

Is your organization IDMP ready?

IDMP (IDentification of Medicinal Products) is a set of international standards developed by ISO that will become mandatory in Europe in a phased approach, effective from 2018, and will also be adopted by the FDA and globally over the next few years.

In Europe, a legal requirement to implement IDMP comes into effect from July 2016, with the first mandate from the third quarter of 2018.

Pharmaceutical and life science organizations need to start their preparation early, as those that fail to comply with the EU IDMP requirements by the fourth quarter of 2018 can be fined up to 5% of gross European revenue.

Linguamatics I2E 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. It is estimated that the average organizational cost to do so, across the five required ISO standards (Figure 1), will be around €2.5 million (\$3m).¹

Thanks to recent developments in text mining, manual curation is no longer the only option for extraction of the necessary data attributes. I2E, Linguamatics' world leading text mining solution, can save your organization time and reduce mistakes on its IDMP-compliance journey.

Linguamatics' knowledge and experience of adapting I2E's capabilities to deliver regulatory requirements place us in a unique position to help organizations find, extract, standardize, and structure data elements from IDMP-relevant unstructured text documents, including:

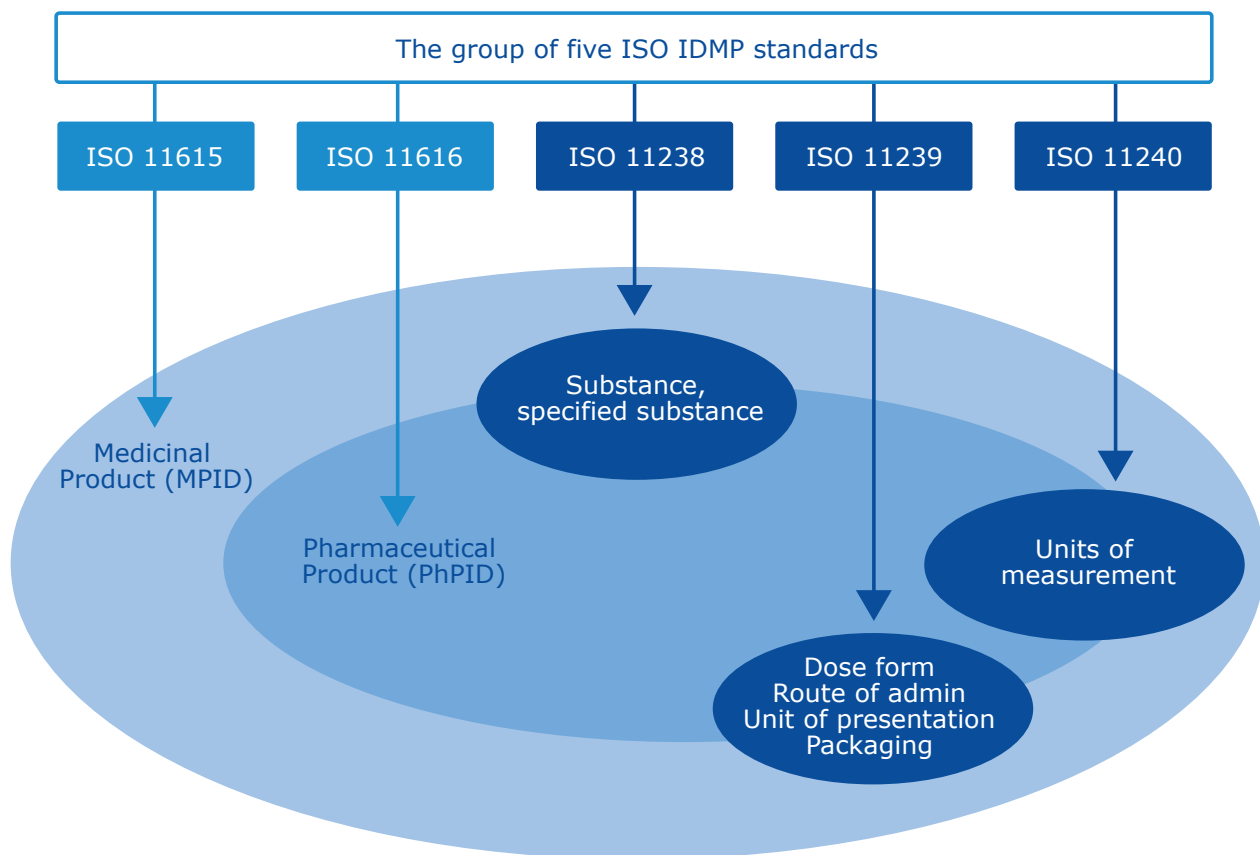
- ◆ Summary of Product Characteristics (SmPC);
- ◆ Manufacturing licenses;
- ◆ Chemistry, Manufacturing and Control (CMC) documents; and
- ◆ Regulatory and compliance documents such as eCTDs (electronic common technical documents).

¹ Cost estimates drawn from the EFPIA Position Paper, October 2014: "Principles for the Implementation of ISO IDMP Standards for EudraVigilance and Development of a Road Map."

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 life cycle, from development through to 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 systematically create a consistent, normalized set of product data, 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 when the IDMP framework is still evolving.

Figure 2: Top: I2E can extract structured results for key data elements, e.g. pharmaceutical dose form, name, and strength, from a set of Summaries of Product Characteristics (SmPCs). Bottom: a cached copy of the SmPC document, showing the highlighted mark-up for the extracted text around Glivec®. Clicking on the "hit" mark-up in the tabular results takes the user directly to the correct place in the document, enabling rapid and efficient review.

Doc	Compound	name	strengthPart	pharmaceuticalDoseFo..	Hit
Glivec_SmPC_clean	▼ Imatinib Mesylate	Glivec 50 mg hard capsules	50 mg	Glivec 50 mg hard capsules	1 Glivec 50 mg hard capsules
		Glivec 100 mg film-coated tablets	100 mg	Glivec 100 mg film-coated tablets	1 Glivec 100 mg film-coated tablets
		Glivec 100 mg hard capsules	100 mg	Glivec 100 mg hard capsules	1 Glivec 100 mg hard capsules
		Glivec 400 mg film-coated tablets	400 mg	Glivec 400 mg film-coated tablets	1 Glivec 400 mg film-coated tablets
Hepsera_SmPC_clean	Adefovir Dipivoxil	Hepsera 10 mg tablets	10 mg	Hepsera 10 mg tablets	1 Hepsera 10 mg tablets
Mimpara_SmPC_clean	▶ Cinacalcet Hydrochloride	Mimpara 30 mg film-coated tablets.	30 mg	Mimpara 30 mg film-coated tablets.	1 Mimpara 30 mg film-coated tablets.
Pegasys_SmPC_clean	▶ Peginterferon Alfa-2a	Pegasys 90 micrograms solution for injection in pre-filled syringe	90 micrograms	Pegasys 90 micrograms solution for injection in pre-filled syringe	1 Pegasys 90 micrograms solution for injection in pre-filled syringe
Urorec_SmPC_clean	▶ Silodosin	Urorec 4 mg hard capsules	4 mg	Urorec 4 mg hard capsules	1 Urorec 4 mg hard capsules
Yervoy_SmPC_clean	▶ Ipilimumab	▶ YERVOY 5 mg/ml concentrate for solution for infusion	5 mg	YERVOY 5 mg/ml concentrate for solution for infusion	1 YERVOY 5 mg/ml concentrate for solution for infusion
Zelboraf_SmPC_clean	Vemurafenib	Zelboraf 240 mg film-coated tablets.	240 mg	Zelboraf 240 mg film-coated tablets.	1 Zelboraf 240 mg film-coated tablets.
Actos	▶ Pioglitazone Hydrochloride	Actos 15 mg tablets	15 mg	Actos 15 mg tablets	1 Actos 15 mg tablets
Levitra	▶ Vardenafil Hydrochloride Trihydrate	Levitra 5 mg film-coated tablets	5 mg	Levitra 5 mg film-coated tablets	1 Levitra 5 mg film-coated tablets
ZelborafINN	Vemurafenib	Zelboraf 240 mg film-coated tablets.	240 mg	Zelboraf 240 mg film-coated tablets.	1 Zelboraf 240 mg film-coated tablets.

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Glivec 50 mg hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 50 mg imatinib (as mesilate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule

White to yellow powder in a light yellow to orange-yellow opaque capsule, marked "NVR SH".

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Glivec is indicated for the treatment of

- adult and paediatric patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment.

I2E is proven

I2E is a world leading, agile, scalable, real-time natural language processing (NLP) based text mining solution. I2E already enables 17 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 the NLP text mining power of I2E.

I2E 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;
- ◆ different styles from document authors;
- ◆ content can be verbose or tabular;
- ◆ MedDRA or SNOMED-CT coding for harmonization of adverse events, indications;
- ◆ different languages; and
- ◆ flexibility needed as IDMP framework timelines and scope evolve.

Why wait?

To understand the power of NLP text analytics for your IDMP-compliance strategy, contact us now: IDMP@linguamatics.com