CASE STUDY

Transforming Early Phase Acute Ischemic Trial Delivery Through Strategic Execution

From ER to endpoint—REV Clinical accelerates stroke trials with precision

Study Details

- Phase: Phase 1b Study
- Indication: Acute Ischemic Stroke
- Patients: 16 (Phase 1b – Randomized trial); 12 (Phase 1b – single arm / Single dose); 24 (Phase 1b single arm / two doses)
- No of Sites: 08 sites
- Country of Execution: USA

The Challenge

Sponsor required a partner with proven Acute Ischemic Stroke (AIS) therapeutic expertise capable of navigating the unique operational, enrollment, safety, and time-sensitive execution challenges associated with early-phase AIS trials while ensuring rapid, high-quality study delivery

Strategic Approach & Execution

- Targeted Sites: High-volume stroke centers; protocol embedded in workflow.
- 24×7 Support: Real-time decisions for eligibility, safety, and execution.
- Proactive Risk Management and Monitoring: Remote monitoring with skilled CRA for early issue detection & resolution ensuring endpoint integrity & data accuracy .
- PI Engagement: Regular interactions driving accountability & prioritization
- DSMB Alignment: Timely, high-quality data for efficient oversight.
- Acute Readiness: Site training aligned to emergency workflows
- Integrated Safety Review: Holistic assessment of ConMeds, labs, and clinical events
- Safety Reporting: Timely, accurate AE/AESI/SAE capture

Outcome & Impact

- On-time enrollment within critical stroke window (≤12 hours from onset)
- >90% endpoint data completeness
- 100% on-time SAE reporting compliance
- Zero critical audit findings