Maintaining double-blind amid dosing complexity

A biotechnology company specializing in serious diseases needed support for a double-blind study where the investigational product (IP) was an intravenous (IV) injection, while the standard of care (SOC) comparator was an oral therapy. The trial involved multiple drug types, and the study team needed to track various dispensation scenarios, supply strategies, visit parameters, and maintain the blind.

Challenge:

Maintain study blind amidst treatment and visit complexity

Protocol complexity

Multiple treatment arms

The study had to accommodate almost a dozen different drug types. The IP was an IV injection, while the SOC comparator was an oral therapy with an IV option. The protocol allowed the investigator to switch the subjects from oral treatment to IV treatment at any time (or back to oral treatment). Adding complexity was that the SOC dosing regimen included multiple drug types—one of which had multiple drug options depending on the diagnosis.

To prevent participants and clinicians from deducing their treatment arm based on the therapy administration route, participants randomized to the IP would also receive a placebo oral SOC, and participants randomized to SOC would also receive a placebo IV.

Variable visits and dosing

Trial participation followed several unique visit schedules, with multiple types of visits depending on treatment arm and drug type.

Operational complexity

Multiple treatment arms

Subjects were allowed to move between sites for their visits.

Study teams had to manage the treatment, visit, and site complexities, all while maintaining the blind.

Solution:

IRT system that accommodates multiple drug and visit types without unblinding clinicians or patients

Because of the double-blind design, the study team needed a powerful and flexible IRT to support patient and drug logistics across different therapy administration routes, visit schedules, and site attendance options. To respond to the study's specific requirements, Suvoda leveraged its IRT technology to allow trial logistics to be as robust, accurate, unbiased, and efficient as possible.

Issue	Solution
Maintaining study double-blind The use of two different routes of drug administration—an IV investigational product and an oral standard of care—could inadvertently reveal which treatment group a subject belonged to, potentially unblinding a clinician to their assignment.	**Unblinded and blinded accountability functions** The IRT incorporated unblinded drug information features, which allowed blinded site users to perform most dispensing visits without viewing any unblinding drug dispensation information. It also added an extra unblinded confirmation, including all the dispensation information the unblinded pharmacist needs. Several other areas in the system were adjusted to preserve the blind as necessary.
Drug dispensation tracking The study team needed to track the dispensation scenarios for almost a dozen drug types.	**Dynamic dose and dispensation management** IRT users could add and change dose and dispensation configurations from oral to IV and vice-versa mid-study. Suvoda also included several data points to keep track of the various switches for confirmations and reports.
Subject and site tracking Subjects were able to move freely between multiple sites. Site teams needed access to information at the respective locations, while the pharmacist needed some lead time to prep the drugs.	**Flexible site functions** Several robust features were built into the IRT: • "Manage Site Links" allowed users to link sites together. • "Advance visit registration" prompted users to record planned drug administration date. • Visit schedule projection calculations to make sure the subject visit stayed on the same day as their visit schedule.
Mid-study amendments As the study progressed, the team required additional IRT data tracking.	**Protocol management** For agile protocol management, users could easily select the protocol version for each site. A custom Protocol Activation History Report was included to show when and what protocol versions are active for each site.

Result:

Real-time flexibility, visibility, and control in study operations

1. **Enhanced Study Data Integrity:**
   Suvoda IRT successfully preserved data integrity with thorough capture and tracking of essential data points while maintaining the blind.

2. **Efficient Study Management:**
   The study team could effectively handle multiple drug dispensation scenarios and visit schedules with Suvoda IRT, which enhanced the overall study management and minimized disruptions.

3. **Reduced Delays in Trial Operations:**
   Suvoda's 100% on-time delivery and powerful IRT functions meant reduced study delays associated with protocol modifications.

These outcomes were achieved through robust features and functionalities designed in the Suvoda IRT solution to address the complexities of the study, ultimately contributing to the successful execution of the trial.

About Suvoda

Suvoda is a global clinical trial technology company working to transform patients' experience in complex, life-sustaining studies in therapeutic areas like oncology, central nervous system (CNS), and rare diseases. Founded in 2013 by experts in eClinical systems, Suvoda empowers sponsors, CROs, sites, and patients to manage even the most urgent moments in the most urgent trials through advanced software solutions delivered on a single platform. Headquartered outside Philadelphia, Suvoda also maintains offices in Portland, OR, Barcelona, Spain, Bucharest and Iasi, Romania, and Tokyo, Japan. The company's Net Promoter Score (NPS) consistently exceeds the technology industry average, contributing to the company being selected by trial sponsors and CROs to support more than 1,800 trials across more than 95 countries. To learn more, visit suvoda.com and follow Suvoda on LinkedIn.

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