

INSIGHTS

Clinical Trial Supply Management

Success with SAP

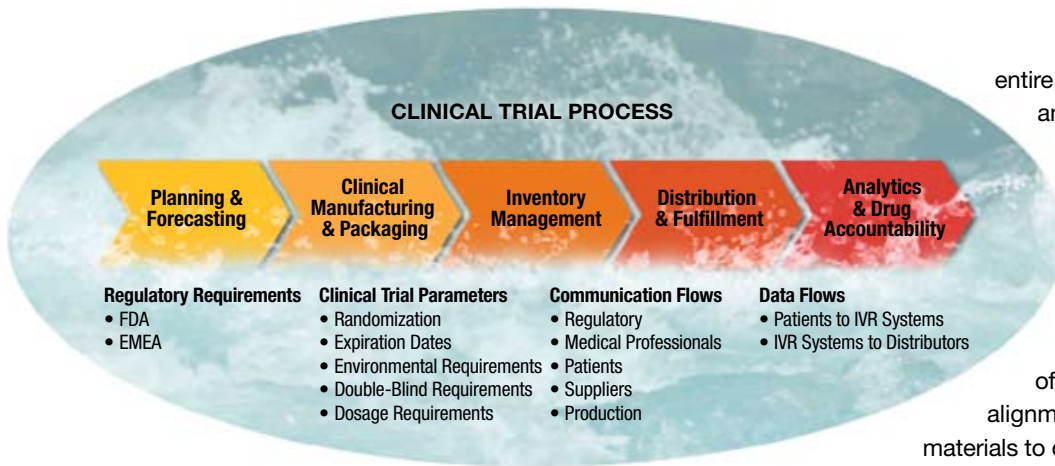
Your objective is clear: bring new drugs to market faster, more efficiently and at lower cost. To do this you must navigate the challenging waters of the clinical trial process. A key success factor during clinical trials is to insure the clinical trial supply chain process works extremely well.

The management of clinical trial supplies covers a broad range of critical and complex tasks: demand forecasting, raw material acquisition, drug production, packaging and labeling, distribution to clinical site trials, coordination with investigational parties, distribution to patients and the patient replenishment process. If your organization partners with Contract Manufacturing Organizations (CMOs), the success of your clinical trial supply chain is even more dependent on effective collaboration with these important business partners. But other complexities also exist.

Clinical trials typically lack long-term stability data, so most investigational studies must contend with the logistics of short expiration dates for the drug. Patient enrollment often comes in multiple waves, some patients do not complete the study, and new patients enroll to replace those who left the study. While these dynamics further compound the challenge of accurate production forecasting, having sufficient supply to meet the demands of the study is essential: running out of stock will jeopardize the validity of the entire study.

Regulatory and globalization constraints also exist. FDA and EMEA regulations apply at every point along the process. Geographically dispersed studies add to the challenges. AMR Research reports that between 2006 and 2010, the number of clinical trials conducted in North America and Western Europe will fall from 55% of all studies to just 38% as more investigational work is conducted in China, India and Africa. Despite these challenges, study parameters must nonetheless be respected, including randomization protocols, blindness standards and drug environmental parameters. Finally, patients need access to customer service representatives or an integrated voice response system to initiate the replenishment process. Replenishment orders must be filled accurately: ***the right drug must go to the right patient at the right time, every time.***





entire supply chain using SAP Demand and Supply Planning for Life Sciences, SAP ERP, and SAP Extended Manufacturing for Life Sciences.

SAP Demand and Supply Planning can significantly increase efficiency and accuracy of demand forecasting and improve alignment of supply for clinical trial

materials to demand. Changing requirements resulting from staggered patient enrollment in trials, patient non-completion of the study, and even increased geographic complexity are efficiently addressed and instantly visible. Improving forecast accuracy will reduce clinical supply cycle time and inventory costs while optimizing the production process.

SAP also addresses inventory management challenges - such as inventory carrying costs, inventory overage and expiration management - by increasing the visibility of inventory throughout the supply chain. SAP includes solutions for Web-based access to inventory management and reports. Batch Management and Classification is used to manage patient kits while maintaining randomization and blindness standards. Kits may be serialized using SAP Auto ID, and a randomization table is available in the CTSM solution to report details of randomization patterns. Standard reports are available to track inventory information related to expiry dates, kit numbers and batches. These features in SAP make the inventory management process for clinical trial supplies much more effective.

Additionally, SAP uses components of the CRM Customer Interaction Center or the NetWeaver Business Communications Management application to connect to Integrated Voice Response (IVR) systems and data. Interfaces to 3rd party applications are also available to integrate IVR data with SAP. Efficient capture of order details translates to reduced order fulfillment and replenishment cycle times by accurately selecting relevant patient kits for delivery to the right place and patient while maintaining study blindness. SAP offers standard functionality to automate compliant label generation for materials and patient kits.

As complex as the clinical trial supply chain is, optimizing this critical business process is vital for your organization’s ability to launch new products quickly and efficiently. Your competitors are optimizing their clinical trial supply chain and will view their improved processes as a key part of their competitive advantage. Clearly, improvement is not optional.

The good news is that there is a solution to the challenge and the solution does not involve large investments in new software and systems. The first step of the solution is to develop a process to optimize demand forecasting accuracy, integrate demand and supply planning, effectively manage resources, time and inventory, and measure performance to stated supply chain objectives. Defining this Clinical and Operations Planning (C&OP) process is essential. Second, you need a system to support the entire supply chain process. The same SAP system you’ve implemented to manage commercial supply chain issues can be leveraged to optimize the clinical trial supply chain as well.

SAP addresses the challenges of Clinical Trial Supply Management

SAP offers life sciences companies the Clinical Trial Supply Management (CTSM) solution, an integrated and collaborative approach leveraging core SAP processes and functions for planning, production, inventory management, labeling, distribution, reporting and accountability. The SAP CTSM solution can eliminate the challenge and hassles associated with a disjointed technology landscape and enable internal collaboration and communication across all supply chain functions. A comprehensive CTSM solution ensures visibility across the

Another key challenge in clinical trial supply processes is accurate and appropriate performance monitoring. The SAP CTSM solution has key performance indicators (KPIs) that enable proactive monitoring of the critical supply chain process. SAP has very strong analytics tools which will provide your business with the measurements it needs to succeed.

In summary, SAP offers a comprehensive solution for minimizing challenges associated with end-to-end supply chain processes for clinical trial supplies.

SAP CTSM – an integrated, superior approach

Recent analyst research conducted by AMR concluded one of the most important best practices for improving clinical trial supply management was to develop an integrated approach for managing the supply chain.² SAP CTSM offers a fully integrated supply chain approach for managing clinical trials. The range of solutions available in SAP increases full process visibility – helping to tear down silos and walls that exist between functions in many organizations. Many silo-style solutions are available in the marketplace, but compared to these, SAP best addresses the challenge of ensuring communication flows in all directions along the **entire** supply chain.

It is also critical to consider the investment required for improving the supply processes. New systems and solutions involve added investment and new system architectures. This means more money and greater support requirements. A key advantage SAP customers realize when they leverage their existing SAP investment is a quicker and more integrated implementation of the CTSM solution.

ROBUST
SAP ERP/R3
<ul style="list-style-type: none"> • SAP ERP / R3 - Production Planning & Execution (PP-PI) • Materials Management (MM) • Quality Management (QM) • Classification & Batch Management • Randomization for Sample Tracking • Label Printing • Serialization for Sample • Sales & Distribution

What SAP CTSM functionality should my company should use?

Industry leaders are adopting a C&OP process to optimize the clinical trial supply chain. Key components of the C&OP process include accurate demand forecasting at the investigator site level, a cross-functional oversight team led by a senior executive, clearly defined performance metrics, proactive supply and demand management and a clear plan to effectively manage conflicting priorities and tradeoffs. Definition of this process will provide your organization with key inputs and the information required to define characteristics of the SAP CTSM solution most appropriate to your organization.

We also recommend that our clients first understand their SAP landscape and supply chain related functions that are presently implemented. It is equally important to leverage the C&OP process to identify the specific goals your organization wants to meet while improving its clinical trial supply

ADVANCED
SAP ERP/R3, SAP SCM, SAP BW
<ul style="list-style-type: none"> • SAP ERP / R3 - Production Planning & Execution (PP-PI) • Materials Management (MM) including Kit Level Inventory Management • Warehouse Management • Quality Management (QM) • Sales & Distribution • Classification & Batch Management • Randomization for Sample Tracking • Label Printing • Serialization for Sample • BW Reporting • Basic Portal/Web Integration (e.g. Web based access for inventory) • SAP QM Notifications or Trackwise for Deviation/Customer Compliant Management

MOST COMPREHENSIVE
SAP ERP/R3, SAP SCM, EH&S, BW/BO Reporting & Analytics, SAP CRM CIC or BCM (NetWeaver)
<ul style="list-style-type: none"> • SCM APO - Demand Planning (DP), Supply Network Planning (SNP), Planning & Detailed Scheduling (PPDS) • SAP ERP / R3 - Production Planning & Execution (PP-PI) • Materials Management (MM) including Kit Level Inventory Management • Warehouse Management • Quality Management (QM) • Classification & Batch Management • Randomization for Sample Tracking • Environment Health & Safety (EH&S) including Label Printing • SAP Auto Id for Serialization of Sample • BW/BO for Reporting & Analytics • Supply Network Collaboration (SNC) for integrating suppliers & contract manufacturers (Web enabled) • Portals / ESOA architecture for Web based/blackberry access to critical transactions (e.g. Inventory) • CRM or NetWeaver Business Communication Management for integrating IVRS (Interactive voice recognition) with 3rd party application • SAP QM Notifications or Trackwise for Deviation/Customer Compliant Management. • BW/BO Reporting (KPI and Dashboard)

Figure 1: SAP CTMS - What landscape is right for you?

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management process. A robust CTSM solution is available for various ranges of SAP functionality and can quickly demonstrate improvements in the clinical trial supply chain process.

Figure 1 is intended to assist your organization in determining and aligning an SAP solution that will optimize your clinical trial supply chain processes. At a high level, use these figures to understand the range of CTSM solutions available in SAP, identify the functionality currently implemented in your organization, and the SAP functionality required to best support the supply chain process goals.

CTSM – the benefits are clear

Simply put, optimizing the clinical trial supply chain allows you to bring products to market faster and more efficiently, giving your company valuable competitive advantage. In the already difficult timelines that exist in many clinical trials, clients who leverage SAP as a solution find that they can **reduce supply cycle times by 40-70%**. Furthermore, through much better control of clinical trial supplies SAP clients find that **expenses related to drug inventory can be reduced by 5-25%**.³ Quicker cycle times mean better and more efficient studies while reduced drug inventory means lower costs and more efficient studies.

However, the greatest benefit is the ability to leverage your improved clinical trial supply chain as a competitive advantage. In a recent AMR study, only 23% of pharmaceutical/biotech companies surveyed rated their clinical trial supply chain as being 'extremely effective'. Most of your competitors simply do not have an excellent clinical trial supply chain.

Given the challenges in the clinical trial supply chain, those who have an 'extremely effective' clinical trial supply chain also have a substantial competitive advantage over their peers.

Shouldn't that be your organization too?

How Can Clarkston Help?

As one of SAP's first national implementation partners and a multiple SAP America Award of Excellence winner, we have been delivering successful SAP projects worldwide for 18 years, building a consistent record of success. In fact, in a recent client satisfaction survey, "Knowledge," "Dedication" and "Results" were the words our clients used to describe us.

Not only do we have deep expertise in the Life Sciences industry but our consultants have many years of experience bringing process and technology innovations together to create powerful supply chain solutions in your industry. From clinical trials to commercial production, through FDA regulations and global challenges, our consultants will help you meet new demands. Our many success stories, consistently high rate of repeat business, and unparalleled customer satisfaction rating all mean one thing: our knowledge, coupled with our dedication, is a winning formula for results.

References

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3. "Pharmaceuticals: Clinical Trial Supply Management," SAP, <http://www50.sap.com/businessmaps/B3BEE4C3D5AF4F2B9E3DE2A8C1B4674C.htm>



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