

ENSURING A PEDIATRIC PATIENT'S SAFETY DURING A GLOBAL RARE DISEASE TRIAL

A pharmaceutical company was conducting a global Phase I/II trial for a drug designed to treat pediatric patients with acid sphingomyelinase-deficient Niemann-Pick disease, a rare disorder. The sponsor enlisted Covance Central Laboratory Services (Covance CLS) to manage the collection, processing, shipment and testing of these critical samples. The results of the tests enabled physicians to determine how best to proceed with the patients' treatment and informed key drug development decisions.

One patient, a three-year-old girl in Brazil, suffered a severe adverse event (SAE) at one of her drug infusion visits. Due to heightened concern over this patient, it was imperative that tests following subsequent infusions be completed and reported as quickly as possible. The treatment was given every other Tuesday, with post-treatment sample collection visits on the subsequent Wednesdays and Thursdays. Shipments from Brazil are routinely received in Indianapolis within two days, meaning the Thursday collection samples would arrive at the lab on Saturdays.

Understanding the Challenge

► The sponsor needed to:

- Quickly verify that liver function and hematology results were within expected ranges and monitor the patient's metabolism of the drug.
- Resolve any holds on the visit tests as soon as possible. This was a common problem because, despite multiple re-training sessions, the site often did not fill out requisitions completely, resulting in holds. Holds delay reporting of the data to the investigator site and the sponsor.
- Expedite processing of specimen management (SM) samples so they could be rapidly shipped to a referral lab which performs critical pharmacokinetic (PK) testing.

Accelerated Processing of Critical Samples

When an SAE affected a patient in the trial ensuring the patient's safety with future treatments required extra steps to be taken by Covance CLS. The regional study coordinator (RSC) worked with the sponsor to compile the key sample accession numbers (unique identifiers of patient visits) and airway bills in order to expedite the receiving and registration of those samples. As soon as each accession was entered into the database, it was monitored for any holds, which would prevent the sample from being processed and reported in the urgent timeframe required for the patient's safety.

In the event that a requisition was missing information and therefore placed on hold, the RSC and Investigator Support team worked together to quickly resolve the issue, emphasizing that the samples were from a pediatric patient who had suffered a SAE. Covance was often able to receive the samples on a Saturday, resolve any holds and ship the samples to the referral lab without delays, in order to be tested within the required timeline.

Originally, the infusion visits were scheduled to last 24 weeks. However, it became apparent that the patient would need to keep receiving the drug past that date. To ensure that an extension to the protocol took place without disruption, Covance CLS worked with the sponsor to enable infusions through week 30 and confirm the sponsor received the corrected data file reflecting the additional data.

Value to Our Sponsor

Placing the patient at the center of the experience and being flexible in response to the unique needs of this trial enabled Covance CLS to provide the physician the necessary information to effectively monitor and treat the three-year-old patient. The patient was able to stay on the trial protocol, and the sponsor did not need to face the costs and delays involved in having to recruit a replacement patient for this rare disease. In addition, the sponsor was provided the critical information needed to help track and rapidly process the PK samples, which aided understanding about how the drug was processed by patients. Through a close partnership dedicated to patient centricity, the patient's safety was verified throughout the clinical trial.



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The Americas + 1.888.COVANCE
(+1.888.268.2623) + 1.609.452.4440
Europe / Africa + 00.800.2682.2682 +44.1423.500888
Asia Pacific + 800.6568.3000 +65.6.5686588

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