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Designing a Sustainable Veeva Vault RIM Information Model

A Comprehensive Guide to Architecture, Governance, and Long-Term Platform Health

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Executive Summary: The Architecture of Longevity

In the life sciences industry, a RIM system is only as good as its data integrity. A sustainable information model in Veeva Vault RIM is not a static configuration but a living framework. To prevent the model from becoming brittle—which manifests as slow performance, reporting gaps, or inability to adopt new Veeva features—organizations must shift from application-centric design to data-centric architecture.

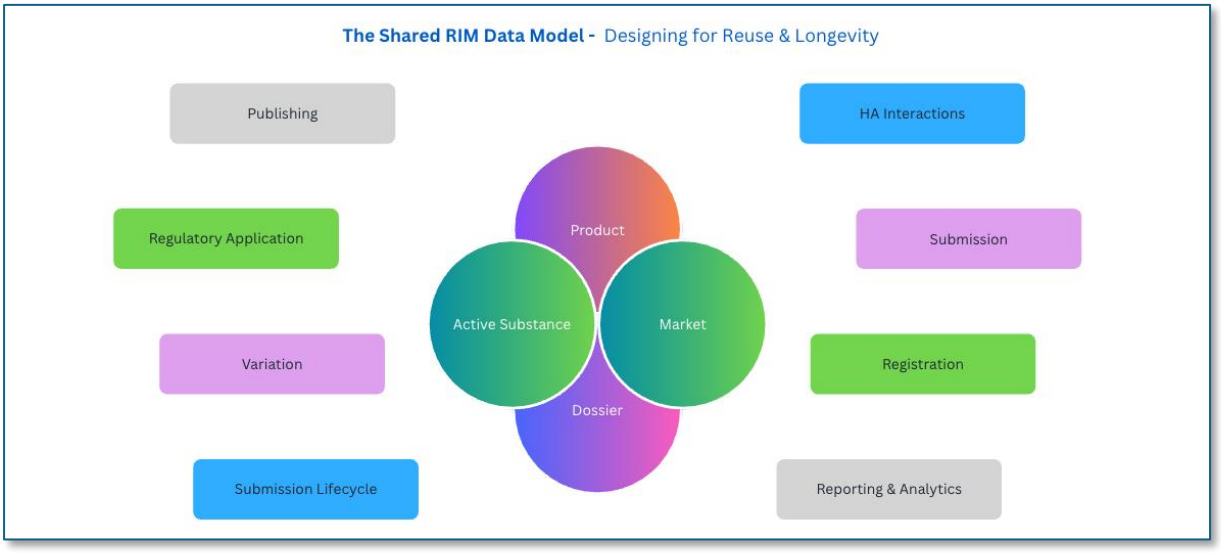
This whitepaper presents a practitioner-led perspective on designing a sustainable Vault RIM Information Model that remains stable amid regulatory change, organizational growth, and continuous publishing demands. It is written for RIM Program Owners, Vault Architects, and the Centre of Excellence (CoE) lead responsible for long-term platform health

Key Outcomes of This Guide:

- Understand the foundational principles of a unified, sustainable data model
- Learn to balance customization with platform stability
- Implement governance frameworks that prevent technical debt
- Design for scalability and regulatory readiness (IDMP)
- Establish measurable health checks and performance benchmarks

Foundational Pillar: The Shared Data Model

The most common point of failure is a siloed configuration between Vault Registrations, Submissions, and Archive. Sustainability starts with a **Unified Model.**



Core Business Keys: Building the Foundation

Identify stable entities (Product, Active Substance, Market) that act as "Hubs." These become the anchors of your information architecture.

Best Practice: Avoid using temporary identifiers from legacy systems that may change. Instead, use globally recognized identifiers like:

- Product: Use Global Trade Item Number (GTIN) or internal Product Master ID
- Active Substance: Use UNII (Unique Ingredient Identifier) codes
- Market: Use ISO 3166-1 country codes
- Organizations: Use DUNS numbers where applicable

Object Relationships: Managing Complexity

Use Many-to-Many relationships judiciously. Over-relying on complex parent-child hierarchies can lead to "locking" issues during high-volume data loads.

Example of Problematic Design:

Scenario	Impact
Three-level hierarchy: **Product → Variant → SKU**	Updating Product locks all Variants and SKUs, blocking concurrent users
Circular relationships: **Submission ↔ Application ↔ Dossier**	Creates update conflicts and unpredictable save behavior
Deep nesting (>3 levels)	Exponential performance degradation on bulk operations

Recommended Approach: Use flat junction objects for Many-to-Many relationships. For example, instead of Product → Registration, create Product-Registration-Link object.

Reference Data Harmonization

Ensure that picklists (e.g., Dosage Form, Route of Administration) align with international standards like ISO IDMP.

Critical Standards:

- Pharmaceutical Dose Forms: ISO 11239
- Routes of Administration: ISO 11238
- Units of Measurement: ISO 11240
- Substance Terminology: ISO 11238
- Medicinal Product Identifiers: ISO 11615 and 11616

Avoiding the "Over-Customization" Trap

Veeva releases updates three times a year. Heavy customization of standard objects often blocks these updates or requires expensive remediation.

Standard vs. Custom Objects: The Decision Framework

Rule of Thumb: Always prioritize Standard Objects. Custom objects should only be created when a unique business process exists that cannot be mapped to the Veeva reference model.

Decision Matrix:

Requirement	Use Standard Object	Create Custom Object
Track product registrations	✓ Use Registration object	✗
Track clinical trial submissions	✓ Use Submission object	✗
Track internal safety assessments (company-specific)	✗	✓ Create Safety_Assessment__c
Manage promotional materials (off-label)	✗	✓ Create Promotional_Item__c

Workflow Simplicity

Avoid replicating legacy manual processes into digital workflows. Use "Out-of-the-Box" (OOTB) workflows to ensure compatibility with Veeva's "Continuous Publishing" and "Active Dossier" features.

Case Study: Workflow Complexity Gone Wrong

Scenario: A pharmaceutical company created a 12-step approval workflow for registration documents, mirroring their paper-based process with parallel reviews, conditional branches, and manual routing.

Outcome: Average document approval time increased from 5 days to 18 days. The workflow broke when Veeva introduced Dynamic Access Control (DAC), requiring 40 hours of consultant time to remediate.

Solution: Simplified to a 3-step workflow using OOTB lifecycle states (Draft → Review → Approved) with role-based access. Approval time dropped to 3 days, and upgrades became seamless.

Naming Conventions

Implement a strict, global metadata naming convention. This prevents "configuration clutter"—where multiple fields or document types exist for the same purpose.

Standard Naming Convention:

- Custom Objects: [BusinessEntity]__c (e.g., Safety_Assessment__c)
- Custom Fields: [purpose]__c (e.g., submission_deadline__c)
- Document Types: [Region]_[Type]_[Version] (e.g., EU_SPC_v1)
- Workflows: WF_[Object]_[Purpose] (e.g., WF_Registration_Approval)
- Picklists: PL_[Domain] (e.g., PL_Dosage_Form)

Technical Scalability and Performance

A model that works for 1,000 records may break at 100,000.

Design Area	Sustainability Strategy
Security Model	Use Dynamic Access Control (DAC) instead of manual sharing rules to reduce administrative overhead.
Data Ingestion	Utilize the **Direct Data API** for high-speed extractions (up to 100x faster than traditional REST APIs).
Lifecycle States	Keep lifecycles lean. Too many states create "workflow fatigue" and complicate reporting.

Performance Benchmarks

Baseline Performance Targets:

Operation	Target Performance	Warning Threshold
Page load (list views)	< 2 seconds	> 5 seconds
Record save (standard object)	< 1 second	> 3 seconds
Bulk data load (API)	> 1,000 records/min	< 500 records/min
Report generation	< 30 seconds	> 2 minutes

Indexing Strategy

Vault automatically indexes certain fields, but custom fields require explicit indexing for optimal query performance.

Fields to Index:

Any field used in list view filters or sorting

- Fields used in workflow entry criteria
- Fields referenced in Vault Query Language (VQL) WHERE clauses
- Foreign key fields (relationship lookups)
- Fields used in scheduled reports

Warning: Over-indexing (indexing rarely-used fields) can slow down write operations. Limit to fields with >80% query usage.

Data Archival Strategy

Vault performance degrades when object tables exceed 500,000 records. Implement archival policies to maintain optimal performance.

Recommended Archival Triggers:

- Documents: Archive after 7 years of inactivity (or per retention policy)
- Submissions: Archive superseded submissions after approval + 2 years
- Audit Trails: Export to external system quarterly (Vault retains 7 years)
- Inactive Products: Move to "Sunset" lifecycle state instead of deletion

Future-Proofing for Regulatory Shifts

Sustainability implies the ability to adapt to external changes without internal breakage.

IDMP Readiness

Structure your Registration and Product objects to support the five ISO IDMP domains:

- Substance (ISO 11238): Active ingredients and excipients
- Pharmaceutical Product (ISO 11615): Formulation details
- Medicinal Product (ISO 11616): Branded products
- Regulated Authorization (ISO 11239): Registration details
- Referential Data (ISO 11240): Units, routes, forms

Implementation Checklist:

IDMP Domain	Required Vault Object	Key Fields
Substance	Substance__c (custom)	UNII Code, Substance Name, Molecular Formula
Pharmaceutical Product	Product__c (standard)	PhPID, Dosage Form, Strength
Medicinal Product	Product__c (standard)	MPID, Trade Name, Marketing Authorization Holder

IDMP Domain	Required Vault Object	Key Fields
Regulated Authorization	Registration__c (standard)	Authorization Number, Authority, Status
Referential Data	Picklists (standard)	Route Code, Form Code, Unit Code

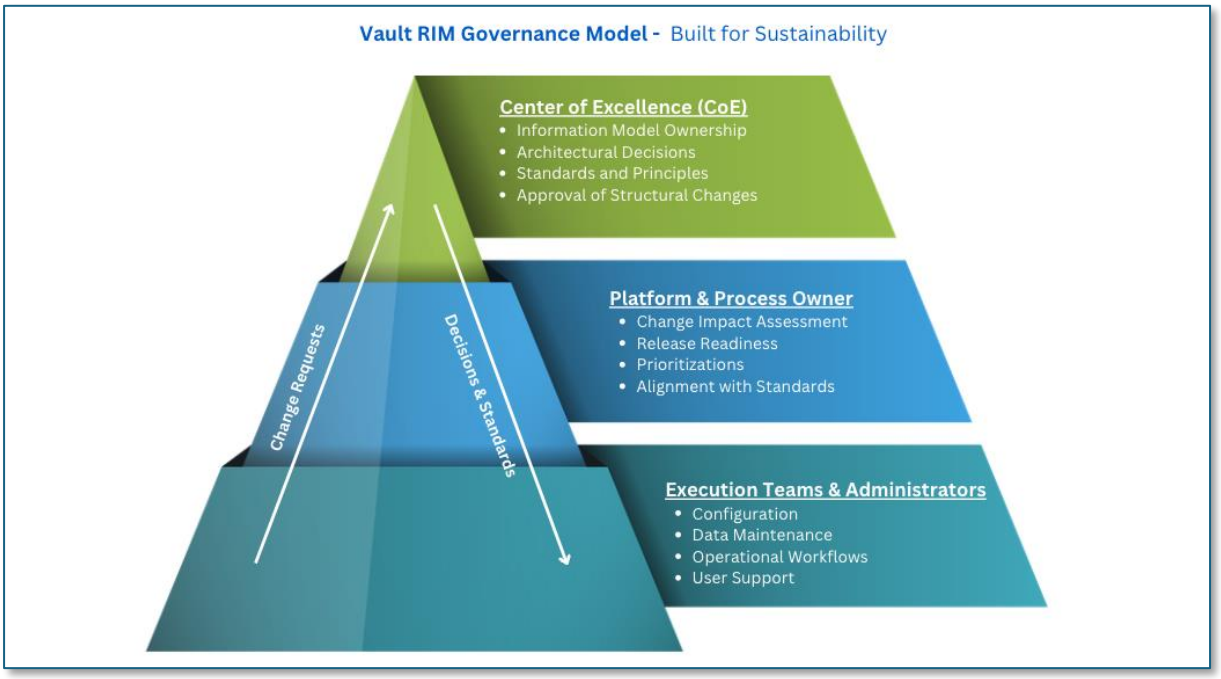
Global Content Plans

Use templates that allow for local variation without breaking the global structure. This allows affiliates to manage country-specific requirements within a unified framework.

Template Strategy:

- Global Master Template: Contains core sections required by all regions
- Regional Override Sections: Allow affiliates to add country-specific content
- Locked vs. Editable: Global sections are locked; local sections are editable
- Version Control: Regional changes tracked separately from global updates

Governance: The Human Element



The technical model will eventually break if there is no governance. Sustainability requires both technical excellence and organizational discipline.

Center of Excellence (CoE)

Establish a RIM CoE to evaluate every change request against the "Sustainability Principle."

CoE Structure:

Role	Responsibility	Time Commitment
CoE Lead	Final decision authority, escalation point	25% FTE
Vault Architect	Technical design, impact assessment	50% FTE
Data Steward	Reference data management, quality checks	20% FTE
Business Analyst	Requirement translation, user liaison	30% FTE

Periodic Health Checks

Conduct bi-annual "Vault Health Checks" to identify redundant fields, unused document types, and performance bottlenecks.

Health Check Schedule:

- Q1: Metadata audit (identify ghost fields and unused objects)
- Q2: Performance baseline (establish benchmarks for next 6 months)
- Q3: Governance review (assess change request adherence)
- Q4: Upgrade readiness (prepare for annual Veeva release)

Veeva Vault RIM Governance Charter

Purpose & Scope

The purpose of this Charter is to define the decision-making framework for the Veeva Vault RIM Information Model. It ensures that any changes to the system whether metadata, workflows, or object structures maintain the integrity of the **Global Design Baseline.**

The "Golden Rules" of Change Management

To ensure the model doesn't "break" over time, all change requests must be filtered through these three criteria:

1. **Standard First:** Can this requirement be met using "Out-of-the-Box" (OOTB) functionality?
2. **Global Impact:** Does this change become brittle downstream reporting for other regions or products?
3. **Upgrade Compatibility:** Will this configuration require manual remediation during the next Veeva Release (General Availability)?

Governance Tiers

Tier	Scope	Approval Authority	Example
Tier 1 (Low Impact)	Field-level changes, picklist updates, UI modifications	Vault Admin (1 day turnaround)	Add new value to "Submission Type" picklist
Tier 2 (Medium Impact)	New custom objects, workflow changes, security model updates	CoE Lead + Architect (5 day turnaround)	Create custom object for Clinical Trial tracking
Tier 3 (High Impact)	Standard object modifications, API integrations, structural changes	Steering Committee (15 day turnaround)	Modify Registration object hierarchy

Change Request (CR) Workflow

Sustainability is maintained through a rigorous "Gatekeeping" process:

- Intake: Requestor submits a business requirement (not a technical solution) via standardized form.
- Impact Assessment: The CoE analyzes the effect on the Shared Data Model, performance implications, and upgrade compatibility.
- Prototyping: Changes are modeled in a Sandbox environment to check for performance lag, "Reference Ledger" conflicts, and user experience.
- Approval: Tier 2/3 approvers give the green light only if the change is "Sustainability-Compliant" (passes all three Golden Rules).
- Implementation: Change deployed to Production with full documentation and rollback plan.

- Post-Implementation Review: Performance metrics monitored for 30 days; lessons learned documented.

Data Stewardship & Ownership

Every "Core Object" in the Information Model must have an assigned **Data Steward** responsible for data quality, completeness, and lifecycle management.

Object Category	Data Steward	Responsibilities
Product/Registration Objects	Regulatory Operations	Maintain product master data, registration status updates, license renewals
Submissions/Dossier Objects	Global Submissions Management	Manage submission workflows, dossier compilation, authority interactions
Reference Data (Controlled Vocabularies)	RIM CoE	Align picklists with ISO standards, manage global vs. local value sets

Conclusion: The Next Step

A sustainable Veeva Vault RIM model is built on the principle of "Standardize where possible, Customize where necessary." By anchoring your design in the shared Vault platform and adhering to global data standards, you create a system that evolves with the industry rather than becoming technical debt.

The Three Pillars of Sustainability:

- Technical Foundation: Unified data model, optimized performance, IDMP-ready structure
- Governance Framework: Change control, periodic health checks, clear ownership
- Continuous Improvement: Bi-annual audits, upgrade readiness, knowledge transfer

Organizations that invest in sustainable design today avoid the costly platform migrations of tomorrow. The time to act is now—before technical debt compounds and platform limitations constrain your regulatory agility.

Appendix A: The RIM Sustainability Health Check

This checklist is designed for Vault Administrators and the RIM Center of Excellence (CoE) to ensure the Information Model remains lean and high-performing.

Phase 1: Metadata & Object Hygiene

- **Redundant Field Audit:** Identify custom fields with $>80\%$ null values. These are often "ghost fields" created for one-time projects that now clutter the UI.
- **Picklist Harmonization:** Check for "Duplicate Intent" in controlled vocabularies (e.g., having both "USA" and "United States" in a country picklist).
- **Naming Convention Adherence:** Ensure all custom objects and fields follow the c_ prefix and clear business-standard labels.
- **Orphaned Objects:** Identify custom objects with zero records created in the last 12 months—candidates for archival or deletion.

Phase 2: Performance & Structural Integrity

- **Relationship Complexity Review:** Audit objects with more than two levels of parent-child nesting. High nesting increases the risk of record-locking during bulk updates.
- **Workflow Bottleneck Analysis:** Identify workflows that have been "In Progress" for >90 days. This usually indicates a process that is too complex for the digital model.
- **Security Overload:** Check the number of Sharing Rules. If you have hundreds of manual rules, it is time to migrate to **Dynamic Access Control (DAC)** to improve page load times.\
- **API Call Volume:** Review Vault API Usage Logs. Unexpected spikes often signal inefficient external integrations that need optimization.

Phase 3: Upgrade & Regulatory Readiness

- **OOTB Alignment:** Compare custom objects against the latest **Veeva RIM Reference Model**. If Veeva has released a standard object for a process you currently handle with a custom one, plan a migration path.
- **IDMP Data Completeness:** Run a report on mandatory ISO IDMP fields (e.g., Pharmaceutical Product ID). A sustainable model must have high data density in these core areas.
- **API Usage Limits:** Review the **Vault API Usage Logs**. Unexpected spikes in API calls often signal "broken" or inefficient external integrations.

- **Veeva Release Notes Review:** Assign a team member to review every Veeva release announcement for deprecated features or breaking changes.

About Wolvio Solutions

Wolvio Solutions is a modern IT consulting and services company specializing in digital transformation across Life Sciences, Healthcare, and Regulated Industries. With deep expertise in Veeva Vault, Cloud Ops, and intelligent automation, we help organizations implement scalable, compliant, and user-friendly solutions that drive business efficiency and innovation.

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