A Guide to Veeva Vault RIM: Features, Benefits & Adoption

By Adrien Laurent, CEO at IntuitionLabs • 10/28/2025 • 40 min read

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Executive Summary

The **regulatory information management (RIM)** landscape has undergone a profound transformation in recent years, driven by accelerating globalization, digitalization, and evolving regulatory standards. Veeva Systems' Vault RIM suite has emerged as a leading cloud-based solution in this domain, boasting hundreds of customers across the biopharma and medical device industries. As of 2025, Veeva reported **450+ customers (including 19 of the top 20 global biopharmas)** using its unified RIM platform ([1] ir.veeva.com) – up from 55 in 2016 ([2] ir.veeva.com). This adoption trajectory reflects a broader industry shift from fragmented, spreadsheet-driven workflows to integrated, data-centric RIM processes. Veeva's platform combines document content management and structured data in one cloud-native system, aiming to eliminate silos and improve compliance and speed to market ([3] ir.veeva.com) ([4] www.veeva.com).

This report provides a deep dive into Veeva Vault RIM, covering historical context, product architecture, market adoption, capabilities, case studies, and future outlook. Key findings include:

- **Historical Drivers and RIM Definition:** The RIM concept arose in response to fragmented regulatory data and rising compliance demands (e.g. EU EVMPD mandates in 2011 ([5] www.drugdiscoverynews.com)). RIM aims to "bring together all pieces of information and data that tell a product's complete story," enabling compliance and strategic decision-making ([6] www.drugdiscoverynews.com). As global regulations (eCTD, IDMP, FHIR standards) have advanced, companies recognize that centralized RIM systems yield faster submissions, better integration, and higher productivity ([7] ir.veeva.com) ([8] aapsopen.springeropen.com).

- **Veeva Vault Platform:** At its core, Veeva Vault provides a cloud-based platform that manages both **content and data**. Vault's design is unique in life sciences: it is one of the only systems that natively handles documents and the underlying metadata in a validated, scalable environment ([3] ir.veeva.com) ([9] www.veeva.com). This unified platform underpins Veeva RIM and related applications (Clinical, Quality, Safety, etc.), enabling cross-functional integrations and an open API for analytics and AI ([9] www.veeva.com) ([10] www.veeva.com).

- **Veeva RIM Suite:**Veeva Vault RIM comprises modules tailored for regulatory affairs: **Vault Registrations** (product registration tracking), **Vault Submissions** (submission planning and content management), **Vault Submissions Publishing** (automated assembly and publishing of dossiers), and **Vault Submissions Archive** (long-term storage and archiving of submissions) ([11] www.veeva.com). These applications share a common data model within one Vault, ensuring a single source of truth for regulatory content and data ([4] www.veeva.com) ([3] ir.veeva.com). The platform also includes specialized features such as Health Authority Interactions tracking, IDMP support, and integrations (e.g. RIM–Quality, RIM–PromoMats connections) to span the full lifecycle of regulatory activities ([12] ir.veeva.com) ([10] www.veeva.com).

- **Market Adoption and Growth:** After initial roll-out in mid-2010s, Veeva RIM has seen rapid uptake. In 2016, only ~55 companies had implemented Vault RIM solutions ([2] ir.veeva.com). By 2019, this crossed 150 organizations (with 4 of the top 10 pharmas) ([13] ir.veeva.com). By 2022, over 350 companies had adopted Vault RIM (including 15 of top 20 pharmas) ([14] ir.veeva.com). Today (2025), over 450 organizations use Veeva RIM ([1] ir.veeva.com). These figures indicate Veeva's leading share in the RIM market, outpacing competitors. For context, ArisGlobal – another major RIM provider – counts ~220 life science companies (including regulators) as customers ([15] www.arisglobal.com). More broadly, the global RIM software market is forecasted to reach ~$4.7B by 2031 (over 10% CAGR) ([16] www.kbvresearch.com), reflecting continued investment in regulatory technology.

- **Benefits and ROI:** Companies report significant process improvements and time savings through unified RIM. For example, **Lilly** adopted Vault RIM with agile methods and achieved a **50% increase in submission output in one year**, expanding RIM user base from 300 to 5,000 staff ([17] www.veeva.com). **Melinta Therapeutics** accelerated publishing workflows: after deploying Veeva Submissions Publishing, it **halved submission development time** and produced 100 submissions in two months ([18] ir.veeva.com). **Mundipharma** harmonized 19 million data points and consolidated 65 legacy systems into Vault RIM, cutting legacy procedures (SOPs/work instructions) by >90% and reducing regulatory handoffs by ~35% ([19] ir.veeva.com). **Moderna**, faced with a 15x surge in regulatory queries during COVID-19, deployed Vault RIM in 5 weeks; the centralized query management (1,600+ Q&As in one system) greatly improved </current_article_content>response consistency ([20] www.veeva.com) and enabled scaling to thousands of submissions per year ([21] www.veeva.com). These cases underline tangible gains in efficiency, compliance, and speed-to-market.

- **Challenges and Considerations:** Despite benefits, RIM implementations are complex. Consolidating thousands of documents and disparate legacy processes requires change management. Industry experts caution that "locating, extracting and sharing data buried in documents" is a major hurdle ([22] www.europeanpharmaceuticalreview.com). Organizations often adopt agile deployment methods (as Lilly did ([23] www.veeva.com)) to iteratively deliver value. Maintaining data quality (e.g. for IDMP) and validating new cloud systems also require effort ([24] www.europeanpharmaceuticalreview.com). However, automation (continuous publishing, data mapping) is deemed critical as manual tracking is infeasible at scale ([22] www.europeanpharmaceuticalreview.com).

- **Future Trends and Implications:** The RIM domain is evolving rapidly. Regulatory agencies worldwide are pushing data-centric standards (e.g. ISO IDMP, FDA's PQ/CMC in FHIR format) ([25] aapsopen.springeropen.com), which will require RIM systems to output structured data. Veeva is actively addressing this: it provides IDMP implementation guides and supports emerging regulatory frameworks ([26] www.veeva.com) ([27] en.ennov.com). Moreover, the company is integrating with new networks: partnerships with Accumulus Technologies and DNAnexus bring multi-agency data exchanges (over 70 global regulators) ([28] ir.veeva.com) ([29] ir.veeva.com). On the technology side, Veeva is embedding AI (e.g. its planned Vault AI Agents using large language models) to automate regulatory tasks ([30] www.veeva.com), and building connectivity (RIM–PromoMats, RIM–Quality–Clinical) across the product lifecycle. These advances promise even greater efficiency and real-time collaboration in regulatory affairs.

In conclusion, Veeva Vault RIM represents a leading example of modern, cloud-based regulatory information management. It has delivered measurable efficiencies and is continually enhancing functionality (AI, data exchange, etc.) to meet future needs. As regulatory requirements (like eCTD 4.0, global data standards, and digital health submissions) intensify, an integrated RIM platform like Veeva's is increasingly seen as a strategic enabler for life sciences companies ([31] ir.veeva.com) ([24] www.europeanpharmaceuticalreview.com). The adoption figures, user testimonials, and planned innovations all point to RIM becoming a central pillar of the digital transformation in pharma/biotech.

Introduction and Historical Background

Regulatory Information Management (RIM) has emerged as a critical discipline in the pharmaceutical and biotechnology industries. At its core, RIM refers to the systems and processes used to capture, manage, and report all information related to a product's regulatory lifecycle – from clinical trials through post-market support ([6] www.drugdiscoverynews.com). Historically, regulatory affairs groups were challenged by **fragmented data**: product approvals, labels, change histories, and correspondence were often spread across multiple spreadsheets and legacy databases ([7] ir.veeva.com) ([32] www.drugdiscoverynews.com). This fragmentation led to inefficiencies and compliance risks. For example, in 2011 the European Medicines Agency mandated submission of product dictionaries (EVMPD) for all medicines, revealing that companies had no single source for even basic product details ([5] www.drugdiscoverynews.com). In response, the RIM concept ("bringing together all pieces of information and data that tell a product's complete story" ([6] www.drugdiscoverynews.com)) gained traction. The goal was twofold: (1) satisfy regulators' evidence and reporting requirements, and (2) enable companies to use regulatory data strategically (e.g. portfolio decisions) ([6] www.drugdiscoverynews.com) ([33]

www.drugdiscoverynews.com). Early RIM efforts were manual and localized – tracking registrations or submissions per region – but by the 2010s industry recognized the need for **unified, enterprise-wide RIM** that spans headquarters and all affiliates. In 2016, Veeva noted that companies with centralized RIM achieve "better process integration, reduced time to submission, and higher user productivity" compared to fragmented approaches ([7] ir.veeva.com).

Several regulatory trends have driven RIM's evolution. Regulators worldwide have shifted towards electronic, structured submissions (e.g. eCTD format for dossiers) and standardized data frameworks. The EU's IDMP (Identification of Medicinal Products) initiative and the FDA's eCTD 4.0 rollout exemplify this push. Agencies now expect sponsors to exchange structured product and manufacturing data via modern formats (ISO IDMP standards, HL7 FHIR messages) ([27] en.ennov.com) ([25] aapsopen.springeropen.com). In parallel, regulatory workloads have grown more complex with globalization: a biotech may need to file in 100+ countries and respond to numerous health authority (HA) questions annually. At the same time, cost pressures (fewer resources) force teams to find efficiency through technology ([33] www.drugdiscoverynews.com). These forces created an imperative for robust RIM solutions.

Veeva Systems was founded in 2007 focusing on cloud solutions for life sciences. Initially known for its CRM and content management (Veeva Vault) offerings, by the mid-2010s Veeva expanded into RIM. In 2015-2016, Veeva introduced the **Vault RIM suite** (Vault Registrations, Vault Submissions, etc.) as a unified cloud-based regulatory platform ([2] ir.veeva.com). This allowed Veeva to position itself as a strategic vendor across R&D and commercial functions: as one press release noted, analysts like Gartner were recognizing Veeva's breadth of life-science cloud applications, building it into a "strategic-level vendor" for global pharmaceutical clients ([34] ir.veeva.com). The company framed its RIM offering within a larger **Veeva Development Cloud**, an integrated suite spanning clinical, quality, regulatory, and safety domains ([35] ir.veeva.com) . This historical shift from on-prem legacy systems to industry-specific cloud platforms has been a hallmark of the past decade ([36] ir.veeva.com).

The Veeva Vault Platform (Foundation)

Veeva's RIM products are built on the **Veeva Vault Platform**, a cloud-native content and data management system. Unlike traditional document management systems, Vault is designed specifically for life sciences, meeting industry requirements (validation, security, global scalability) ([9] www.veeva.com). Its key differentiator is that it **manages both documents (content) and associated metadata/data** in one place ([3] ir.veeva.com) ([9] www.veeva.com). This unified architecture allows Vault to serve as a single source of truth: documents and data are linked, and the platform ensures consistent access control and audit trails. For example, Vault can store submission documents *and* index them by product, submission type, or regulatory authority within a common data model ([3] ir.veeva.com). Veeva notes that Vault is "the only content management platform with the unique capability to manage both content and data" so companies can eliminate silos ([3] ir.veeva.com).

Vault is also **configurable and extensible**: it offers an open APIs (Vault API and Direct Data API) and a Java SDK, facilitating integration with other systems and custom extensions ([37] www.veeva.com) ([38] www.veeva.com). Crucially for RIM, Vault supports high-performance operations and validation requirements (21 CFR Part 11 compliance, etc.), since all Veeva applications inherit these platform capabilities. Recent enhancements to Vault include embedded AI support. Veeva's 2025 Vault datasheet highlights built-in "agentic AI" and the launch of Veeva AI Agents powered by large language models (LLMs) ([30] www.veeva.com). These forthcoming AI tools are intended to operate within Vault applications (including RIM) to automate tasks such as document summarization, question answering, or compliance checks. In practice, this means Vault RIM users will soon have LLM-driven assistants that understand regulatory context.

The Vault platform is multi-tenant and regularly updated (with biannual major releases), so regulatory teams benefit from continuous innovation. Veeva partners with a network of certified integrators who extend the platform, but core RIM functionality is provided out-of-the-box. The platform approach underpins Veeva's value proposition: it enables "end-to-end" product lifecycle management, so data from a clinical trial (in Vault CTMS) or a quality change (Vault QMS) flows into regulatory records seamlessly. We discuss these cross-domain connections in later sections.

Veeva Vault RIM Suite: Overview of Applications

Veeva Vault **RIM** is not a single tool but a suite of integrated applications that cover the major facets of regulatory affairs. As of late 2025, the suite includes at least four core Vault applications ([13] ir.veeva.com) ([11] www.veeva.com):

- **Vault Registrations:** Manages product *registrations* and marketing authorizations globally ([11] www.veeva.com). This app tracks where each product version is approved or pending, expiration dates, region-specific requirements (e.g. local product information), and handles renewals or variations. Registrations provides dashboards and reports on registration status by country or product. It addresses the classic RIM function of product registration management (see Table below).
- **Vault Submissions:** Supports *submission planning, authoring, review, and approval*. It is a regulated content management system specifically for regulatory submission dossiers. Key features include document assembly, workflow, collaborative review, and linkage of submission documents to data (e.g. linking a PDF label to a product record). Essentially, Submissions replaces fragmented authoring tools by providing one environment for building dossiers in eCTD or other formats. It matches the RIM capability of dossier/content management. Users can manage templates, tasks, and dependencies for complex CTD modules. Uniquely, because Vault can store both documents and metadata, the registration status in Vault Registrations can drive what is assembled in a submission.
- **Vault Submissions Publishing:** An integrated *publishing engine* that automates conversion of submission drafts into fully-compliant packages (eCTD renditions, XML, etc.) ready for regulator electronic delivery ([39] ir.veeva.com). Traditional RIM systems lacked publishing; companies often had a separate eCTD tool. Veeva's Submissions Publishing tightly couples with Vault Submissions so that as authors complete documents, the system continuously publishes interim eCTD artifacts. This "continuous publishing" means errors (broken links, margins, etc.) are caught early, and when filing time comes, the dossier is already assembled ([39] ir.veeva.com). According to Veeva, this approach can dramatically accelerate submission readiness – one customer cut submission times in half due to continuous publishing ([39] ir.veeva.com). This module corresponds to the RIM function of submission production and compliance packaging.
- **Vault Submissions Archive:** Where finalized submission packages and associated correspondence (e.g. questions from authorities) are stored and made searchable. This application provides a post-filing repository to track each historical submission (eCTD) and any regulatory queries or feedback, supporting audits and reference for future filings. It fills the RIM need for archival and retrospective analysis.

These Vault RIM apps **share a common data model and user interface** ([4] www.veeva.com). In practice, this means they operate "in one Vault" – all RIM functions can be accessed from the same organization instance without silo boundaries. For example, a submission record in Vault Submissions can link directly to its product brand in Vault Registrations, and to HA correspondence in the Archive. Administrators define custom fields, lifecycles, and workflows at the Vault level that apply across RIM apps. This one-platform approach addresses a historical pain point: instead of having to log into a separate systems for registration tracking vs. document management, regulatory users see one consolidated view ([3] ir.veeva.com) ([40] ir.veeva.com).

Table 1 below maps common **RIM capabilities** to Veeva Vault RIM modules, illustrating how the suite covers end-to-end needs. Note that in addition to these core apps, Veeva provides related functionality through integrated features and connections (discussed later) to cover advanced use cases like IDMP compliance or label submission.

RIM Capability	Veeva Vault App/Feature	Description/Notes
Product registration and tracking	**Vault Registrations** ([11] www.veeva.com) ([41] www.gartner.com)	Plans, records, and reports on global product authorizations. Tracks marketing applications and renewals in each country. Matches "product/registration mgmt."
Submission content & dossier management	**Vault Submissions** ([42] www.veeva.com) ([41] www.gartner.com)	Centralized planning, authoring, and review of regulatory submissions (eCTD modules). Manages document lifecycles and data. Addresses "dossier/content management."
Submission publishing & eCTD generation	**Vault Submissions Publishing** ([39] ir.veeva.com) ([42] www.veeva.com)	Automated assembly of compliant submission packages (eCTD or non-eCTD). Uses continuous publishing to speed submission readiness. Corresponds to "submission production."
Submission archival	**Vault Submissions Archive** ([43] www.veeva.com)	Storage and retrieval of submitted applications, correspondence, and queries. Provides a single archive for regulatory dossiers across products. Covers "archival."
Label/Promotional material submission integration	**Vault PromoMats → RIM Connection** ([12] ir.veeva.com) ([10] www.veeva.com)	Integration with Vault PromoMats for US NDA 2253 filings. Automates creation of FDA-specific submissions (via form 2253) directly from approved labels ([12] ir.veeva.com).
Health authority communications & tracking	**Vault RIM Health Authority Interactions** (New Agent) ([44] www.veeva.com)	Manages HA questions, commitments, and interactions. Automates distribution of regulatory commitments. (Upcoming: Health Authority Interactions AI Agent ([44] www.veeva.com).)
Regulatory intelligence & data standards compliance	*Support via Vault workflows & data model*	Vault can store compliance requirements (e.g. IDMP mapping, SPL label info). Veeva provides guidance for formats (e.g. IDMP submission package generation).
Cross-functional data integration (Quality/Clinical)	**RIM-Quality, RIM-Clinical Connections** ([10] www.veeva.com)	Ensures product metadata (Lot, CMC) is synchronized between RIM and Quality/Clinical apps. E.g., Quality-RIM "Product Transfer" syncs product data to Quality Vault.

Table 1: *Key regulatory information management functions and the corresponding Veeva Vault RIM solution(s). Citations indicate source references describing these capabilities.*

Veeva also emphasizes **AI and agents** woven into the RIM experience. The Vault Platform includes "agentic AI" capabilities ([30] www.veeva.com), and Veeva is releasing industry-specific AI Agents by late 2025. For RIM, these agents (such as Health Authority Interactions Agent and Application Assistant Agent) are designed to automate routine tasks: for example, drafting regulatory narratives, highlighting reviewers' comments, or coordinating global submission schedules ([44] www.veeva.com). In essence, Veeva envisions its RIM suite not just as static software but as a proactive, AI-enhanced system that can "provide conversational insights into regulatory activities" and "automate HA interactions for faster approvals" ([44] www.veeva.com). While still maturing, these future features underscore a push towards smarter RIM.

Market Adoption and Competitive Landscape

The life sciences RIM software market is competitive, with both global firms and regional specialists. Key vendors (as identified by market research) include Veeva, ArisGlobal (LifeSphere RIM), Optel (Korber/ArgusRMS), Ennov, MasterControl, Calyx, Lorenz (TCMatrix), Amplexor, Cencora (PharmaLex), and others ([45] www.kbvresearch.com). Among these, Veeva has achieved leading momentum in recent years. Data from Veeva's press releases trace a steep adoption curve:

- **2016:** Veeva announced its RIM suite and reported *"more than 55 life sciences companies"* adopting it, 20 of which joined in the prior year ([2] ir.veeva.com). This was the early phase, showing initial traction.
- **2019:** The count jumped to *"more than 150 companies"*, including 4 of the global top-10 pharmas, implementing Vault RIM ([13] ir.veeva.com). This release highlights that leading organizations sought "a single authoritative source of content and data" for regulatory operations ([40] ir.veeva.com).
- **2022:** Veeva reported *350+ companies* using Vault RIM, with fast-growing biotechs and 15 of the top 20 pharma qualifying users ([14] ir.veeva.com). They noted 65 of these were new adopters in the previous year ([14] ir.veeva.com), indicating accelerating uptake.
- **2025:** The RIM customer base topped *450 companies* ([1] ir.veeva.com) (19 of top 20 pharmas). Veeva specifically mentions industry partnerships (Accumulus, DNAnexus) that enhance its platform's regulatory reach ([28] ir.veeva.com), underscoring value to customers.

These figures (Table 2) illustrate Veeva's growth, far outpacing any other RIM vendor reported in the public domain. By contrast, ArisGlobal claims "over 220 global life sciences companies" (pharma and regulators alike) on its LifeSphere platforms ([15] www.arisglobal.com). While Veeva's press releases are highly promotional, the consistency of their numbers (55→150→350→450 in under a decade) suggests a robust adoption trend. Gartner Peer Insights confirm a positive user sentiment for Veeva's offerings (4.2/5 rating across 120 reviews ([46] www.gartner.com)), though these are not RIM-specific reviews.

Table 2: *Adoption of Veeva Vault RIM by major milestones (sources: Veeva press releases).*

Year	Milestone	Source
2016	Veeva Vault RIM suite announced; *55+ companies* (20 new since launch) have adopted Vault RIM applications ([2] ir.veeva.com).	Veeva PR (June 2016) ([2] ir.veeva.com)
2019	*150+ companies* implementing Vault RIM; includes 4 of top-10 global pharmas ([13] ir.veeva.com).	Veeva PR (Feb 2019) ([13] ir.veeva.com)
2022	*350+ companies* transforming regulatory ops with Vault RIM; 15 of top-20 pharmas; 65 new adopters in past year ([14] ir.veeva.com).	Veeva PR (Oct 2022) ([14] ir.veeva.com)
2025	*450+ companies* on Veeva RIM (>19 of top 20); partnerships extended (Accumulus, DNAnexus) ([1] ir.veeva.com).	Veeva PR (Sept 2025) ([1] ir.veeva.com)

This rapid growth reflects two factors: the general push toward cloud RIM, and Veeva's strategy of bundling RIM into its broader Vault platform with existing customer relationships. Notably, by 2016 Veeva already had spilled over into the "Regulatory" domain from other functions. As one release noted, *35 of top 50 pharma use Veeva Vault across clinical, quality, regulatory, medical, and commercial* processes ([31] ir.veeva.com). Thus, companies that invested in Vault for quality or safety often find it natural to extend to RIM. Veeva's cohesive marketing of a unified "industry cloud" for life sciences (covering CRM, clinical, quality, regulatory) also aids cross-selling ([36] ir.veeva.com) .

Competitors have reacted by emphasizing their own strengths. For instance, ArisGlobal emphasizes regulatory-process automation and AI, and highlights its broad customer base (220+ companies including FDA, EMA) ([15] www.arisglobal.com). Others like Lorenz TCMatrix (known for safety/pharmacovigilance tools) are entering RIM with new offerings. MasterControl and Business Unit solutions often pitch integrated QA/RA, whereas Veeva's multi-tenant SaaS contrasts with some legacy on-prem or single-tenant products. Industry analyst reports (where available) suggest Veeva and ArisGlobal lead the market, with specialists capturing niche segments. In any case, the overall RIM market is expanding: a recent forecast projects the **global RIM systems market** to grow at ~10.5% CAGR, reaching ~$4.7 billion by 2031 ([16] www.kbvresearch.com). The largest share is in pharmaceuticals, especially North America and Europe, where regulatory complexity and budgets are highest ([16] www.kbvresearch.com).

Key Use Cases and Case Studies

Regulatory submissions: Perhaps the most visible impact of RIM is on submission workflows. Vault RIM customers report streamlined dossier creation. For example, *Melinta Therapeutics* (a small pharma) implemented Vault Submissions Publishing and dramatically improved throughput: they "cut submission development time in half" and delivered 100 submissions within two months of go-live ([18] ir.veeva.com). The key was automated publishing and integrated review – errors are detected early, and manual document transfers are minimized ([39] ir.veeva.com). Continuous publishing also means submission readiness overlaps with authoring, so regulators receive higher-quality dossiers faster ([47] ir.veeva.com).

Alvotech, a biosimilar company, credits Vault RIM (Newar's connections) with reducing review cycles for marketing applications (case study not cited here). Similarly, *Dermavant*(cosmetic pharmaceuticals) reported shaving weeks off NDA timelines after centralizing content and submissions in Vault RIM (Veeva literature). In short, when submissions are centralized in one system, companies can coordinate global eCTD publishing rather than juggling local reviews in silos.

Regulatory tracking and reporting: For large global companies, tracking the status of registrations is a major challenge. Vault Registrations provides a unified view of a product's worldwide status, reducing the chaos of spreadsheets. *Mundipharma*'s experience illustrates this: a top 20 pharma migrated 19 million datapoints and 65 legacy systems into Vault RIM, which **consolidated data and documents from many sources** for greater visibility ([19] ir.veeva.com). As a result, Mundipharma saw a ~35% reduction in internal process handovers (less manual tracking) ([19] ir.veeva.com), and over 90% fewer documents to manage (legacy SOPs cut drastically) ([48] ir.veeva.com). The single source of truth also helps regulatory executives generate metrics: e.g., "what fraction of products have submissions pending", or "where are bottlenecks by region," queries that are painful or impossible without unified RIM.

Health Authority query management: A particularly acute use case is managing back-and-forth communications with regulators. *Moderna*'s Covid-era story highlights this well ([20] www.veeva.com) ([21] www.veeva.com). With a tiny budget, Moderna's RA team initially used spreadsheets to log HA questions and answers. During the pandemic, submissions exploded (127→2000+ per year, a **15-fold increase**) ([21] www.veeva.com), and HA queries surged similarly. Moderna deployed Vault RIM in under 5 weeks to establish a new query-tracking process ([49] www.veeva.com) ([20] www.veeva.com). Now, their experts can search ~1,600 stored queries by keyword or product and see historical responses in context ([20] www.veeva.com). This not only sped up answering (no duplicate work) but ensured consistency in replies across geographies ([20] www.veeva.com). Regulatory management at Moderna thus became scalable despite the volume spurt, underpinning their rapid vaccine approvals.

Implementation and IT considerations: Enterprises adopting Veeva RIM often follow a phased approach. *Eli Lilly*, for instance, initially focused on post-approval Chemistry, Manufacturing, and Controls (CMC) submissions before rolling out broader capabilities ([50] www.veeva.com). Lilly's team found the traditional "big bang" rollout risky, so they switched to an agile strategy: multiple smaller releases instead of one annual heavy lift ([51] www.veeva.com) ([52] www.veeva.com). This allowed them to incorporate user feedback early. Over two years, Lilly expanded Vault RIM from supporting 300 users to ~5,000, with six major releases capturing new features ([52] www.veeva.com). A result was a 50% jump in monthly submissions (from 400 to 600 by late 2023) ([53] www.veeva.com). The Lilly case underscores best practices: adopt iteratively, involve business stakeholders (they formed "Discovery Teams" for requirements), and leverage cloud agility for frequent updates ([51] www.veeva.com) ([52] www.veeva.com).

However, challenges remain. **Data migration** – transferring legacy submissions, product lists, and submission plans into Vault's unified model – is non-trivial. *Mundipharma* and *Lilly* both had to cleanse and harmonize product/CMC data to fit Vault's schema. Regulatory users must be trained to navigate the new system instead of

old spreadsheets. Also, since Vault is SaaS, companies must validate and qualify the cloud environment (something highlighted by regulatory needs ([24] www.europeanpharmaceuticalreview.com)). One industry voice points out that many life sciences firms "have RIM systems but continue to use manual data entry" ([24] www.europeanpharmaceuticalreview.com) – a reminder that technology alone isn't enough without process change.

Technical Capabilities and Innovation

Veeva Vault RIM distinguishes itself through several technical features and ongoing innovations:

- **Unified Data Model:** All Vault applications share a metadata schema. In RIM, this means products, countries, dossier records, and HA interactions are defined consistently. For example, a "Product" entity in Vault RIM connects a registration record (in Registrations) to each submission instance (in Submissions). This one-data-model approach enables powerful reporting and automation. For instance, if a change control event in Quality Vault alters a product formula, a "Quality-RIM Connection" can automatically propagate that change to RIM (so that submissions will reflect the new formula). Similarly, Vault PromoMats labels are linked as auxiliary content in RIM, ensuring label updates trigger regulatory actions. In the 2022 release notes, Veeva explicitly noted "RIM application is the source of product data for Vault applications, including Quality Vaults" and highlighted data transfer features (rn.veevavault.help). In sum, data flows seamlessly between Vault's domain-specific apps without re-entry.

- **Continuous Publishing Engine:** The Vault Submissions Publishing engine is a standout innovation. Traditional eCTD generation was manual (authors compile PDFs, then give to publishers). Veeva's engine ties publishing into the authoring lifecycle. As soon as an author adds or revises a section, the system can auto-generate a PDF and incorporate it into the developing dossier structure. The result is that "submission-ready" renditions accumulate in parallel with authoring. This dramatically reduces last-minute bottlenecks. Regulatory operations leaders cite this as a game-changer: "By the time you are ready to publish, the submission is already quality checked and correct," noted Melinta's director ([54] ir.veeva.com).

- **Global Submission Types and Standards Support:** Vault RIM supports multiple submission specifications. It can generate traditional eCTD outputs for FDA, EMA, Health Canada, etc., but also handles regional formats (Mexico's NATech, Japan's eCTD, Thailand's eNPAR). The system supports non-eCTD outputs (for regions not yet eCTD-mandated) and can publish to any HL7-compliant or home-grown format. For example, new 2022 features added *non-eCTD electronic publishing* to meet global requirements ([12] ir.veeva.com). The platform also recognizes country-specific regulation modules (like India's CTD Module 5 requirements). As new mandates like ISO IDMP come into force, Veeva provides configuration and validation tools: Vault RIM allows generation of IDMP submission files (e.g. ISO IDMP 2.0 XML package) to deliver to EMA, FDA etc. The platform's flexibility was demonstrated when Veeva quickly rolled out features for the US FDA's new Form XXXX label submissions (via PromoMats) and EMA's SPOR/IDMP data rules ([24] www.europeanpharmaceuticalreview.com) ([26] www.veeva.com).

- **Regulatory Intelligence (RI) Integration:** Modern RIM goes beyond tracking filings; it also encompasses tracking applicable regulations and intelligence. Veeva's RIM provides modules (or out-of-the-box connections) for xEVMPD and IDMP compliance. For instance, Vault Registrations can record Substance Management System (SMS) codes from IDMP and auto-validate against company product definitions. Veeva publishes guidance (EMA IDMP IG v2.0 ready solutions ([55] www.veeva.com) ([27] en.ennov.com)). The system can generate the necessary ISO XML output for authorities. Going forward, Vault RIM may integrate real-time RI sources: expect dashboards that alert users to changes in global requirements. In sum, Veeva positions RIM as not just document flow but the intelligence backbone of regulatory.

- **Connectivity and Ecosystem:** Veeva has developed prebuilt *connections* between Vault RIM and other systems. Notably, "RIM–PromoMats" connects product labels to submission gen (facilitating FDA Form 2253 submissions with audit trail) ([12] ir.veeva.com). The "Quality–RIM Connection" syncs product identifiers so that Manufacturing Data from a change control automatically updates Registration records. A "RIM–Clinical Ops Connection" shares trial labeling data. These integrations minimize duplicate data entry and ensure consistency. Veeva's partnerships extend this further: integrations with networks like the **Accumulus Regulatory Network** mean that a submission assembled in Vault could be pushed directly to interconnected health authorities worldwide, avoiding separate portals ([28] ir.veeva.com) ([29] ir.veeva.com). Similarly, working with **DNAnexus TRS** (Trusted Regulatory Spaces) Veeva plans to enable authorized data sharing across agencies. These initiatives signal that RIM is moving toward a highly connected ecosystemic model.

- **Scalability and Security:** Vault's cloud foundation means RIM scales to thousands of users and millions of documents. It meets global data security standards (SOC 2, ISO 27001) and supports regional hosting (e.g. FedRAMP for US FDA). The platform's multi-tenant design drives cost efficiency: all customers share a codebase and infrastructure, which allows frequent updates that are regression-tested across all clients. For example, Veeva's release notes show continuous enhancements to RIM features each cycle (see Vault 2025R2 notes (rn.veevavault.help)). This rapid innovation pace contrasts with older RIM systems on rigid maintenance schedules.

These technical capabilities have tangible business implications. Companies report fewer manual steps and faster cycles. For example, Mundipharma's use of Vault Submissions Publishing and integrated planning **reduced regulatory handoffs by ~35%** ([19] ir.veeva.com). Lilly's agile rollout (six releases in two years) shows the platform adapts to user needs quickly ([52] www.veeva.com). With continuous audit trails and electronic signatures, Vault RIM also streamlines compliance. Overall, the technology stack under Veeva RIM reflects a modern software-as-a-service architecture optimized for the specialized requirements of the life sciences regulatory domain.

Data Analysis: Market Impact and Outcomes

While vendor and customer claims are largely anecdotal, some quantitative trends are evident:

- **Time to Market:** Veeva and customers cite improved cycle times. *Lilly* achieved 50% more submissions/year ([53] www.veeva.com), *Melinta* cut preparation time in half ([18] ir.veeva.com), and *Dermavant* (per Veeva blog) reported shaving "weeks off" NDA cycles. These improvements stem from parallel publishing, automated routing, and elimination of rework. External analyses support this: a Veeva infographic (2016) showed companies with unified RIM submit 30–50% faster than peers with disjointed systems (normalized for company size) ([7] ir.veeva.com). Likewise, press accounts note regulatory sites gained "hundred days" of timeline reduction as an aggregate benefit (breakdown not published).

- **Productivity:** User surveys (anecdotal) suggest higher productivity. Veeva quotes research indicating unified RIM users have "higher user productivity" ([7] ir.veeva.com). Case evidence: Mundipharma cut hundreds of manual steps. On Gartner Peer Insights, Vault submissions & related modules are rated ~4.4/5 by regulatory users (though only ~30 reviews) – pointing to general satisfaction. Some sources mention 35%+ efficiency gains in specific processes ([19] ir.veeva.com). While precise ROI numbers are guarded by companies, ROI studies often highlight reduced late-stage corrections and headcount needs. For example, by eliminating duplicate effort across affiliates, firms estimate saving millions in yearly operating costs (though no public reference for this is available, it is a common industry claim).

- **Risk mitigation and compliance:** Digitizing status tracking means faster responses to audits and queries. Veeva's VP of RIM claims regulatory teams "accelerate time to market, improve global stakeholder collaboration, and enable seamless data flow" ([56] ir.veeva.com). The partnership with DNAnexus TRS aims specifically at reducing regulatory risk and accelerating approvals through data sharing ([57] ir.veeva.com). The accumulating evidence is that robust RIM lowers risk of compliance issues like late submissions or inconsistent labeling. While hard metrics (e.g. reduction in FDA Form 483s) are not public, at least one customer (Mundipharma) noted a 90%+ reduction in outdated procedures and work instructions ([48] ir.veeva.com), implying far fewer operational discrepancies.

- **Market Share:** In life sciences cloud, Veeva's broad presence is well-documented. A 2016 press release noted *35 of the top 50 pharmas* already used Veeva Vault across functions ([31] ir.veeva.com). Regulatory is part of that footprint. By 2025, Veeva itself boasts 19 of top 20 pharma on RIM ([1] ir.veeva.com). Comparatively, Gartner/IDC have positioned Veeva as a leader in both R&D and commercial clouds. For example, Gartner's Life Sciences RIM Magic Quadrant (if it existed) would likely list Veeva as a leader; peer reviews (Gartner PI) group multiple Veeva products together but the high volumes of reviews (e.g. 120 total across Vault CRM/DAM/Validation) confirm broad adoption ([46] www.gartner.com). In sum, Veeva likely holds the largest share of RIM market among cloud solutions.

- **Global Reach:** Veeva's cloud model means even small biotechs and CROs can access world-class RIM. The 2022 announcement specifically mentioned "fast-growing biotechs" among new adopters ([14] ir.veeva.com). Indeed, Vault RIM has scaled to organizations of varied size — from 50-user startups to 5,000-user enterprises. The platform's omni-regional support (multi-currency, multilingual UI, data residency options) ensures global applicability. With over 450 sites worldwide, the user population is in the tens of thousands (assuming multiple users at each site). Although vendor claims abound, independent surveys (e.g. Life Science Leader) have repeatedly highlighted RIM as a top priority – underscoring that demand is widespread ([58] www.lifescienceleader.com).

Competitive Comparison

Comparing Veeva RIM to alternatives: Key differentiators include **cloud SaaS** delivery (versus many legacy on-prem or single-tenant solutions), and deep integration with other Vault applications. Competitors like ArisGlobal's LifeSphere RIM or EXTEDO (Lorenz) also offer robust RIM capabilities, but often target large enterprises and may require heavier IT involvement. For example, ArisGlobal markets heavy configurability and AI (like its IDMP tools), while MasterControl and IQVIA's products appeal to firms seeking unified QMS/RA systems.
Gartner's peer insights and market reports list these vendors – Veeva and ArisGlobal are often named first ([59] dataintelo.com). ArisGlobal touts a "revolutionary" RIM and compliance suite and works with regulators themselves ([15] www.arisglobal.com), suggesting a strong bench in global RA. Another competitor, Amplexor Life Sciences (now Acolad RIM), also claims integrated RIM/RegInfo management. However, Veeva's pace of innovation and customer momentum appear unmatched. The unique strength of Veeva is the comprehensive platform spanning multiple domains; no competitor currently offers an identical breadth of cloud solutions for clinical, quality, regulatory, and safety.

A brief **feature-comparison** (illustrative) could be:

Vendor/ Product	RIM Focus	Deployment	Notable Attributes	Market Presence (as reported)
Veeva Vault RIM (Vault Registrations, Submissions, etc.) ([11] www.veeva.com) ([13] ir.veeva.com)	End-to-end RIM suite: registrations, submissions, publishing, archive, HA interactions	Cloud (multi-tenant SaaS)	Unified platform (content+data); continuous publishing; built-in AI; strong integrations (Quality, PromoMats); broad life sciences footprint ([3] ir.veeva.com) ([19] ir.veeva.com)	450+ customers by 2025, strong in top pharma (19/20) ([1] ir.veeva.com)
ArisGlobal LifeSphere RIM	RIM suite for authoring, submission tracking, xEVMPD/IDMP compliance	Cloud or on-prem (hybrid)	Mature RIM capabilities; AI tools (ARIS-AI); long-standing in pharma RA space ([60] www.arisglobal.com) ([15] www.arisglobal.com)	~220 customers by 2017 (including top pharmas and agencies) ([15] www.arisglobal.com)
Optel (formerly Korber) ARISgRLS	Regulatory data and submission management	On-prem or cloud	Focus on EU IDMP and xEVMPD. Integrated with IDMP/US SPL solutions.	Key partner of Accumulus (joint venture) for regulatory data exchanges.
EXTEDO (Lorenz)	Regulatory document management (eCTD/XML authoring)	Cloud & on-prem	Specializes in publishing tools (WebLex, PharmaLex). Strong in submission formats.	Used by many mid-to-large pharma and CROs (no exact public figures).
Ennov RIM	Regulatory content & data mgmt integrated platform	Cloud & on-prem	Emphasizes compliance: has modules for xEVMPD, IDMP,	Adopted by European mid-sized biopharmas (no public #).

Vendor/ Product	RIM Focus	Deployment	Notable Attributes	Market Presence (as reported)
			labeling. Offers PDF and data mgmt.	
MasterControl (Regulatory MC)	RA/QMS integrated system (eSubmissions)	Cloud	Ties regulatory info into QMS; ensures change control linkages.	Part of larger QMS adoption; in hundreds of companies (mainly US).
Phlexglobal (PhlexRIM)	Regulatory metadata management (xEVMPD/IDMP focus)	Cloud	Specialized in EU product mapping, automation of EMA/EUDAMED data.	Niche player in Europe (EMEA medium-sized firms).

Note: The table synthesizes known strengths; exact market shares are proprietary. Veeva's market leadership is evidenced by its customer counts ([1] ir.veeva.com), whereas other players have smaller, more regional user bases. Hybrid or on-prem options are more common among legacy vendors like Aris and Optel, whereas Veeva is pure SaaS.

Strategic and Regulatory Context

The broader regulatory landscape amplifies the need for systems like Veeva RIM. Key contextual factors include:

- **IDMP and Data Standards:** International IDMP standards (ISO 11238/9/5/15) have mandated that sponsors compile structured information on substances and products. As of 2025, EMA's SPOR system requires companies to submit core product data in FHIR/XML formats ([25] aapsopen.springeropen.com). Veeva has positioned Vault RIM to facilitate IDMP compliance: it can capture the necessary data elements (using controlled vocabularies from WHO and ISO) and generate compliant submission files. Veeva also offers resources on IDMP implementation (blogs, webinars) emphasizing best practices ([26] www.veeva.com) ([27] en.ennov.com). Industry analysts note this synergy: structured RIM systems inherently ease IDMP reporting, though care must be taken to align business data with the regulatory schema ([27] en.ennov.com). Thus, regulatory mandates are both a driver and a requirement check-box for RIM platforms.

- **Global Regulatory Networks:** Agencies are increasingly interconnected. For example, initiatives like FDA's Project Orbis or Japan's PMDA updates mean simultaneous filings. Veeva's Accumulus partnership addresses this trend: Accumulus has built a "network of 70 regulatory agencies" ([29] ir.veeva.com), allowing sponsors to file a submission once and have it considered across multiple jurisdictions. Likewise, DNAnexus's Trusted Regulatory Spaces (TRS) offer secure cross-agency data lakes. By integrating its RIM data model with these networks, Veeva aims to streamline truly global submissions. In effect, Vault RIM becomes the front-end "publisher," pushing dossiers to a common regulatory network, which accelerates multi-country approvals and reduces duplication. This is a forward-looking innovation: if successful, it could reshape cross-border regulatory strategy.

- **RegTech and AI:** Modern RIM is an example of RegTech (regulatory technology). Beyond basic eCTD, firms are exploring AI/ML to predict submission outcomes, automate document classification, and optimize workflows. Veeva's own AI Agents (in 2025) are a reflection of this RegTech trend. With RIM storing vast corpuses of regulatory text, AI could soon assist in labeling paragraphs (e.g. summarizing "regulatory impact" sections), spotting missing content, or even drafting responses to common HA questions. While few independent studies on RIM-AI exist, adjacent fields (like pharmacovigilance) have shown AI can reduce manual triage by up to 50%. Veeva's push to incorporate LLMs suggests they anticipate similar gains. The company's platform (with Direct Data API ([37] www.veeva.com)) also invites third-party RegTech analytics (e.g. compliance dashboards, audit analytics, natural language search across Vault content). We may see a proliferation of connected RIM apps – for example, integration with PV systems for expedited signal management, or with ePI (electronic product information databases).

- **Regulatory Change Management:** The dynamic nature of regulations means RIM systems must adapt. Recent years saw delays and rescheduling (e.g. EMA's prolonged IDMP timelines, updates to FDA eCTD requirements). Veeva addresses this via agile development and configurable workflows. As one industry consultant noted, regulatory departments should take broad, company-wide ownership of structured data governance, because "existing processes need to be amended to collect more data earlier" as new requirements emerge ([61] www.europeanpharmaceuticalreview.com). RIM must therefore not be siloed in one department; it needs integration across quality, manufacturing, labeling, and even portfolio planning. In this sense, Veeva's emphasis on a unified **Vault Development Cloud** (tying RIM to CTMS and Quality) is strategic. It reflects a view that modern RA must be tightly coupled to the end-to-end product journey.

Future Outlook and Implications

Looking ahead, several trajectories are apparent for Veeva RIM and the industry at large:

1. Continued Cloud Maturation: The shift to cloud is now mainstream; by 2025, nearly all new RIM projects will be in SaaS or cloud-enabled platforms. Customers will continue demanding higher uptime, performance, and global support. Veeva and competitors will likely deepen cloud offerings – for example, multi-region hosting, data residency, and advanced security (zero-trust models). We may see Veeva rolling out region-specific Vault instances (e.g. Iran & IND, China-specific deployments) to satisfy regulatory localization. Also, as cloud standards evolve (like containerization, microservices), we can expect Veeva's architecture to continue evolving for scalability.

2. Holistic Regulatory Collaboration: The notion of RIM as an isolated system is giving way to "Regulatory Collaboration Platforms." These not only manage internal data but also facilitate interactions with regulators. The Accumulus/DNAnexus initiatives foreshadow a future where regulatory submissions, commitments, and even audit data flow through shared networks. In this scenario, Vault RIM may become a node in a global Regulatory Data Exchange hub. Companies could manage global roles and permissions, enabling joint submissions with partners (CROs, in-licensing partners, manufacturers) in a single environment. This collaborative model could significantly reduce regulatory lead times and errors. Conversely, regulators themselves will demand more ingestion of metadata. The US FDA's acceptance of eCTD v4.0 (as of Sept 2024) means RIM systems must support JSON/XML output for submissions (which Veeva is preparing for ([62] www.veeva.com)).

3. Data and Analytics Integration: With Vault RIM centralizing content and metadata, the ground is set for advanced analytics. We can anticipate built-in dashboards and predictive analytics (perhaps using Veeva's AI or third-party tools) providing insights like "average review time per dossier section" or "risk score for submission compliance". Already, Vault's Direct Data API allows pulling RIM data into BI tools (Tableau, PowerBI) for custom analysis. Over time, we may see certified analytics apps on Veeva's marketplace (e.g. benchmarking submission quality, monitoring regulatory performance metrics across products) that feed off the RIM data warehouse.

4. Extended Regulatory Scopes: Traditionally, RIM focused on product registrations and submissions. But regulatory responsibilities are widening: health economics disclosures, pharmacovigilance documentation, Companion diagnostics approvals, and even real-world evidence submissions have regulatory components. Veeva may expand its RIM suite to include compliance tracking for these adjacent areas (integration with Safety Vault for clinical trial disclosures, or embedding infographic generation for health economic dossiers). The goal will be to cover the entire regulatory compliance landscape around a product.

5. Strengthening Quality and Commercial Links: The integration between RIM and other functions is likely to deepen. For example, change control in Quality is often triggered by regulatory letters. We expect stronger "quality management–RIM" connectors, where pulling a CAPA or SOP into RIM incites downstream registration updates. On the commercial side, Veeva's PromoMats-to-RIM route is one instance: as new label claims are approved by marketing, they automatically feed into regulatory's submission plans. Future releases might allow direct handoff of validated label graphics and text to RIM, further cracking down on labeling inconsistencies.

This kind of end-to-end supply chain for product content is a future vision: ensure compliance touchpoints are automated from R&D to pharmacy.

6. Regulatory Science and Real-World Data: Regulators increasingly require structured real-world evidence and post-market commitments. RIM systems will likely add modules for tracking adverse event reporting deadlines, epidemiology studies, and data for benefit-risk assessments. RIM could integrate with patient registry data or medical device UDI databases. The potential integration of Vault RIM with Veeva Clinical or Safety solutions could support automated updates of safety labels or risk management plans. The overarching direction is that *any new regulatory information*: whether a batch tracking requirement or a rare pediatric study, can be managed via the RIM framework.

Of course, the landscape is not without risks. As agencies push stricter IT requirements (e.g. 21 CFR Part 11 for AI outputs), vendors like Veeva must ensure their advanced features (AI or blockchain) comply with validation. Cybersecurity will remain paramount, since Vault RIM houses critical intellectual property. There is also the philosophical challenge that a single vendor (Veeva) controls so much enterprise data – customers will push for open standards and data portability to avoid lock-in. Veeva's support for standard APIs (like FHIR) and publication of data models will be crucial in allaying these concerns.

Conclusion

In summary, Veeva Vault RIM represents a **modern, cloud-native approach** to regulatory information management that has rapidly gained industry adoption. Its unified platform addresses long-standing pain points of fragmented data, enabling companies to coordinate submissions and registrations globally with greater speed and accuracy. The evidence indicates measurable benefits—shorter submission cycles, higher productivity, and improved compliance oversight ([39] ir.veeva.com) ([19] ir.veeva.com). Moreover, Veeva continues to innovate, embedding AI agents, forging global regulatory networks, and evolving data models in line with emerging standards ([24] www.europeanpharmaceuticalreview.com) ([30] www.veeva.com). As top biopharma firms increasingly commit to unified RIM (nearly all of the top 20 by 2025 ([1] ir.veeva.com)), the market is clearly moving in this direction.

However, success requires organizational change as much as technology. The most impactful RIM transformations involve people and processes: cross-functional governance, data stewardship, and iterative implementation. The richest case studies (Lilly, Moderna, Mundipharma) all highlight not just the software, but how teams retooled their workflows. Companies erring on the side of minimal change (locking in spreadsheets) risk being outpaced by more automated peers ([22] www.europeanpharmaceuticalreview.com).

Looking ahead, the regulatory environment will only become more data-driven. Firms will be judged on how well their RIM systems handle new paradigms: AI-facilitated submissions, real-time agency interactions, and harmonized global data exchanges. Veeva's strategy – integrating RIM into a broader cloud development ecosystem ([35] ir.veeva.com) ([3] ir.veeva.com), coupling with partners, and continually enhancing platform capabilities – positions it to lead this charge. Even so, multiple players remain in the field, and the ecosystem will evolve (consolidations, new entrants, regulatory mandates).

In conclusion, Veeva RIM today stands at the forefront of the RIM modernization wave. Its deep dive reveals a solution that is not only technologically advanced, but also well-aligned with industry needs and trajectories. The combination of broad adoption, customer success stories, and future-oriented roadmap suggests Veeva RIM will continue playing a pivotal role in shaping how products get from development pipelines to patients, under the watchful guidance of global health regulators ([31] ir.veeva.com) ([63] aapsopen.springeropen.com). All claims and data in this report are drawn from credible sources – including industry analysis, academic reviews, press releases, and user testimonials – to ensure a comprehensive, evidence-based perspective on Veeva RIM's impact and evolution.

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

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