Veeva Label Concept Tracking: A Guide to Replacing Spreadsheets

By Adrien Laurent, CEO at IntuitionLabs • 11/24/2025 • 30 min read

veeva vault rim | label concept tracking | pharmaceutical labeling | ccds management | labeling compliance | deviation management | country tracker spreadsheet | regulatory affairs

Executive Summary

Global pharmaceutical companies face daunting challenges in maintaining **labeling compliance** across dozens of countries and hundreds of local markets. Historically, many organizations have relied on **ad hoc "country tracker" spreadsheets** to log updates to a product's Company Core Data Sheet (CCDS) and local labels. However, these manual approaches are error-prone, resource-intensive, and difficult to scale. For example, Moderna's labeling team found that monthly updates to the CCDS—multiplied across every local market—became "too unwieldy for a spreadsheet" ([1] www.veeva.com). Errors in labeling are common and can have severe consequences: one industry survey found that *"69% [of respondents] blamed human error for mistakes in label printing"* ([2] pharmaphorum.com), and another noted that disconnected, manual systems "make it extremely difficult to update and maintain label databases" ([3] www.rdworldonline.com). In short, relying on spreadsheets is widely seen as a "fast track to regulatory non-compliance" ([4] www.chromatographyonline.com).

To address this, Veeva Vault RIM has introduced **Label Concept Tracking and Deviation Management**, a structured, automated feature set designed to replace manual trackers and provide a single source of truth for labeling changes. Unlike spreadsheets, this solution embeds label updates within the regulatory lifecycle: when a **Labeling Event** (e.g. a CCDS revision or Safety change) is created in Vault RIM, users specify new core data sheet content and expected timelines. Vault then **automatically generates country-specific activities** and tracks any **local deviations** (when a health authority rejects or alters the proposed label changes). All changes and timelines – both global and local – become visible in real time in the system (regulatory.veevavault.help) ([5] www.veeva.com).

This report provides an in-depth analysis of Veeva's Label Concept Tracking feature, placing it in historical context and examining its design, functionality, and benefits. We review how global regulatory teams traditionally managed labeling (often via spreadsheets and fragmented tools ([6] www.astrixinc.com) ([7] www.acolad.com)), the pitfalls of those methods (audit failures, manual errors ([4] www.chromatographyonline.com) ([2] pharmaphorum.com)), and the evolution toward digital RIM solutions. We present the technical underpinnings of Veeva's solution – including new data objects and automation rules introduced in recent releases (rn.veevavault.help) (regulatory.veevavault.help) – and evaluate its impact through real-world examples. The report includes case studies (notably Moderna's implementation ([8] www.veeva.com) ([5] www.veeva.com)), data-driven comparisons of manual vs. automated approaches, and discussion of broader implications for regulatory strategy and technology adoption. All claims are supported by credible sources and data where available.

Introduction and Background

Pharmaceutical **labeling** – the information (text, safety warnings, artwork, etc.) that accompanies a drug product – is **critical for patient safety and regulatory compliance**. Globally, every marketed drug has a *Company Core Data Sheet (CCDS)* (also known as a: Company Core Data Sheet, Reference Safety Information, or Master Label) that represents the manufacturer's official product information. National and local labels are then derived from the CCDS to meet each country's language and regulatory requirements ([9] pmc.ncbi.nlm.nih.gov) ([7] www.acolad.com). By design, *local labels often differ from the CCDS*, since individual health authorities may mandate additions or modifications (such as country-specific sections or translations) ([9] pmc.ncbi.nlm.nih.gov) ([7] www.acolad.com). For example, an international label might add extra safety data required only in certain countries, or the wording might be altered to reflect local medical practice.

Maintaining this global labeling alignment has become increasingly complex. Large companies may have products approved in **50–100+ countries**, each with its own regulatory authority, language, and timeline ([10] www.acolad.com) ([11] www.veeva.com). Managing these variations often involves dozens of label versions and

translation files. In one extensive audit, a Fortune 100 drugmaker collected labels from **≈100 countries in 50 languages** to check for local deviations ([10] www.acolad.com). Local translators and affiliates (often decentralized) can introduce discrepancies: "local translators or authors might misinterpret the company's prime reference document (CCDS)… or add extra elements because local HAs require specific data" ([7] www.acolad.com). The result: a mosaic of labeling across markets that must remain consistent with the global core, yet compliant with each region's rules.

Historically, many regulatory teams have tackled this by **manual processes**. The CCDS is updated centrally, then distributed (often via email or tracking systems) to affiliate/regional teams. Each affiliate then produces its local label. Teams would often maintain a **"Country Tracker" spreadsheet** – an Excel or similar file listing each market, label version numbers, due dates, status of submissions, and deviations – to monitor progress. One consulting case noted that pre-digital Reg Affairs groups used *"disparate sets of tools… storing information on multiple SharePoint locations… There were also quite a few spreadsheets."* ([6] www.astrixinc.com). These trackers are flexible but brittle: errors in manual entry, version control issues, and missing data are common. Indeed, industry observers warn that spreadsheets in regulated processes are a recipe for mistakes – one columnist declared spreadsheets a *"fast track to regulatory non-compliance"* ([4] www.chromatographyonline.com) – and any labeling error has potentially grave outcomes.

In parallel, regulatory frameworks have evolved.The ICH and national bodies have provided guidelines for label content (e.g. ICH E3, US FDA-SOP, EU SmPC formats), and electronic submissions (eCTD) have become the norm. Agencies encourage global consistency of safety information, but do not mandate a single harmonized label template across companies ([12] pmc.ncbi.nlm.nih.gov). Indeed, a recent survey highlights that *no common guidelines exist for a "Company Core Data Sheet" structure* ([12] pmc.ncbi.nlm.nih.gov); each manufacturer chooses its own template. The EMA even attempted a centralized "Product Information Management (PIM)" system to streamline CCDS updates, but the project failed to launch ([13] pmc.ncbi.nlm.nih.gov). As a result, many companies still grapple with manual synchronizations of label content post-approval.

Given these challenges, the **need for integrated label management** has become widely recognized. Industry surveys emphasize that disconnected systems severely hamper updating label databases ([3] www.rdworldonline.com), and that compliance considerations drive interest in unified solutions ([14] www.rdworldonline.com). The Veeva Vault Regulatory Information Management (RIM) platform is one modern approach. In 2021, Veeva introduced **Label Concept & Deviation Tracking** within Vault RIM, specifically to address the global labeling maze by embedding tracking of label changes into the regulatory workflow (rn.veevavault.help) (regulatory.veevavault.help). This report explores that feature in depth, contrasting it with legacy methods and situating it within the broader regulatory technology landscape.

Traditional Label Tracking Methods and Limitations

Before solutions like Veeva's feature, companies relied on **manual trackers, spreadsheets, and siloed tools** for label updates. A typical spreadsheet ("Country Tracker") might have hundreds of rows (one per country or label version) and columns for "Original Request", "Local Variation", "Due Date", "Filing Status", etc. Regulatory project teams would update these by hand as events progressed. While low-tech, spreadsheets are prone to **human error**. Incomplete or inconsistent data entry can easily occur when multiple users edit a file. Spreadsheets lack built-in audit trails and version control: it is hard to know who updated a cell or to reconstruct historical changes without meticulous discipline. **Regulatory overhead and compliance audits** suffer: inspectors require documented evidence of label histories and deviations, which is difficult when scattered across private files.

Furthermore, spreadsheets **do not scale**. As one Veeva customer noted, what was manageable with a few markets quickly exploded. Moderna's Senior Director of Global Labeling reported that with the COVID-19 vaccine rollout, *"Local labels had to be customized, and the number of variations we needed to track snowballed really quickly."* Monthly CCDS updates triggered **cascading label changes** worldwide, and ensuring every local update was captured "became too unwieldy for a spreadsheet" ([1] www.veeva.com). In another example, a global company auditing its labels found that it had lost centralized visibility: *"we had lost sight of the state of the local labeling of its products in various locations and did not know what was being submitted to local health authorities"* ([15] www.acolad.com). This fragmentation means that vital information (e.g. a rationale for a local deviation) may not be captured consistently.

Manual processes also introduce delays. Teams must email spreadsheets back and forth (leading to synchronization issues), or coordinate status meetings to update trackers. Timelines are tracked as dates in cells rather than dynamic fields, making it hard to enforce deadlines or propagate changes (for example, if a core due date slips, manual re-calculation is needed). In short, **spreadsheets severely limit visibility and control**. As one industry study put it, disconnected label systems and spreadsheets leave companies "missing out on the productivity and quality gains" of integrated management ([3] www.rdworldonline.com). The cost of errors is high: surveys show frequent labeling QC issues, with 20% of companies reporting monthly errors in clinical labels, most blamed on human mistakes ([16] pharmaphorum.com) ([2] pharmaphorum.com).

Key limitations of manual "Country Trackers" include:

- **Data Entry Errors**: Manual input lacks validation, so mismatches (e.g. wrong label version numbers) can occur unchecked ([4] www.chromatographyonline.com).
- **Lack of Audit Trails**: Spreadsheets don't record which user changed what when. Demonstrating compliance history during inspections requires extra effort.
- **Poor Integration**: Multi-department coordination (Labeling, Quality, CMC, affiliates) is ad hoc. For example, a spreadsheet does not connect directly to the CCDS or regulatory objectives. This puts compliance at risk if a local change is overlooked ([4] www.chromatographyonline.com) ([2] pharmaphorum.com).
- **Scalability Issues**: Tracking dozens of countries and hundreds of label versions becomes "unwieldy" ([1] www.veeva.com). Updating each entry amid frequent core changes is laborious.
- **Visibility and Reporting**: Manual tracker data must be extracted/charts manually to report to management or auditors; real-time dashboards are impossible without re-keyed summaries.

As a result of these pain points, **technology-driven label management** has been increasingly sought. In the labeling industry, only a minority of firms claim full digital integration. One survey found just *14% of pharma manufacturers had fully integrated label systems*, with 34% still using disconnected solutions that complicate database updates ([3] www.rdworldonline.com). Compliance requirements (e.g. GS1, FMD, etc.) and the complexity of modern global portfolios demand better tools. Veeva's Label Concept Tracking aims to fill this gap by migrating label change tracking from spreadsheets into a unified RIM platform.

Veeva Vault RIM: Label Concept & Deviation Tracking

To overcome manual limitations, **Veeva Vault RIM** (Regulatory Information Management) has introduced a layered feature set called *Label Concept and Deviation Tracking*. This capability treats labeling updates as first-class entities within the regulatory workflow. Technically, as of Vault RIM version 21R3 (2021), Veeva **extended the data model** with new objects and fields dedicated to labeling change management (rn.veevavault.help). These include:

- **Labeling Concept** (`labeling_concept__v`): Represents a proposed change to a specific section of the CCDS (e.g. a text amendment in the Safety section).
- **Labeling Deviation** (`labeling_deviation__v`) and **Activity Labeling Deviation** (`activity_labeling_deviation__v`): Capture instances where a local market's accepted label differs from the original CCDS proposal (i.e. deviations).
- New fields on **Event** and **Activity** objects: For example, *Labeling Impact* (flag), *Resulting Local Label*, *Safety Category*, *Trigger Date*, *Due Date*, etc. (rn.veevavault.help).

With these additions, RIM Admins can fully configure an **end-to-end label change process** inside Vault. Figure 1 (hypothetical) illustrates the relationships:

- A **Labeling Event** (a type of regulatory event) is created in Vault to reflect a major change in the CCDS (e.g. new safety data). The user marks *Labeling Impact = Yes*, which exposes additional fields like *CCDS to be Updated*, *Safety Category*, *Trigger Date*, and *Due Date* (regulatory.veevavault.help).
- Within the Event record, the user can define one or more **Labeling Concepts** under a "Labeling Concepts" section. Each concept details *which CCDS section* is changing and the *new text* (or reference to an attached document snippet). For example, a concept might state: "Section 4.5: add new phrase about liver enzyme monitoring".
- The system can then **mass-create Activities** for each market (dependent on product registrations). Each Activity is a task for a local affiliate to implement the label change. When an Activity is created (manually or automatically via impact assessment (regulatory.veevavault.help)), Vault copies the parent Event's Labeling Concepts into the Activity (so each market sees the same proposed changes) (regulatory.veevavault.help).
- Local affiliates review the proposed label change for their country. They update the Activity with local-specific fields (e.g. actual *Local Label* version, *local due date*, submission status, etc.). If the local health authority **requests a difference** from the core proposal, users create a **Labeling Deviation** record linked to that Activity. This Deviation describes *how* the country's approved text diverges from the CCDS (e.g. "Country A's label will say 'blue-green hair' instead of 'blue hair'" in safety info). Vault can be configured to **auto-generate deviations** when Activities or concepts are rejected (regulatory.veevavault.help).
- The platform then **cascades deviations** as needed: for example, if a deviation is marked "accepted for dependent countries", Vault can automatically apply that status and create related deviation records for all allied markets (regulatory.veevavault.help).

All this work is captured in Vault records, with audit trails and life-cycle controls. Activities and Deviations become searchable and reportable. Because Vault is a single platform, managers can run global dashboards of status and compliance, rather than emailing Excel updates. Key automation features include: copying concepts to activities, auto-calculating due dates based on *Trigger Date* and classification, and auto-creating deviation entries when an action is rejected (regulatory.veevavault.help) (regulatory.veevavault.help). Vault even allows splitting or merging of activities & concepts if markets synchronize changes (regulatory.veevavault.help).

This approach replaces the spreadsheet with structured data:

- **Central Data Model** – All label-change information lives in Vault as records (Events, Concepts, Activities, Deviations) (regulatory.veevavault.help) (rn.veevavault.help). Nothing is "hidden" in a file.
- **Computed Fields & Automation** – Vault calculates deadlines and safety class, and can auto-copy changes to relevant partners. Manual date fudge and email reminders are largely eliminated (regulatory.veevavault.help) (regulatory.veevavault.help).
- **Global and Local Visibility** – Users can view, in one place, the full lineage of a label change: starting from the original CCDS update (Event and Concepts) through each country's response (Activity and Deviations). For example, one customer noted: *"Veeva RIM automatically generates an activity for every impacted*

market, eliminating the need to compile local label deviations by hand… [and] makes the changes and timelines visible globally and locally" ([5] www.veeva.com).

- **Audit Readiness** – Because Vault stores every step, regulatory teams can generate comprehensive reports at audit time. According to Moderna's leader, they can now *"export the latest status information from Veeva RIM to share with senior managers and inspectors"* ([17] www.veeva.com).

Crucially, "Label Concept Tracking" ties into the broader RIM plan. It can be linked to Regulatory Objectives (for local-initiated changes) and Content Plans. In Vault's Create & Manage Event wizard, Concepts and related Change Items can be bundled into a cohesive process (regulatory.veevavault.help). All required permissions are controlled by Vault security. In short, Veeva has built a **digital replacement for Excel trackers** that enforces process and improves data integrity.

Aspect	Manual Tracker (Spreadsheet)	Veeva Label Concept Tracking (Vault RIM)
Data Entry	Entered manually in rows/columns (one country per row). Prone to typos, missing updates.	Captured in Vault records (Events, Activities). Standard fields guide input (e.g. Safety Category, Due Date).
Task Assignment	Users must email spreadsheets or hold meetings to alert affiliates of tasks.	Vault automatically generates an *Activity* for each affected country, assigned to local teams ([5] www.veeva.com).
Timeline Tracking	Due dates are static spreadsheet cells. Managing changes (e.g. extensions) is manual.	Vault computes dates based on *Trigger Date* and process, and updates if dependencies change (regulatory.veevavault.help).
Change Communication	Relies on attachments or notes in the spreadsheet. Difficult to track version differences.	Labeling Concepts capture proposed text changes per section; comments and statuses are logged in Vault.
Deviation Handling	Deviations logged manually, often in free-text notes per country. Hard to aggregate or analyze.	Deviations are discrete Vault objects linked to specific Activities, so all non-conformances are tracked systematically (regulatory.veevavault.help).
Visibility & Reporting	Managers must collate data (e.g. pivot tables, email reports) to see overall status.	Real-time dashboards and views in Vault show global vs. local progress. Reports can be pulled instantly.
Audit and Compliance	No built-in audit trail; relies on email threads and manual archives. High risk of missing documentation.	Full audit trail (who changed what when) in Vault. Complete documentation of labeling decisions is retained.
Scalability	Works for a few countries; becomes unwieldy as more markets are added ([1] www.veeva.com).	Designed for many markets; can handle dozens of countries automatically (regulatory.veevavault.help). Easily adjusts to expanding portfolios.

Configuration and Workflow in Veeva

Implementing Label Concept Tracking in Vault requires configuration by administrators, but it leverages standard RIM workflow constructs. In practice, companies configure certain event and workflow types as "Labeling Events". This involves adding the **Labeling Impact** check-box to the Event page layout (so that marking an event as having labeling impact triggers the feature) (regulatory.veevavault.help). The related *Regulatory Objective* object (used for safety signals or locally-initiated changes) also gains labeling fields (e.g. *Corresponding CCDS*, *Resulting Local Label*) (regulatory.veevavault.help). Once enabled, the process flows as follows:

1. **Create Labeling Event or Objective:** A global regulatory team creates a new Event record when planning a CCDS update (e.g. after a safety review). They mark *Labeling Impact = Yes* and populate metadata (safety category, trigger/due dates). Optionally, they attach the new CCDS document versions (regulatory.veevavault.help). If the change originated in a local market, they might instead flag a Regulatory Objective with *Labeling Impact*.

2. **Define Labeling Concepts:** In the Event record, a "Labeling Concepts" section allows the user to enter one or more proposed changes. Each concept is essentially an instruction tied to a specific CCDS section. For example, a concept could specify "Section 2.1, add new contraindication". These are stored as separate Vault objects, each carrying the safety class and content. The system automatically maintains the Event's *Safety Category* based on the highest category among its concepts (regulatory.veevavault.help).

3. **Generate Local Activities:** After finalizing the concepts, the admin triggers an *impact assessment* or the system does it automatically. Vault then creates an **Activity** for each product-country combination that needs the update (derived from product registrations). Activities inherit the Labeling Concepts from the parent Event (regulatory.veevavault.help). If many markets share requirements, Vault can be configured to skip duplicate creation (e.g. one concept may apply to multiple countries, but could be shared). Each Activity is assigned to the local regulatory affiliate, with its own due date (which can initially copy from the Event but is editable by local teams).

4. **Local Execution & Deviation Capture:** Local teams use the Activity record to plan their submissions. They enter their actual *Local Label* documents and notes. If a health authority **requests a change** from the core proposal, the affiliate uses the Activity's related *Labeling Deviation* object to record it. For instance, if Country X will omit a bullet or add an extra sentence, the deviation entry specifies the "Difference to CCDS" and reason. Crucially, Vault can automate creating deviations: if an Activity reaches a "Rejected" lifecycle state, it auto-creates a deviation record (regulatory.veevavault.help). This ensures no deviation is missed.

5. **Cascading and Roll-Up:** If a deviation is approved for dependent markets (e.g., a block of subsidiaries), Veeva cascades it. The Deviation object can be flagged "Accepted for Dependent Countries", prompting Vault to copy that record to all related Activities and mark them accordingly (regulatory.veevavault.help). This avoids repetitive entry and keeps countries in sync on a shared local decision. Meanwhile, any change in an affiliate's status (approved, amended, etc.) flows into summary views. Managers can roll up data: for example, Vault can compute the earliest *Lead Market Due Date* and cascade deadlines appropriately (regulatory.veevavault.help).

6. **Reporting and Dashboards:** All the data lives in Vault's regulatory module. Users can create custom lists, reports, or dashboards to track the status of Events, Activities, and Deviations. This can replace any manual status meeting; for example, Moderna's team "exported the latest status information from Veeva RIM to share with senior managers and inspectors" ([17] www.veeva.com). By linking to Vault Documents (the updated CCDS, local labels, etc.), the system also preserves a clear audit trail of exactly what text changed where.

The configuration is flexible: Veeva provides **Lifecycle states** for Concepts and Deviations (e.g. "Proposed", "Accepted", "Rejected"). Admins can customize which state transitions trigger automated actions (regulatory.veevavault.help). For instance, the system can auto-name records and assign stages based on an affiliate's decision. For organizations with complex affiliate networks, the dev module supports **dependent country hierarchies** (so that a decision by a lead market can lock in changes for its satellites) (regulatory.veevavault.help). All standard Vault security and reporting rules apply, so only authorized users see or edit labeling data.

In summary, Label Concept Tracking turns regulatory labeling into a **data-centric process**. All inputs (CCDS versions, local labels, deviations) are Vault records. Workflows are enforced with life-cycles. Redundant data entry is minimized by automation. And because everything is integrated into the RIM system, quality controls (e.g. checks for missing concepts, compliance with global core) become easier.

Data Analysis and Comparative Evidence

Transitioning from spreadsheets to an integrated solution yields measurable improvements. While public statistics are limited, internal case data and surveys illuminate the impact:

- **Case Study – Moderna (COVID-19 vaccine):** Before Vault RIM Labeling, Moderna's team updated hundreds of labels via spreadsheets. After three months of configuring the new feature, they saw dramatic gains. Vault RIM *"automatically generates an activity for every impacted market, eliminating the need to compile local label deviations by hand"* ([5] www.veeva.com). The new process allowed them to manage *hundreds of label versions* in one place ([11] www.veeva.com). Productivity increased – one manager noted it *"saved time and made [my] life a whole lot easier"* ([17] www.veeva.com). Crucially, compliance oversight improved: instead of searching spreadsheets during audits, the team now had real-time status and could demonstrate controls to regulators. By late 2022, Veeva RIM supported Moderna's global portfolio in 28 countries (plus the EU), with continuous visibility into *"every label change and cutover date, all in one place."* ([11] www.veeva.com).

- **Case Study – Labeling Audit by Acolad:** In a separate example, a large pharma undertook a massive retrospective labeling audit (with Acolad) due to fears of local non-compliance ([15] www.acolad.com). They had to catalog labels across ~100 countries (50 languages) and found hundreds of discrepancies ([15] www.acolad.com) ([10] www.acolad.com). The manual effort took 18 months, 200 people, and only then did they centralize the findings. With a system like Vault's, such an audit might have been unnecessary because discrepancies would have been captured in real time. The audit's scale is summarized in Table 2 below.

Parameter	Value (Acolad Audit)
Countries reviewed	~100 ([10] www.acolad.com)
Languages covered	~50 ([10] www.acolad.com)
Local label documents reviewed	21,000 (artwork files) ([18] www.acolad.com)
Personnel involved	200 specialists (linguists & assessors)
Duration	18 months ([10] www.acolad.com)

Table 2: Scope of a global labeling audit conducted by a Fortune 100 pharma (source: Acolad) ([10] www.acolad.com) ([18] www.acolad.com).

The sheer size of this effort underscores the complexity Vault RIM targets. The integrated system can handle similarly large portfolios without separate teams pulling data.

- **Industry Surveys:** Broader data backs up these benefits. A NiceLabel/Pharmaceutical Manufacturing survey found that 80% of pharma firms cite **compliance** as the #1 driver for investing in label management technology ([14] www.rdworldonline.com). Meanwhile, only 14% had fully integrated labeling systems; most (over 30%) still juggled separate systems, hampering updates ([3] www.rdworldonline.com). Another survey of clinical labeling errors noted that human mistakes are rampant under manual inspection regimes ([2] pharmaphorum.com). The implication is clear: integrated digital workflows like Veeva's are not just more convenient, they directly address known pain points (integration gaps and human error).

- **Efficiency Metrics:** Although concrete ROI figures are proprietary, Veeva customers report significant time savings. For example, Moderna stated that they deployed the new label management process *in just 3 months* and have since been able to *"scale operations to expedite global vaccine rollout"* ([19] www.veeva.com). Their quarterly core updates now automatically spawn around-the-world activities. Where one reviewer might once have spent days updating a tracker, the process is now minutes of configuration followed by real-time tracking.

- **Risk Reduction:** Beyond metrics, the qualitative benefit is compliance assurance. With all label decisions logged, companies avoid the **"country blind spots"** that spreadsheets allow. Manual trackers are inherently lagging indicators (they reflect past edits); Vault RIM provides monitoring as changes are prepared. This immediacy can prevent late or missed regulatory submissions (and the fines/recalls that can follow). As one expert wrote, *"a cohesive contained report [in software] makes it easier for auditors to access data… reducing… exposure"* ([20] intagras.com). In practice, if a country requests a label deviance, Vault forces it to be documented and reviewed before sign-off, whereas a spreadsheet approach might only catch it after the fact.

The table below compares key aspects of the two approaches, synthesizing the above evidence and industry observations:

Comparison Aspect	Manual Spreadsheets	Veeva Label Concept Tracking
Error Rate	High risk: no validation, many manual entries. Empirically, ~70% of labeling errors are human-caused ([2] pharmaphorum.com).	Lower risk: structured forms and automation reduce data entry errors.
Processing Time	Weeks of coordination for each core label revision (especially at launch).	Real-time processing: system auto-creates tasks, saving weeks of effort ([5] www.veeva.com).
Resource Use	Dozens of staff (global affiliates + home office) manually updating files.	Leaner: one central label team configures the event; affiliates update their tasks in Vault.
Audit Preparedness	Burdensome: compile email threads, charts, PDF snapshots. Likely gaps.	Audit-ready: single source with full history and attached documents.
Collaboration	Siloed: each affiliate works separately; global view comes later.	Integrated: all markets feed progress into Vault, visible to all stakeholders.
Scalability	Weak: adding markets/languages multiplies workload linearly.	Strong: new markets automatically handled by Vault's dependency logic.
Regulatory Compliance	Status often unclear; higher chance of missing a submission.	Status clear; agreements with health authorities documented in system.
Adoption and Training	Minimal tech needed (everyone knows Excel), but high process risk.	Requires learning the RIM skillset, but benefits from enforced process and controls.

In summary, the evidence suggests that replacing spreadsheets with Veeva's Label Concept feature **drastically improves efficiency and compliance visibility**. Case studies and surveys consistently highlight the pitfalls of manual trackers ([1] www.veeva.com) ([2] pharmaphorum.com) ([3] www.rdworldonline.com), while demonstrating that integrated systems address them. The data model and workflow in Vault endow labeling updates with the rigor of a regulated process, not a spreadsheet.

Case Study: Moderna's Implementation

Moderna's COVID-19 vaccine program provides the most detailed public example of using Veeva's Label Concept Tracking. In early 2021, faced with a global rollout, Moderna formed a dedicated labeling department. They were already using Veeva RIM to store label documents, but still tracked changes in spreadsheets ([21] www.veeva.com). Rapid vaccine approvals in dozens of countries created an avalanche of label updates: *"wave after wave of countries, each with its own regulatory pathway… the number of variations… snowballed."* The team realized the spreadsheet approach would not keep up.

Working closely with Veeva, Moderna deployed the label tracking features in an agile manner over a few months ([22] www.veeva.com). Key outcomes reported:

- **Speed of Implementation**: Moderna went live with the new process in just *three months* after configuration and sandbox testing ([19] www.veeva.com). They started by loading two CCDS versions into Vault and immediately began processing changes.
- **Automated Task Creation**: For every CCDS update event, Vault automatically generated a labeling Activity for each impacted country ([5] www.veeva.com). This eliminated the manual step of copying context into

dozens of local trackers. Instead of emailing spreadsheets, affiliates received system notifications.

- **Global Visibility**: The new process provided a single view. "Vault RIM makes the changes and timelines visible globally and locally while the label content is approved, updated, and submitted" ([5] www.veeva.com). For the first time, management could see exactly which markets were still pending, and local teams could see any connected affiliates' decisions.
- **Auditable History**: Because all data sat in Vault, Moderna could easily extract status reports for management and auditors. As the senior director said, she was *"sleeping at night because I know we're in good shape"* ([17] www.veeva.com).
- **Increased Capacity**: With the automated process, Moderna could handle *"a steady stream of new authorizations… managing hundreds of label versions at any one time"* ([11] www.veeva.com). This scalability would likely have been impossible via spreadsheets without adding significant headcount.

Importantly, Moderna's example illustrates not just technology but organizational change. The regulatory labeling, quality, and CMC teams had to work closely to define requirements. They iterated on workflows and reporting until finding the right fit ([22] www.veeva.com). This underscores that while the feature provides the tools, effective use depends on cross-functional alignment and training.

Other companies have piloted or adopted similar approaches, though details are sometimes proprietary. A Veeva customer webinar and partner case study (Astrix) document a large multinational's shift from fragmented SharePoint and spreadsheets to Vault RIM across submissions and labeling ([6] www.astrixinc.com). Firms implementing Label Concept Tracking consistently report *fewer manual errors, better deadline management, and stronger affiliate collaboration*. While specific ROI numbers are sparse, qualitative feedback is uniformly positive: one manager lauded that switching away from Excel *"made my life a whole lot easier"* ([17] www.veeva.com).

Discussion: Implications and Future Directions

The deployment of Label Concept Tracking in Veeva RIM carries several broad implications:

- **Regulatory Process Harmonization:** By embedding labeling workflows into RIM, companies can better align global and local teams. The centralized platform encourages adoption of common terminology and procedures, addressing the issue that "global teams don't always share the same processes or terminology" ([23] www.astrixinc.com). This harmonization can reduce miscommunication and ensure consistent compliance standards across regions.
- **Data-Driven Decision Making:** Consolidated label tracking generates a rich dataset. Firms can analyze trends (e.g. which sections often trigger deviations, which countries routinely require local changes) to anticipate future needs. This analysis was impossible with dispersed spreadsheets. In time, RIM data could even feed machine-learning models for predicting HLAs or optimizing review assignments.
- **Cross-Module Integration:** Veeva's RIM is often integrated with other Vault modules (Submissions, Quality, etc.). Label Concept Tracking can tie into these processes: e.g., approved label changes can trigger document control workflows, or link to eCTD submissions in Vault Submissions. This end-to-end connectivity further reduces manual handoffs. Future enhancements might integrate with clinOps or PV systems (e.g. feeding label updates into adverse event case processing).
- **Future of e-Labelling and PIM:** As noted, regulators have long envisioned a data-centric approach to labeling (EMA's PIM initiative, XML labels, etc.) ([24] pmc.ncbi.nlm.nih.gov) ([24] pmc.ncbi.nlm.nih.gov). Veeva's solution is a commercial step toward that vision. Looking forward, we may see tighter regulatory convergence (e.g. distributed ledger for label versions) where systems like Vault automatically synchronize authoritative label texts with global regulators. Veeva could potentially expand its search/filter capabilities to allow semantic comparison of local vs core text, further automating deviation identification.

- **Challenges and Considerations:** Despite benefits, the shift is non-trivial. Companies must invest in configuration, training, and change management. Not all affiliates are immediately ready to use Vault. Some may resist structured workflows in favor of "the old way". Governance questions also arise: e.g., who in the organization is responsible for maintaining the CCDS vs local content? Designating clear roles is crucial. Additionally, because the feature is only in *RIM Registrations Vaults*, companies without Veeva RIM would not have this natively (though Veeva RIM Licensing is growing). Finally, as with any integrated system, data migration and cleanup (importing spreadsheets into Vault) can be an initial hurdle (some firms use Veeva's professional services or partners like Astrix for this).

Conclusion

Label Concept Tracking in Veeva Vault RIM represents a significant advance in pharmaceutical regulatory technology. It directly addresses a long-standing pain point – the cumbersome **"Country Tracker" spreadsheets** – by treating label changes as structured data and workflows. This transformation is confirmed by industry feedback: manual label tracking is error-prone and unsustainable, while integrated solutions markedly improve efficiency, visibility, and compliance confidence ([1] www.veeva.com) ([2] pharmaphorum.com) ([3] www.rdworldonline.com). The Meztra (Moderna) case study exemplifies these gains: by automating task creation and deviation management, Moderna's team could manage hundreds of label variants across dozens of countries in one unified system ([5] www.veeva.com) ([11] www.veeva.com).

The implications extend beyond one feature. As globalization intensifies and regulations evolve, the need for digital, data-driven processes will only grow. Veeva's Label Concept feature is part of a broader trend toward connected regulatory ecosystems. Companies that embrace such tools can expect to reduce manual effort, accelerate market implementations, and minimize compliance risk. Future developments may include enhanced analytics, even tighter integration with regulatory datasets, and cross-industry standards for label data.

In sum, the "Country Tracker" spreadsheet – a symbol of manual workarounds – is being replaced by sophisticated RIM capabilities. The net effect is a more transparent, auditable, and agile labeling process. For regulators and patients alike, this promises safer products delivered with speed and accuracy.

External Sources

[1] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:In%20...

[2] https://pharmaphorum.com/partner-content/press-releases/survey-finds-quality-control-is-a-major-challenge-in-clinical-labeling#:~:The%2...

[3] https://www.rdworldonline.com/new-survey-reveals-the-importance-of-standardized-label-management-in-pharmaceutical-industry/#:~:%E2%8...

[4] https://www.chromatographyonline.com/view/are-spreadsheets-a-fast-track-to-regulatory-non-compliance#:~:Are%2...

[5] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:To%20...

[6] https://www.astrixinc.com/case/global-pharmaceutical-company-successfully-implements-a-veeva-rim-solution/#:~:Befor...

[7] https://www.acolad.com/en/industries/life-sciences/identifying-local-label-deviations#:~:Maint...

[8] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:devia...

[9] https://pmc.ncbi.nlm.nih.gov/articles/PMC7744299/#:~:autho...

[10] https://www.acolad.com/en/industries/life-sciences/identifying-local-label-deviations#:~:The%2...

[11] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:As%20...

[12] https://pmc.ncbi.nlm.nih.gov/articles/PMC7744299/#:~:Curre...

[13] https://pmc.ncbi.nlm.nih.gov/articles/PMC7744299/#:~:match...

[14] https://www.rdworldonline.com/new-survey-reveals-the-importance-of-standardized-label-management-in-pharmaceutical-industry/#:~:The%2...

[15] https://www.acolad.com/en/industries/life-sciences/identifying-local-label-deviations#:~:In%20...

[16] https://pharmaphorum.com/partner-content/press-releases/survey-finds-quality-control-is-a-major-challenge-in-clinical-labeling#:~:A%20s...

[17] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:In%20...

[18] https://www.acolad.com/en/industries/life-sciences/identifying-local-label-deviations#:~:used%...

[19] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:With%...

[20] https://intagras.com/blog/tracking-pharmaceutical-label-changes/#:~:5.%20...

[21] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:In%20...

[22] https://www.veeva.com/customer-stories/moderna-streamlines-label-management-with-vault-rim/#:~:With%...

[23] https://www.astrixinc.com/case/global-pharmaceutical-company-successfully-implements-a-veeva-rim-solution/#:~:This%...

[24] https://pmc.ncbi.nlm.nih.gov/articles/PMC7744299/#:~:estab...

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.

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.

DISCLAIMER

The information contained in this document is provided for educational and informational purposes only. We make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability of the information contained herein.

Any reliance you place on such information is strictly at your own risk. In no event will IntuitionLabs.ai or its representatives be liable for any loss or damage including without limitation, indirect or consequential loss or damage, or any loss or damage whatsoever arising from the use of information presented in this document.

This document may contain content generated with the assistance of artificial intelligence technologies. AI-generated content may contain errors, omissions, or inaccuracies. Readers are advised to independently verify any critical information before acting upon it.

All product names, logos, brands, trademarks, and registered trademarks mentioned in this document are the property of their respective owners. All company, product, and service names used in this document are for identification purposes only. Use of these names, logos, trademarks, and brands does not imply endorsement by the respective trademark holders.

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.

This document does not constitute professional or legal advice. For specific guidance related to your business needs, please consult with appropriate qualified professionals.