perceptive™ eclinical

Flexible Integrations to Reduce Risks and Increase Efficiencies

CASE STUDY

Keeping the blind of central lab samples and patient treatment across a Phase III and extension trial , whilst optimizing the supply chain.

Contents

Reducing Risks and Increasing Efficiencies through Flexible Integrations

1 CASE STUDY

1.1 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

1.2 OBJECTIVES:

To reduce or eliminate

- data entry
- trial risks

To add or increase

- automation
- efficiency
- visibility and traceability
- adaptability

1.3 SOLUTION:

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

1.4 RESULT:

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

2 INTEGRATIONS SOLUTION: BLINDED PHASE III

2.1 Integration 1: Central lab

- Lab value from the lab, integrated with Perceptive eClinical 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

2.2 Integration 2: EDC

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

2.3 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

2.4 Integration 4: Forecasting system

- Enrolment status and inventory updates from Perceptive eClinical IRT to forecasting system
- Benefits: Tracking of inventory shipments and ability to adapt supply strategy throughout the study

3 INTEGRATIONS SOLUTION: EXTENSION OPEN-LABEL

3.1 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 the 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

3.2 Integration 2: EDC

- Same as for trial 1

3.3 Integration 3: Forecasting system

- Same as for trial 1

KEY HIGHLIGHTS – Perceptive eClinical 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, Perceptive eClinical will advise against it
- Dedicated integration team who support from requirements gathering to UAT
- Perceptive eClinical customer care services team is specifically trained to support integrations

Ready to find out more about what Perceptive eClinical can do for your trial, contact us for a product demonstration.