Clinical Trial Supply Management: A virtual company’s lessons learned

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Disclaimer

The views expressed in this presentation are mine and do not reflect those of my past, present or future employers…
Senior Management View of CTS

Drug Manufacturing → Labeling → Drug Depot

Clinical Sites

What’s so difficult? Devil is in the details…
IMP Characteristics

- Refrigerated storage product
- Stability OK for up to 1M at RT
- Not stable at > 40°C
- Very expensive per unit cost
- Limited supply (only 10% overage)
- On-going stability—retest updates
Clinical Trial Parameters

- 48 sites, 6 countries, 3 continents
- Study duration: 12 month
- Recruitment: 9-12 months
- ~300 subjects total
- 0.5 subjects per month per site
- IMP in 3 month kits
IMP-Driven Decisions

- Cold chain supply
  - Refrigerated shipping
  - Shipments needed to be temperature monitored
- Just-in-time shipping
  - Couldn’t keep inventory at sites
  - Randomization would trigger shipping
Trial-Driven Decisions

- Product manufactured in North America

- Continents
  - North America
  - Europe
  - Asia-Pacific

- All countries in Europe part of EU (!)
  - Single QP release for all of Europe
(Idealized) Product Flow

1. Drug Manufacturing (North America) → Labeling & Packaging (EU) → QP Release
2. Drug Depot (US) → Clinical sites
3. Drug Depot (EU) → Clinical sites
4. Drug Depot (Asia-Pacific) → Clinical sites
Logistic Challenges

- Customs
- Multiple QP release
- Volcanic eruptions

- Find a customs broker—upfront!
  - Got bill for $200K
  - We were able to get most of it back, but…

- Shipping-logistics expert (consultant)
Case Challenge

- Had 3 year stability on old formulation
- Changed IMP formulation
- IMP retest date driven by real-time stability
  - Get stability data from manufacturer
  - Update IMPD
  - Submit to European country authorities with proposed retest extension
  - Receive approval
  - Release newly labeled IMP into inventory
- Shipped 3 month supply
Lessons Learned

- Have enough stability BEFORE you begin 😊
- Map out supply chain and plan for contingencies
- Independent person to track and review inventory & retest dates
  - Person needed to be unblinded to track placebo & active kits
  - Required excellent coordination with regulatory
Other Learning Discussions

- Shipping:
  - Premium provider versus Standard Courier
  - Just-in-time shipping versus inventory at sites
    - Cost of drug and availability
    - Cost of each shipment
- Temperature monitoring
  - Bulk shipments versus Individual shipments
  - Temperature monitors versus warmmarks
Questions?

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