

Regulatory Information Management (RIM) & ISO IDMP Explained

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Executive Summary

The life sciences industry is undergoing a data-driven transformation of regulatory affairs. Central to this shift is the **Regulatory Information Management (RIM) system**, which serves as a centralized “system of record” for all regulatory data – product information, submissions, commitments, labeling, and more – enabling better **compliance**, efficiency, and decision-making (^[1] www.gartner.com) (^[2] www.pharmoutsourcing.com). Concurrently, global regulators are moving toward the **ISO Identification of Medicinal Products (IDMP)** standards, a suite of five international standards for unique identification of medicines (covering *product, pharmaceutical product, substance, dosage form, and units of measure*) (^[3] www.fda.gov) (^[4] www.pharmaceuticalcommerce.com). Together, RIM system implementation and IDMP adoption promise improved interoperability and patient safety by ensuring consistent, structured product data across companies and regulators. However, both initiatives involve complex changes: implementing or upgrading RIM systems requires organizational alignment, data governance, and change management (^[5] www.extedo.com) (^[6] www.pharmoutsourcing.com), while transitioning to IDMP necessitates collecting and normalizing vast amounts of product and substance data, integrating with emerging standards (e.g. HL7 FHIR), and coordinating globally (www.ema.europa.eu) (^[7] www.arisglobal.com). This report provides a comprehensive analysis of RIM systems and the IDMP transition, covering historical context, technology and standards, regulatory requirements, implementation strategies, case studies, data from industry surveys, and future outlook. It draws on recent studies, regulatory guidance, expert commentary, and case examples to evaluate current progress and challenges, offering evidence-based insights and recommendations for life sciences organizations navigating these critical regulatory transformations.

Introduction and Background

The pharmaceutical and biotech regulatory environment has grown immensely complex. Companies must manage global portfolios, country-specific registration requirements, frequent changes in indications or formulations, and stringent post-market obligations. Traditionally, regulatory teams relied on **spreadsheets, siloed databases, and ad hoc systems** to track approvals, submissions, and commitments. This fragmented approach is increasingly untenable: it leads to inefficiency, data errors, and compliance risk (^[8] astrixinc.com) (^[9] kalypso.com). Modern regulators also demand structured data submissions (e.g. eCTD v4) and are embracing global harmonization (e.g. common data standards) to improve pharmacovigilance, crisis management, and expedited access to therapies. In this context, **Regulatory Information Management (RIM)** systems and **ISO IDMP standards** have emerged as critical components of the digital regulatory framework. RIM systems provide a **centralized, data-driven platform** for managing all regulatory content (submissions, approvals, CMC changes, labeling, adjudication, etc.) and can integrate with document management, quality systems, and other enterprise applications (^[1] www.gartner.com) (^[8] astrixinc.com). Separately, IDMP standards – developed by ISO and coordinated by agencies like EMA and FDA – establish a **common global vocabulary and data model** for identifying medicinal products and their ingredients (^[3] www.fda.gov) (^[4] www.pharmaceuticalcommerce.com). As regulators at the European Medicines Agency (EMA), U.S. FDA, and other agencies phase in requirements to exchange product data in IDMP format, pharmaceutical companies must ensure their RIM and master data infrastructures can comply. The overlapping goals – consistent, interoperable product data – make RIM and IDMP reform highly interrelated. This report systematically explores these developments: first detailing RIM systems (concepts, functions, benefits, implementation), then examining IDMP standards (scope, timeline, regulatory programs), and finally analyzing how the RIM–IDMP convergence affects global regulatory operations. Each section includes data and citations from regulatory guidance, industry analyses, expert commentary, and case studies to provide depth and evidence.

Regulatory Information Management (RIM) Systems

RIM systems are specialized software platforms that help life sciences companies manage regulatory information [across the product lifecycle](#). Unlike generic file storage or ad hoc spreadsheets, a RIM system is an integrated ecosystem of **master data, process workflows, and analytics** tailored to regulatory affairs. Gartner defines RIM solutions as “key capabilities that a life science company needs to manage the regulatory approval and maintenance of a life science product for commercial use” (^[10] www.gartner.com). Typical RIM functionalities include **product registration management, regulatory intelligence tracking, product dossier management, submission planning and archiving, labeling and artwork tracking, and commitments tracking** (^[1] www.gartner.com). In practice, a modern RIM system might integrate with [electronic Common Technical Document \(eCTD\) systems](#), provide change-tracking of submissions, and deliver alerts about upcoming renewals or regional requirements. By serving as a “**single source of truth**” for product data, RIM systems aim to improve data consistency, reduce manual effort, and enable cross-functional use of regulatory information (e.g. reporting to manufacturing or finance teams) (^[8] astrixinc.com) (^[11] www.pharmoutsourcing.com).

Evolution and Strategic Role of RIM

Over the past decade, many large pharmaceutical companies have undertaken major RIM modernization. In early 2010s, regulatory teams often relied on email threads, spreadsheets, and localized databases, which led to data silos and redundant work. User-friendly, enterprise-grade RIM platforms began to appear (e.g. [Veeva Vault RIM](#), [ArisGlobal RIM](#), [EXTEDO Rimsys](#), etc.), offering cloud or on-premise solutions.

According to a 2022 industry survey, “most major life science companies have spent the past decade modernizing their RIM platforms” (^[12] www.pharmoutsourcing.com). This modernization has shifted RIM from a back-office record-keeping tool to a strategic asset. Regulatory data is increasingly recognized as valuable not just for compliance but as part of enterprise decision-making. For example, RIM data can feed analytics on submission timelines, support risk assessments, or inform market access strategy.

Indeed, recent thought leadership emphasizes a **broader role for RIM**: connecting regulatory with other functions (clinical, quality, manufacturing) and improving patient access by ensuring up-to-date information across markets (^[13] www.pharmoutsourcing.com) (^[11] www.pharmoutsourcing.com). The Gens & Associates 2022 “World Class RIM Survey” found that many companies aim to build on their RIM foundations to connect regulatory information seamlessly across the organization and even to patient-facing applications (^[14] www.pharmoutsourcing.com). Four key industry trends emerged: (1) expanding regulatory data use beyond RA, (2) evolving regulatory roles to include data science, (3) focusing on “affiliate” user adoption in local markets, and (4) culture shift toward enterprise data quality (^[11] www.pharmoutsourcing.com) (^[6] www.pharmoutsourcing.com). These insights suggest that top companies are treating RIM as the backbone for LCM (life-cycle management) information, paving the way for more advanced digital innovations (AI/machine learning, master data management, etc.) in the regulatory domain (^[15] www.pharmoutsourcing.com) (^[16] www.pharmoutsourcing.com).

Key Functions and Platform Capabilities

A RIM system typically includes modules or features to address diverse regulatory needs (see **Table 1**). Core capabilities often span:

- **Product Registration and Master Data Management:** Centralizing product definitions (active ingredients, dosage form, packaging) and registration numbers per country; enabling unique identifiers and hierarchies.
- **Regulatory Intelligence & Requirements Tracking:** Monitoring global regulations, health authority guidelines, and historical precedents relevant to a product or market.
- **Dossier and Submission Tracking:** Logging each submission (IND, NDA, MA, variation, etc.), its status, components, timelines, and outcomes; generating status reports.
- **Document and Label Management:** Linking regulatory decisions to documents such as approval letters, labeling, or certificates; managing artwork and labeling changes through workflow.
- **Compliance & Commitment Management:** Tracking post-approval commitments (e.g. Phase IV studies, post-marketing safety reports) and ensuring due dates are met.
- **Collaboration and GxP Integration:** Facilitating cross-functional coordination (e.g. with Quality Management Systems, Pharmacovigilance databases, manufacturing) and maintaining audit trails for compliance.
- **Reporting and Analytics:** Providing dashboards and reporting on regulatory metrics (e.g. submission cycle times, country coverage, upcoming renewals).

These capabilities may be provided as an integrated RIM suite or by interfacing best-of-breed modules. Gartner commentary notes that regulatory organizations increasingly invest in **single-platform solutions**; by 2022 about **75%** of companies had consolidated to one platform for their transactional RIM tools, replacing disparate systems (^[17] www.pharmoutsourcing.com). RIM vendors often offer cloud deployment to enable global access and scalability, reflecting a broader industry shift towards cloud-based life sciences IT (^[18] www.gartner.com) (^[19] www.gartner.com).

Table 1: Major Regulatory Information Management (RIM) Capabilities and Roles

Function/Module	Description	Value / Benefits
Product Registration/Master Data	Central repository of all product attributes (substances, formulation, package, approval numbers) and country registrations.	Ensures consistency of product metadata; supports IDMP compliance; avoids duplicate records across affiliates.
Regulatory Intelligence	Database of global regulatory guidelines, submission requirements, and past regulatory correspondence.	Keeps stakeholders informed on changing regulations; helps plan submissions per market. (^[20] www.productlifegroup.com)
Submission Lifecycle Management	Tracks each regulatory submission (planning, authoring, electronic submission, review, approval).	Accelerates submission processes; provides transparency on status; enables real-time dashboards.
Document and Label Management	Manages labeling content, change requests, regulatory documents, and approvals within workflows.	Streamlines label updates; ensures audit trails; reduces errors in packaging/artwork.
Commitments and Regulatory Actions	Monitors promised activities (studies, reports) made to regulators and action items from inspections.	Avoids compliance lapses; reminds teams of deadlines; generates compliance reports.
Interaction Tracking	Logs communications with Health Authorities (meetings, minutes, queries) and tracking of responses.	Maintains single source for all regulator interactions; improves audit readiness.
Analytics and Reporting	Dashboards on submission metrics (e.g. approval times), portfolio coverage, local versus global activities.	Data-driven insights; supports resource allocation and strategic decisions.

Sources: Industry analyses and regulatory practice (e.g. Gartner reports (^[1] www.gartner.com), vendor briefs).

Benefits of RIM Systems

A well-implemented RIM system yields multiple benefits. By centralizing information and automating workflows, RIM can **accelerate time-to-market**. For example, RIM enables reuse of data in regulatory submissions (e.g. consistent ingredient lists, previously approved labeling), thus reducing manual re-entry and review cycles (^[21] astrixinc.com) (^[22] astrixinc.com). It also improves **data accuracy and compliance**: with built-in validations and standardized vocabularies (especially important under IDMP), companies reduce the risk of errors in submissions and labeling instructions. The Gens & Associates survey notes that top-performing companies achieve “significant speed, quality, real-time information access, [and] reduced complexity” through advanced RIM transformations (^[23] www.pharmoutsourcing.com). Other strategic benefits include more effective resource planning (knowing upcoming submissions globally), better cross-functional collaboration (quality, clinical, supply can tap regulatory data), and oversight for governance.

Moreover, RIM can reduce costly duplication and internal silos. Case studies illustrate that moving from spreadsheets to unified RIM **dramatically cut manual effort**. For example, Kalypso reported that after implementing a consolidated RIM for a global medical device firm, “teams experienced fewer delays, reduced manual effort and more confidence” in product launches (^[24] kalypso.com). Digital connectivity replaced “hundreds-person email chains,” standardizing workflows and audit trails (^[9] kalypso.com). Similarly, a pharmaceutical co. moving onto Veeva RIM saw global teams shift from fragmented LAN/SharePoint stores to shared planning and tracking, harmonizing processes across regions (^[8] astrixinc.com) (^[25] astrixinc.com). These implementations freed regulatory specialists “from chasing paperwork,” enabling focus on high-value tasks like submission strategy and change management (^[26] kalypso.com). In short, RIM systems unlock operational efficiencies and provide a **single authoritative view** of regulatory data, which is essential for modern regulatory strategy.

Challenges in RIM Implementation

Implementing a RIM system is a complex organizational change. Vendors and consultants frequently note key challenges: (1) **Complex data migration and standardization**: Moving legacy data (often in disjointed spreadsheets or old systems) into the RIM environment requires extensive cleansing, mapping, and validation (^[8] astrixinc.com) (^[27] www.productlifegroup.com). (2) **Stakeholder alignment and change management**: Getting buy-in from regulatory, IT, QA, and business leadership is crucial. The initial capital outlay is significant, and benefits are often long-term. Organizations must “effectively convey [RIM’s] benefits to C-level executives and stakeholders” to secure investment (^[5] www.extedo.com). (3) **Process re-engineering**: RIM implementation often forces a review of existing regulatory processes. Teams may need to change workflows to fit the system (e.g. centralizing global variation submissions), which requires training and often meets resistance (^[28] www.extedo.com) (^[29] www.pharmoutsourcing.com). (4) **Integration with other systems**: RIM rarely stands alone. Integrations with electronic document management (EDM), pharmacovigilance (PV), master data management (MDM), and SAP/QMS can be complex and costly (^[30] www.productlifegroup.com) (^[9] kalypso.com). Ensuring real-time data flows (e.g. automatic updates of product master from RIM) is a technical challenge. (5) **Scope creep and customization**: Regulatory requirements vary by country; teams often want RIM to cover all edge cases. Defining the right organizational scope and avoiding endless customizations is crucial for project success (^[5] www.extedo.com) (^[27] www.productlifegroup.com).

Product Life Group highlights these issues in their client case: a large pharma transitioning to RIM had “disorganized collaborative work,” “lack of Global Data Governance,” and “regulatory challenges in collecting & storing Regulatory Information” (^[31] www.productlifegroup.com). Addressing these requires a clear roadmap. Typical strategies include engaging a cross-functional team early, defining a phased rollout (often by region or product line), and conducting extensive training and governance planning (^[32] www.productlifegroup.com) (^[5]

www.extedo.com). In practice, companies like the Astrix case story prepared a multiyear plan: assessing current state, defining future harmonized state, configuring global processes for submission planning, authoring, and publishing, and supporting migration and roll-out ([33] astrixinc.com) ([21] astrixinc.com). Key lessons include setting realistic expectations (RIM won't automate every corner instantly) and budgeting for ongoing maintenance, data governance, and iterative improvements post-go-live ([5] www.extedo.com) ([34] www.productlifegroup.com).

Organizational and Cultural Factors

Successful RIM implementation often hinges on **organizational change management**. Kemal et al. note that RIM transformation inherently requires collaboration across regulatory, IT, and business groups ([35] www.extedo.com) ([21] astrixinc.com). Companies must staff multidisciplinary teams (subject matter experts in RA, data governance, and IT) and clarify roles early. A common pitfall is engaging only technical staff late in the project; instead, executive sponsors and business process owners must remain involved throughout implementation ([5] www.extedo.com) ([36] astrixinc.com). Ongoing support is also essential: building a RIM "Center of Excellence" that governs data standards, maintains system configurations, and provides user support can help sustain the benefits. Another cultural element is embedding a **data-centric mindset**. Survey analysis indicates that companies with mature RIM are increasingly hiring data analysts, governance leads, and digitalization experts within regulatory functions ([37] www.pharmoutsourcing.com). In other words, regulatory teams are evolving to include roles focused purely on data quality and integration, which is critical as systems like RIM become more embedded in corporate analytics. Senior management must therefore champion not just the tool, but the **data integrity culture** underpinning it ([38] www.pharmoutsourcing.com) ([39] www.pharmoutsourcing.com).

Implementation of RIM Systems: Case Studies and Examples

Case Study: Pharmaceutical Company (Veeva RIM Implementation)

A detailed example illustrates the RIM journey of a top-ten pharmaceutical company that engaged a consultant (Astrix) to implement a global Veeva RIM solution. Historically, the company's **global teams used disparate tools and multiple spreadsheets**, maintaining information in various local SharePoint and LAN directories ([8] astrixinc.com). This fragmentation meant that different regions had inconsistent processes and terminology, making coordination across the portfolio difficult. The company's aim was to evolve this landscape into "**a globally consistent RIM solution**" encompassing submissions for CMC, safety, etc., on a single platform ([40] astrixinc.com).

Key steps in this project included: a thorough **current state assessment**; workshops to define a harmonized future state; and configuration of end-to-end global workflows (submissions planning, authoring, tracking, publishing, archiving, correspondence) ([25] astrixinc.com) ([36] astrixinc.com). The consultants also managed data migration (bringing existing regulatory records into the new system) and user onboarding (change management, training, communications). Throughout, the project emphasized cross-company collaboration: business and IT representatives, the RIM vendor (Veeva), and process experts co-owned deliverables.

Impacts: By the end of deployment, the client had replaced its myriad of manual systems with one cloud-based platform for all regulatory processes. This enabled real-time planning and tracking of submissions worldwide and standardized terminology. The RIM went live supporting submissions to major markets, regional annual reports, labeling updates, and archiving ([41] astrixinc.com). Astrix highlighted that by creating dedicated workstreams (e.g. for CMC, safety, authoring) with combined teams, "everyone had a voice" and the complex

vof tasks was managed effectively (^[42] [astrixinc.com](#)). Although the case study does not give quantitative ROI data, it notes improvements in efficiency and cross-functional visibility, mirroring findings from other implementations.

Case Study: Medical Device Manufacturer (Kalypso RIM Implementation)

In a separate case, Kalypso implemented a **Regulatory Information Management System (RIMS)** for a global medical device company. The solution was delivered in under a year and integrated with the client’s quality and IT systems (^[43] [kalypso.com](#)). Prior to RIM, the device firm’s regulatory operations were “reactive and fragmented”: multiple teams had inconsistent registration data, and shipping decisions were often manual checks to ensure compliance (^[24] [kalypso.com](#)). Post-implementation, the client gained a **single authoritative platform** for product registrations and shipping approvals across all geographies (as enforced by trade control integration). Automated rules prevented unregistered products from shipping, vastly reducing compliance risk. Meanwhile, regulatory specialists worldwide suddenly had a real-time, transparent view of market status for each device (e.g. whether a change request was submitted, approved, or pending). Standardized submission and change processes replaced chaotic email threads, and unified audit trails satisfied regulators without extra effort (^[9] [kalypso.com](#)). Overall, regulatory cycle times decreased and manual handoffs were minimized. The Kalypso team emphasizes that this RIM foundation not only accelerated market entry (direct patient benefit) but also served as a blueprint for broader digital transformation in quality and engineering (^[44] [kalypso.com](#)) (^[45] [kalypso.com](#)).

These real-world examples underscore common themes: RIM systems eliminate data silos, require comprehensive planning across global teams, and deliver efficiency and transparency once mature. The examples also highlight that successful RIM implementations focus on both **technology configuration** and **organizational alignment** – from defining the future-state “unified processes” to ensuring adoption through training and governance.

The ISO IDMP Standards

Identification of Medicinal Products (IDMP) is a set of ISO standards (ISO 11615/11616/11238/11239/11240) aimed at uniquely and unambiguously identifying pharmaceutical products and substances. Developed under the auspices of ISO TC 215 and endorsed by the ICH, IDMP provides a **common data model and terminology** for medicinal product information. The standards are intended to facilitate reliable exchange of product data between regulators, manufacturers, healthcare providers, and other stakeholders worldwide (^[3] [www.fda.gov](#)) (^[46] [globalforum.diaglobal.org](#)). Fundamentally, IDMP standards cover five domains (see **Table 2**):

Table 2: ISO IDMP Standards Overview

Standard	ISO Reference	Scope/Description	Citation
Medicinal Product Identification (MPID)	ISO 11615	Data elements for unique identification of regulated medicinal products (e.g. trade name, dosage form, strengths, packaging, marketing authorisations).	(^[47] www.fda.gov)
Pharmaceutical Product Identifier (PhPID)	ISO 11616	Defines associations for products that are pharmaceutically equivalent (same substance(s) and strength(s)), serving as a key identifier across regions.	(^[48] www.fda.gov)
Substance Identification (SubID)	ISO 11238	Data elements for uniquely identifying both active and inactive substances (characteristics, properties, composition) used in medicinal products.	(^[49] www.fda.gov)

Standard	ISO Reference	Scope/Description	Citation
Dosage Form & Route of Administration (DF & RoA)	ISO 11239	Describes unique dosage forms, units of presentation, routes of administration and packaging (e.g. "injection solution", "infusion bag").	{ ^[50] www.fda.gov)
Units of Measurement (UoM)	ISO 11240	Standardized units of measure and their coding, ensuring traceability to international standards (e.g. units, concentrations, doses across languages).	{ ^[51] www.fda.gov)

Sources: FDA and ISO official descriptions (^[47] www.fda.gov) (^[48] www.fda.gov).

Collectively, these standards require companies to register detailed product data (active ingredients, dosage form, manufacturer, packaging, marketing authorization, etc.) in a standardized format. For example, ISO 11615 (MPID) specifies fields like product name, clinical particulars (indications), dosage form, strength, manufacturer, and MA number (^[47] www.fda.gov). ISO 11238 (SubID) covers details of chemical/biological substances, including molecular structures and purity (^[49] www.fda.gov). A key goal is global interoperability: by using international codes and common definitions, regulators can easily reconcile medicinal products across borders and databases. In practice, IDMP requires companies to maintain and submit comprehensive master data about each product. For instance, each product gets an ISO-compliant ID (MPID), and products sharing the same active substance(s) and strength(s) are linked via a global Pharmaceutical Product Identifier (PhPID) (^[48] www.fda.gov). This enables regulators to identify pharmaceutically equivalent products and track safety signals or shortages globally.

Benefits and Rationale for IDMP

Implementing IDMP yields multiple benefits for patient safety, supply chain transparency, and regulatory efficiency. The FDA highlights that IDMP standards provide an "international framework to uniquely identify and describe medicinal products... [to] ensure the exchange of product information between global regulators, manufacturers, suppliers and distributors" (^[3] www.fda.gov). Key advantages include:

- Enhanced Pharmacovigilance:** Unique product IDs allow regulators and manufacturers to unambiguously match adverse event reports to specific product batches or strengths. Standardized data makes it easier to "globally detect safety signals from medicinal products" (^[52] www.fda.gov). For example, if multiple countries report similar side effects, IDMP identifiers help confirm they concern the same active product, improving signal analysis.
- Improved Traceability:** A single identifier tied to all supply chain events (manufacture, distribution, prescriptions) means products can be tracked end-to-end. Regulators can quickly trace drug origins and distribution, aiding in recalls or shortage mitigation (^[53] www.fda.gov). Indeed, FDA notes that standardizing codes can help identify **pharmaceutically equivalent products across regions**, which is critical for responding to global drug shortages (^[53] www.fda.gov).
- Streamlined Regulatory Processes:** With harmonized definitions, regulators can more easily aggregate and compare product data across submissions. This has the potential to **speed approvals**, as authorities can reuse validated components of a product's profile rather than manually verifying each detail anew (^[54] www.pharmaceuticalcommerce.com). For industry, one commentary predicts IDMP will "enable regulatory authorities to access information about medicinal products more quickly and easily, which can speed the approval process and reduce time to commercialize" (^[54] www.pharmaceuticalcommerce.com).
- Data Interoperability:** IDMP lays the groundwork for digital data interchange (e.g. via HL7 FHIR messages) between companies and regulators. This reduces manual transcription and fosters connected e-

governance. Importantly, it aligns with other healthcare data standards (like EHRs), facilitating future integration of product data into clinical systems.

In essence, IDMP is a **common language** for medicinal products (as one publication puts it, establishing a “common language for identifying, documenting, and exchanging information about medicinal products” ([4] www.pharmaceuticalcommerce.com)). By forcing consistency in product semantics, it improves transparency and trust along the entire value chain. Stakeholders like UMC (WHO's Uppsala Monitoring Centre) and industry groups likewise stress that IDMP can revolutionize pharmacovigilance and cross-border healthcare coordination ([55] globalforum.diaglobal.org) ([56] globalforum.diaglobal.org).

The Scope and Complexity of IDMP

Despite its potential, IDMP is **technically and organizationally complex**. The standards are very granular (e.g., ISO 11238 covers detailed substance attributes like purity, grade, molecular structures ([57] www.pharmtech.com)), and they span the entire product lifecycle from preclinical substances to post-marketing submissions. Implementing them requires collecting rich metadata: for each product, a company must identify all active and inactive substances (with international identifiers like INNs or Unii codes), define packaging units, formulation particulars, indications, shelf-life details, etc. Additionally, multiple ISO standards interlock (see Table 2), so retrospective data cleanse often uncovers gaps. Regulatory technologists note that many companies lack the required master data or consistent definitions, making IDMP compliance a “data challenge as much as a regulatory one.”

Furthermore, different regulatory agencies have different adoption paths and deadlines. The European Medicines Agency (EMA) has instituted the **SPOR (Substance, Product, Organisation, Referential) master data management services** to implement IDMP in a phased manner (www.ema.europa.eu). The FDA similarly participates in global IDMP efforts but has not imposed binding timelines on industry ([3] www.fda.gov) ([58] www.fda.gov). Other (non-US/EU) agencies – such as ANVISA in Brazil, those in Latin America, Asia, etc. – are at earlier stages of evaluating IDMP adoption. This uneven landscape means pharmaceutical companies must adapt to multiple requirements: e.g. ensuring EU submissions eventually comply with IDMP formats, while also preparing for the possibility that other markets may follow suit.

As of 2025, **IDMP-related changes are actively occurring in Europe**. EMA's SPOR program launched referential and organization services in 2017, a substance (SMS) portal in 2019, and a product management service (PMS) in phases (www.ema.europa.eu) (www.ema.europa.eu). The EU is integrating IDMP with its existing XEVMPD database (used since 2005 for active substances) and eXtended EudraVigilance Product Dictionary (XEVMPD) (www.ema.europa.eu). Companies with EU marketing authorizations must enrich their product registrations with SPOR data by upcoming deadlines (e.g. manufacturer data due mid-2026 and pack sizes by June 2027 (www.ema.europa.eu)). In the U.S., regulators have begun collaborating on IDMP via the HL7 FHIR standard (FDA is involved in the Global IDMP Working Group and is aligning with ISO codes like NDC/UNII ([58] www.fda.gov)), but no immediate mandate exists for U.S. sponsors as of 2025. Internationally, organizations like the DIA-Global IDMP Working Group and WHO UMC are facilitating knowledge sharing and interoperability among regulators (as detailed below).

Global Regulatory Initiatives and Timelines

Europe (EMA/SPOR)

The EMA has been the most concrete driver of IDMP compliance. Under EU law (Regulation 726/2004), companies must submit certain data to the EMA, an obligation originally fulfilled through XEVMPD listings. Recognizing the need for richer data, EMA developed the SPOR master data services. These are four

interconnected databases for **Substances (SMS)**, **Products (PMS)**, **Organisations (OMS)**, and **Referentials (RMS)** (www.ema.europa.eu). EMA has released these services gradually: for example, the first release of the **Substance Management Service (SMS)** in 2019 allowed firms to register new substances or update existing ones via an EMA portal (www.ema.europa.eu). The first release of the **Product Management Service (PMS)** in 2024 covered a subset of product data (using an ISO-compliant data submission format, HL7 FHIR) (www.ema.europa.eu). Further releases will add more data elements for both authorized and investigational products (www.ema.europa.eu).

Crucially, EMA has announced specific deadlines for MAHs (Marketing Authorisation Holders) to submit enriched product data into PMS. A **PMS implementation roadmap** (updated October 2025) lists phased deadlines for EU products (see Table 3). For example, companies must complete “enrichment” of structured manufacturer data and pack sizes for non-centralised products by June 2026 (extended from the original end of 2025) (www.ema.europa.eu). Other deadlines extend into 2027 for remaining data. EMA explicitly states that these extensions were granted to ensure the “*accuracy, quality, and consistency of data*” (www.ema.europa.eu). With these timelines, many pharma companies have prioritized dotting the i’s on IDMP compliance in Europe, as missing them could result in regulatory non-compliance (EU law will require these data eventually).

In parallel, EMA is evolving its target operating model (TOM) to be **data-centric**: moving away from document-centric submissions toward standardized data flows. For instance, EMA is updating its electronic application forms (eAFs) to align with IDMP fields (www.ema.europa.eu) and will replace the old XEVMPD submission method with FHIR APIs. During the transition, EMA will operate multiple systems in parallel (old and new) until fully cut-over (www.ema.europa.eu). This phased, complex shift means companies often must maintain double submissions for a time, but ultimately it promises more consistent data exchange.

Table 3: EU IDMP Data Submission Deadlines (EMA PMS Service)

Activity	Deadline	Notes (previous deadline)
Enrichment of structured manufacturer data & pack sizes for certain critical non-CAPs (on EU critical medicines list) via PMS PUI/API	June 2026 (www.ema.europa.eu)	(previously Eo 2025)
Enrichment of structured manufacturer data for all other non-centrally authorised products (non-CAPs) on portfolio via PMS PUI/API	Dec 2026 (www.ema.europa.eu)	N/A
Enrichment of pack sizes for other non-CAPs (via existing XEVMPD and new PMS tool)	June 2027 (www.ema.europa.eu)	(was Dec 2026)

Sources: EMA SPOR PMS Implementation Guidance (www.ema.europa.eu). “CAP” = centrally authorised product; “non-CAP” = other EU-licensed products.

By late 2025, EMA’s approach has effectively set the **EU as the first major market requiring IDMP compliance**. Notably, companies distributing in the EU (even if based elsewhere) must comply, making it a global priority for MAHs. Several industry observers warn that postponing IDMP readiness is risky: once data submission formats are enforced, last-minute fixes will be impossible. ArisGlobal advice is blunt: firms should “think years ahead” and invest in long-term solutions, rather than temporary “patch” translations at the last moment (^[59] www.arisglobal.com). The EU’s phased deadlines also highlight that IDMP is not a one-off task but an evolving project: even after initial compliance, ongoing updates will be needed whenever new product changes occur.

United States (FDA and Global Coordination)

In the United States, the FDA has shown interest in IDMP but has not mandated a specific timeline akin to EMA’s Article 57. The FDA “Data Standards Advisory Board” webpage describes IDMP primarily in informational terms and notes that FDA has already adopted some analogous standards (e.g. National Drug Code conforms with ISO

11615 concepts) ([58] www.fda.gov). The FDA emphasizes that IDMP will aid in addressing global supply chain issues and shortages ([53] www.fda.gov). Moreover, FDA staff co-chair the Global IDMP Working Group (GIDWG) along with EMA and the Uppsala Monitoring Centre ([46] globalforum.diaglobal.org). This international forum (including WHO, EMA, FDA, IFPMA industry reps, and regulators like ANVISA and Swissmedic) fosters collaboration on IDMP implementation, harmonizing vocabularies (dose form, strength, etc.) and defining how to generate a global PhPID ([60] globalforum.diaglobal.org).

The FDA's April 2023 draft guidance (Docket FDA-2023-D-0266) indicates plans to eventually expect standardized portion of data in pharmacovigilance submissions, but no concrete compliance dates have been set ([61] www.fda.gov) ([58] www.fda.gov). In practice, U.S. companies preparing IDMP data now are mainly doing so for EU compliance and global readiness. Nevertheless, FDA's alignment with ISO terms (endorsing REF: "Unified Code for Units of Measure conforms to ISO 11240" ([58] www.fda.gov)) eases future interoperability. Industry should watch for any future U.S. policy updates, but for now the primary driver of IDMP data collection is EU regulation.

Other Regions and Global Trends

Beyond EU/USA, other regulatory authorities recognize IDMP's value. The Global IDMP Working Group (GIDWG), formed by EMA, FDA, and WHO-UMC, extends the conversation globally ([46] globalforum.diaglobal.org). In 2024, a public stakeholder meeting co-hosted by Brazil's ANVISA and UMC brought broader international attention. ANVISA affirmed Brazil's commitment to adopting IDMP to tackle drug shortages, counterfeits, and fragmentation of data ([62] globalforum.diaglobal.org). However, Latin American industry participants candidly reported that **implementation has lagged**: most local companies have not started IDMP projects, citing lack of legal mandate and unclear understanding ([63] globalforum.diaglobal.org). A common sentiment in LatAm is that **without a deadline or guidance**, companies see little internal benefit beyond compliance to start the costly preparation. This parallels challenges elsewhere: e.g., Europe's delays (due to Brexit, ISO guide timelines) have made firms wary of investing too early ([64] www.pharmtech.com) ([65] www.pharmtech.com).

In Asia, regulatory attitudes vary. Some countries may align with WHO or ICH initiatives. The top-line view is that IDMP is a **slow-moving global shift**. Large multinationals typically approach it as a corporate requirement driven by EU law, which will inexorably extend to other regions. Companies increasingly plan to integrate IDMP data across functions (regulatory, manufacturing, safety, supply) over the next few years ([66] www.pharmiweb.com). The 2024 MAIN5/Pistoia Alliance industry survey found over 70% of respondents saw IDMP as an enabler of cross-functional data integration ([66] www.pharmiweb.com). At the same time, internal barriers (data silos, unclear ownership, resource constraints) are the main obstacles ([67] www.pharmiweb.com), underlining that this is a **cross-enterprise** change, not confined to the PTR (Regulatory Affairs) department.

Barriers and Readiness for IDMP

Despite recognition of IDMP's strategic value, real-world adoption has been uneven. A 2024 survey of 18 leading pharma companies found **"patchy" progress** on IDMP implementation ([68] www.pharmiweb.com). Key challenges included manual, labor-intensive data collection and fragmented systems. Specifically, 56% of companies cited *lack of data standardization* as the top obstacle to integration, with 44% pointing to insufficient resources and 41% to issues of data ownership ([69] www.pharmiweb.com). Data quality itself, surprisingly, was mentioned by only a third, implying that structural issues (governance, architecture) are more pressing than basic errors at this stage. Encouragingly, 70%+ respondents view IDMP as crucial for cross-department data sharing ([66] www.pharmiweb.com). Many are investing in master data management, data hubs, and the Pistoia Alliance's IDMP-Ontology to map between systems ([70] www.pharmiweb.com). The table below summarizes the main IDMP readiness barriers identified:

Table 4: Surveyed Barriers to IDMP Implementation (Pharma Industry)

Barrier	% of Respondents	Source
Insufficient data standardization (lack of common vocabularies)	56%	(^[69] www.pharmiweb.com)
Limited resources (budget/staff)	44%	(^[69] www.pharmiweb.com)
Unclear data ownership/responsibility across functions	41%	(^[69] www.pharmiweb.com)
Insufficient strategic planning (no long-term IDMP roadmap)	(quoted qualitatively)	(^[63] globalforum.diaglobal.org) (^[59] www.arisglobal.com)
Low company awareness/understanding of IDMP	(qualitative)	(^[71] globalforum.diaglobal.org)

This data highlights that the challenge is largely organizational and technical: creating the infrastructure (data models, MDM, RIM extensions) and governance rather than lack of conceptual support for IDMP. Indeed, industry experts advise that companies need multi-year planning and enterprise solutions (not quick fixes) to fully leverage IDMP (^[59] www.arisglobal.com). Those who wait may find themselves exceeded by regulatory mandates: as one consultant warned, relying on “stopgap solutions” for last-minute compliance is unsustainable when standards like IDMP become widespread (^[59] www.arisglobal.com).

Integration of RIM and IDMP

As regulatory data standards shift, RIM and IDMP are naturally converging topics. RIM systems will often be the **primary tool to manage and submit the data needed for IDMP compliance**. For example, a RIM can store structured product details (ingredients, dosages, routes of administration) in line with IDMP terminology. Leading RIM vendors have already begun enhancing their platforms to support IDMP workflows: capabilities include IDMP data models, specific submission exports (e.g. FHIR bundles), and validation against reference terminologies. For instance, Veeva Vault RIM provides configurable fields and validation logic that align with IDMP elements (e.g. IDMP Reference Strength, Regulatory Authorization details) (^[72] www.productlifegroup.com). ArisGlobal also markets workflows for SPOR data submission (the “IDMP Reference implementation” mentioned on their resource page).

From a strategic perspective, **implementing a modern RIM system is often seen as a prerequisite for IDMP readiness**. A strong RIM foundation ensures that product and submission data are already centralized and controlled, making it easier to add the IDMP-specific attributes. Conversely, companies that still use legacy or fragmented systems will face even more difficulty collecting consistent IDs for all products and substances. Many regulatory experts recommend treating IDMP as an extension of the RIM/master-data strategy, not as a completely separate IT project. For example, Propera Group (CDISC, etc.) suggests that IDMP compliance will require robust **master data management (MDM) practices for regulatory data**, implying close ties between RIM and MDM systems (^[73] www.celegence.com).

The intersection also raises interesting questions of **scope ownership**. Product and substance master data often span departments (e.g. chemistry, manufacturing, regulatory affairs). Implementing IDMP will require cross-functional data governance: who maintains global substance synonyms? How do manufacturing sites feed purity data into the regulatory system? Best-practice companies are forming steering committees that include RA, PV, QC, supply chain, and IT, to define a unified “truth” of product data.

Technological Considerations

A technical enabler of the RIM–IDMP integration is the move toward **data standards and APIs**. The EMA's use of HL7 FHIR as the data exchange standard for IDMP (e.g. as the basis of the SPOR API (www.ema.europa.eu) (www.ema.europa.eu)) is key. FHIR is a modern, API-friendly format familiar in healthcare IT, which means RIM vendors can build FHIR-based submission connectors. Companies should configure their RIM (or adjacent MDM) to produce FHIR-compliant outputs. For example, RIM records might expose an API endpoint that, when given a product ID, returns an IDMP-compliant JSON payload. This approach contrasts with the old eCTD “document-based” exchange, moving instead to “live” data interfaces.

In parallel, the adoption of **controlled vocabularies** is vital. IDMP relies on standard codes (e.g. INNs for substances, EDQM terms for dosage forms, UCUM for units). RIM systems must incorporate these vocabularies, usually by interfacing with reference data (for instance, EMA's Referentials Management Service provides official lists for forms and units). Failure to use standard terms will cause validation errors. Thus, part of RIM implementation nowadays includes integrating such terminology services. Some companies are also looking at semantic technologies: as mentioned in the industry survey, there is growing interest in tools like the Pistoia Alliance's IDMP-Ontology, which uses web ontology language to link IDMP entities, enabling smarter data queries and AI usage (^[74] www.pharmiweb.com).

Organizational and Strategic Impact

For life sciences companies, aligning RIM and IDMP implementations can create synergies but also requires coordination. Many organizations form **digital regulatory transformation programs** that cover both RIM upgrades and IDMP compliance under one umbrella. The idea is to treat product data as an enterprise asset: define global data standards (aligned to ISO) once, then use them for all regulatory processes, manufacturing, quality systems, etc. In practice, this might be a multi-year digital transformation program. Companies often work with external consultants (like those cited above) who have expertise in both RIM and IDMP to guide the process.

Governance frameworks need updating: e.g. updating SOPs to require use of IDMP terms in all regulatory submissions, or adding data stewards to data-centric RA change control. Importantly, the **future state** for many firms is a regulatory environment where RIM houses all the necessary IDMP attributes and automatically pushes updates to regulators via new interfaces, thus eliminating manual reporting. Adopting IDMP forces a mindset shift: regulatory information is no longer “filed away” in dossiers, but entered upfront as structured data. According to ArisGlobal, companies that invest in a long-term IDMP solution will gain agility as new markets and regulations come online (^[59] www.arisglobal.com). Conversely, those who delay may fall behind technologically and incur “overwhelming” burdens later.

Data Analysis and Evidence-Based Insights

This section highlights quantitative findings from industry surveys and reports that illuminate the RIM/IDMP landscape. Evidence underscores that companies view both RIM modernization and IDMP preparedness as critical yet challenging initiatives.

RIM Adoption Metrics

- **Adoption Prevalence:** A 2022 benchmark survey (76 organizations globally) found that while regulatory modernization is widespread, full global roll-out of unified RIM systems is still incomplete. Only **32% of companies** claimed full global RIM adoption, with another 54% “working towards” it (^[6] www.pharmoutsourcing.com). This indicates that despite heavy investments (starting around 2013), many firms still have fragmented platforms or rely on legacy processes in some regions. It also suggests that a

majority of mid-size or local affiliates remain “infrequent users” of RIM. ([6] www.pharmoutsourcing.com) ([75] www.pharmoutsourcing.com).

- **Investment Focus:** The same survey showed investment shifting to advanced capabilities: about **75% of companies** now prefer a single integrated RIM platform rather than multiple point solutions ([17] www.pharmoutsourcing.com). Around half of respondents reported significant investment in master data management foundations by 2022 ([76] www.pharmoutsourcing.com) (e.g. 51% working on master/reference data solutions). Corporations are also piloting AI/ML tools (24%), submission collaboration platforms (32%), and knowledge management (18%) ([77] www.pharmoutsourcing.com). This points to RIM evolving beyond mere record-keeping into an analytics and automation hub.
- **Resource Changes:** In top-performing companies with mature RIM, there has been a notable increase in “data roles” within regulatory departments: **63%** had dedicated data analysts on the regulatory team, **44%** assigned data governance roles, and **44%** had a digitalization lead ([37] www.pharmoutsourcing.com). This demonstrates an organizational shift, validating that RIM modernization is **driving changes in skill-sets**, not just software.

These data suggest that while RIM adoption is advancing, many firms are still on the journey. The industry is at a transition point where initial platform roll-outs are largely done, and attention turns to higher-order goals (data strategy, cross-functional usage, affiliates). Many companies thus face “the last mile” challenges of getting every region and function fully on board ([78] www.pharmoutsourcing.com). RIM investments are becoming more strategic, aligned with other digital health trends, rather than purely operational.

IDMP Readiness Survey

As discussed, formal data on IDMP readiness is scarcer, but recent surveys and reports shed light on the state of affairs:

- A benchmark study by MAIN5/Pistoia (2024) surveyed 18 pharma companies, finding **mixed maturity**. Over **70%** of companies recognized IDMP’s value for enabling cross-functional data integration ([66] www.pharmiweb.com). Notably, respondents plan to integrate IDMP data across regulatory, manufacturing, PV, supply chain, and quality in the next 3 years, with plans for clinical and commercial data in 3–5 years ([66] www.pharmiweb.com). This reflects an industry consensus that IDMP is more than a RegAff task; it is a backbone for multi-department data alignment.
- However, **progress is uneven**. The study highlights persistent issues: manual data practices are common, and companies still struggle with defining a single “source of truth.” Quality concerns (only 33% flagged it as an issue) were overshadowed by structural barriers (standardization, ownership). Ironically, data quality was not top of mind, suggesting many have not yet fully measured it, or that they assume cleaning and standardization themselves is what IDMP is about.
- A DIAGlobal Global Forum (Nov 2024) report on IDMP meetings confirms these findings. It recounts that many organizations **lack a clear understanding** of IDMP requirements. For example, in Latin America, despite ANVISA’s push, most local firms “struggle with inconsistent data and absence of master data systems” ([71] globalforum.diaglobal.org), and readiness is low without legal compulsion. These qualitative insights, while not numerical, echo the survey data: companies appreciate IDMP’s long-term benefits but face immediate practical gaps.

Taken together, the evidence indicates that within the industry:

- There is **growing awareness** of IDMP’s strategic importance (a majority of major companies plan to incorporate it soon).

- The main obstacles are **organizational and data-architectural**. Firms are on a spectrum: some large multinationals have dedicated teams working on IDMP, while many mid-sized or emerging-market companies have barely started.
- **Deadline extension** (like EMA's 2025 extensions) was likely necessary given survey feedback; industry associations in Europe negotiated for more time due to Covid disruptions and the complexity noted above.

Cost and Market Trends

While publicly available figures on RIM or IDMP project costs are rare (likely proprietary), market analyses hint at growing investment. For instance, Grand View Research projects high double-digit annual growth (CAGR ~15%) for the Regulatory Information Management market through 2030 (^[79] www.grandviewresearch.com), driven by “core compliance mandates,” globalization, and digitalization in pharma. Similarly, as IDMP compliance becomes required for submissions, many vendors (RIM, MDM, PV providers) are reporting strong demand for IDMP solution services. Although precise ROI data is scarce, companies frequently justify RIM projects by citing reduced submission times, lower error rates, and avoided regulatory fines. Given the high cost of non-compliance (e.g. market suspensions, rejects), even relatively small efficiency gains can yield significant value. The alignment with IDMP also has high existential value: an EU MAH failing to submit required IDMP data risks losing marketing status.

Case Studies and Real-World Examples

Beyond generic cases, specific examples from industry publications illustrate these themes. We summarize two representative cases here:

- **Case A (Global Pharma, Veeva RIM)**: A leading global pharma consolidated regulatory processes on Veeva RIM, replacing siloed spreadsheets. The company harmonized submission workflows (planning, authoring, publishing) globally. Post-deployment, the company achieved a unified process for major regulatory activities (e.g. joint reviews of CMC and safety) (^[41] astrixinc.com). The RIM now supports activities such as authoring multi-market dossiers, tracking global labeling changes, and archiving regulatory records. Key success factors were executive sponsorship and a phased rollout. Challenges included aligning terminology across geographies and migrating vast historical data. The case notes an intangible but strong outcome: “everyone had a voice” in the process, and adoption was high because local teams felt represented (^[42] astrixinc.com).
- **Case B (Medical Device, Kalypso)**: A medical device maker saw dramatic improvement after implementing a centralized RIMS. Pre-implementation, offices across regions had different registration tracked manually. Post-implementation, global registration data was migrated into the RIM, which was integrated with trade control systems (^[43] kalypso.com). The RIM provided a **single source of truth**: regulatory and quality teams worldwide could see real-time status of every device registration. Process changes were standardized, eliminating hundreds of person-hours of “manual handoffs” in submission reviews (^[80] kalypso.com). The RIM even improved patient impact: by speeding market entry for critical devices, it indirectly improved patient care (^[26] kalypso.com). The project acted as a blueprint for the company’s broader digital strategy.

These exemplars, while differing in industry, share features: replacing fragmented legacy practices, focusing on end-to-end processes, and tightly coordinating the technology with organizational change. They also demonstrate measurable internal ROI (time saved, fewer errors) and external value (faster product launches, better compliance). On the challenge side, both underscored the demand for **ongoing improvement**: tracking regulatory changes doesn’t stop at Go-live, and new phases (like IDMP data fields) may be added later.

Future Outlook and Implications

Evolving Regulatory Landscape

The shift to RIM and IDMP is part of a broader trend toward digital regulatory processes. eCTD v4.0 (an upcoming submission standard) will likely incorporate IDMP-aligned data sections, making digital drug dossiers true data deliverables. We also see regulators exploring more **real-time data exchanges**: for instance, the FDA's interest in API-based submissions (similar to how EMA uses FHIR) suggests a move away from periodic snapshots to continuous data connectivity. Moreover, the integration of RIM with other enterprise systems (clinical trial registries, supply chain, PV databases) could unlock new analytics: e.g. predictive compliance monitoring or automated cross-product interactions. The survey data suggests investments in AI and advanced analytics are already in the pipeline (^[76] www.pharmoutsourcing.com) (^[81] www.pharmoutsourcing.com). In 5–10 years, we might expect RIM systems that not only manage data but also **recommend actions** (e.g. propose submission plans based on past success rates) and automatically generate portions of regulatory documents.

Pharmacovigilance stands to benefit: with standardized product IDs, post-market surveillance may become far more efficient. Global pharmacovigilance networks could quickly aggregate adverse event data using PhPID, enabling faster global signal detection. Likewise, supply chain digitization (e.g. serialization, blockchain for provenance) could tie into IDMP to ensure authenticity and traceability.

Industry and Patient Impacts

For industry, the combined movement means regulatory affairs shifts from a reactive cost center to a strategic data asset. Firms that successfully implement RIM+IDMP can reduce compliance risk (fewer rejections and queries), open new markets faster, and leverage regulatory data for product strategy (e.g. identifying global shortages or competitor movements). Smaller and mid-size companies may face challenges due to limited resources; this may spur new service models or outsourced solutions. Vendors will continue innovating – for example, with cloud-based RIM-as-a-Service offerings, pre-built IDMP data entry templates, and integration hubs.

For patients and healthcare systems, the long-term promise is **safer and more accessible medicines**. IDMP's global identifiers can help ensure that if a drug is recalled in one country, equivalent products elsewhere are flagged immediately. By streamlining trials and approvals through standardized data, therapies might reach patients faster while maintaining safety oversight. Moreover, better product information (e.g. machine-readable labels) can improve prescribing and administration safety. Regulatory data transparency may even allow external researchers to do meta-analyses on drug safety across borders.

Continuing Challenges and Research Directions

Despite momentum, numerous hurdles remain. Data privacy and intellectual property concerns over sharing detailed product data must be managed. Companies must also guard against data overload: IDMP will massively increase the volume of structured data, raising questions about who maintains it all. On the technology side, cybersecurity of these critical systems (especially if cloud-based) is paramount. Regulators and industry alike will need consistent audits and validation of IDMP/RIM systems. Finally, ensuring global harmonization is a non-trivial policy challenge: as noted by observers, mismatches in legal accountability (some regions may implement IDMP as law faster than others) create uncertainty. Ongoing public–private collaboration (forums like GIDWG, IFPMA workshops, etc.) will be essential to iron out these issues.

From a research perspective, areas for further work include: development of best practices for data transition (e.g. ETL processes for legacy data into IDMP schema), evaluation of AI tools to automate curation of product information, and case studies comparing outcomes (e.g. regulatory approval times) pre- and post-RIM/IDMP.

Continuous benchmarking will help quantify benefits. Interdisciplinary research bridging regulatory science, information technology, and health outcomes can also explore the ultimate impact on patient safety and access.

Conclusion

Regulatory Information Management systems and ISO IDMP standards represent complementary pillars of a new regulatory paradigm. RIM provides the infrastructure – the comprehensive software backbone – for managing product and submission data. IDMP provides the standardized data model and vocabulary that global regulators are converging upon. Together, they move the industry away from siloed documents toward a data-centric ecosystem. The evidence shows companies recognize this: surveys and case studies reveal widespread RIM modernization efforts and growing commitments to meet IDMP requirements, despite substantial challenges (^[66] www.pharmiweb.com) (^[8] astrixinc.com). Achieving these transformations demands disciplined project execution, binding corporate governance of data, and cross-functional collaboration. But the rewards – faster approvals, better risk management, and ultimately safer therapies – justify the effort. As the regulatory environment evolves (e.g. EMA's new SPOR/IDMP services, emerging FDA data initiatives), pharmaceutical companies must align their operations accordingly. Future successes will likely come to those who view RIM and IDMP not as separate compliance obligations, but as **foundational elements of digital strategy** that enable innovation and resilience in an increasingly complex global market.

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IntuitionLabs - Industry Leadership & Services

North America's #1 AI Software Development Firm for Pharmaceutical & Biotech: IntuitionLabs leads the US market in custom AI software development and pharma implementations with proven results across public biotech and pharmaceutical companies.

Elite Client Portfolio: Trusted by NASDAQ-listed pharmaceutical companies including Scilex Holding Company (SCLX) and leading CROs across North America.

Regulatory Excellence: Only US AI consultancy with comprehensive FDA, EMA, and 21 CFR Part 11 compliance expertise for pharmaceutical drug development and commercialization.

Founder Excellence: Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

Custom AI Software Development: Build tailored pharmaceutical AI applications, custom CRMs, chatbots, and ERP systems with advanced analytics and regulatory compliance capabilities.

Private AI Infrastructure: Secure air-gapped AI deployments, on-premise LLM hosting, and private cloud AI infrastructure for pharmaceutical companies requiring data isolation and compliance.

Document Processing Systems: Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

Custom CRM Development: Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

AI Chatbot Development: Create intelligent medical information chatbots, GenAI sales assistants, and automated customer service solutions for pharma companies.

Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

AI Consulting & Training: Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at <https://intuitionlabs.ai/contact> for a consultation.

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IntuitionLabs.ai is North America's leading AI software development firm specializing exclusively in pharmaceutical and biotech companies. As the premier US-based AI software development company for drug development and commercialization, we deliver cutting-edge custom AI applications, private LLM infrastructure, document processing systems, custom CRM/ERP development, and regulatory compliance software. Founded in 2023 by [Adrien Laurent](#), a top AI expert and multiple-exit founder with 20 years of software development experience and patent holder, based in the San Francisco Bay Area.

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