Overcoming Common Supply Chain Pitfalls

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Agenda

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- Highlight areas of the supply chain that are commonly overlooked.
- Look at associated timelines, emphasizing the impact of improper planning.
- Discuss best practices to address common pitfalls.

Demand Forecast

- Establish baseline
- Source of data for decision making
- Trending

Assign Responsibility: Know Your Stakeholders & Resources

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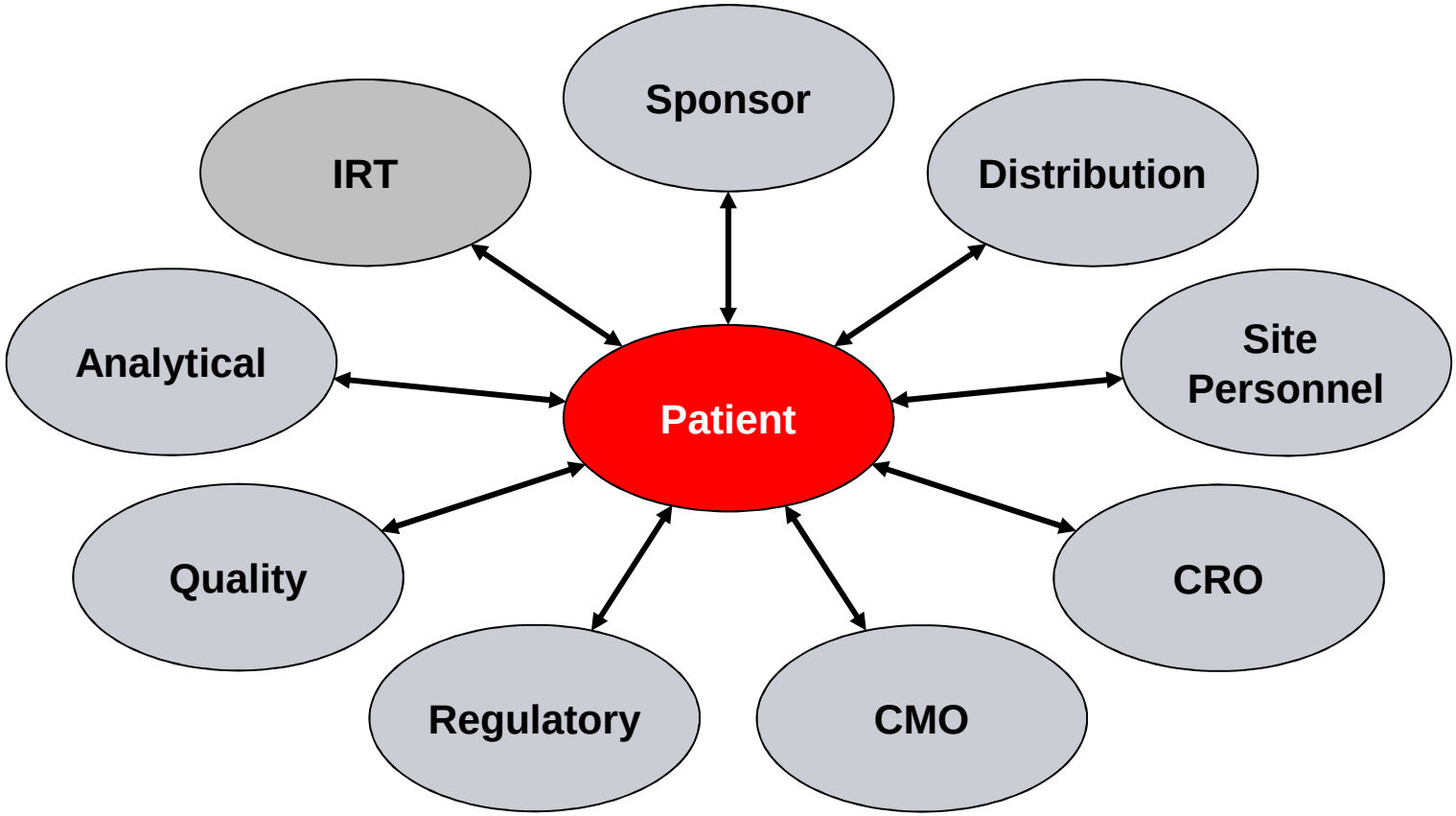
- Establish team and roles/responsibilities
- Maintain contact lists.
- Make firm agreements on timing with decision makers.
- Preparing for adequate resources to address spikes in work.

Who are the stakeholders?

People and Systems using Effective Communication



Integrated Supply Chain Management

Impact

Delays

Drug Product Delivery to Site Delivery: 4 months

- Consider receipt process
- Production
- Documentation creation and approval
- IRT Release
- Transit
- Temperature Excursions

Solutions

- Make Detailed Project Plan clearly visible to entire team
- Transition documents containing:
  - study details
  - roles/responsibilities
  - unique processes
  - contact list
  - drug valuation
- Establish agreements (and associated timelines) with stakeholders

Pay Attention at Set-up

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- Understand how the IRT releases drug, orders drug, confirms receipt, records dates.
- Request a mock or sample of patient supplies. Inadequate packaging/labeling of drug that is similar in appearance.
- Consult with health authorities before study start to ensure unique or creative processes (e.g. method of temperature monitoring, labeling) meets regulatory requirements.
- Prepare for common critical path items - label approval, health authority study approval, QP release, returns management.

Impact

- Unblinding
- Start-up delays
- Drug shortages

Establish Processes

- Import License Tracking
- Consistent valuation
- Expiry/retest date extensions and rework of supplies.
- Temperature monitoring and excursion assessment
- Changing Regulations

Impact

- **IL Tracking**
  - – leads to major delays in shipping required supplies to participating countries.
- **Valuation**
  - – certain countries will question the value of drug before allowing clearance into country (as some companies claim lower values to decrease taxes/duties on the import).
- **Expiry/retest date extensions**
- **Temperature Monitoring and Excursion Assessments**
  - – prolonged turnaround time for temperature excursion assessment.

Import License Tracking

Process-flow

Start-up:

- Gather import country requirements
- Record Regulatory Authority approval dates, date for which initial IL in place, and initial IL quantities.
- Create timelines for raising initial depot/site orders in line with dates above.
- Once depots/sites receive initial depot order, track IL's, as outlined under *Maintenance*.

Import License Tracking

Process-flow

Maintenance – For Quantity Based ILs:

- Establish trigger that will prompt IL renewal.
- Regularly obtain updated forecasted depot/site orders (shipment dates and quantities per item type)
  - If forecast not available, assess distribution and calculate burn rate. Burn rate will provide basis for determining shipment volume/frequency.
- Keep account of IL quantities in tracker.
- When trigger reached, renew IL.
- Record quantity on new IL and track as outlined above.
- **For Time Based IL's,** establish time point trigger and notify accordingly.

IL Trackers

Country	Date of Regulatory Approval	IL Required?	Date of Initial IL	Lead Time for new IL	Is IL per shipment, time or quantity based?	If time based, Expiry Period (months)	Current IL expiration	IL Quantity Format (e.g., tablets, final kit)	Special Requirements (e.g., BSE/TSE, lot specific IL)	Notes (e.g., imports may continue during renewal)

FOR QUANTITY BASED IMPORT LICENSES

Country:				Planned Depot Orders (Shipment Date)							
Item Type	IL Quantity Format (e.g., tablets, final kit)	Initial IL Quantity	Current IL Quantity	MO/YR	MO/YR	MO/YR	MO/YR	MO/YR	MO/YR	MO/YR	MO/YR

Temperature Excursion Monitoring

- Establish Stakeholders
  - Who is reporting excursions?
  - Who is evaluating for disposition?
    - Preliminary evaluation based on standard ranges?
    - If outside of range – Analytical or Quality Groups?
- Establish source documents/systems for temperature ranges (with the latest data)
- Agree turnaround times
- Keep metrics to ensure all stakeholders doing their part.
- Trend to address recurring issues.

Expiry Update Process

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- Goal is to ensure drug at site on time while reducing number of shipments and conserving drug at depots.
- Consider – shipment configurations, budget and drug constraints, shelf life of product, visit schedule, amount of customization required in IRT.
- Blinding: Order all? +1 per shipment? Where are unblinded drug orders going?
- Are the drug orders being transmitted to distributor and is the required information detailed on the orders?

Changing Regulations

- Audit findings. Import Requirements. Label text.
- Road blocks: drug and budget shortage.

Summary

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- Create Baseline Forecast
- Know Your Team Members
- Pay Attention at Study Start
- Establish Processes