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# Infosys Clinical Trial Supply Management (CTSM) solution

## Turbocharge your clinical trials

Modern technology is changing everything from the way we work and live to the way we do business. It is driving change and creating opportunities to connect in unprecedented ways, including in clinical trial supply management (CTSM).

Connected people and systems make all the difference in delivering timely, accurate results.

Pharmaceutical companies strive to engineer hope as they go through the process of researching drugs that have the potential to improve the lives of so many.

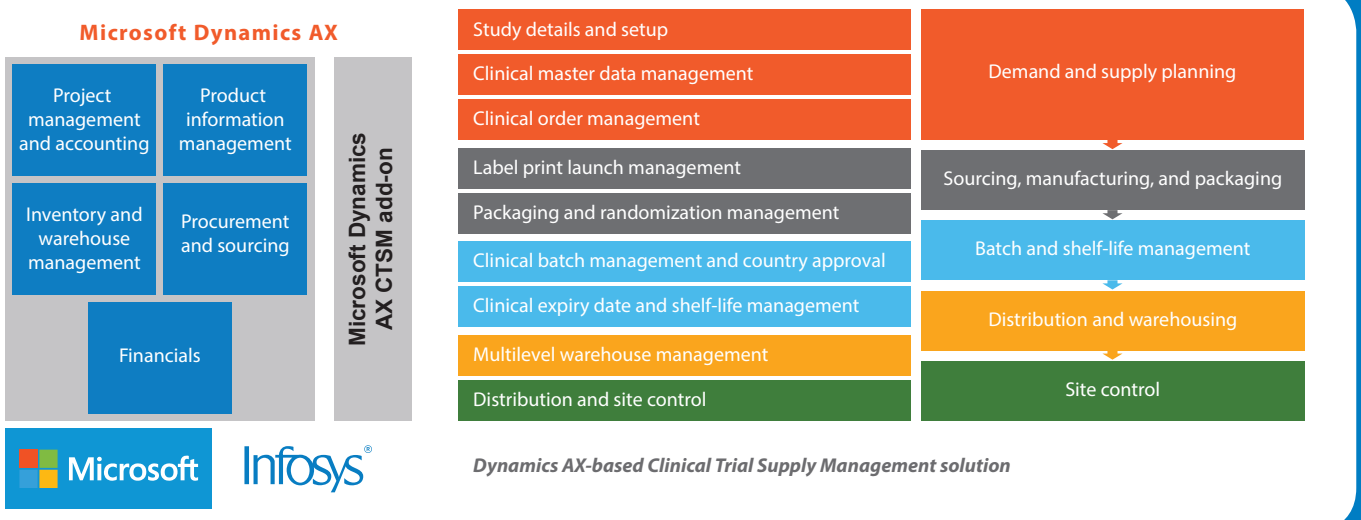
An efficient CTSM serves to accomplish this goal more quickly, and with more accurate results.

## Microsoft Dynamics AX based CTSM solution

This solution helps biotechnology and pharmaceutical companies, and contract research organizations (CROs) manage supply chain activities in clinical trials. With timely and accurate supply of drugs to patient sites at optimum cost, it improves overall control while ensuring compliance with regulations and good manufacturing practices (GMP). Key industry challenges such as a lack of visibility in supply chain, uncertainty in demand, meeting regulatory requirements, and site and integration management with CROs, are managed efficiently. The new cloud-based version of the CTSM solution offers increased visibility across the clinical trial supply chain (CTSC) – driving greater manufacturing and warehouse efficiencies while further ensuring compliance. For example, enterprises can respond faster to changes in demand based on actual enrollment and patient turnaround during trials.

**Incorporate this exceptional tool to:**

- Integrate easily with existing Microsoft Dynamics and other ERP solutions, incorporating business processes and other unique requirements of clinical trials
- Enable mobile transactions to take advantage of real-time data entry for faster decision-making
- Eliminate the need to invest in or manage expensive infrastructure dedicated to clinical trial management through our pay-per-use basis
- Manage everything from clinical data, demand planning, and randomization, to clinical label printing, and specialized packaging needs
- Meet industry and compliance standards such as Safe Harbor




*Dynamics AX-based Clinical Trial Supply Management solution*

## Solution overview

Infosys CTSM solution on Dynamics AX provides an intuitive user interface similar to Microsoft Office applications, ensuring rapid user adoption while taking advantage of robust back-end analytics tools. It leverages the AX project management module to have a tight integration with financials.

## Key features of CTSM solution

- Study details and setup
- Clinical master data management
- Clinical order management
- Label print launch management
- Packaging and randomization management
- Clinical batch management and country approval
- Clinical expiry date and shelf-life management
- Multilevel warehouse management
- Distribution and site control
- Compliance to CFR Part-11-related regulatory and security aspects

## Customer benefits

| Strategic supply chain benefits | Cost efficiency | Privacy, regulatory norms | Speed and flexibility |
|---|---|---|---|
| • Connect supply chain with external entities<br>• Support R&D acquisitions for clinical supply<br>• Support quality by design to ensure aligned data for process analytical technology | • Higher manufacturing and warehousing efficiency while maintaining compliance<br>• Proactive management of manufacturing and distribution<br>• Enable continuous improvement<br>• Transparency of budget planning | • Secure data with access and password control<br>• Enforce quality and regulatory controls in clinical orders<br>• End-to-end IoT tracking from drug substance to clinical site delivery<br>• CFR Part-11-related regulatory and security aspects | • End-to-end visibility, and responsiveness to clinical demand changes<br>• Planning from upstream production to clinical site to get a common view of risks |

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For more information, contact askus@infosys.com