

Summary

Our client was faced with a drastic increase in the amount and complexity of clinical protocols. Neither their legacy system nor its support organization was up to this sudden change in paradigm. Lodestone Management Consultants transformed their clinical supply chain and enabled their current SAP® implementation with Lodestone's SAP Certified CTSM Add-on® solution to a system fit for 21st century paradigms.

Our Client

Our client is a leading human therapeutics company in the biotechnology industry. For more than 25 years, the company has tapped the power of scientific discovery and innovation to advance the practice of medicine.

Our client pioneered the development of novel products based on advances in recombinant DNA and molecular biology, and launched the biotechnology industry's first blockbuster medicines. Today, as a Fortune 500 company serving millions of patients, our client continues to be an entrepreneurial, science-driven enterprise dedicated to helping people fight serious illness. During this project the focus was on the supply chain of clinical trial materials from receipt of APIs to shipments to depots and clinical sites.

CTSM fit for 21st century paradigms

Initial Situation

The initial situation concerning internal and external landscape and developments showed:

- Increased volumes of clinical protocols (tripled in size since 2001)
- Increased complexity and magnitude of clinical protocols (globalization of trials)
- A legacy system that has reached critical limits jeopardizing the clinical activity
- An unsupported custom built platform and obsolete interfaces

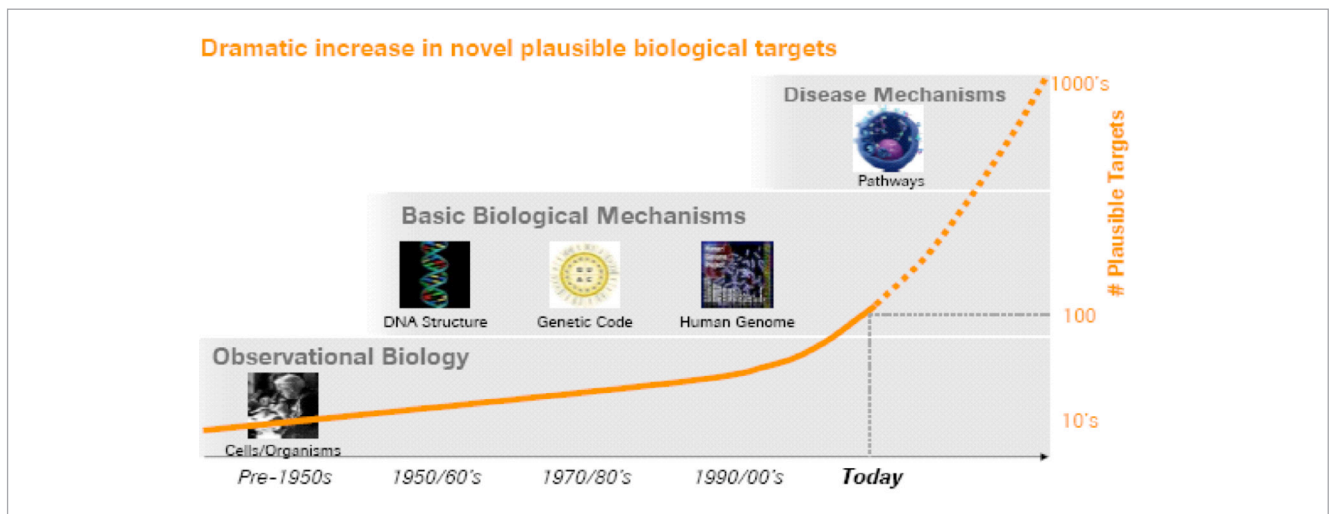
This resulted in:

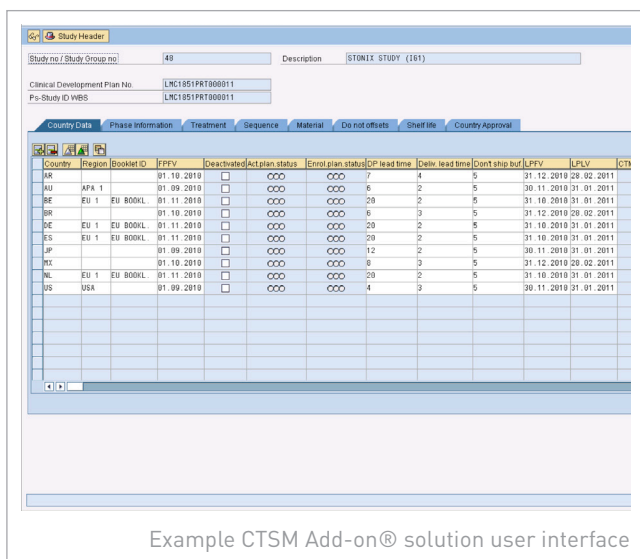
- High compliance risk and potential for agency exposure
- Numerous manual workarounds to minimize outage and cover systems gaps

The Business Objectives

Redeploy the functionality of the legacy systems to SAP for the following activities:

- Planning of finished goods (master production schedule and material requirements planning)
- Finished goods inventory management (packed treatment kits)
- Quality disposition
- Distribution
- Returns and reconciliation
- IVRS (Interactive Voice Response Systems) partner integration





The Benefits

The new clinical supply chain solution enables the drastic optimization of manufacturing and warehousing processes, resulting in:

- Efficiency gains, inventory integrity and the elimination of multiple manual workarounds
- Reduction of expired inventory and shortages
- Elimination of double entry and inconsistent data by synchronization of SAP with the CTMS (Clinical Trial Management System) and the regulatory approval system which ensured orders are released promptly and appropriately
- Full traceability and reconciliation, enabling identification and localization of product boxes and product lot numbers from receipt of API to depots and clinical sites
- Elimination of manual interventions by automatic creation of IVRS replenishment and distribution orders in the system
- Increased efficiency and reliability by optimization and barcode scanning in the picking and packing of shipments

The Solution

Lodestone's SAP Certified CTSM Add-on® solution was implemented in the areas of clinical packaging, inventory management and distribution.

Some highlights of the solution are:

- Migration of all active study data to SAP
- Study characteristics tool to define and store all study key figures and data in SAP, e.g., participating countries and materials, regulatory and EUdraCT (European Union Drug Regulating Authorities Clinical Trials) requirements, relevant IVRS partner information
- Enhanced planning design used the finished drug product demand to create finished drug product planned independent requirements. The forecast at the level of patient kits is loaded into SAP and then drives the short term packaging planning, and the medium term filling and inspection planning
- The replenishment of multiple depots over the world is fully harmonized, as well as the management of box and batch inventory held by each depot
- Cycle counting functionalities are deployed to ensure the integrity of the inventory data and to clear anomalies
- Interfaces support the automatic creation of IVRS replenishment and distribution orders in the system without manual intervention
- Reconciliation data is directly managed in SAP

Lodestone Contribution

- Lodestone was the partner for the conceptual design and implementation of the new clinical trials demand and supply solution
- Lodestones' specialists together with the business experts defined the new processes during the design phase
- Design and coordination of the SAP based development for clinical supply chain characteristics
- Knowledge transfer during training activities

Why Lodestone?

Lodestone is a global management consultancy, committed to designing and delivering solutions that enable companies to thrive in today's complex business environment.

Lodestone has a proven track record in the pharmaceutical industry as well as a deep understanding of global supply chain concepts and strategies and possesses the expertise to successfully implement and optimize clinical supply chain processes.

