Kalleid

Clinical Supply Chain Application Implementation for a Global Biopharmaceutical Company

PROJECT OVERVIEW

A global biopharmaceutical company was using two legacy applications and unreliable Excel-based tracking tools to manage an extremely complex clinical supply chain supporting hundreds of global clinical trials conducted annually. In order to more effectively control costs, the company decided to implement a new clinical supply chain application to support better planning and management of production, supply and demand for all clinical products.

Given the differences in the maturity of the two legacy clinical supply chain management systems, together with significant business process variations across different sites and the widespread use of paper-based tracking, the harmonization effort for this project was broad and demanded ongoing collaboration across Quality, Clinical Supply Chain, Pharmaceutical Sciences, and IT teams. Because of our expertise in facilitating organizational change management (OCM) and a track record of success with similar projects in other biopharmaceutical companies, the customer chose Kalleid to run Communications, Training, and business standard operating procedure (SOP) workstreams for this project for sites located in both the United States and Japan.

BUSINESS CASE

The customer was experiencing several issues with their clinical product supply chain that served to increase timelines and costs:

- **Supply stock outs**
- **Excessive inventory costs**
- **Inconsistent business process across sites**
- **Lack of effective data-driven decision tools for planners**

The customer hoped to eliminate these problems quickly and adopted an aggressive timeline for implementation of a clinical supply chain solution to support planning and oversight. This project was expected to deliver a number of important business improvements for the organization:

- **Improved Patient Experience:** Proactive management of the supply chain to effectively deliver the right dose to the right patient at the right time

- **Cost Savings:** Reduced inventory spending (i.e., overage, storage, number of batches purchased, etc.) through more effective trial lifecycle planning

- **Improved Governance:** Improved visibility of the end-to-end supply chain and supporting analytics to enable increased data-based decision making

- **Alignment with R&D Priorities:** Increased operational effectiveness and agility to enable effective management of a diverse pipeline of 200-250 clinical trials within an outsourced model
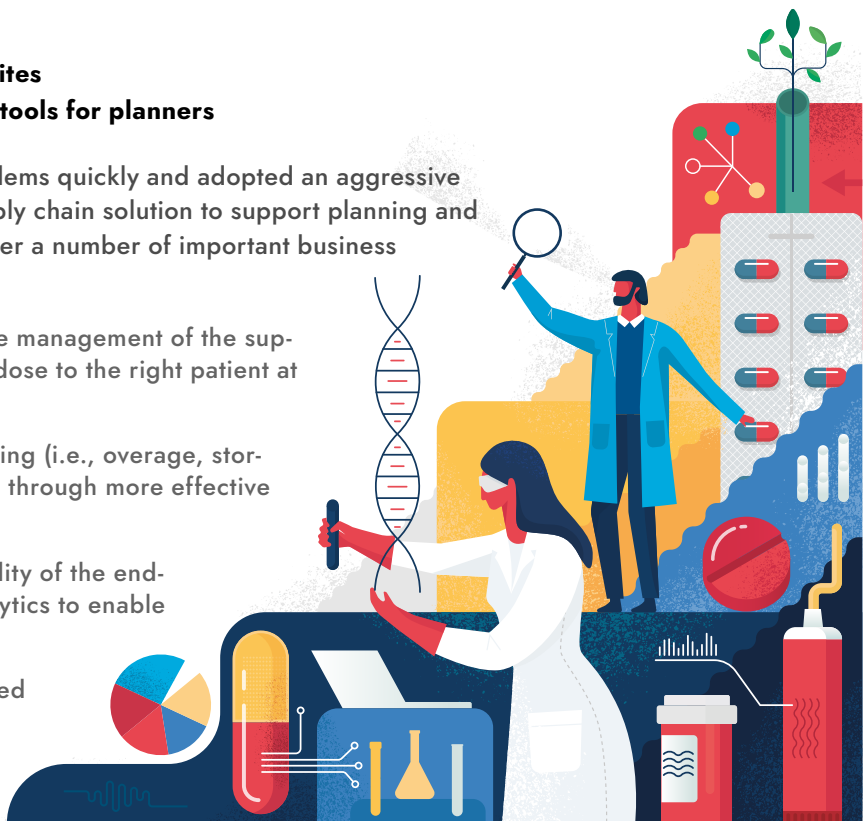
Due to the aggressive timeline for the implementation of this new platform and the diversity of existing practices, an effective change management program to support stakeholder transition and user adoption of this truly global approach to clinical supply chain management was essential to capitalize on these potential business benefits.

SERVICES PROVIDED

The services provided by the Kalleid Team to the customer within the contracted workstreams included:

- **Change Management Assessment.** The Kalleid Team conducted 28 interviews in both the United States and Japan to assess current experience and identify opportunities to support stakeholders. A final report with recommendations was delivered to the customer.

- **Communication Plan.** A Communication Plan was developed to keep stakeholders informed on relevant aspects of the project. The Kalleid Team implemented this plan with regular newsletters, intranet blog updates, socialization materials for 13 town halls, strategic material development for leadership, superuser materials, FAQ maintenance, deployment notifications and more.

- **SOP Development and Support.** The Kalleid Team was involved in preparing and finalizing business SOPs for the customer, which were loaded into a document management system. Kalleid professionals coordinated and facilitated business alignment in all aspects of this process—including the critical identification of process gaps which became apparent in the development of training materials and scenarios.

- **User Guide Development.** The Kalleid Team wrote, edited and helped to finalize 3 different user manuals with 150+ pages of step-by-step instructions and screenshots. In addition to enabling hands-on training, these guides became the go-to support tool in the days after go-live, thus minimizing the burden on Superusers and the ticket system.

- **Training Material Development and Delivery.** The Kalleid Team designed and delivered 1 overview course and 3 role-specific courses, which included hands-on scenarios, step-by-step instructor guides, and the plan/delivery of all tailored training data. In addition, Kalleid professionals provided logistics and coordination for 20 different training sessions, including the design and load of all the supply chain data needed for tailored practice scenarios in the application sandbox.

In the course of delivering the services described above in the contracted workstreams, it became apparent that the Testing work stream was projected to miss its critical milestone for go-live readiness. Our Team was able to identify a potential synergy between readiness activities and User Acceptance Testing (UAT) and proposed a collaborative approach to UAT that helped bring testing in a week early.

While working closely with business representatives on UAT, our Team discovered that the system requirements which were developed by another team were not sufficient to fulfill operational needs. As a result, Kalleid Team members leveraged the existing relationship with the SOP team to identify and design the necessary adjustments to business processes that ultimately led to the successful delivery of the project.

> **Kalleid Team members utilized their fluency in our integrated approach to IT projects to provide additional value to the customer in this project beyond just the OCM work we were contracted to deliver.**

The following additional services were provided by the Kalleid Team to help bring the project over the finish line:
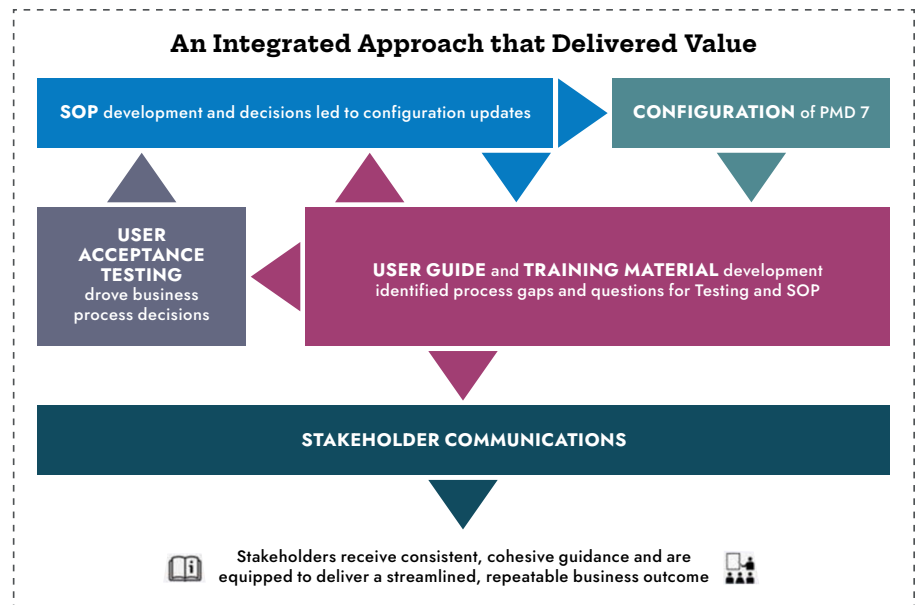
- **User Acceptance Testing Support.** Edited, updated and executed 7 different user acceptance testing (UAT) scripts, including the creation of the only end-to-end functional testing script.
- **Data Migration and Documentation.** Kalleid utilized our Japan partner to complete a CDS template and user instructions, while supporting local data migration needs.

RESULTS DELIVERED

As a result of successful implementation of the new system, the customer now has one global clinical supply chain system that provides automated inventory management, real-time data analytics for efficiency and safety, and accurate and timely forecasting and planning. The Kalleid OCM program for this project embedded a business-led approach to supporting impacted stakeholders with the tools and messaging they needed to maximize and sustain user adoption of the new system and process. The customer is very happy with the enthusiastic user response to the new capabilities and our tailored knowledge transition laid the foundation for a seamless shift to ongoing user support and maintenance led by a community of subject matter experts.

Kalleid Team members utilized their fluency in our integrated approach to IT projects to provide additional value to the customer in this project beyond just the OCM work we were contracted to deliver. By seeing the "big picture," our Team successfully identified and helped to correct improper system requirements that would have led to necessary project rework and significant delays if not detected early. We also collaborated with the testing team to build an approach that brought their timelines in by at least a week. These contributions were critical to the overall success of the project, and we are proud of the fact that we didn't need to add any resources to make these additional contributions. Given that our Team members are very well-versed in our integrated approach to IT projects, they had the required skills to identify these issues and just needed to bill for additional hours in order to solve them.

An Integrated Approach that Delivered Value

SOP development and decisions led to configuration updates

CONFIGURATION of PMD 7

USER ACCEPTANCE TESTING drove business process decisions

USER GUIDE and TRAINING MATERIAL development identified process gaps and questions for Testing and SOP

STAKEHOLDER COMMUNICATIONS

Stakeholders receive consistent, cohesive guidance and are equipped to deliver a streamlined, repeatable business outcome

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