Best Practice Approaches to Improving Clinical Supply Chain Management

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A variety of challenges complicate trial supply management

- Multiple languages
- Country-specific regulations
- Shorter timelines for patient enrollment
- Lack of historical data to create accurate forecasts
- Complex protocols
- Cross vendor alignment
- Logistical challenges in transporting and distributing trial drug
A new model is needed to drive greater quality, speed and efficiency.

Integrated processes and tools can improve visibility and enable optimal execution across the entire supply chain – and throughout the life of your trial.
Proper supply planning is a critical first step in the process.

**Identify Key Stakeholders**
- IRT
- Quality
- Regulatory
- CRO
- CMO
- Clinical Team
- Drug Management Team

**Gather Information**
- Randomization design
- Treatments
- Visit schedule
- Unblinding procedures
- Ancillary and concomitant supplies
- Sample size, patient, duration

**Define Roles and Responsibilities**
- Governance chart
- Technical agreement
- Project plans
- Deliverables checklist
- Standardized and process flows
Lessons learned from prior trials set the stage for future success

- Form strategic partnerships across functional teams to reduce risk, time and cost
- Have pre-defined working processes for outsourcing stakeholders
- Be actively engaged in timeline management across cross-functional deliverables
- Establish well-coordinated import/export applications
- Understand that IRT delays can negatively impact when supplies can be shipped, which can impact First Patient First Visit (FPFV) milestones – get started on this as early as possible!
Establishing a baseline forecast informs manufacturing and distribution

A forecast predicts demand based on clinical events and patient activity in the clinical trial supply chain over a period of time.

Reduces the Risk of Stock-Outs

Manages – and Minimizes – Cost

Optimizes Inventory and Maintains Balance
Steps to forecast generation

1. **ESTABLISH A DATA COLLECTION PLAN**
   - Outlines which study variables will drive product demand
   - A baseline is then established to inform manufacturing and distribution plans

2. **UTILIZE EXPERIENCE**
   - If assumptions are used, rely on historical data of regional clinical trials to ensure accurate forecasting and baseline generation.

3. **MAKE ADJUSTMENTS**
   - Using IRT throughout the study to refresh the baseline forecast based on real-time data
   - Variances from the forecast can be detected and used to optimize shipping/distribution
Packaging design is another area that should be addressed early-on

<table>
<thead>
<tr>
<th>KEY CONSIDERATIONS</th>
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<tr>
<td><strong>PRODUCT TYPE:</strong> Comparator and study drug will be blistered and in wallets</td>
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<td><strong>PATIENT COMPLIANCE:</strong> Need to reduce the possibility of over dosing as much as possible</td>
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<td><strong>SITE COMPLIANCE:</strong> Ambient storage (if possible) / clean and neat kit design</td>
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<td><strong>BLINDING:</strong> Indicating the strength of comparator will not unblind the study</td>
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<td><strong>COST:</strong> Comparator is relatively expensive</td>
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<td><strong>COUNTRIES:</strong> Country specific requirements. i.e., booklet labels, child resistant requirements</td>
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<tr>
<td><strong>VISIT SCHEDULE:</strong> Quantity and kit configuration</td>
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<td><strong>SHELF LIFE:</strong> Potential of expiry updating</td>
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When distribution is optimized, ‘just enough’ investigational product is on hand

For best results, begin planning when the protocol is still under development

- Identify study milestones that will affect product demand
- Understand regulatory and logistical details that may impact delivery
- Perform a thorough risk analysis
- Design a system that delivers requisite supply
- Adjust supply based on shifting demand and environmental factors

When the proper ordering, tracking, and information-sharing processes are in place within the IRT, every function along the way can monitor supply and demand, working proactively to forestall potential issues
Supply distribution considerations

- Meeting import/export regulations
- Minimizing transportation cost
- Maintaining temperature stability across climatic zones
- Complying with return and destruction regulations
IRT plays a central role in supply management

- Monitor Depots and Site Inventory
- Enrollment/Randomization
- Visit Schedule/Drug Assignment
- Resupply Requests
Technology should link and integrate key supply management activities

**Forecasting / Simulation**
- Initial forecast
  - Projected patient demand
  - Visit schedule
  - Protocol variables
  - Scenario comparisons
- Net forecast inputs
  - Site inventory
  - Patients dispensing events
  - Expiry date

**MRP**
- Creates planned production orders based on:
  - Forecast
  - Safety stock
  - Pending production orders
  - Existing inventory
  - Site inventory
  - Item bill of materials

**Manufacturing Plan**
- Detailed component planning

**Distribution**
- Depots and sites

**Dispensing**
- To patients

**Data Integration with IRT (IVRS/IWRS)**

- Inventory Release File
- Drug Orders
- Patient Event Data

- Actual patient event data considered in net forecast
- Inventory at or in transit to sites considered in net forecast
- Vendor and depot inventory considered by MRP

*Enables greater visibility and accuracy across the entire supply chain*
Automate execution and reporting to improve decision-making

Get Real-time via Reports

Collect, collate and analyze data

Make decisions to optimize demand and reduce IP wastage

Adjust settings in IRT and upstream process
A partnership model can help sponsors who lack internal resources.

**KEY PARTNER ASSESSMENT CRITERIA**

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<th>Details</th>
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<td>System and procedures must ensure both quality and efficiency</td>
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<tr>
<td>Global footprint</td>
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<td>Demonstrated stability and maturity in the industry over time</td>
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<td>Proven technology to support the process</td>
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<td>Responsive service and proactive communications</td>
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<td>Flexible offerings that can be customized, if needed</td>
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Summary

Taking a more strategic approach to supply chain management can pay dividends later on.

Key benefits include reduced drug wastage, faster timelines, and lower cost.

Start with an overall supply plan and central project manager, then develop follow-on plans, e.g., forecasting.

IRT is a critical success factor in proper supply management.

Partnering may be an option, especially for less experienced sponsors.
Questions?
Thanks for attending

• For more information:
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