

End to end Clinical Trial Supply Achieving Process Excellence

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CTSM is a leading factor in
conducting clinical studies

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A leading factor in conducting clinical studies is the efficient management of clinical supplies.

Clinical trials are an essential part of the product development process for both pharmaceutical and biotech companies and if run efficiently can provide the company with a competitive advantage. Clinical trials also form a major component of the overall cost of drug development. Stakeholders point to the clinical costs as a barrier to innovation. The FDA has confirmed as part of its “Critical Path Initiative” that “Streamlining Clinical Trials” is one of the key priorities – June 2008 (<http://www.fda.gov/oc/initiatives/criticalpath/report2007.html>)

Improving the process can have a significant impact: a solution that supports integrated processes, inventory visibility, and compliance in manufacturing and distribution of clinical trials supplies. These fundamental improvements are seen as key to the growth of pharmaceutical and biotechnology companies.

Lodestone Management Consultants finds that transforming internal processes and implementing a supply chain strategy based on best practices and SAP technology leads to significant improvements in efficiency and cost effectiveness.

Clinical Trial Supply Management

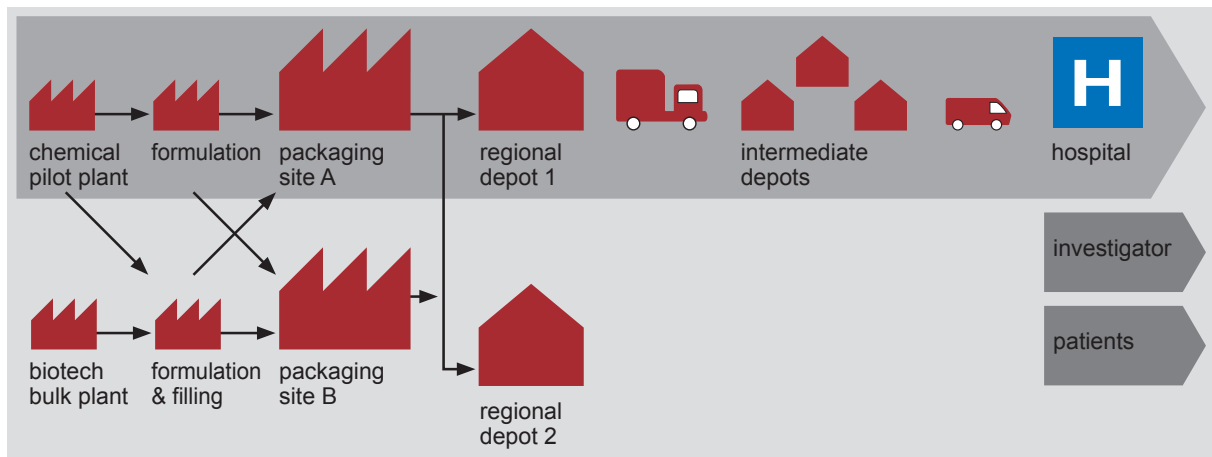


Figure 1

The clinical development phase is the longest and most expensive part of bringing a new drug or medical device to market. Efficient management of clinical study supplies across the supply chain along with precise planning and coordination of activities, both within and outside the organization, are key to successfully conducting clinical studies. (Figure 1)

This paper examines the key challenges of clinical trial supply management and explores the potential solutions available.

Challenges

Three distinct parts of the clinical trials supply management process – planning, manufacturing, and distribution – pose significant challenges.

Planning

Before a trial begins, calculations must be made: how much of the drug and placebo/comparator is required for all patients across the length of the study? Basic formulas, the number of investigative sites x the number of patients per site x dosage x the duration, can be used to provide an initial forecast. However, when the trial begins, a range of factors inevitably alter these original forecasts and impact planning. Three key factors include:

Patient Recruitment

Patient recruitment will vary at, and across, various investigative sites due to a number of factors including: patient availability, patient drop outs, study extensions, investigator performance etc. This results in “staggered enrollment” and fluctuations in demand over the length of the clinical trial.



Expiration Dating

Expiration dating also has an impact on planning and supply management. In many cases clinical supplies must be manufactured prior to the availability of long-term stability data. Delays and or low enrollment can result in the clinical supplies expiring during the course of the trial. This may subsequently require medications to be relabeled or discarded, requiring the manufacture of replacement materials.

Integration across all Manufacturing Steps

A specific plan, at the right level, is required for each step in the supply chain. The key challenge is the ability to keep these plans integrated and aligned.

These factors, among others, pose significant challenges to the organization and its ability to conduct accurate planning and forecasting.

Chemical/Biotech production, Pharmaceutical production & Packaging

The production of clinical supplies in many ways mirrors the manufacturing of commercial drugs. For instance, all operations and processes must be fully compliant with current Good Manufacturing Processes (cGMPs), and are subject to audit by regulatory agencies such as the US Food and Drug Administration (FDA).

However, clinical supply manufacturing faces a number of distinct challenges, including:

- Inadequate production or supply of active pharmaceutical ingredients (API) or biotech bulk
- Shortening of expiration date due to lack of long-term stability data
- Necessity to package small product lots
- Manufacture of different dosages and placebos
- Blinded studies require medications and packaging to appear identical

Distribution

Compliant shipments of the drugs to many investigational sites, often in different countries, can be difficult to achieve as there is a need for:

- Adherence to Good Clinical Practices (GCP) and cGMP regulations
- End to end tracking of the drug throughout the value chain
- Reliable and efficient accountability processes so that drugs are reconciled, returned, and destroyed appropriately
- Access to inventory at distribution sites for distribution planning
- Sharing information with I(W)VRS partners (Interactive (Web) Voice Response System)
- Investigator site stock control in order to achieve end to end distribution planning

Developing a supply chain strategy that addresses the challenges posed in planning, manufacturing and distribution is critical. Any disruption to the end to end supply of clinical trial materials can have significant impacts on the success of a clinical study. Delays in shipments or “stock outs” can lead to patient disqualification, damage to investigator relationships, delays in trial completion; potentially the entire study could be jeopardized.

How SAP technology can help

SAP has a wider scope and is more integrated than the best of breed systems. Extending the SAP footprint to include CTSM means that the entire supply chain is now run on the same environment and allows for full integration and adoption of company and industry best practices.

Specific SAP technology can significantly enhance and improve the processes for planning, manufacturing and distribution of clinical trial supplies. Standard SAP processes for Life Sciences companies can be leveraged to a certain extent and can help to enforce “supply chain” thinking e.g. packaging and distribution should not be isolated processes as is the case at many organizations. However specific SAP clinical trials supply management functionality is still required to create a complete solution:

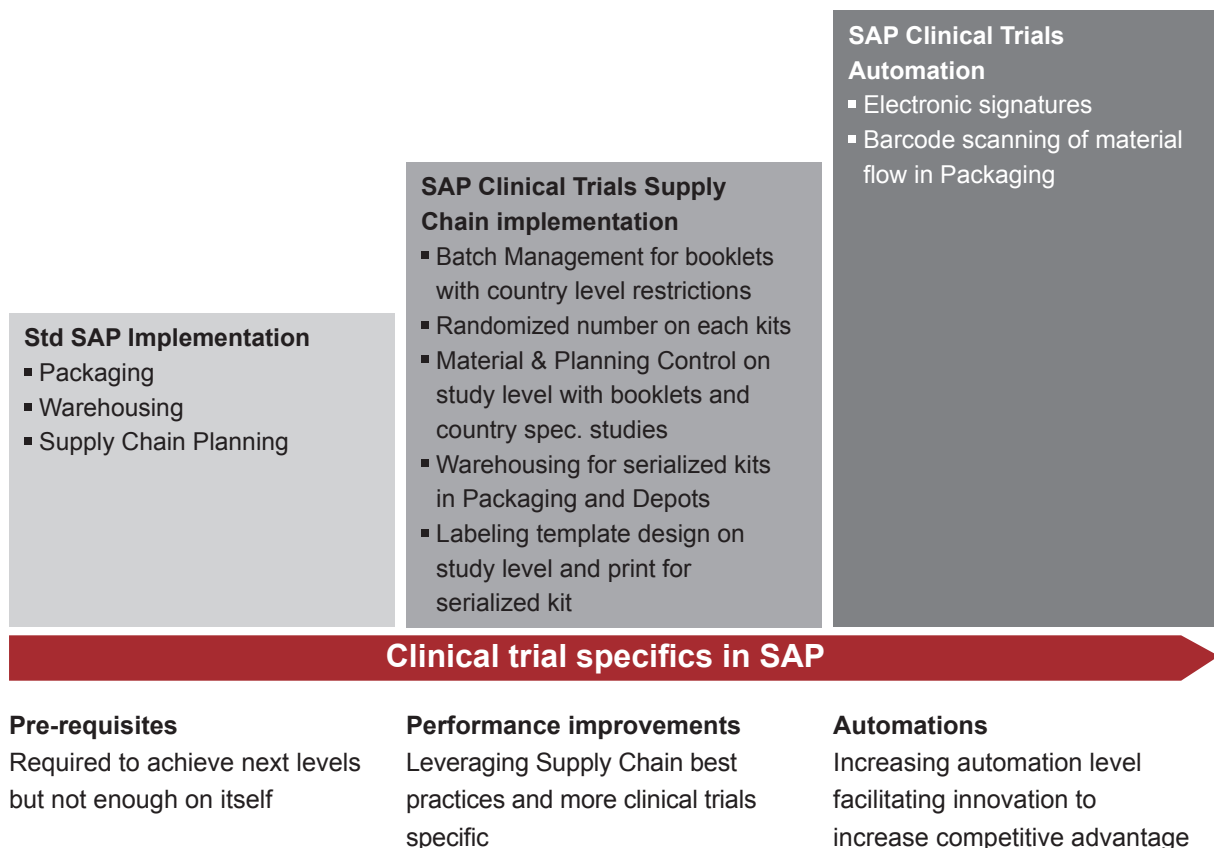


Figure 2

An SAP system with processes based on supply chain best practices and enhanced to handle the intricacies of clinical trials will increase the effectiveness and efficiency of the clinical trial organization resulting in reduced time to market, shortened study timelines and reduced R&D costs.

Planning

Demand calculation functionality helps with the initial forecasting and subsequent planning processes. The demand forecast should be developed at each distribution point that is supplying to investigators. The commitment of planned packaging orders must take place in time to meet the most recent demand placed at the distribution point. This commitment to planned demand supports just-in-time (JIT) packaging and labeling of product to increase flexibility in the supply chain.

Material requirements planning functionality allows for different planning horizons. Long term plans are required for chemical and biotech bulk plant, medium term plans are required for pharmaceutical production.



Rough-cut capacity planning helps maintain manufacturing capacity, and provides visibility of potential date and material shortfalls.

Safety-stock planning functionality can be used to ensure reasonable availability levels. Any last-minute demand changes are updated in the planning process and resolved using interactive planning to create a new demand-supply scenario.

Distribution requirements planning functionality helps the global supply chain planner make adjustments during distribution planning: they can evaluate study-based demand requirements, taking into account the on-hand inventory, to provide the net study requirement. The output will be planned orders for packaging, purchase requisitions for to-be-purchased items, and a plan for just in time distribution of the study materials to the receiving network.

Chemical/Biotech production, Pharmaceutical production and Packaging

Process order handling on the shop floor supports good manufacturing practices. Shop floor data collection systems, using barcode scanning devices, help manage the execution of manufacturing, packaging, labeling and shipping activities to automate traceability.

Batch allocation functionality covers the allocation of batches to process orders in every production step. Enhanced batch allocation functionality is typically required in clinical trials due to regulatory, country and shelf life restrictions.

Randomization tools allow you to create medication numbers according to state-of-the-art statistical algorithms. A randomization manager incorporates the externally generated randomization data in the process orders.

Labeling management allows the design of label templates that can be used for a study and/or a participating country. The label printing needs to be integrated with process order handling. The labels need to be printed for serialized materials or for batched materials before packaging operations are started.

Distribution

Batch search and determination functionality covers the semi-automatic and automatic selection of batches for shipping.

Warehouse management and shipping of serialized kits is highly automated with Radio Frequency scanning and process controls to avoid errors in picking are integrated in the terminal dialogs.

General

E-records and E-signatures meeting regulatory requirements are supported and will become more important in the future.

Inventory management provides a structured inventory backbone for registering all chemical/biotech and pharmaceutical production, packaging and distribution stocks across the network.

The current SAP solution suite can enable the clinical trials supply chain in a unique way. There is no other best of breed system to enable an end to end supply chain management.

SAP alone is not the solution

A solid foundation ensures maximum impact of your SAP technology. However systems alone are not the solution.

Several critical success factors must be managed from a very early stage in the project.

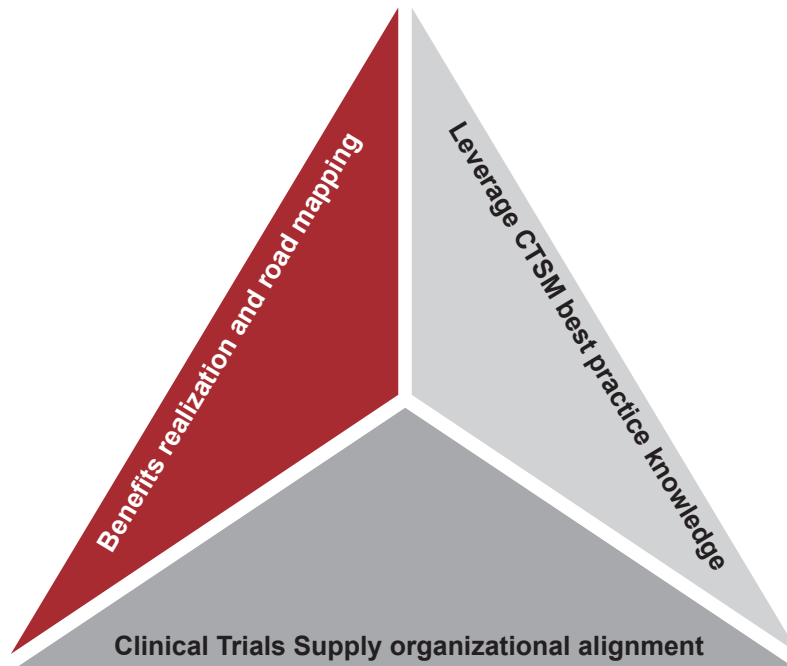


Figure 3

Benefits realization and road mapping

Organizations must first analyze their current situation and define their business priorities for clinical trials:

- Improve inventory visibility? Which materials? Also downstream distribution?
- Reduce material overage?
- Replace a legacy system as it is falling apart or the system is not validated?
- Leverage our current SAP landscape and support organization?
- In-sourcing of packaging or distribution?
- New regulatory requirements?
- Minimize risk of recalls?
- New cold chain requirements?
- Increase efficiency?

Beyond building a business case for investment approval, this activity provides fundamental insights for the business into the program, promotes a change in current thinking and provides a reference point for all stakeholders throughout the life cycle of the project.

The business case must clearly identify the benefits and establish related performance measures. In establishing performance measures the organization creates the basis for monitoring continuous improvement.

The business case cannot be delivered in one phase as the transformational change may be too dramatic. A road map phasing the benefits of realization will be critical to the success of the company journey.



Leverage CTSM best practice knowledge in the to be process design

The project starting activities need to be carefully planned. As there are no off-the-shelf solutions that address the complexities or integrated requirements in Clinical Trials Supply Management, a proof of concept phase is the preferred approach to suggest solutions for the complex and specific clinical trials processes. People confuse a “prototyping” approach with a “proof of concept” approach. A prototype is a system prepared with master data by technical people, the user presentation tends to focus on isolated units of information processing or automation. Business people usually get lost trying to understand the process innovation and clinical trial best practices. A proof of concept starts from a holistic view on the Clinical Trials Supply Management solution. The end-to-end processes are presented by demonstrating pre-configured modules and supported by Powerpoint to clarify any missing soft-ware components. This approach increases business buy-in and allows Technical Development departments to begin to re-think the manufacturing and supply chain management.

The reinforcement and understanding of CTSM best practices needs to be a coordinated effort throughout the project, especially during the process definition phase. The best practices of SAP CTSM technology are key inputs into the detailed process design.

People must also be clear on the best practice concepts of “globally harmonized” and “integrated system” environments.

A thorough understanding of the new process and its benefits will help ensure a successful implementation and increase user acceptance.

Ensure Clinical Trials Supply Organizational Alignment

The implementation of new processes can transform the business and significantly impact many functions: Demand Planning, Materials Planning, Clinical Trial Packaging, Chemical or Biotech Pilot plant, Subcontractors, Distribution, IV(W)RS Service Providers, etc.. It is imperative that these new processes be formalized as written procedures which include roles and responsibilities. This information must be clearly communicated to the organization with training provided on new responsibilities and procedures.

Life Sciences companies must recognize that their “Technical Development” personal were initially recruited to add scientific value and to innovate new products. Generally their current career development plans have not included a track for gaining expertise in lean clinical trials manufacturing or demand & inventory planning best practices. Planning and execution of learning activities integrated with above design tasks is critical to guide the project and end-user community into the new CTSM vision.

Conclusion

A significant opportunity exists for Life Sciences companies to improve the efficiency and cost effectiveness of their clinical trial supply chains.

In the most successful cases, companies have started with a solid foundation – including a clear vision and a solid business case. They have introduced a comprehensive program – based on SAP technology, and supported by a change management program and organizational transformation.

An SAP system with processes based on supply chain best practices and enhanced to handle the intricacies of clinical trials will increase the effectiveness and efficiency of the clinical trial organization resulting in reduced time to market, shortened study timelines and reduced R&D costs.



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Ralph is the engagement Partner for a large global Pharmaceutical player. In his delivery role Ralph supports Lodestone's clients in ERP Strategy, ERP Transformation projects and as Program Manager. Ralph has been on ERP transformation projects in the Pharmaceuticals, Chemicals and Industrials for more than 16 years (14 years SAP).



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Before working as a consultant, Geert gained a broad experience in the Electronics and Machine industry in supply chain functions and was responsible for various change and performance improvement projects in an international context. Geert has 13 years consulting experience, mainly in supply chain management projects in logistics centers, manufacturing plants and distribution. Geert is focusing both on innovative Life Sciences SAP projects and on Operational Strategy projects.



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 developed significant experience and expertise in Clinical Trial Supply Management and has a proven track record in delivering solutions to global Life Sciences companies.

