CALYX™

CASE STUDY

Reducing Risks and Increasing Efficiencies through Flexible Integrations

SITUATION:

THE TRIAL TEAM WAS CONCERNED WITH THEIR ABILITY TO:

- Keep the blind of central lab samples, used for both stratification and dose determination
- Keep the blind of patient treatment when moving from the Phase III trial to the extension trial
- Optimize the clinical supply chain across both trials

OBJECTIVES:

- To reduce or eliminate
  - > data entry
  - > trial risks
- To add or increase
  - > automation
  - > efficiency
  - > visibility and traceability
  - > adaptability

SOLUTION:

Calyx integrated data from central labs, as well as from the company's EDC, shipment tracking, and forecasting systems into our IRT solution.

RESULT:

The integrated solution reduced trial risks and data entry while increasing efficiencies and visibility into drug inventory to optimize the clinical development program.

01 TRIAL

INTEGRATIONS SOLUTION: BLINDED PHASE III

Integration 1: Central lab

- Lab value from lab integrated with Calyx IRT
- Value used as a stratification factor and a dose determination
- Blinded value
- **Benefits:** Reduced trial risks through maintaining blinding of lab results; automated stratification

Integration 2: EDC

- Patient and visit details transferred from screening onward
- Pre-populated forms in EDC with values from Calyx IRT
- **Benefits:** Reduced data entry through pre-population of data in the EDC

Integration 3: Shipment tracking system

- Bi-directional integration
- Shipment request, date of shipment, dispatch notification, medication arrival confirmation
- **Benefits:** Increased depot efficiency and increased visibility of shipment status

Integration 4: Forecasting system

- Enrollment status and inventory updates from Calyx IRT to forecasting system
- **Benefits:** Tracking of inventory shipments and ability to adapt supply strategy throughout study

02 TRIAL

INTEGRATIONS SOLUTION: EXTENSION OPEN LABEL

Integration 1: Patient transfer

- Patient details transferred from trial 1 to trial 2; confirm if the patient is eligible based on trial 1 status; confirm whether patient belongs to the site
- No unblinding when transferring patients
- Automated continuation of medication
- **Benefits:** reduced trial risks through maintaining the blind across trials; reduced data entry by site; seamless continuation for sites

Integration 2: EDC

- Same as for trial 1

Integration 3: Forecasting system

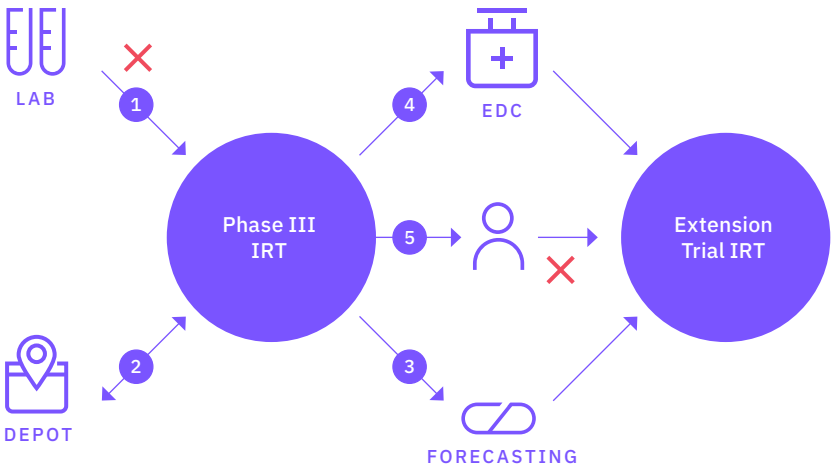
- Same as for trial 1

KEY HIGHLIGHTS

- Calyx sends 10,000+ files per day with other systems across all live studies
- All integrations are tailored to trial-specific needs
- Active safeguards and alerting prevent issues from occurring
- If an integration does not add sufficient value, Calyx will advise against it
- Calyx customer care services team is specifically trained to support integrations

Used in over 4,000 global clinical trials, Calyx IRT takes the worry out of randomization and supply management—so you can concentrate on study success. Contact us at: hello@calyx.ai

OPTIMIZATION THROUGH INTEGRATIONS: REDUCE DATA ENTRY AND INCREASE QUALITY WITH CALYX



1. Unblinding lab samples
2. Bi-directional depot shipment data
3. Enrollment and inventory status update
4. Patient status and visits
5. Patient transfer to open label extension

✕ Risk of unblinding

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Reliably solving the complex.

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