



# **Clinical Trial Supply Management: A virtual company's lessons learned**

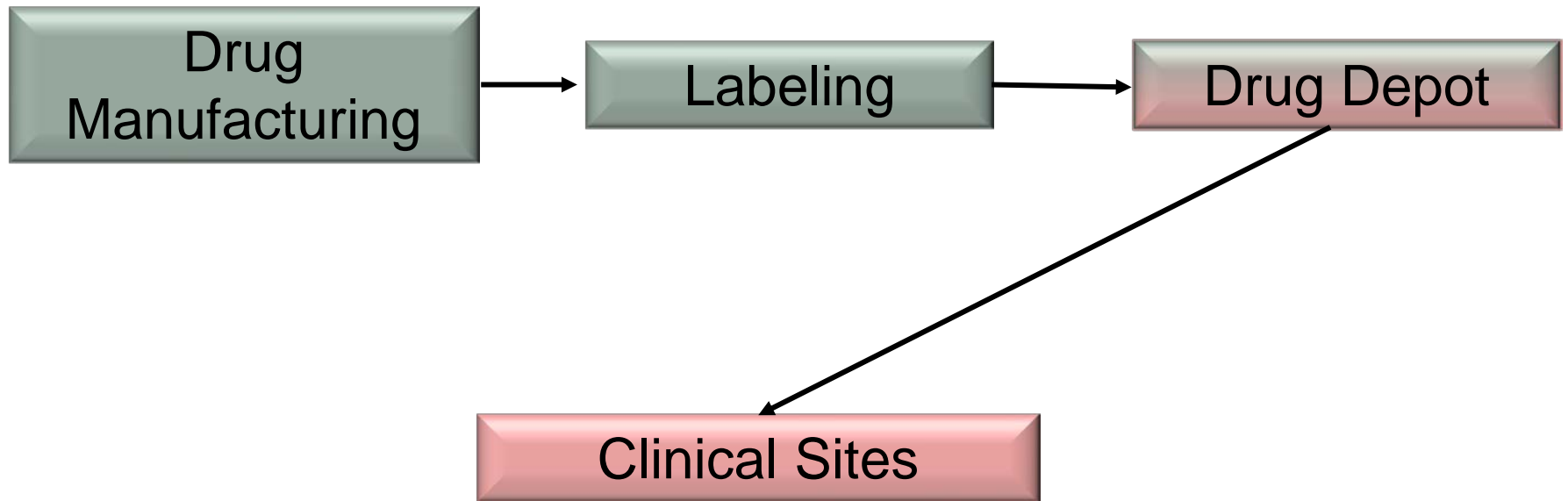
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# Disclaimer

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



*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  $> 40^{\circ}\text{C}$
  
- 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

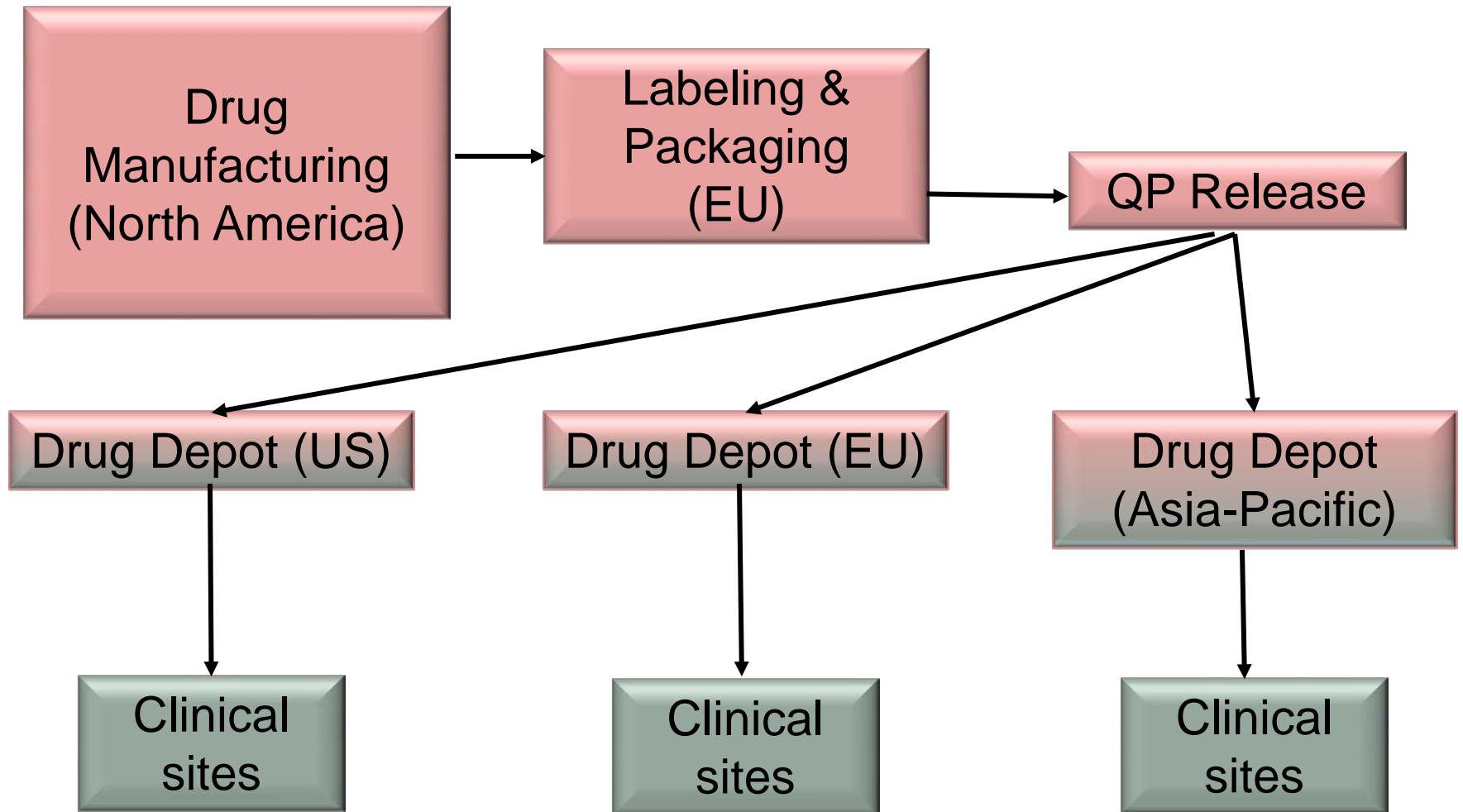
# IMP-Driven Decisions

- 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

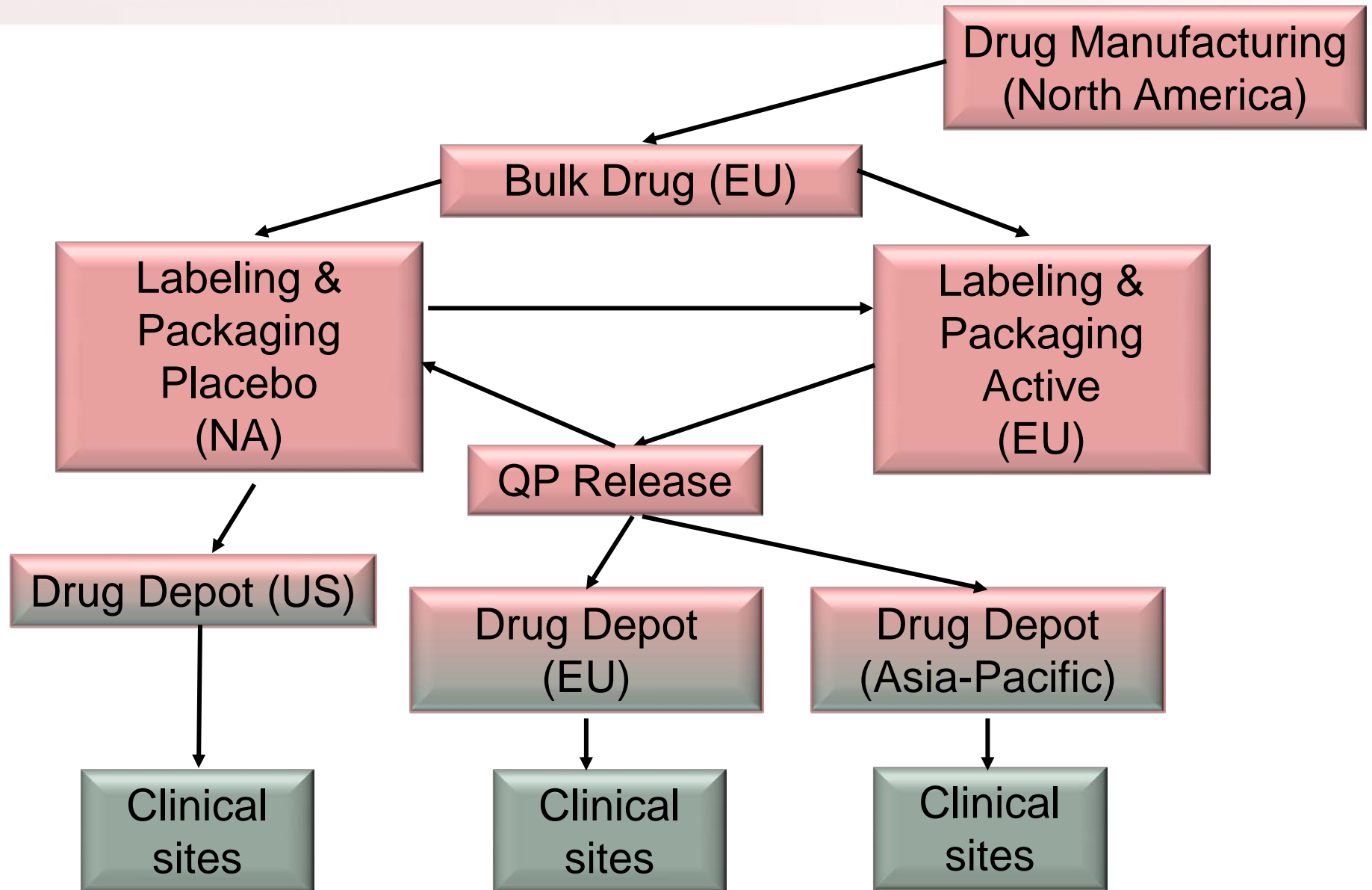
- Product manufactured in North America
- Continents
  - North America
  - Europe
  - Asia-Pacific
- All countries in Europe part of EU (!)
  - Single QP release for all of Europe

# (Idealized) Product Flow





# Actual Product Flow



# 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?

**Special Thank You to:**

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