Clinical Trial Supply - Executive Viewpoints on Challenges and Orchestration Opportunities

Jitendra Kumar

Director Innovation and Technology

Thermo Fisher Scientific

Tereance Puryear

Solution Consultant, Senior

TraceLink

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Session Backdrop

- Supply chain digitalisation can improve speed, provide enhanced visibility and intelligence in the clinical supply environment like it does in the commercial supply chain.

- In looking at the supply network of trial sponsors, contract manufacturers, logistics providers, and trial sites, hear about current and emerging opportunities for the digitalisation of clinical supply transactions and why tighter orchestration of the network participants ensure precision and resiliency in this highly dynamic environment.

The State of Clinical Trials: By the Numbers

30% Average dropout rate across all clinical trials

85% of clinical trials fail to retain enough patients

3-9 Months for average point-to-point IT integration

1 of 10 Drug which enters clinical trial phase gets approved

$35K+ Average operational cost per day of a clinical trial

10-15 Years from drug discovery to market approval

12-15 IT systems used in a typical clinical trial

2.6 Billion dollars to bring a drug to market*

*includes cost of successful and failed programmes across the board

Major Clinical Trials Challenge – Disconnected Systems

Many **disconnected systems** to manage various aspects of Clinical Supply Chain and Clinical Trials

- **Sponsor** – (ERP / CTMS)
- **CRO** – Clinical Trial Management System (CTMS)
- **CDMO** – ERP / MRP
- **CMO Packager** – ERP / MRP
- **IRT** – Randomization and Patient drug allocation (IxRS)
- **3PL** - Logistics
- **Miscellaneous Systems**
  - Electronic Trial Master File (eTMF)
  - Electronic Patient Reported Outcome (ePRO)
  - Electronic Clinical Outcome Assessment (eCOA)

Challenges

- **Disconnected Data & Supply Chain**
- **Lack of Visibility & Transparency**
- **Decision Making Delays**
- **Poor Demand Planning**
- **Drug Waste**
- **Patient Recruitment**
- **Low Patient Retention**
- **Patient Adherence**
- **Admin Burden – Paper/ Data Redundancy**
- **High Cost**

Clinical Trial Supply Business Operation Mode

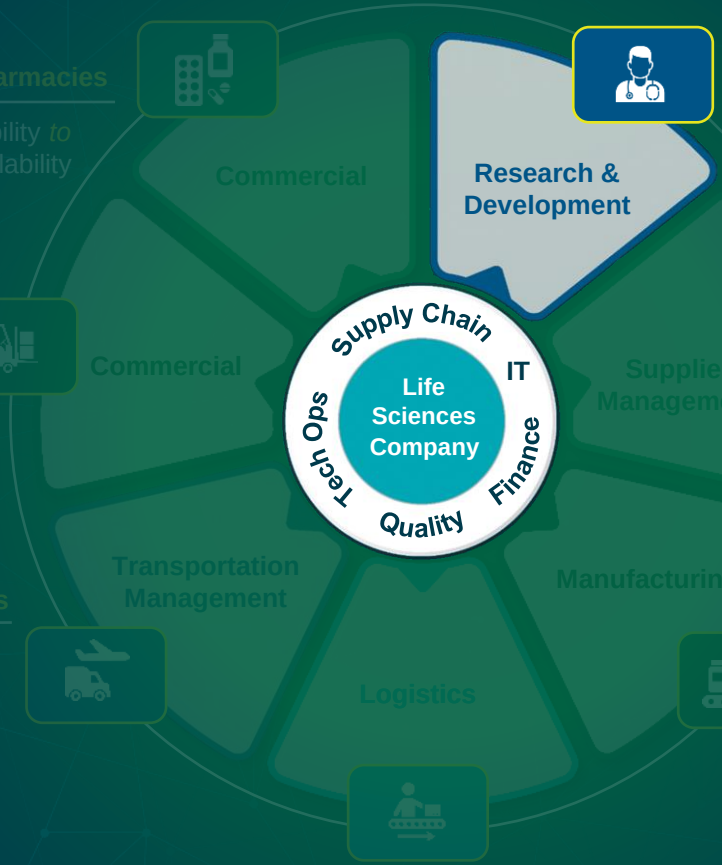
Current State Challenge

- E-Mail / Portals
- Point-to-point proprietary system integrations with each stakeholders
- Lack of data standards adoption for data sharing
- Average 3-9 months for enabling IT system integration (ERP, MRP, IRT, 3PL, Order Management, etc.)

Future State Required

- Data sharing industry standards adoption
- Integrate-once with stakeholders using multi-enterprise network
- Enable speed for data sharing to improve efficiency, quality and colleagues experience

Orchestrating Outcomes in Clinical Supply Chain



Clinical Supply Chain (CDMO, 3PL, Clinical, etc.)

Product & Patient Orchestration *to achieve* Supply Precision

Hospitals & Pharmacies

Drop Ship Visibility *to optimize* Product Availability

Distributors & Wholesalers

Order-to-Cash *to enable* Financial Reconciliation

Direct Suppliers

Procure-to-Pay *to acquire* Predictable Lead Times

Transportation Providers

Shipment Tracking *to achieve* Cost Optimization

Contract Manufacturers

Production Tracking *to achieve* Working Capital Optimization

Logistics Providers (3PL / 4PL)

Inventory Tracking *to achieve* Service Level Maximization

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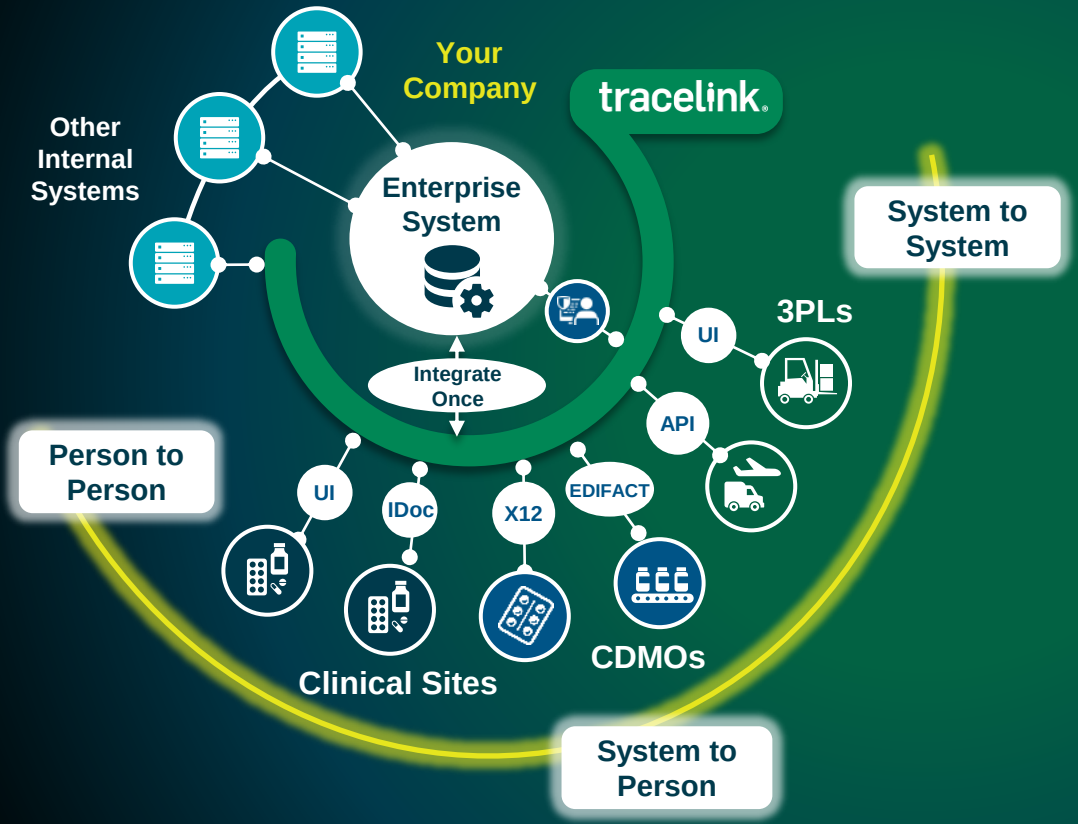
MINT for Clinical Supply Chain



Integrate-Once™ for:

- **Drug Receipt**
  - Advance Ship Notice (Despatch Advice)
  - Receiving Advice
- **Inventory**
  - Inventory Balance Request & Report
  - Inventory Status (Release Status, Kit Status Change)
- **Packaging**
  - *Packaging Order Request*
  - *Production Order Approval*
  - *Production Batch Record Approval*
- **Distribution**
  - Ship Order Request
  - Ship Order Acknowledgement
  - Shipping Advice
- **Reconciliation**
  - Drug Return Order
  - Destruction Confirmation

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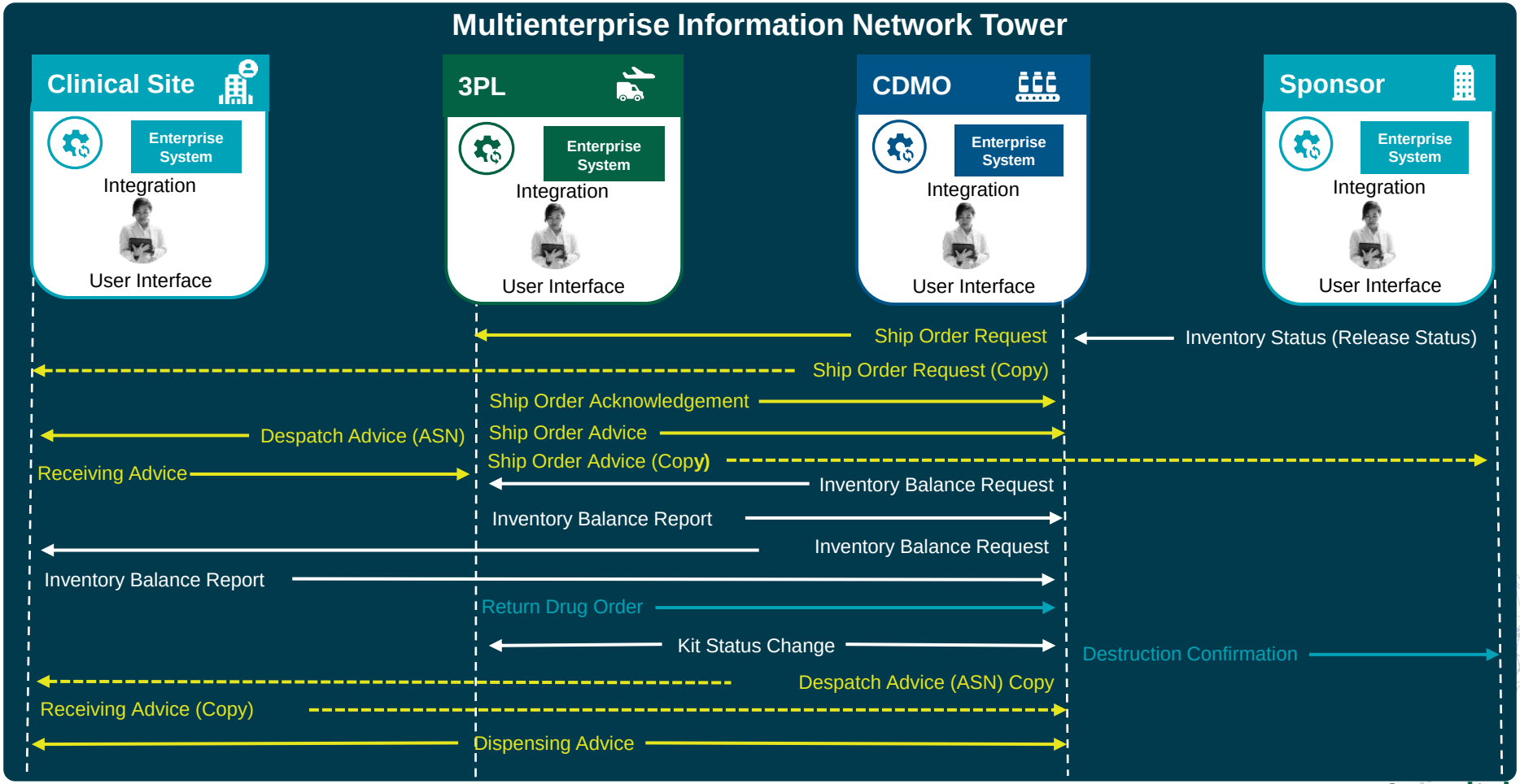
MINT Transaction Flow for Clinical Supply Orchestration



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The “Win-Win” Outcome: Why Your Clinical Partners Will Benefit from MINT

- Real-time exchange of inventory release status keeps clinical partners updated and ensures accurate execution of clinical process.
- Electronic ship order exchange ensures clinical sites receive the kits and medicines with consistent, predictable notice, on-time and in-full.
- Ensure that the energy, efforts and resources are focused on clinical trial outcomes, and not on chasing order and delivery status.
- Using in real-time information exchange between systems ensures better execution of the clinical trial and can reduce time to commercialization.
- Single multi-modal integration to TraceLink reduces IT costs related to maintaining outdated modes of information exchange, including EDI and point-to-point integrations.
- CDMOs and 3PLs can use the single link to improve the operational efficiency and reduce costs with other clinical trial customers.

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