

Implementation of the IDMP standards in the European Union

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Introduction

IDMP (acronym for Identification of Medicinal Products), as a suite of five different standards, is the International Organization for Standardization's (ISO) facilitation of the unique identification of medicinal products when viewed in the context of medicinal products' safety. These standards specify the use of definitions for identification and description of medicinal products for human use. The European Medicines Agency (further in the text: EMA) with the implementation of the Article 57(2) from the Regulation (EC) No 726/2004 kicked-off a digitalization initiative that supported by the IDMP implementation strives to further the communication between the shareholders in the process of registering medicinal products for human use and tracking their safety, ultimately improving the public health, (Groenning, 2017). By default, this type of standardization requires introduction of digital solutions and investing from the industry side into domains and processes that broaden the scope of their work. However, the benefits in their enhanced effectiveness in the regulatory and pharmacovigilance processes are invaluable (Koshechkin et al., 2017).

Master data

For proper facilitation of the IDMP standards, companies and regulators must adopt the postulates of "master data". Master data is a concept of creating and maintaining a pool of information that represents data about the business entities that provide further context for business transactions, (Data Management Association, 2017). In other words, it is data, which empowers the creation of context for other data. Master data is an

invaluable tool for the pharmaceutical industry. Managed properly, it provides companies the might of efficient communication of information about their products with regulators, which in turn enables faster registration procedures, and therefore a more complete market presence. Meticulously collecting the master data for the products in a pharmaceutical company means thorough business awareness for its benefits, collective strategic thinking on behalf of the company, which leads to all-encompassing effort. Everybody needs to be on the same page since the benefits, even though not immediately detectable, are inarguably present, both for the companies and for the patients.

EMA implementation of the ISO IDMP standards

EMA is implementing the ISO IDMP standards in phases. The entire project is divided into four parts, each defining a separate data management service, which in turn describes one of the four pillars of master data for pharmaceutical products (Substances – SMS, Products – PMS, Organizations – OMS, Referential – RMS). Consequently, the complete project encompasses defining, collecting, maintaining and managing data about active and inactive substances, medicinal products, organizations and referential. Two of the intended projects (OMS and RMS), concerning the organizations and the controlled vocabularies that describe certain attributes of products (e.g., dosage forms, units of measurement, routes of administrations), already provide master data to the electronic application forms for every regulatory activity. Therefore, two of the four projects are in function and require ongoing communication with the industry. The postulates concerning the management of

the active and non-active substances and the medicinal products (SMS and PMS, respectively) will be established in a recursive fashion, i.e., iteratively. The first iteration of the SMS gave users a chance to submit term addition through the EMA service desk. This way, the Agency manages the data, with future iterations connecting and synchronizing SMS with the European substance reference system database, which is a prequel for the SMS user interface. The largest and most comprehensive pillar of the four, the PMS is yet to see the light of day. Namely, the Agency predicts that covering the authorized medicinal product part of the ISO IDMP standards will replace the current data submission format. EMA already requires companies to submit data after approval of certain regulatory activities through the xEVMPD requirements, which stemmed from Article 57(2) from the Regulation (EC) No 726/2004 (European Parliament and Council, 2004). This data was, and until full ISO IDMP implementation is, being sent and evaluated separately from the actual documentation required by the regulatory activity, alongside supporting documentation, most commonly the Summary of Product Characteristics (SmPC). Using this process EMA built and maintained certain databases that provided a starting point for the process of ISO IDMP implementation. Currently, industry stakeholders should submit data about their products using the data standard referred to as xEVPRM (standing for eXtended EudraVigilance Product Report Message). This format shall be appended by a submission format compatible with the ISO IDMP standards, the HL7 “FHIR” format. FHIR stands for Fast Healthcare Interoperability Resources and is an appealing format for exchange of medical information because of its truly modern web services approach (Setyawan et al., 2021). This standard incorporates bundles of information into “resources”, each linked with a unique identifier. Its standard provides for easy search from any device or application. Just by assigning the standard identification codes, similar to the URLs, this standard eliminates and cuts down the process of exchanging data between different systems.

Conclusion

ISO IDMP and its global implementation signify a lot of efforts and resources on part of the industry, in order to increase the quality of the processes of development, production and control of the medicinal product. However, the proper management of the information regarding these processes ensures greater efficiency during the implementation of the novelties. With greater efficiency a more robust process will emerge, which will lead to better overall quality of the processes. ISO IDMP is a standard intended to align every pharmaceutical

company’s business aspect in the production and control of the quality, efficacy and safety of its products, by implementation of meticulous data management. With these standards executed in the everyday procedures the company runs smoothly, which in every way provides for better healthcare in the global sense.

References

- Data Management Association, 2017. DAMA-DMBOK: Data Management Body of Knowledge.
- European Parliament and Council, 2004. Regulation (EC) No 726/2004 of the European Parliament and of the Council.
- Groenning, N., 2017. Data management in a regulatory context // *Front. Med. Frontiers Media S.A.* 4. <https://doi.org/10.3389/fmed.2017.00114>
- Koshechkin, K., Lebedev, G., Fartushny, E., 2017. Implementation of IDMP Standards as a Means of Creating a Unified Information Space in the Field of Drug Circulation. *Procedia Computer Science* 176 (2020), 1745–1753. <https://doi.org/10.1016/j.procs.2020.09.213>
- Setyawan, R., Hidayanto, A.N., Senses, I.D., Suryono, R.R., Abilowo, K., 2021. Data Integration and Interoperability Problems of HL7 FHIR Implementation and Potential Solutions: A Systematic Literature Review. 5th International Conference on Informatics and Computational Sciences (ICICoS) <https://doi.org/10.1109/ICICoS53627.2021.9651762>