How to Become IDMP Compliant and Gain Additional Insights Using SAS®

Challenges

- **Standardizing source data to IDMP-compliant data**. Standardizing data is the core IDMP challenge. The source data can be both structured and unstructured and be spread over different departments and systems, leading to poor data quality.
- **Managing controlled vocabularies and other reference data**. About half the data for IDMP conforms to controlled vocabularies. These vocabularies must be managed and updated to ensure compliance.
- **Achieving efficient data remediation and governance across the organization**. Without efficient workflow management and data remediation, data issues will not be resolved efficiently, thus increasing the overall costs.
- **Extracting IDMP-relevant content from documents (i.e., SmPCs)**. Many organizations find it difficult to make efficient use of content from summaries of product characteristics (SmPCs) and other unstructured data sources.

Identification of Medicinal Products, or **IDMP,** is the global regulatory standard for describing medicinal products. By ensuring that all stakeholders use the same language and vocabulary, IDMP is expected to improve patient safety globally.

In practice, IDMP is a group of five ISO standards that facilitate the unique identification of approved and investigational medicinal products. These unique identifiers support regulatory interoperability and signal detection across geographic regions.

IDMP Adoption in the EU and US

The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) are the first regulatory authorities adopting IDMP. Other regulatory authorities are in the planning phase.

Implementation guidelines for the US are expected to be available by Q4 2019. In Europe, they should arrive around the same time or soon after, due to the relocation of EMA following Brexit. Once IDMP standards are enforced, companies marketing medicinal products will be required to submit data on medicines and their ingredients to the respective regulatory authorities and in accordance to defined, controlled terms.

EMA's approach to implementing the IDMP standards is based on the four domains of master data management comprising pharmaceutical regulatory processes:

- Substance.
- Product.
- Organization.
- Referential.

Collectively, this data is referred to as SPOR data. In June 2017, the SPOR Task Force, established by the EMA with national competent authorities and industry involvement, released Organization Management Services and Referential Management Services for usage by the industry. This was a critical milestone and significant step toward IDMP compliance.

Data standardization is a core competency of SAS and is a key enabler for advanced business analytics. SAS has been a leader in the implementation of CDISC standards and uses the Observational Medical Outcomes Partnership common data model for real-world intelligence.

How SAS Can Help

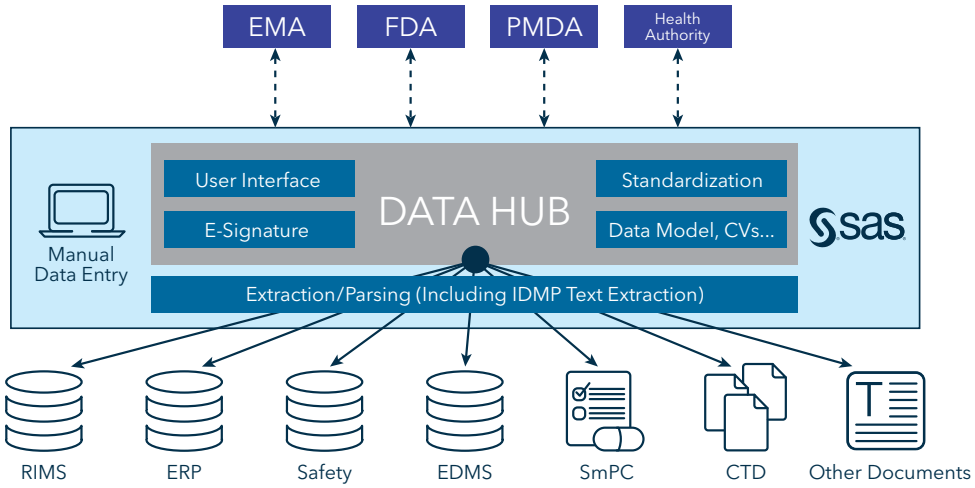
SAS supports all delivery models including results-as-a-service, starting initially with text extraction functionality.

SAS delivers a single platform supporting all IDMP data standardization activities – while providing added value beyond compliance with SAS Analytics. We also bring deep regulatory knowledge and industry experience to the development of an IDMP platform.

Using SAS, companies can extract, parse and integrate data from all relevant structured and unstructured data sources. Data quality checks can be performed to ensure that the data adheres to the IDMP standards and controlled vocabularies. An authoritative data hub includes built-in feedback mechanisms that allow companies to update source data in operational systems (see figure).

In summary, the SAS platform:

- Provides advanced master data management capabilities to extract, parse and integrate data from all relevant data sources.
- Accelerates the implementation by using SAS software's IDMP logic, including:
  - Advanced IDMP text extraction from unstructured data sources (e.g., from SmPCs).
  - An IDMP quality knowledge base, including standard definitions and business rules for more efficient IDMP standardization of source data.
  - An IDMP target data model within the data hub.
  - The ability to send IDMP-compliant data to health authorities.
- Provides decentralized, intuitive IDMP data remediation supported by workflows that allow line-of-business users to quickly and efficiently remediate data issues.
- Enables customers to build and easily maintain IDMP data flows in-house (or outsource this to partners).
- Ensures full data lineage and traceability, as well as support for data impact assessments.
- Enables customers to apply data visualization, reporting and advanced analytics to gain additional (cross-organizational) business insights.
- Delivers a foundation to meet other business needs and regulatory requirements beyond IDMP, such as the General Data Protection Regulation, which will take effect in May 2018.



SAS takes a platform approach to IDMP compliance.

Delivering Value Beyond IDMP Compliance

While becoming IDMP-compliant may be your primary objective, achieving this goal using SAS software delivers business value across the enterprise by enabling your company to be more competitive. With the SAS platform:

- IDMP data is standardized and readily available for use across your enterprise for analysis. It can also be combined with other company data or publicly available data for even deeper insights.
- The data hub supports better decision making by enabling users to unify previously siloed, cross-functional data sources and generate insights from it.
- Users can discover valuable information hidden in unstructured, text-based documents.
- Users can explore and visualize all their data quickly and easily, and then expand and use more advanced analytics.

Learn More

SAS has a proven approach to IDMP compliance that's based on years of industry experience and includes unmatched technologies for data management, data preparation, analysis, visualization and more. To learn more about how SAS can help your organization accelerate IDMP compliance while adding significant, additional value across your business, contact your SAS representative or visit sas.com/idmp.

To contact your local SAS office, please visit: sas.com/offices

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