

Ensuring Trial Continuity through Supply Chain Changes

SITUATION

Many situations can arise during clinical trials that can't be foreseen before study start-up. You need an effective trial supply management system to ensure trial continuity, regardless of the changes your trial might face.

This case study reviews two examples of sponsors needing to relocate a depot across several trials, and how Calyx's IRT system effectively enabled changes to the supply chain in each scenario to ensure patients and sites were not impacted.

CHALLENGE

In both examples, the sponsor faced significant, unexpected changes as they conducted their trials. They needed supply chain management expertise to advise on how to best manage complex situations, including:

- Relocating a depot
- Minimizing impact to several dozen existing studies
- Not disrupting supplies to existing or new patients
- Managing a high-risk situation
- Implementing central coordination

#1: DEPOT MOVE FROM UK TO EU DUE TO BREXIT

KEY FOR SUCCESS – ALLOW FLEXIBILITY

Sponsor-specific requirements:

- Switch on demand for each study
- Switch control given to supply chain manager
- Instantaneous update upon switch

Solution:

- Identify impacted studies
- Ahead of switch, supply chain manager transferred the medication from the UK to the EU depot in IRT
- Depot update transaction applied to each study
- Automatic medication availability checks

- New depot creation
- Batch records transfer
- Update country inventory management settings
- Same-day checks by IRT team to ensure all shipment requests would be sent to the right depot
- Centralized oversight and coordination across all studies affected

RESULT

- 40 studies switched successfully
- No impact on patients' treatment dispensing

#2: CHANGE OF DEPOT SUPPLYING APAC COUNTRIES

KEY FOR SUCCESS — MOVE QUICKLY

Sponsor-specific requirements:

- Switch all studies at once
- Leverage configurability of IRT to switch automatically

Solution:

- Identify impacted studies
- Agree to keep depot configuration and integration between inventory management system and depot identical to avoid in-depth updates
- Extend the resupply period intermittently
 - > Ensure sites have sufficient storage

- Extend system shipment look-ahead period, including overage to mitigate risks
- Raise shipments automatically
- Reset shipment look-ahead period
- Perform actions across all studies on the same day
- Centralized oversight and coordination across all studies affected

RESULT

- 33 studies switched successfully
- No impact on patients' treatment dispensing

Contact hello@calyx.ai to learn how Calyx's expertise in IRT can ensure your trials' success.

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