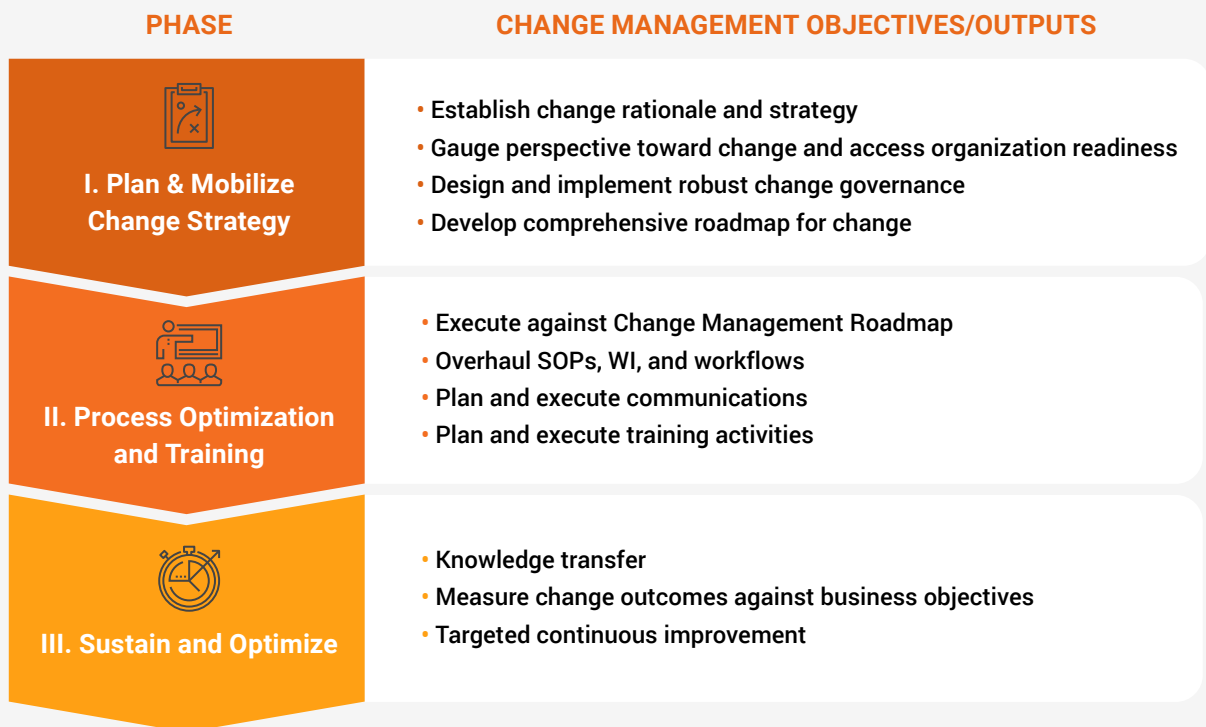**Veeva MedTech**

CUSTOMER STORY

Veeva Business Consulting Supports Digital Clinical Transformation at a Leading Global Medical Device Company

Engagement Background

Terumo Medical Corporation (the customer) engaged Veeva MedTech Business Consulting to lead change management efforts around the roll-out of the Veeva Vault Clinical Platform. Veeva Business Consulting partnered with the customer's sponsorship to execute a 3-phase organizational change management engagement to plan and deliver a sustainable and measurable digital transformation strategy for the Clinical Research & Operations Team.

PHASE	CHANGE MANAGEMENT OBJECTIVES/OUTPUTS
I. Plan & Mobilize Change Strategy	• Establish change rationale and strategy • Gauge perspective toward change and access organization readiness • Design and implement robust change governance • Develop comprehensive roadmap for change
II. Process Optimization and Training	• Execute against Change Management Roadmap • Overhaul SOPs, WI, and workflows • Plan and execute communications • Plan and execute training activities
III. Sustain and Optimize	• Knowledge transfer • Measure change outcomes against business objectives • Targeted continuous improvement

I. Plan and Mobilize Change Strategy

The customer's well executed organizational change started with a vision and plan. The mobilization phase focused on understanding business goals, implementing right-sized change governance, and laying out a detailed plan for change.

Establish Change Rationale & Strategy

From the onset of the engagement, Veeva Business Consulting partnered with the customer's sponsorship to map out a case for change and change strategy that addressed current state challenges, business goals, and mechanisms for change associated with the forthcoming transformation.

"We brought forward Vault Clinical to shift to a more efficient way of managing clinical studies and engaging with global regulatory authorities."

Senior Manager, Clinical Data Management

SPECIFIC BUSINESS GOALS ASSOCIATED WITH THE TRANSFORMATION INCLUDED

1
Streamlined, technology enabled clinical processes

2
Optimized engagement and interactions with regulatory authorities

3
Improved collaboration, visibility, and reporting

4
Enhanced compliance and inspection readiness

Once established, the case for change and change strategy served as a 'NorthStar' for change for the customer's leadership and impacted stakeholders, while reinforcing the business rationale of work to come.

Gauge Perspectives Toward Change & Assess Organization Readiness

Stakeholder input and engagement was a top priority for the customer's executive sponsorship throughout the engagement. A series of stakeholder interviews was conducted to gain insights from an array of impacted team members. These data points provided a critical line of sight to the challenges of customer end users, awareness around the upcoming change, and insight into areas of change resistance.

"Partnering with Veeva Business Consulting to conduct stakeholder interviews allowed our leadership team to gather candid feedback and understand how to best support our personnel throughout the transformation with Veeva Vault."

Senior Manager, Clinical Data Management

The stakeholder analysis provided the executive sponsorship with the information necessary to fine-tune change management priorities and proactively identify and mitigate pockets of resistance and other threats to successful transformation.

Design & Implement Robust Change Governance

Establishing governance at the customer ensured partnership and input from the right functional leadership. A two-tiered governance model was implemented consisting of a Steering Committee (SteerCo) and Change Champion Network.

Steering Committee members provided functional input into the case for change, change strategy, and change roadmap and served as key decision makers as it relates to the change management process and future state. The Change Champion Network consisted of influential clinical stakeholders at different levels in the organization, who worked with end users to drive adoption and compliance. The Change Champion Network was optimally positioned between the SteerCo and end-users to drive change objectives further into the customer's organization by ensuring accountability, providing support to end-users, and reinforcing key messaging, expectations, and process steps. The Change Champion Network proved critical to ensure that SteerCo decisions translated into execution by customer end-users.

"The structure of the Change Champion Network included stakeholders at multiple levels of the Clinical Research & Operations Team, which allowed them to be highly effective at engaging with end-users and solidifying the change movement."

Senior Manager, Clinical Data Management

Implementing right-sized governance to shape, reinforce, and optimize the organization's future state was imperative for successful and sustained top-down change.

Develop Comprehensive Roadmap for Change

Once the business goals and specific needs of the customer were understood, a comprehensive change project plan was created to capture the key areas of effort and address items identified from the change impact analysis. The change roadmap served as a tool for mapping and managing the extensive list of activities and dependencies associated with the change effort. Additionally, the roadmap reinforced accountability across the customer's Clinical Research & Operations Team for change management activities such as process and WI updates, communications, and training activities.

As Phase I of the change management engagement concluded, Veeva Business Consulting shifted focus to enabling the desired change. Phase II focused on execution of critical activities to align and prepare stakeholders and address pockets of resistance including, process optimization, consistent and clear communication, and focused user onboarding to master core competencies.

Overhaul SOPs, Work Instructions (WI), and Workflows

A critical next step for operationalizing change at the customer was to create clear documentation of future state business processes to set clear expectations and requirements for the team. Customer SMEs worked closely with Veeva Business Consulting to understand how day-to-day activities of the Clinical Research & Operations Team would be impacted by the introduction of Vault. The output of this exercise was 15 role-based workflows that mapped out how, when, and by who key decisions and activities would be owned, managed, and executed in and outside of the Veeva Vault Platform. Optimized workflows were then aligned and packaged with existing SOPs and WIs to ensure high-level business requirements were supported by the specific workflows outlined for the Vault system.

Plan & Execute Communications

Commitment to regular communication is fundamental to the success of any Change Management effort. To address this need, the customer and Veeva Business Consulting developed a communications plan that outlined a series of communication events and detailed timing, cadence, channel, core messaging, audience, and owner of each communication. This plan leveraged a variety of communication mechanisms including formal, highly planned leadership messaging like town halls and in-system demos as well as informal channels like emails and self-service reminders to reach audience members at different points in their journey. Veeva Business Consulting drove development of communications in alignment with the customer's 'future' state processes and Vault capabilities. Partnership between the customer and Veeva Business Consulting to drive awareness and alignment across the Clinical Research & Operations Team resulted in a higher level of preparedness and streamlined the transition for impacted personnel.

Plan & Execute Training

Customer sponsorship and Veeva Business Consulting collaborated to efficiently up-skill team members for success with updated processes and tools. A training plan was implemented outlining a sequence of role-based learning objectives based on future state process and tools.

Custom training collateral including Vault playbooks, Quick Reference Guides, and in-system walkthroughs were created to address specific Vault configuration and process requirements. These materials were provided to the Clinical Research & Operations Team to support initial training activities and as part of a Vault 'Tool Kit' for ongoing use.

"A tailored approach to training allowed our organization to maintain a focused and efficient pathway to end user competency and compliance while avoiding the pitfalls of blanket training."

Senior Manager, Clinical Data Management

III. Sustain and Optimize

Veeva's perspective on Change Management is that the initial engagement and subsequent change is only the beginning of a successful business transformation. Therefore, Veeva and customer sponsorship ensured the right mechanisms were in place to sustain, measure, and continuously improve the new operational paradigm.

Knowledge Transfer

As Phase I & II of the change management engagement wrapped up, Veeva Business Consulting worked closely with customer sponsorship to ensure continuity of Change Management activities beyond the initial engagement. This included a re-evaluation of roles and responsibilities for key change management activities such as training reinforcement, measurement, and continuous improvement. Additionally, critical change management collateral (Governance documents, RACI, Communications, and Training Materials) was centralized into a Vault 'Tool Kit' to ensure the team had all required resources readily available.

Measure Change Outcomes Against Business Objectives

The customer recognized that a fully-baked approach to measuring the success of a business transformation is critical to ensure accountability, communicate ROI, and identify continuous improvement opportunities. Veeva Business Consulting provided guidance and best practices as customer sponsorship developed a KPI framework to align business objectives with Vault data outputs. Additionally, Veeva Business Consulting ensured that the customer had the right technical knowledge to efficiently measure what matters and use data in the Clinical Vault to answer critical strategic and operational questions at different levels of the organization.

Targeted Continuous Improvement

Once the future state was brought into fruition and business outcomes are periodically measured against benchmark and/or target values; the ongoing process of identifying and executing continuous improvement opportunities comes center stage. The change governance model provided an effective top-down framework for prioritizing, driving execution, and championing adoption of improvements on an ongoing basis.

Organizational change management is a fundamental part of your digital transformation journey:

Veeva MedTech recognizes that organizational change management is an important part of your organization's journey with the Veeva Vault Platform. With medtech-specific expertise across domains spanning dozens of engagements, Veeva Business Consulting understands the nuances associated with planning and delivering lasting organizational change to maximize the ROI associated with your organization's investment in technology.

> *"A structured approach to change management allowed us to establish cornerstone processes, skills, and knowledge for how our organization would operate with Veeva Vault."*
>
> **Senior Manager, Clinical Data Management**

To speak to a member of our team about Organizational Change Management, or similar offerings, contact Ryan Quinn at ryan.quinn@veeva.com or Nicole Feist at nicole.feist@veeva.com.