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Identification of Medicinal Products
How to build a strategy that will transform your business

In response to the requirements of Good Vigilance Practices, the pharmaceutical industry and regulators have embarked on a journey to Identification of Medicinal Products (IDMP) compliance.

A company's first and most crucial step towards achieving IDMP compliance is to determine where the relevant data is residing within the organisation or externally. A thorough and diligent analysis can provide a solid understanding of the current state and highlight any gaps to be bridged.

Deloitte brings together its global resources, regulatory expertise, industry knowledge, and unique IDMP accelerators to support the pharmaceutical industry on this important journey to increased patient safety.

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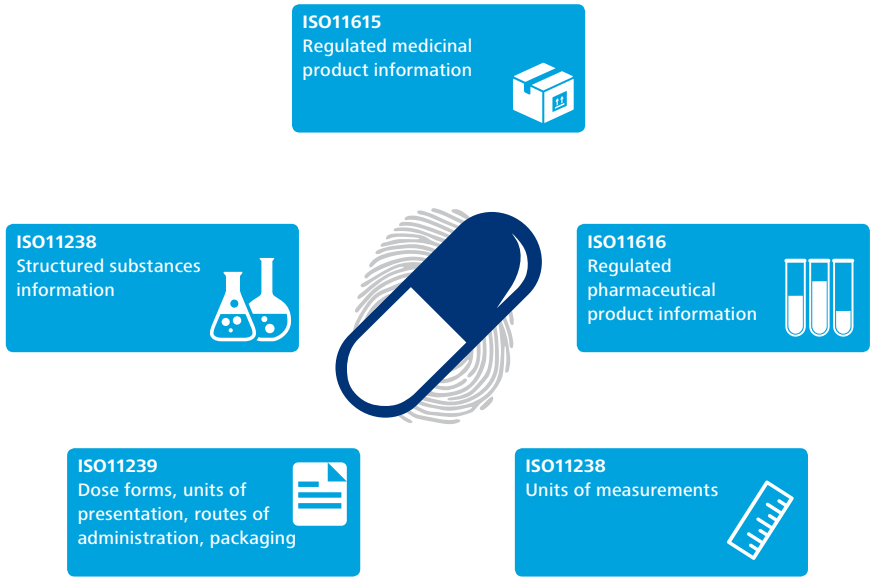
The IDMP imperative

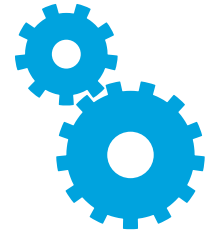
IDMP standards are being developed and implemented by the International Organization for Standardization (ISO) and regulators in response to a worldwide demand for internationally aligned specifications for medicinal products.

The five standards include the regulated medicinal product information; the regulated pharmaceutical product information; units of measurement; dose forms, units of presentation, routes of administration, and packaging; and structured substance information (Figure 1). Together, these standards allow for the definition, characterisation, and unique identification of regulated pharmaceutical products across their entire lifecycle – from development to authorisation and marketing.

Figure 1. IDMP is comprised of five standards



Over the next few years, pharmaceutical organisations will be mandated (in an iterative approach) to electronically submit and maintain product information on an ongoing basis. The need to be compliant is expected to drive organisations to make significant changes to current product-related processes and systems, ushering in a new era of cross-functional collaboration.



IDMP will be a game-changer in terms of using process and technology integration to improve patient safety. IDMP will provide companies with an opportunity to make product data work more effectively from a business perspective via improvements in data quality and usage.

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Beginning the journey to IDMP readiness

IDMP's broad and cross-functional scope requires a corporate-wide effort to align on standards, master data management, data governance, and identification of authoritative source systems. This presents a pharmaceutical company with an opportunity to transform how it manages data across the entire lifecycle of a medicinal product.

The first and most crucial step towards achieving IDMP readiness is to understand the meaning of all data attributes detailed in the ISO standards and determine where in the organisation the relevant data resides. A thorough and diligent fit-gap analysis can provide a solid understanding of the current state and highlight any gaps that must be bridged to reach compliance.

The data elements defined in the ISO IDMP standard follow the Authorised and Investigational Medicinal Products lifecycle and span various domains:

- Medicinal product name
- Regulated documents
- Marketing/clinical trial authorisations
- Manufacturing organisations and operations
- Clinical particulars
- Pharmaceutical products
- Substances information
- Packaging & medical devices

In many cases, IDMP-relevant data is neither created nor maintained in a company's information systems. Our experience shows that often more than 60 percent of IDMP attributes are available solely in unstructured text format. Fortunately, the majority of the required IDMP data can be retrieved from the set of regulated documents that a company prepares and submits to authorities for a medicinal product's registration (Figure 2).

Figure 2. Most IDMP data can be retrieved from a product's registration documents

Marketing Authorisation (MA Application Form, Summary of Product Characteristics)

Clinical Trial Authorisation (MCTA Application Form, Protocol, Investigator's Brochure)

Chemistry, Manufacturing and Controls (Module 2/3 of the (e)CTD dossier)

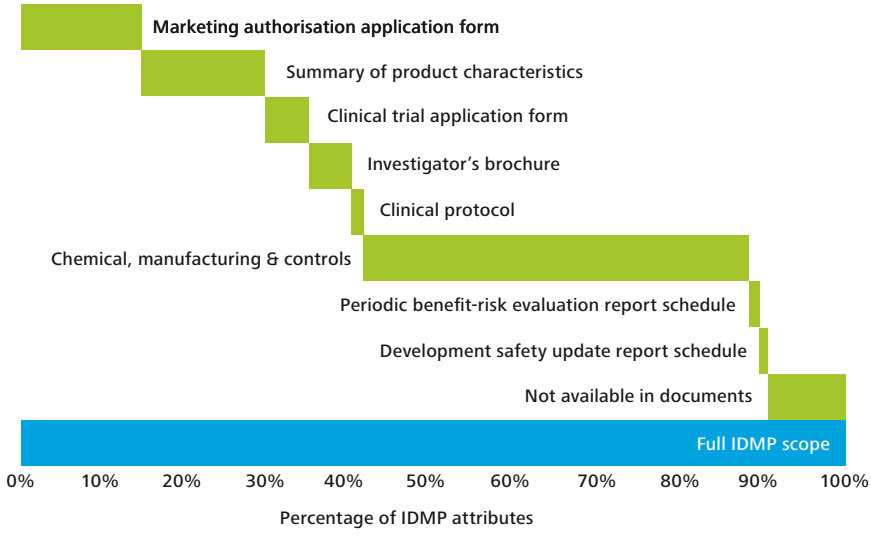
The format and structure of these regulated documents vary, and multiple versions are not uncommon. Primary factors for the differences include:

- **Product age**: Some of the older Authorised Medicinal Products have likely been on the market for several years. Only regulated documents for products authorised after July 2003 follow the mandatory (e)CTD format.

- **Approval procedure:** Depending on the nature of the procedure (centralised/ decentralised/mutually recognised procedure [MRP]) some documents follow a locally defined structure.

The amount and type of IDMP attributes contained in regulated documents may be quite extensive, as seen in Figure 3.

Figure 3. Breakdown of IDMP attributes by regulated document



Source: Deloitte research

Deloitte's experience has shown that often more than 60 percent of IDMP attributes are available solely in unstructured text format. This finding is supported by Deloitte's benchmark survey of mid-to-large biopharmaceutical companies, in which project stakeholders projected that less than 50 per cent of their IDMP data elements will be populated directly from source systems.

Some IDMP attributes cannot be retrieved from regulated documents but are likely to be maintained in a company's information systems (Figure 4).

Figure 4. Company systems with IDMP attributes

It is imperative that a company checks any data that is maintained in its systems to verify its completeness, consistency, and quality before submission. Our experience shows that companies almost always overestimate the quantity and quality of IDMP data expected to be readily available from their systems. Sometimes medicinal product information is not captured at the required level of granularity; other times the data sets are incomplete.

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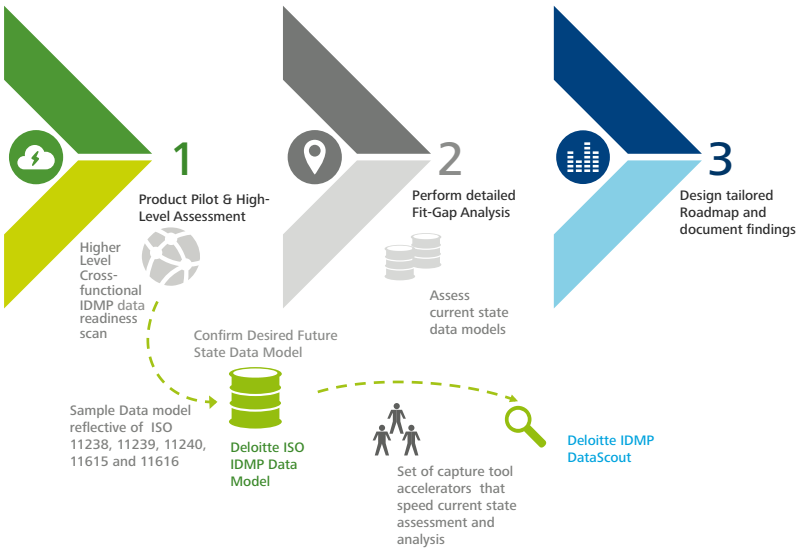
Deloitte approach: Three steps to inform the path forward

We bring together our global resources, regulatory expertise, industry knowledge, and unique IDMP accelerators to support the pharmaceutical industry on this important journey to compliance and increased patient safety.

Our tailored, three-step approach, which includes the use of our DataScout accelerator, addresses each company's specific needs and organisational complexity to inform the path forward (Figure 5).

Figure 5. IDMP fit-gap analysis



Step 1: Conduct IDMP product pilot and high-level assessment

During the IDMP product pilot phase, we collect two or more IDMP value sets of product data modelled after the IDMP ISO standard to do a high-level, current-state assessment. By selecting, for example, one Authorized and one Investigational medicinal product from a company's portfolio, we cover most of the IDMP data scope.

This provides:

- a solid understanding of the IDMP data model requirements, using familiar data examples that establish a common vocabulary
- an understanding of the scope of data the company needs to capture and maintain in order to achieve IDMP compliance, as some aspects of the data model may not apply to a company's product type.

The IDMP assessment provides an overview of IDMP complexity by leveraging 10-15 interviews with subject matter experts across key business functions (Figure 6).

Figure 6. High-level assessment subject areas

Clinical Trial Authorisation (MCTA Application Form, Protocol, Investigator's Brochure)

Marketing Authorisation (MA Application Form, Summary of Product Characteristics)

Regulatory Information Management System

Informatics responsible(s) for key Regulatory and Master Data Systems

Supply chain, packaging, manufacturing and drug supply regulatory experts

Safety responsible(s) (including Summary of Product Characteristics and PSUR

Biological responsible(s) for substance-related information in CMC

Key outcomes from the high-level, current-state assessment include:

- an understanding of where in the organisation the IDMP data resides
- knowledge of the authoritative systems for key IDMP data elements
- an initial overview of potential data gaps
- identification of focus areas for conducting a deep-dive in the next phase.

Step 2: Perform detailed fit-gap analysis

The detailed fit-gap analysis and tailored roadmap depict a snapshot of the company's current-state information landscape and determine the strategic and tactical steps required to close gaps and work towards achieving compliance in a timely manner. It evaluates the high-level impact on data management, process and governance, and the strategies to standardise and harmonise IDMP source data elements.

Key outcomes from current state analysis include:

- sources of IDMP data elements
- IDMP data quality analysis results
- structured vs unstructured data analysis
- IDMP data elements mapped to the source of record.

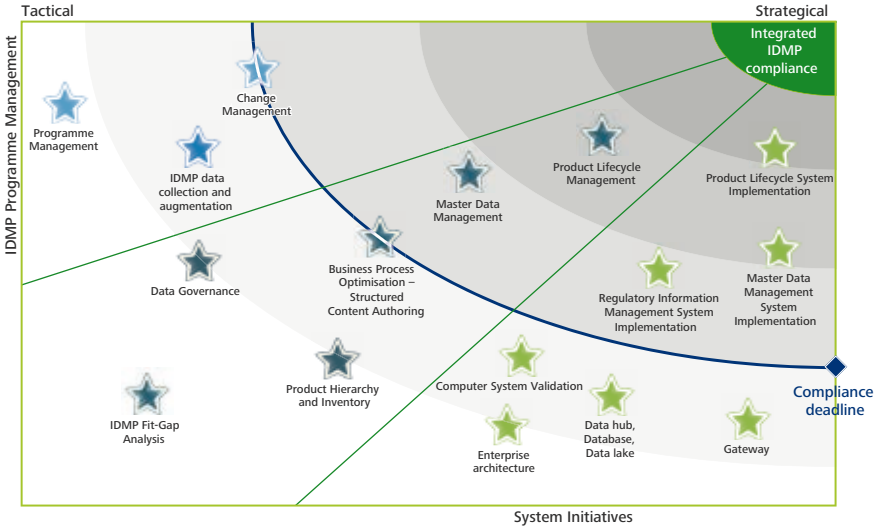
Key outcomes from the fit-gap analysis include:

- identified gaps in source data quality
- strategies to validate, cleanse, and improve source data quality.

Step 3: Design tailored roadmap

The IDMP roadmap documents findings and provides a pathway to compliance and includes project prioritisation that reflects the evolving IDMP timeline and internal drivers and constraints (Figure 7).

Figure 7. Illustrative projects that inform the IDMP roadmap



Key outcomes include:

- strategies to standardise and harmonise IDMP source data elements
- proposed recommendations to close gaps and mitigate risks
- proposed projects and solutions with recommendations for prioritisation
- prioritised roadmap with high-level costs.

Deloitte IDMP accelerators

Our unique IDMP accelerators can help a pharmaceutical company move quickly and efficiently ahead in its journey to IDMP compliance. The accelerators can be used to speed-up analysis of the current state; they also support data capture and maintenance.

Accelerator #1: Deloitte IDMP data model

We leveraged our understanding of the full ISO IDMP model and our cross-functional regulatory, data and informatics expertise to build our IDMP data model which is:

- mapped to regulated documents' specific sections for easy access to relevant data
- pre-loaded with our interpretation of the information expected for ambiguous fields
- available in an easy and intuitive navigable form, which reduces ISO standard complexity and can be understood by people without a technical background.

Accelerator #2: Deloitte IDMP DataScout capture and analytics tool

The proprietary Deloitte DataScout tool (Figure 8) plays an integral role in accelerating the fit-gap analysis and enabling the desired level of transparency across various stakeholders.

Figure 8. Deloitte IDMP dataScout

DataScout provides and manages the current ISO IDMP data model to record data sources, data "fits" and data "gaps" for IDMP attributes. Together with the contacts in charge of the data element, the technical details for each attribute, and data quality metrics, the DataScout provides real-time reporting on assessment findings and progress. DataScout features include:

- web application tailored to the needs of a holistic IDMP fit-gap analysis
- user-friendly navigation to access IDMP attribute definitions, contacts, and related systems mapping
- real-time access to dashboard and data assessment metrics
- data model-driven capture and reporting tool
- IDMP data relationships and definitions
- modular export capability for data model elements and data definitions
- support for the full ISO IDMP data model (~1700 data elements).

Road to compliance

Complex standards and evolving timelines present challenges for pharmaceutical companies seeking to develop a robust IDMP compliance programme. Deloitte's industry and regulatory experience, tailored, three-step approach, and unique IDMP accelerators can support companies along the road to readiness.

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