

## Clinical Trial Supply Management (CTSM)

Clinical trials are a critical phase in a long and complex drug development lifecycle.

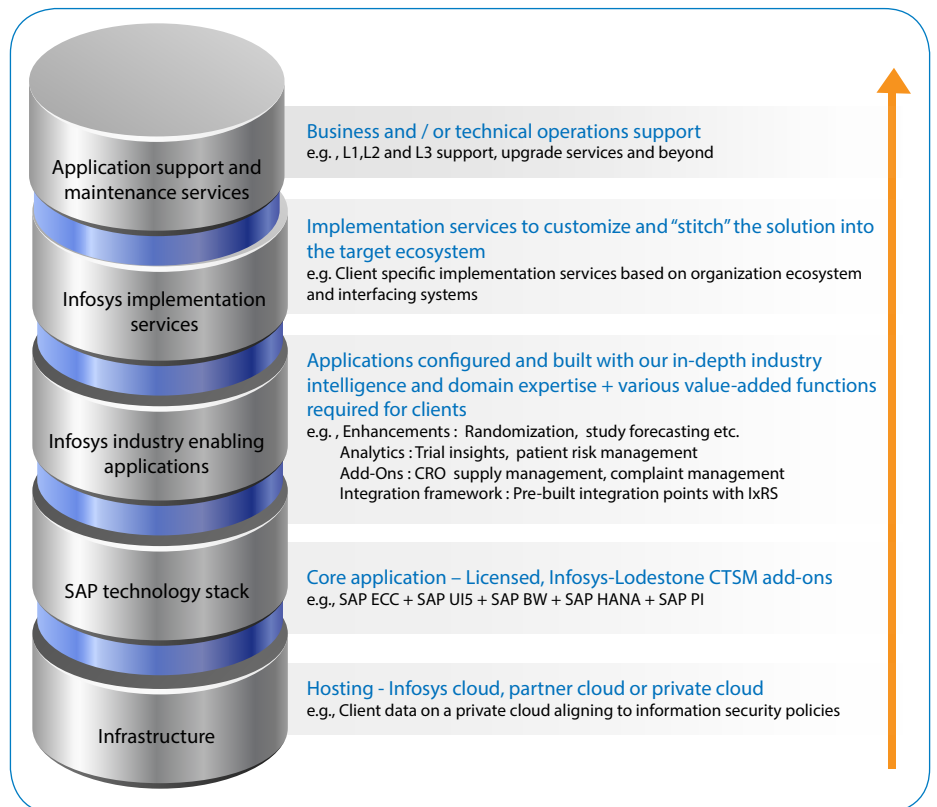
Although several pharmaceutical companies use SAP for commercial supply chains, they are often unable to effectively leverage it for CTSM. Drug makers need an efficient supply chain with an effective IT infrastructure to meet their clinical trial goals. These may include accurate and timely supply of drugs to patient sites, at optimum cost while ensuring compliance with regulations and Good Manufacturing Practices (GMP).



## Infosys Cloud-based Clinical Trial Supply Management Solution

On HANA	On Mobile	On Cloud	With Ariba
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Infosys-Lodestone's comprehensive on-premise SAP based CTSM solution addresses the unique challenges involved in the clinical trial supply chain. The CTSM solution is now available on the cloud with a specific focus on the mid-market segment and contract research organizations (CROs). This solution is on HANA database and is integrated with Ariba for enhanced performance and tighter integration between suppliers and customers. Cloud enables agility and cost optimization while maintaining the best-in-class features of the highly scalable Infosys-Lodestone on-premise solution. It enhances inventory visibility and cost tracking throughout the supply chain while ensuring adherence to regulations and industry best practices. The solution also offers end-to-end ownership of the R&D IT functions for clinical trials.



## Key Features

1. **Clinical data management** - Create and update (manually and / or automatically via an interface) clinical study master data while providing a single source of information to all business units on the clinical under way
2. **Demand planning** – Calculate enrollments or demand for different delivery units / pack types at each trial site
3. **Randomization** - Create and manage randomized lists and allocate medication numbers to packaging process orders for follow-on packaging and label printing
4. **Clinical packaging** - Create hierarchical packaging of MedKits, boxes and pallets with unique sequence numbers and print barcoded labels for delivery units
5. **Clinical distribution** - Enable industry specific medication number allocation to both supply and replenishment deliveries
6. **Clinical projects planning and budgeting** - Capture all scheduled activities for a project using Project Planning, a powerful tool, together with planned costs and material with a hierarchy of work breakdown structure (WBS) as required
7. **Intuitive user interface** - Perform key business functions on SAP UI5-based screen with intuitive and user-friendly interface for extensive adoption of the solution and user satisfaction
8. **Mobile-enabled transactions** - Enable real-time data entry for faster decision making by allowing remote access to transactions
9. **Pay-per-use model** - Pay only for what you use with zero investment in on-premise infrastructure

## Solution Benefits

- Improves control of overall project cycle for clinical trial management including logistics and scheduling and costing for end-to-end clinical trial supply chain
- Enables traceability of materials, variants, kits throughout the supply chain
- Improves compliance standards by means of “user status” at project / WBS level, Document Management System (DMS) and e-signature
- Eliminates hardware maintenance costs
- Reduces implementation costs by up to 50%
- Reduces running costs by 30% - 40%
- Decreases lead time by 10% -15%
- Reduces inventory overages by 30% - 40%
- Shortens the clinical trial cycles by up to 10%

### Cloud enabled features

1. **Seamless integration and collaboration** - Enhances data collaboration between multiple agencies by simultaneous upload and access to information
2. **Centralized systems** – Allows access to the system / application from any location and at anytime
3. **Data collection and management** – Enables faster data collection and consolidation for rapid transmission to different sites globally

For more information, contact [askus@infosys.com](mailto:askus@infosys.com)

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