specifications for medicinal products. It will support exchange of information between regulators, pharmaceutical companies, sponsors of clinical trials and globally maintained data sources.

Why Unique IDMP Identifiers?

To reliably identify and trace the global use of medicinal products and the materials within medicinal products.

Why Is It Urgent?

Pharmaceutical companies having marketed products in Europe must comply with ISO IDMP by Q4 2018 (current regulatory timeframe). Pharmaceutical companies are currently assessing and making decisions on approach and technology for IDMP adoption. Considering that cross-organizational IT solutions take at least six to twelve months to implement, the IDMP deadline is approaching quickly.
Europe Now; US and Other Regions in Next Wave

EMA in the EU has set Q4 2018 as the deadline to comply with IDMP iteration 1 for the industry. The US, Japan and other regions have not announced IDMP deadlines yet, but are expected to do so in the near future.

Which Organizational Process Areas Are Affected by IDMP?

IDMP impact is cross-organizational. The primary business areas that must provide source data to IDMP are regulatory affairs, product supply/manufacturing, packaging, product safety, research/CMC and clinical development. Typically the IDMP project is anchored in regulatory affairs or corporate IT.

What Data?

The source data will be integrated and standardized toward an IDMP data (target) model that consists of approximately 225 to 300 prime characteristics of the pharmaceutical product (i.e., medicinal product name, packaging container, substance, dosage form, route of administration, therapeutic indications, etc.). Each “characteristic” should be viewed as an IDMP data field and is either mandatory, conditional or optional. The IDMP standardization must be done for all EU marketed products and products in development that the pharmaceutical company has in its portfolio.

Figure 6 shows some of the data that is required, the business process areas involved, and which source systems are typically involved.

Figure 6. Data required, the business process areas involved, and which source systems are typically involved.