

Case Study

Successful Special Procedure Study Conduct: Cerebrospinal Fluid (CSF) and Concurrent Muscle Biopsy



Sponsor

Small biotech emerging
from stealth mode



Study Facts

First-in-Human (FIH)
Single Ascending Dose (SAD)
study to evaluate
therapeutic protein (TP)



Population

48 Healthy Volunteers



Location

Clinical Pharmacology Unit
in San Antonio, TX
Bioanalytical Lab
in Austin, TX



Challenges

The sponsor needed input and expertise on design to include a complex sampling of multiple matrices for innovative analysis.

- Pharmacokinetic (PK) profile in multiple matrices:
 - › Serum
 - › CSF
 - › Muscle tissue
- Binding of TP at neuromuscular junctions from muscle biopsies using immunohistochemistry.
- Concentrations of pEphA4, pSrc, total EphA4, and total Src in human peripheral blood mononuclear cells (PBMCs).



Solutions

Worldwide and the sponsor collaborated quickly to conduct several technical calls so that the study could begin running promptly. Our experienced team demonstrated proficiency in collecting and processing specialty tissues in a single study.

- Cerebrospinal fluid
- Muscle tissue biopsies
- PBMCs



Outcomes

- Successful completion of conduct.
- Full recruitment and retention of subjects throughout the duration of the study.
- Successful collection and processing of all sample types and timepoints.

Our accessible leadership, well-trained staff, private procedure area for collection and safety monitoring, and co-located bioanalytical lab allow us to conduct complex evaluations and procedures in a safe and timely manner.

Contact our team to learn more today 