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.

IQVIA 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 IQVIA NLP text mining solution can save your organization time and reduce mistakes on its IDMP compliance journey.

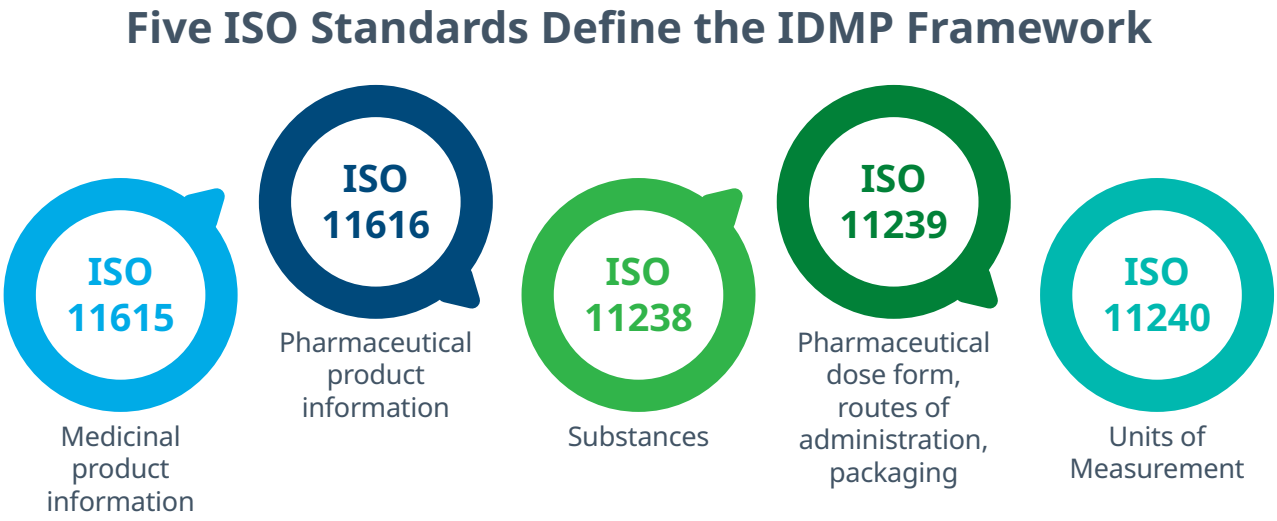
IQVIA's knowledge and experience of adapting the capability of our natural language processing (NLP) to deliver regulatory requirements places it in a unique position to help organizations to find, extract, standardize and structure data elements from IDMP-relevant unstructured text documents, including:

- 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.

Figure 1: Each ISO IDMP standard defines data elements and structures for unique identification and exchange of a certain aspect of a medicinal product



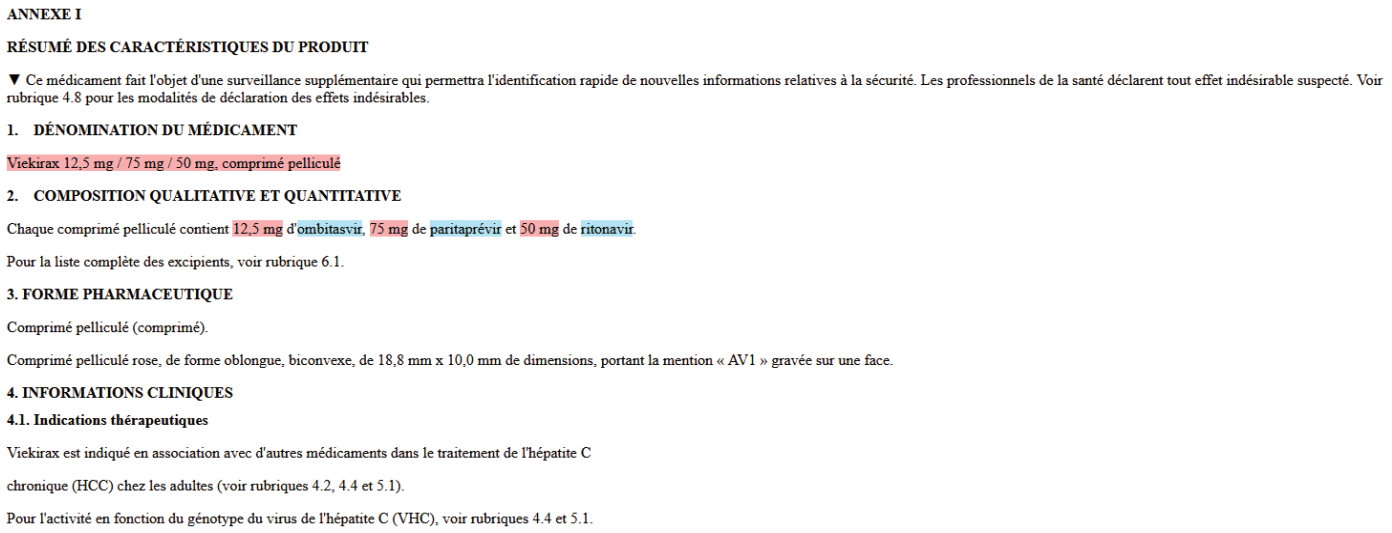
Benefits of text analytics for extraction of IDMP data elements

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.

Figure 2: IQVIA NLP can extract structured results for key data elements (e.g. pharmaceutical dose form, name, strength) from a set of SmPCs

Doc	Substance Name	Full Name	Invented	Strength	Pharmaceutical Dose ..	#Hits	Hit
viekirax_fr	OMBITASVIR	Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé	Viekirax	12,5 mg / 75 mg / 50 mg	comprimé pelliculé	1	Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé ... Chaque comprimé pelliculé contient 12,5 mg d'ombitasvir, 75 mg de paritaprévir ...
	PARITAPREVIR	Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé	Viekirax	12,5 mg / 75 mg / 50 mg	comprimé pelliculé	1	Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé ... 12,5 mg d'ombitasvir, 75 mg de paritaprévir et 50 mg de ritonavir...
	RITONAVIR	Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé	Viekirax	12,5 mg / 75 mg / 50 mg	comprimé pelliculé	1	Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé ... 75 mg de paritaprévir et 50 mg de ritonavir.
viekirax_en	OMBITASVIR	Viekirax 12.5 mg/75 mg/50 mg film-coated tablets	Viekirax	12.5 mg/75 mg/50 mg	film-coated tablets	1	Viekirax 12.5 mg/75 mg/50 mg film-coated tablets ... Each film-coated tablet contains 12.5 mg of ombitasvir, 75 mg of paritaprevir ...
viekirax_de	OMBITASVIR	Viekirax 12,5 mg/75 mg/50 mg Filmtabletten	Viekirax	12,5 mg/75 mg/50 mg	Filmtabletten	1	Viekirax 12,5 mg/75 mg/50 mg Filmtabletten ... Jede Filmtablette enthält 12,5 mg Ombitasvir, 75 mg Paritaprevir und ...
trumenba_fr	NEISSERIA MENINGITIDIS	Trumenba suspension injectable en seringue préremplie	Trumenba		suspension injectable en seringue préremplie	1	Trumenba suspension injectable en seringue préremplie ... de la sous-famille A1,2,3 de Neisseria meningitidis de sérogroupe B 60 microgrammes
trumenba_en	NEISSERIA MENINGITIDIS	Trumenba suspension for injection in pre-filled syringe	Trumenba		suspension for injection in pre-filled syringe	1	Trumenba suspension for injection in pre-filled syringe... Neisseria meningitidis serogroup B fHbp subfamily A1,2,3 ...
trumenba_de	NEISSERIA MENINGITIDIS	Trumenba Injektionssuspension in einer Fertigspritze	Trumenba		Injektionssuspension in einer Fertigspritze	1	Trumenba Injektionssuspension in einer Fertigspritze ... Neisseria meningitidis Serogruppe B fHbp Unterfamilie A1,2,3 ...

Figure 3: Cached copy of the SmPC document, showing the highlighted markup for the extracted text around Viekirax



ANNEXE I

RÉSUMÉ DES CARACTÉRISTIQUES DU PRODUIT

▼ Ce médicament fait l'objet d'une surveillance supplémentaire qui permettra l'identification rapide de nouvelles informations relatives à la sécurité. Les professionnels de la santé déclarent tout effet indésirable suspecté. Voir rubrique 4.8 pour les modalités de déclaration des effets indésirables.

1. DÉNOMINATION DU MÉDICAMENT

Viekirax 12,5 mg / 75 mg / 50 mg, comprimé pelliculé

2. COMPOSITION QUALITATIVE ET QUANTITATIVE

Chaque comprimé pelliculé contient 12,5 mg d'ombitasvir, 75 mg de paritaprévir et 50 mg de ritonavir.

Pour la liste complète des excipients, voir rubrique 6.1.

3. FORME PHARMACEUTIQUE

Comprimé pelliculé (comprimé).

Comprimé pelliculé rose, de forme oblongue, biconvexe, de 18,8 mm x 10,0 mm de dimensions, portant la mention « AV1 » gravée sur une face.

4. INFORMATIONS CLINIQUES

4.1. Indications thérapeutiques

Viekirax est indiqué en association avec d'autres médicaments dans le traitement de l'hépatite C

chronique (HCC) chez les adultes (voir rubriques 4.2, 4.4 et 5.1).

Pour l'activité en fonction du génotype du virus de l'hépatite C (VHC), voir rubriques 4.4 et 5.1.

Clicking on the "hit" markup in the tabular results takes the user directly to the correct place in the document, enabling rapid and efficient review.

IQVIA NLP is proven

IQVIA 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.

IQVIA 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

TOP 10 PHARMA COMPANY

IQVIA worked with a top 10 pharma company 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 the company significant time and resources.

MULTINATIONAL RESEARCH-BASED PHARMA COMPANY

For a multinational research-based pharmaceutical company, 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. IQVIA 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.

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