

Summary

Roche required a powerful operating model in order to deal with the increasing number of clinical trials, the higher complexity of studies, and internationally diverse regulatory requirements. Lodestone was chosen as delivery partner for the definition and implementation of the new clinical trial supply chain because of its valuable expertise in the life science industry, business processes and technology. Within a project duration of less than three years, Roche was able to improve business value at a minimum risk.

For Roche, this innovative project within technical development is a cornerstone in achieving world class supply chain management and execution.

ROCHE PHARMACEUTICALS

Headquartered in Basel, Switzerland, Roche is a leading research-focused healthcare facility with emphasis in pharmaceuticals and diagnostics. As the world's largest biotech company, Roche provides unique medical solutions in the field of oncology, virology, inflammation, metabolism, and CNS. The Group is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics, and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medication and diagnostic tools that enable tangible improvements in the health, quality of life, and survival of patients. In 2008, Roche had over 80,000 employees worldwide and invested approximately 9 billion Swiss Francs in research & development, which led to a sales value of 45.6 billion Swiss Francs.

For more information: www.roche.com.

Global Clinical Supply Chain Transformation for Roche

Initial Situation

Roche holds clinical packaging facilities in the US and Europe. Several regional distribution centers are in place for direct shipments to sites in one region, while local depots serve only one or more countries.

The existing Clinical Trial Management (CTM) application for randomization, packaging & labeling needed to be replaced as the solution had reached the end of its life cycle.

Roche produces and distributes investigational medical products for multiple global clinical studies on an annual basis. These studies depend on a timely delivery of the medication to be tested to the research sites throughout the world.

Each packaging facility, regional distribution centre and local depot operated independently, which resulted in separated batch management, disconnected planning and inventory reporting processes using different applications.

Further urgent business needs for new system functionalities, e.g., study design, patient enrollment and material planning, shelf life monitoring, restrictions controlling packaging and distribution, multi lingual booklets and labels and distribution order management triggered the initiation of this project.

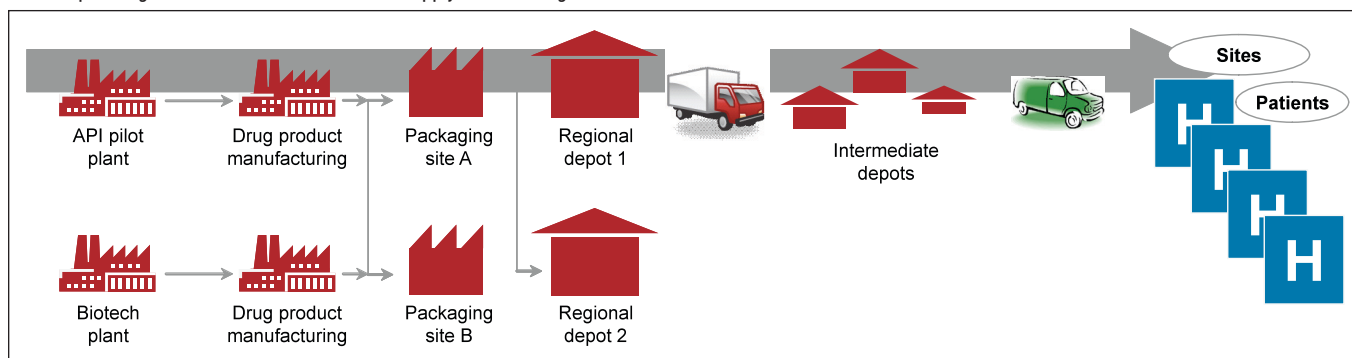
Within the duration of the project, the business case revealed substantial benefits by implementing a new operating model for end-to-end clinical supply chain management.

The Business Objectives

Roche defined very ambitious objectives for their future clinical trials business

- Further increase of service to investigators and patients
- Add more pro-active activities & mechanisms to the organization
- Streamline drug ordering & distribution processes
- Continuous improvement in the end-to-end clinical trial supply chain

New operating model for end-to-end clinical supply chain management



Petra Bielmeier, Roche

Global Head of Clinical Trials Operations

"The implementation was very successful and delivered the results we were expecting. Lodestone played a key role in the success of the project delivering not only SAP technical expertise but very deep life sciences industry and process knowledge. The ability of Lodestone to speak 'our language' was quite unique and was the reason for our fruitful long-term relationship."

Martina Wiemers, Roche

Information Manager

Technical Development & Global Quality

"The business project members in turn learnt about the capabilities of the SAP software. This inspired them to adapt their business processes accordingly or to reflect them much better in a software solution, respectively."

Menno Vlietstra, Roche

Area Head

Global Supply Chain, Finance, HR Global Delivery

"Roche is one of the first companies to have clinical drug supply and many integrated business processes supported by the new SAP software. I was really impressed what business and solution architects managed together to literally squeeze out of standard SAP whilst staying compliant with all Roche policies."

The Solution

The following design principles were driving new processes, organizational structures, and systems

- Holistic view of supply chain starting with technical development
- Set-up of a global distribution network of central, regional and local depots
- Increased visibility of operations by reporting and performance management
- Seamless integration for outsourced activities
- Consolidated IT support across technical development and commercial operations

A True Transformation

Some key changes were implemented in order to transform the supply chain

- Shifts in responsibilities and workload, e.g., master data feeding the planning, manufacturing and distribution in an integrated way requires more effort than for one step only
- New skills, e.g., study based planning across the supply chain for all studies
- More responsibility for operational functions and shorter communication lines

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The CTSM SAP Solution

Clinical Trial Supply Management (CTSM) is the SAP add-on toolset for clinical trial supply chain management and covers specific clinical trial requirements, such as

- Ability to run open/blinded studies and multi-country level studies
- Multi lingual labels compliant with individual country regulations
- Clinical project and/or study driven planning across manufacturing, packaging, and distribution
- Randomization tables management and integration with packaging and labeling
- Improvement of packaging for blinded studies
- Use-by-date control and shelf life prolongation
- Downstream distribution order management up across depots and up to the site
- Integration with I(V)WRS, Interactive Voice/Web Response System, and CTMS, Clinical Trial Management System

The Benefits

Roche has implemented a solution with numerous benefits

- More responsive supply to uncertain clinical demand
- Enforce compliance by embedding the regulatory controls in the process
- Integration of IV(W)RS and CTMS information into SAP
- Improved shelf life management of clinical supply chain inventories
- Fully compliant business processes and validated system
- Internal IT support allowing continuous process improvement in clinical supply
- Fully automated traceability of shipments from regional depots to clinical sites

Lodestone Contribution

Solution architecture and scope control

Development of an integrated solution based on standard SAP components and specific clinical trials solutions.

Process and organization design and implementation

Definition and implementation of new, harmonized processes for the clinical supply chain.

SAP design and implementation

Implementation of a SAP based application including add-ons for all clinical trial processes and organizations in scope. Support in implementing specific clinical trial requirements like study design, clinical forecasting & material planning, randomization management, multilevel packaging & warehousing, clinical batch derivation, batch use controls, I(V)WRS and CTMS integration, label design and approval, and clinical distribution order management.

Why Lodestone?

Lodestone was chosen because of its deep clinical trials industry business processes and technology expertise enabling Roche to realize business value with minimum risk.

Lodestone is a global management consultancy, committed to designing and delivering solutions that enable companies to thrive in today's complex business environment. Our extensive life sciences experience combined with our thought, leadership, and expertise in delivering innovative solutions has made Lodestone a leader in SAP enabled business transformation.