Is Your Organization IDMP Ready?

**IDMP (IDentification of Medicinal Products) is a set of international standards that will become mandatory in Europe from Q1 2023, and will be adopted globally over the next few years**

IDMP is a set of five ISO standards designed to standardize the description of marketed medicinal products. IDMP will be used in support of a broad range of regulatory and pharmacovigilance requirements, but also beyond these: for example, for clinical trial registrations, and potentially into European-wide support of patient healthcare records.

Pharma organizations face a rapidly shortening time frame to prepare for full transition of regulatory data and systems to comply with this complex mandate. IDMP will be mandatory worldwide for all Marketing Authorization Holders in ISO countries. The EMA will be the first health agency to mandate compliance with ISO IDMP (initially from Q1 2022, mandatory from Q1 2023), with the FDA not far behind.

**Linguamatics NLP can help your organization to be IDMP ready**

Capturing the 300–2,000 data entities required per product, 70% of which lie in unconnected silos of unstructured text, demands time, resources and investment.

Thanks to recent developments in text mining, manual curation is no longer the only option for extraction of the necessary data attributes. The Linguamatics NLP text mining solution can save your organization time and reduce mistakes on its IDMP compliance journey.

Linguamatics' knowledge and experience of adapting the capability of our natural language processing (NLP) to deliver regulatory requirements places it in a unique position to help organizations to find, extract, standardize and structure data elements from IDMP-relevant unstructured text documents, including:

- **Summary of Product Characteristics (SmPC)**
- **Manufacturing Licenses**
- **Chemistry, Manufacturing and Control (CMC) documents**
- **Regulatory and Compliance documents such as eCTDs (electronic common technical documents).**

**IDMP overview**

There are five ISO IDMP standards (see Figure 1). Together they allow for the definition, characterization and precise identification of regulated pharmaceutical products during their lifecycle, from development through into marketing. IDMP standards are intended to support applications and processes where it is essential to accurately identify and trace any use of a particular medicinal product.
Benefits of text analytics for extraction of IDMP data elements

A text analytics approach brings benefits over manual data extraction from unstructured text. Copying and pasting relevant data from documents into spreadsheets is intensive, repetitive and tedious work, and is prone to errors. Text mining uses business rules and standard vocabularies to create a consistent normalized set of product data, systematically, and can be used across tens, hundreds or thousands of documents. Business rules can be rapidly translated into search queries, and this flexibility is key as the IDMP framework evolves and matures.
Linguamatics NLP is proven

Linguamatics provides a world leading agile, scalable, real time NLP-based text mining solution. It already enables 19 of the world’s top 20 pharmaceutical companies to meet regulatory requirements, and is used across the drug development pipeline. Various government bodies (including the FDA) and healthcare providers also benefit from NLP’s text mining power.

Linguamatics NLP can help you solve the challenges of IDMP data capture from unstructured data containers, such as:

- data extraction from internal and external documents
- differing document types and formats
- MedDRA or SNOMED-CT coding for harmonization of adverse events, indications
- flexibility as the IDMP framework evolves.

Case studies where NLP brings value to pharma organizations

Linguamatics NLP has been used by top pharma companies such as Johnson & Johnson, Mundipharma and others.

JOHNSON & JOHNSON

Linguamatics worked with J&J Consumer to extract IDMP data elements from regulatory documents such as SmPCs and regulatory dossiers. Challenges included a varied set of documents in mixed formats, some up to 50 years old, in five different languages (English, French, Spanish, German, Italian). The output was mapped to the J&J schema for their IDMP submission and internal business use. Over 1,300 documents were processed, with an overall accuracy above 94%, saving J&J Consumer significant time and resources.

MUNDIPHARMA

For Mundipharma, we developed an NLP data factory approach, with an enterprise workflow to automate the identification, extraction and coding of data elements from regulatory documents in preparation for IDMP implementation. NLP queries were developed to extract the individual data elements using standard and customized ontologies, as well as linguistic features of SmPCs. Linguamatics NLP provides an agile environment for rapid query development: an ideal tool to help deliver IDMP compliance. Business rules can be rapidly translated into search queries, and this flexibility is key while the IDMP framework is still evolving.