Life Sciences Case Study

PROJECT OVERVIEW

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Project Management for an In-House Clinical Inventory Management and Distribution System

The client, a leading pharmaceutical and biotechnology company, transformed from a research-stage organization focused on precision medicine to an enterprise with a diverse clinical portfolio spanning several modalities.

The client faced challenges with their clinical supply inventory data, which was dispersed across various in-house systems, CMOs, IRT systems, and site-managed systems. This fragmentation made it difficult to obtain a consolidated view of depot inventory. Additionally, vendor constraints limited visibility and flexibility between virtual and physical supply chains, hindering the clinical supply team's ability to rearrange shipments effectively.

Recognizing the limitations of off-the-shelf solutions, the client chose to develop a tailored in-house clinical inventory management and distribution system for their Clinical Supplies and Development Operations. To ensure the success of this initiative, they engaged Clarkston’s project management experts to streamline the development of the in-house solution, aligning it with the GAMP 5 framework and seamlessly integrating Agile methodologies.

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INDUSTRY:

Life Sciences

PRODUCTS AND SERVICES :

Biotech

PRIMARY OBJECTIVES:

- Provide centralized, end-to-end inventory visibility by tracking inventory and goods movement throughout the clinical supply chain
- Gain visibility to depot-depot and depot-site shipments and allow flexibility to reallocate supply across the supply chain
- Enable drug pooling for flexible and optimal drug allocation across multiple protocols/studies
- Establish a centralized software to facilitate clinical supply inventory QA country approval and QA patient disposition processes
- Accomplish centralized product temperature excursion tracking and dispositioning

RESOLUTION:

- Orchestrated and implemented project management processes based on the GAMP 5 Agile framework for the development of the client's custom-built GxP solution
- Facilitated and managed cross-functional team discussions to ensure alignment and collaboration
- Supported the implementation of the GAMP 5 risk-based validation approach, ensuring that all systems and processes adhered to regulatory standards
- Developed a proof of concept to leverage generative AI for producing project documentation in the required format

KEY BENEFITS:

- Improved visibility and flexibility in managing and monitoring clinical supply chain operations
- Reduced lead times for clinical supply in response to protocol amendments
- Shortened lead times for initiating new clinical trials
- Enhanced data integrity, continuity, completeness, and consolidation, resulting in improved transparency, greater visibility, and better inspection readiness

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KPIs

- Reduced clinical supply lead time for protocol amendments by 2 to 4 weeks, facilitating quicker adaptation to protocol changes
- Shortened lead time for clinical supplies in new trials by 2 to 4 months, expediting the initiation of new clinical trials
- Enhanced the flexibility and responsiveness of supply production and distribution across multiple studies

CONTACT US

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