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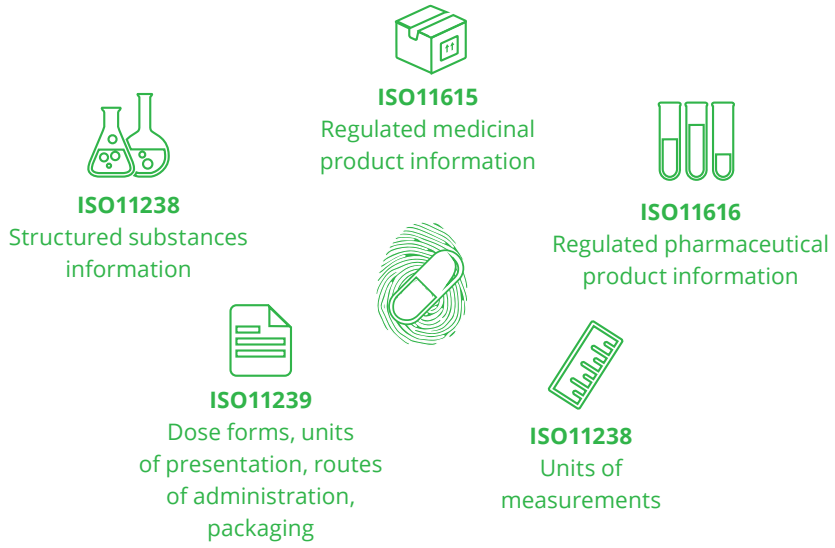
The building blocks of IDMP implementation

Unlock the power of data to transform business and improve patient health

The potential benefits of meeting evolving Identification of Medicinal Product (IDMP) requirements extend far beyond regulatory compliance. Through IDMP implementation, pharmaceutical companies can unlock the power of product data to transform their business and improve patient health.

Figure 1. IDMP is comprised of five standards



Identification of Medicinal Products (IDMP) is a set of five data standards from ISO, the International Organization for Standardization (Figure 1) that allow for the definition, characterization, and unique identification of regulated pharmaceutical products across their lifecycle, from early clinical development through marketing authorization, ongoing management, changes and, ultimately, withdrawal.

Under the IDMP standards, pharmaceutical and biotech companies will be required to electronically submit detailed product data and maintain it on an ongoing basis.[1] Collecting this data is expected to:

- Link product and safety information across global regulatory agencies
- Increase the biopharma industry's signal detection capabilities to quickly identify product risk issues, including recalls
- Connect critical product information within health care systems
- Help facilitate the creation of global drug dictionaries and product dossiers

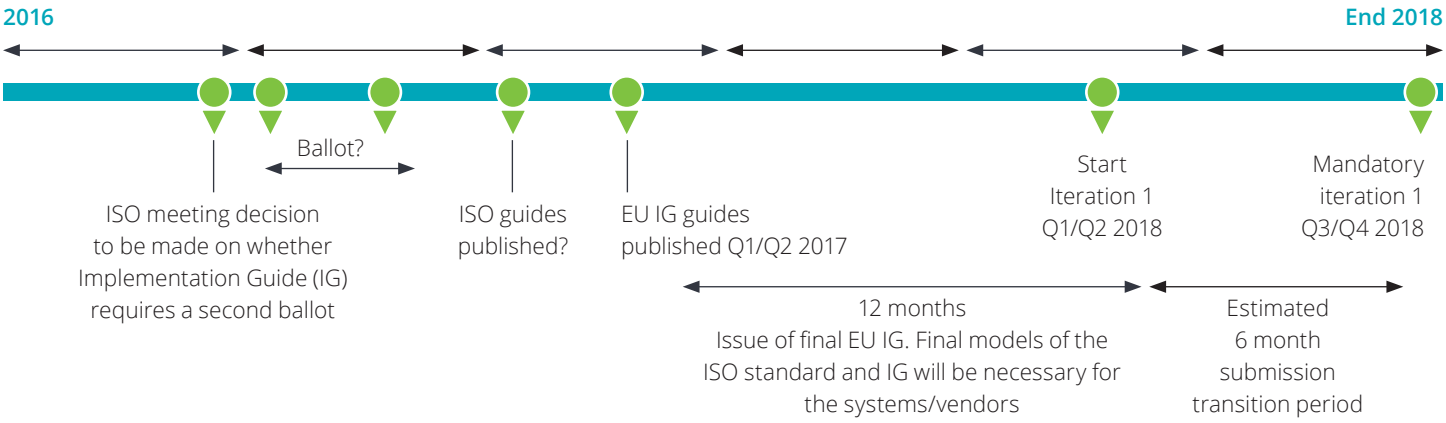
1 Implementation of the ISO IDMP standards, European Medicines Agency, Accessed May 2016

While the IDMP timeline has been dynamic, in the European Union (EU) clarity is starting to emerge around the first round of guidance (Figure 2). The United States and other markets should expect to see increasing activity over the next few years.

Becoming IDMP-compliant is expected to drive biopharma organisations to make significant changes to current product-related processes and systems, ushering in a new era of cross-functional collaboration and paving the way for opportunities to generate transformational benefits beyond compliance.

Additionally, the European Medicines Agency (EMA) is engaging in efforts to drive regulatory standardization for core IDMP master data governing Substance, Product, Organization and Referential (SPOR) data, for which a subset will also be expected to be leveraged in other EU directives, further making IDMP implementation critical. This article addresses the challenges and opportunities of IDMP implementation and describes a path forward for biopharma companies.

Figure 2. IDMP Timeline



Subject to update and change

Source: SPOR Task force and info from European Medicines Agency—Data submission on medicines—Implementation of the ISO IDMP standards

Implementation challenges

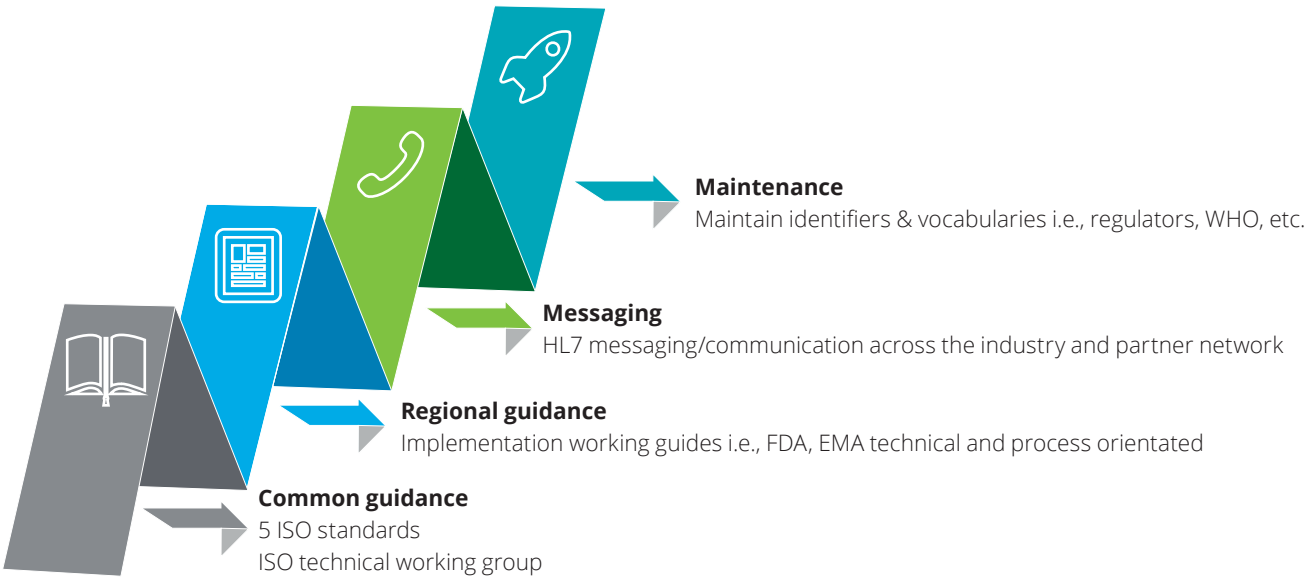
Many biopharma companies struggle with collecting and maintaining product information because it is typically siloed, unstructured and manually intensive to update. IDMP compliance adds to the challenge, as companies are finding that a majority of required IDMP data does not reside in their information technology systems; rather, the data exists as text within product submission documents.[2] Further, relationships between product documents and global registrations are not effectively linked and data quality can be an issue. Thus, meeting IDMP requirements is likely to be overwhelming and costly for many companies, especially since they must also address IDMP's timing and interdependencies along with other synergistic regulatory imperatives (e.g., Falsified Medicine Act, Clinical Trials Directive, ISO Individual Case Safety Report [ICSR], electronic application forms [eAF], supply chain quality metrics, electronic common technical document [eCTD], labelling) that will also look to make use of IDMP data.

A lack of accurate, well-integrated data can have significant, negative impacts on biopharma industry product quality and profitability, as evidenced by:

- Increasing time needed to conduct impact analyses and manage variations
- Delays in effective signal detection that may compromise patient safety
- Recalls emanating from improper product release
- Manufacturing rework and waste
- Inefficiencies related to extended information searches
- Unanticipated costs linked to inspection findings.

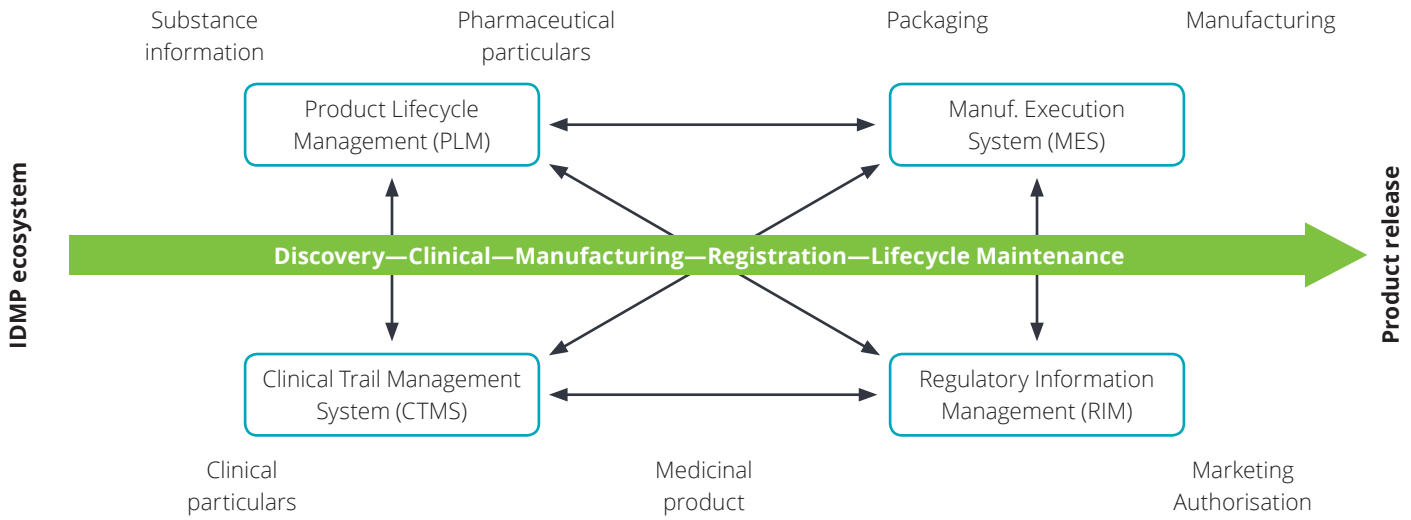
EMA is pursuing a phased approach to IDMP implementation, and the initiative's scope and timing continue to be refined and pushed out. Updated guidelines will be released over a multi-year period starting in 2016 and continue to expand in scope with each iteration (Figure 3). Once the final implementation guidelines are published, biopharma companies will have 12 months before they are required to begin submitting product data and an additional six months before the EMA commences enforcement.[3]

Figure 3: Rollout of IDMP guidance



2 Source: Deloitte research across eight life sciences companies
3 Implementation of the ISO IDMP standards, European Medicines Agency, Accessed May 2016

Figure 4: Product master data shared across systems



Biopharma companies will need to address both business- and technology-focused guidance documents that have several components to them:

- The ISO standards constitute the common data guidance.
- Regional guidance describes the implementation process for specific data elements, their business rules, and timing which are expected to be vary across EMA, FDA and PMDA.
- The technical messaging used to communicate IDMP information to regulators and partners is HL7-based.
- The maintenance of controlled vocabularies and identifiers will be managed by both the regulators and other external sources e.g., Global Substance Registration System (GSRS), Medical Dictionary for Regulatory Activities (MeDRA), Quality of Medicines and Healthcare (EDQM) and Unified Code for Units of Measure (UCUM).

Potential opportunities

IDMP is expected to provide a robust data management capability based on a set of standards that overcome traditional drug development, manufacturing, and marketing silos. As envisioned, IDMP-compliant processes and systems will help companies align their data and information to provide an accurate, single source of truth. In the future, data will be automatically captured, stored at the proper level of granularity, propagated, and kept current—regardless of what system is being queried—to improve processes and support better decision-making and insights through analytics. As depicted in Figure 4, master data, which is shared across multiple authoritative systems, will be aligned and synchronized.

The mandate to implement the ISO IDMP standards should provide a framework for achieving uniformity, accuracy, consistency, and availability of SPOR data across product lines. Leveraging this authoritative information is expected to facilitate:

- Compliant registration of authorized and investigational products in IDMP format across health authorities and manufacturing facilities
- Meaningful analytics that support improved strategic and operational decision-making
- Increased and more timely awareness and understanding of product change-related impacts
- Improved data visibility and maintenance capabilities for master data, which reduces data duplication and inconsistency throughout the enterprise
- Reduction of costs resulting from lack of information, rework, or poor data quality.

The path forward

While the EMA and other regulatory agencies continue to address IDMP scope and timing issues, a window of opportunity is open for biopharma companies to look at IDMP implementation and the broader application of SPOR data as a means to unlock the power of data, transform their business, and improve patient health. The following steps comprise a suggested path forward:

1. Determine organisational awareness and understanding. Required IDMP data may be "owned" by numerous departments and functions, each of which may play a role in IDMP implementation. Answering the following questions will help to determine awareness and comprehension, and drive message creation to support IDMP planning and change management activities:

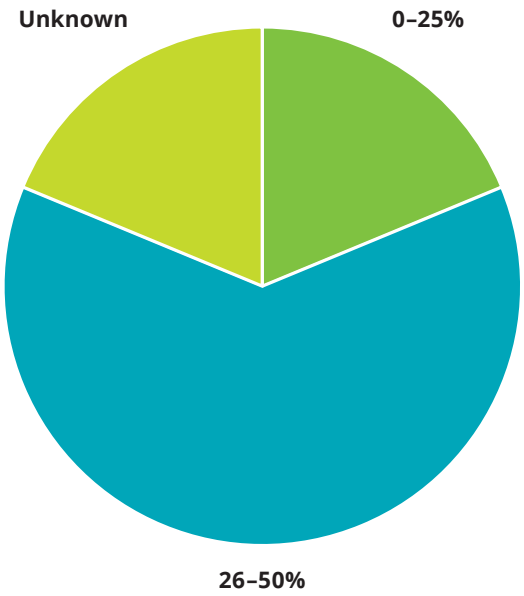
- Are draft IDMP standards and estimated agency implementation dates well understood?
- Are executives aware of IDMP's magnitude and scope across functions and its impact on other directives?
- Is there alignment around an IDMP vision that addresses compliance and other achievable benefits?
- Has an IDMP implementation strategy for both short- and longer-term needs as well as a roadmap been developed?
- Is it clear which internal organization is ultimately responsible for the IDMP data?
- Are an IDMP assessment and data-gathering underway?

A detailed system and data "fit-gap" assessment will be key to help companies identify the steps needed to develop and maintain an authoritative record of both structured and unstructured IDMP data.

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 study of 10 mid-to-large biopharmaceutical companies in which project stakeholders projected that less than 50 percent of their IDMP data elements will be populated directly from source systems.

Deloitte's IDMP Benchmark Study October 2015

% of IDMP data elements expected to be populated directly from source systems based on stakeholder replies to Deloitte's benchmark study



2. Conduct a system and data "fit-gap" assessment. Approximately 20-25 percent of a company's IDMP data is structured and sits in multiple systems that require identifying an authoritative source. More importantly, 75-80 percent of IDMP data is in unstructured documents (mostly PDF files) generated by various authors (Figure 5). Further, some of these unstructured documents likely are scanned and not always reliable for Optical Character Recognition (OCR) and parsing (extracting specific data values from a document).

3. Collect IDMP data. One of the biggest IDMP-related challenges, especially for mid- to large-size pharmaceutical companies, is collecting the required data for IDMP registration and maintenance activities, especially since IDMP's defined vocabulary is more granular than what is in use today. Extracting the data from documents and systems with 100 percent accuracy, while difficult, will be necessary to generate the requisite high-quality information to submit to health authorities. While the Summary of Product Characteristics (SmPC) is a good initial candidate, there will be many other submission documents containing IDMP data where data collection will be needed.

4. Refine processes to enable data reuse. IDMP process touchpoints exist throughout the product lifecycle (Figure 6). Implementation will provide opportunities to refine existing data capture processes to access structured data elements earlier in upstream applications. This, in turn, should create follow-on opportunities to reuse the structured information in other downstream applications. The resulting benefits may be profound: structured data can be reused from system to system or system to document, as in Structured Content Authoring. Data reuse also may negate the need to perform redundant quality checks.

Figure 5. Most IDMP data can be retrieved from a product's registration documents

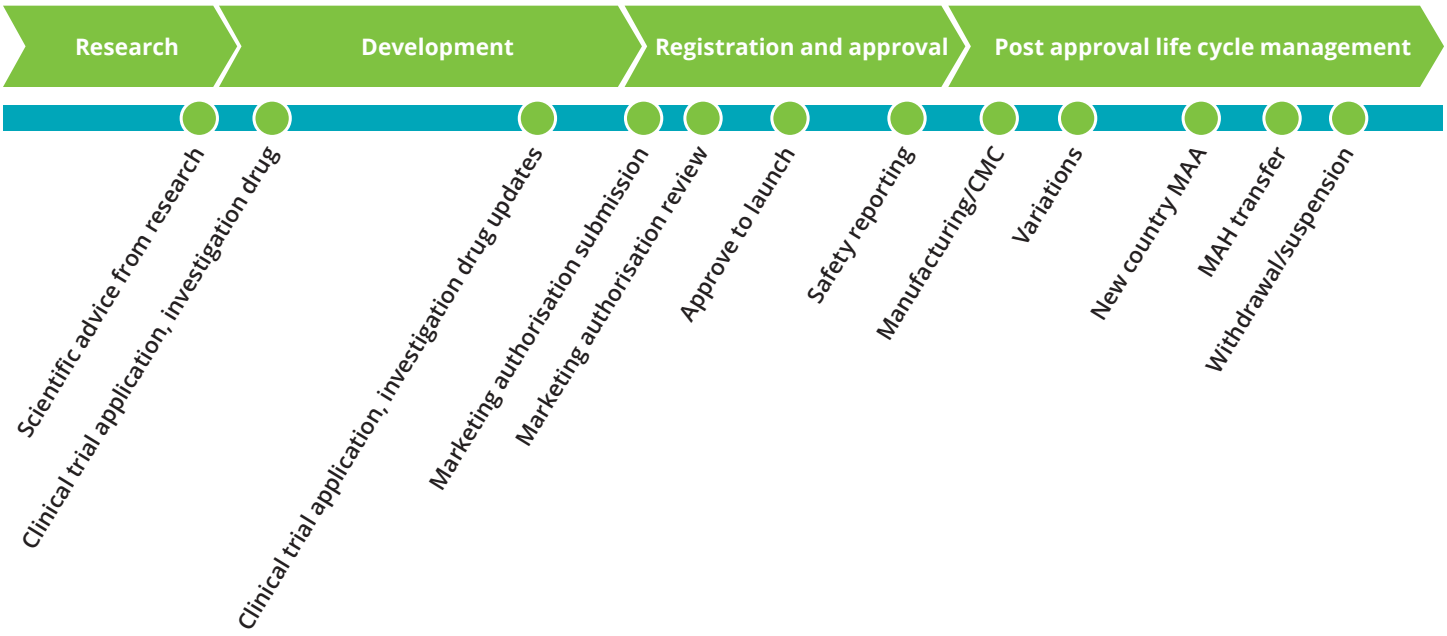
Marketing Authorisation
(MA Application Form, Summary of Product Characteristics)

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

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

Since most of today's IDMP data sits in unstructured documents, companies over time likely will increase the amount of IDMP data they intend to capture in their authoritative structured systems. This, along with the fact that some of IDMP data may be coming from external partners such as contract research organizations (CROs) or managed care organizations (MCOs), means that processes may need to be continually modified and aligned across the product lifecycle to best capture full value from data reuse.

Figure 6: IDMP touchpoints across the product lifecycle



5. Establish governance structure. Managing IDMP data, technology, and the overall product information lifecycle requires a robust, enterprise-level governance structure, and appropriate policies and procedures, particularly since the data will reside in many departments and each may argue that their version is the "authoritative" source. Neither federated nor decentralized models can provide end-to-end alignment or seamless data handoffs across processes, functions, and geographies. Additionally, governance should extend across corporate boundaries to strategic services providers (e.g., CROs and CMOs) and joint venture partners to realize the full benefits of harmonized data. Establishing and maintaining accountability and a culture of data ownership is the goal.

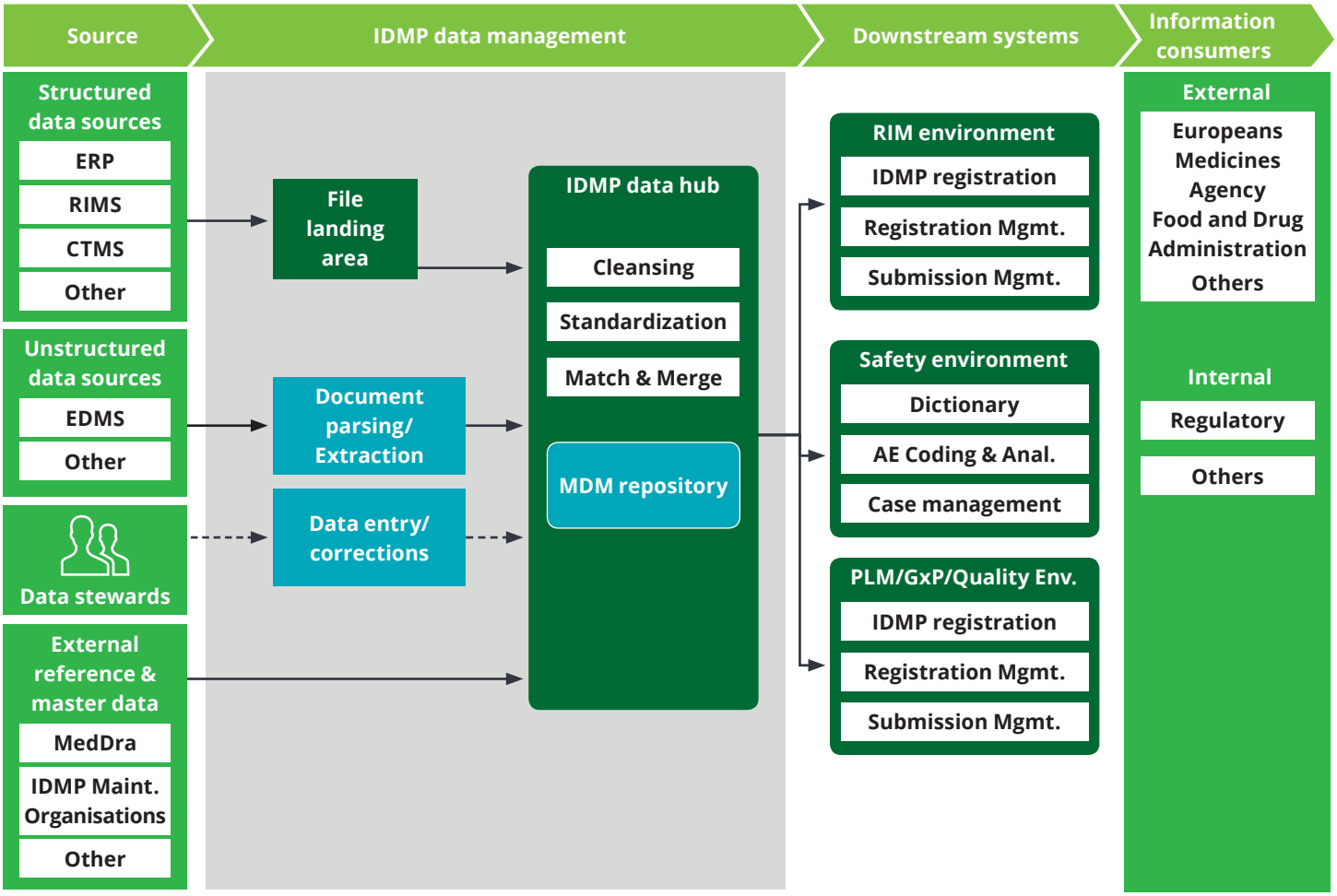
6. Align and curate key data. In an ideal world, all product information is harmonized, structured, and stored in a single system. In reality, even structured data is stored and manipulated in multiple, often disconnected systems. As depicted in Figure 7, Master Data Management (MDM) can provide many capabilities required to manage IDMP data, including:

- Integrating with existing source systems
- Converting data to a standard format
- Applying business rules to (a) determine which source should be used for each attribute and (b) derive additional attributes
- Applying match/merge rules to a "trusted external source" to enrich data
- Supporting data governance via a user friendly user-interface and automated work flow
- Maintaining data versions and showing how data has changed over time as well as providing a comprehensive audit trail throughout the product lifecycle
- Publishing a "single version of the truth" for consumption by other systems
- Maintaining IDMP Controlled Vocabularies (CV)

When data is properly curated, other systems and processes that touch the data can work together more effectively to maintain the same data format, structure, and values.

While MDM is an important component of an IDMP solution, there are other key considerations for IDMP to be effective. IDMP will require that key data be aligned through an effective combination of MDM and content management, in combination with a proper change control, which will include supporting integrations across various systems in ERP, product lifecycle management, clinical, safety and regulatory and submission functions.

Figure 7: Master Data Management



7. Integrate systems. Thorough, cross-functional information system integration will be essential to sustaining IDMP compliance.

IDMP will need to be introduced to an existing ecosystem that spans functional groups who will need to adopt and absorb IDMP overtime with uncertaintee abound. Today's system ecosystem will contain a mixture of commercial off-the-shelf software and custom solutions, each with varying product information hierarchies, controlled vocabularies and data model designs. Data and process granularities in existing systems and data models are not aligned to the IDMP standards, yet applications will continue to be managed and governed under their existing application lifecycles. Opportunities to extend these applications or build new IDMP granularity into the next lifecycle versions will need to be explored. Similarly, mechanisms should be designed with flexibility in mind that would allow authoritative IDMP information to be easily aggregated and consumed across a wider set of systems and processes, while allowing existing systems to evolve over time.

Roadmap to business transformation

The business case for IDMP implementation should extend beyond a regulatory compliance initiative. IDMP provides an opportunity to implement a leaner integrated operating model that supports business transformation and improved patient health. Biopharma companies should develop a roadmap of strategies to leverage IDMP's value-added opportunities and synergies with other regulatory drivers that will also make use of IDMP. Doing so may concurrently help to bring all investigational and marketed products into compliance and define a new norm for improved processes, quality, and stakeholder communications.

Meeting IDMP requirements is a complex process, with many moving parts. Efficient and effective implementation will require companies to develop a vision and global IDMP strategy to drive alignment, collaboration, and cooperation; establish a technology architecture and foundational capabilities to support master data management and integrate data from numerous source systems; define an enterprise-level governance structure; and implement a program of work to address IDMP compliance holistically. Achieving program goals also calls for executive awareness and support, as well as investments in people, process, and technology to sustain data quality and achieve strong returns on investment in compliance and operational excellence.

Contacts

Kurt Conger
Director
Deloitte Consulting LLP
US—Philadelphia
+1 215 446 3417
kconger@deloitte.com

Marcel Lissinna
Specialist Leader
Deloitte Consulting LLP
US—New York
+1 973 602 5016
mlissinna@deloitte.com

Michael Andreas Graf
Director
Deloitte AG
CH—Zurich
+41 58 279 7345
mgraf@deloitte.ch

Fiona Maini
Director
Deloitte & Touche LLP
UK—London
+44 20 7303 4767
fmaini@deloitte.co.uk

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