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CTSM ADD-ON SUITE®

An effective SAP solution for efficient Clinical Trials Supply Management

In today's competitive environment, pharmaceutical, medical device and biotech industries (Life Sciences) need to reduce their R&D costs and time-to-market. These objectives are difficult to achieve in Life Sciences as mounting pressure from authorities to reduce prices and stringent regulations are a fatal combination for either cost savings or innovation.

Life Sciences must focus on their own productivity during the Research & Development (R&D) cycle to bring new products into the market place. R&D companies need to unlock the potential in the clinical supply chain area as the efficient and effective management of supply chains are a key element to Life Sciences success.

End-to-end integration of the R&D Supply Chain with the CTSM Add-on Suite®

Infosys Consulting has significant experience and expertise in Clinical Trials Supply Management, from strategy to implementation. Its proprietary **CTSM Add-on Suite®** introduces a complete set of tools and industry best practices to manage the end-to-end clinical trial supply chains – from manufacturing of drug substance and drug product, packaging of primary packs and clinical finished goods, to the distribution and dispensation of medication to patients at the clinical site.

The **CTSM Add-on Suite®** leverages existing core supply chain management capabilities of SAP® and can be customized to accommodate the intricacies, business processes and unique requirements of clinical trials in Life Sciences. We offer a range of services for clinical supply chain transformations which includes operational strategy, road mapping, business case development, IT strategy, concept and detailed design, integration services to best of breed systems and external suppliers, system implementation encompassing all required support activities, project management, people change management and computer system validation.

The solution manages end-to-end clinical trial supply chain in SAP and can be used for both internal and external operations. These are the CTSM Add-ons from our portfolio:

SAP Global Partner

CTSM Add-ons

CTSM Add-On Suite® SAP® Certified Powered by SAP NetWeaver

- CTSM001 Clinical Warehouse and Container Management
- CTSM002 Forecasting & Characteristics Tool
- CTSM003 Randomization Management and Packaging
- CTSM004 IRT/IVRS and CTMS Integration
- CTSM005 Clinical Order Management
- CTSM006 Clinical Stock Management
- CTSM007 Clinical Batch Management: Study Country Status Management
- CTSM008 Shelf Life Management: Expiry Date Calculation
- CTSM009 Clinical Label Management
- CTSM0010 Web-enabled CTSM for Drug Manufacturing, Packaging, Distribution
- CTSM0011 Just In Time Packaging Tool
- CTSM0012 Digital Clinical Medication Management: Web/Mobile Site Control Tool

All components ensure full backward and forward traceability of clinical supplies and compliance to ensure integrity of clinical trials. A selection of core functionalities:

Forecasting and Characteristics Tool (FCT)	• Study Master Data • Hub and site-level planning • Planned vs. actual enrollments (CTMS and IRT integration) • Site and Country Grouping • Scenario Management, Simulation	**Expiry Date-Based Planning (EDBP)** *new automatic planning solution reducing overages and avoiding a potential out-of-drug situation*
Sourcing, Manufacturing & Packaging	• Kit ID Generator and Randomization tool for scrambled medication list generation and management • Integrated Labeling Solution: Design, Web-based Phrase Library and Approval workflow • Paperless packaging: PI Sheets with XSteps, Pack Verification, Electronic Batch Records (EBR), etc. • CMO Web Portal	**Just-in-time packaging:** *patient-centric 'on-demand' model increasing flexibility and cost-savings compared to replenish-to-stock model*
Warehouse Management & Distribution	• Enhanced serial number and order management • Automated warehouse picking with radio frequency devices • Multi-level SAP® Handling Units with auto-generated structure • Integration with CTMS and IRT (IVRS) systems • Distribution Web Portal	
Quality, Batch & Shelf Life Management	• Shelf Life Management: Stability, Regulatory Approved/Filed Shelf Life • Batch Allocation Cockpit, supporting complex use-by-date calculation scenarios • Use-by-date Extension Simulation and approval tool • Study-Country Status Management with multi-level regulatory controls including genealogy checks • 21 CFR Part 11 compliance	
Clinical Site Control	The next step in our solution expansion, ensuring a fully patient-centric Supply Chain: • Site Inventory Control • Subject Randomization • Web / Mobile Site Access (Fiori) • E-labeling: display of label in the language of the mobile user • Patient mobile app for intake adherence monitoring	**eMeds:** *Digital Clinical Medication Management*

Key benefits

- Proven integration with non-SAP information technology systems like IRT (Interactive Response Technology), CTMS (Clinical Trials Management System)
- No impact on core SAP code
- Direct controlled SAP access for external partners (manufacturing, packaging, distribution) via CTSM web portals
- Full traceability of API, drug substance, primary packs, and clinical finished goods throughout the supply chain – from manufacturing, to distribution, to the clinical site
- Compliance with regulatory requirements and timely drug supply to patients
- Improved performance and reduced costs in the R&D supply chain by:
  - Increase in demand forecast and production planning accuracy
  - Reduction in inventory overages by improved planning and just-in-time packaging
  - Reduction in time-to-market by shortening lead times and clinical trial cycles
  - Leveraging existing licenses to improve the return on investment and guarantee access to a support infrastructure for continuous improvements

Why Infosys Consulting

The Infosys **CTSM Add-on Suite®** was originally developed by Lodestone Management Consultants, a full subsidiary of Infosys that is now operating as Infosys Consulting. The journey started with process consulting at major pharmaceutical companies over 10 years ago, and evolved into a very robust set of SAP accelerators enhancing standard SAP modules and transforming them into a fit for R&D, continuously improved to keep up with market trends.

Our global team enables companies to thrive in today's complex business environment. Our client-focused consultants, with a passion for excellence, offer a unique mix of technical and business process expertise.

CTSM Add-on Suite® has been implemented at leading global pharmaceutical companies. We have become a trusted advisor for our clients* and a strategic partner in the implementation of best practices and industry standards.

For more information, contact askus@infosys.com

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