CASE STUDY

How Proactive Data Management and Site Enablement Accelerated a Phase IIa ALS Trial

Situation

A global Phase IIa clinical trial in Amyotrophic Lateral Sclerosis (ALS) faced operational delays at a high-enrolling site

- Therapeutic Area: Neurology (ALS)
- Phase: IIa
- Scope: Global, multi-site

Limited site engagement led to delayed data entry and a growing backlog of queries, placing interim analysis timelines at risk as the milestone approached.

Challenge

The sponsor needed to urgently:

- Resolve 100+ open queries (many >30 days old)
- Improve EDC data completeness
- Re-engage an underperforming site
- Ensure database readiness for interim analysis

Without intervention, delays could impact database lock and overall program timelines.

ALS is a rare, progressive neurodegenerative disease that affects motor neurons, leading to loss of muscle control. Clinical trials are challenging due to rapid disease progression, small patient populations, and the need for precise, high-quality data collection.

The Stiris Solution

Site Management & Engagement

Instead of taking a prescriptive approach, Stiris established a highly collaborative relationship with the site coordinator through a partner-driven, listening-focused approach to understanding site-specific constraints and priorities. This created stronger alignment, reduced operational friction, and improved responsiveness to clinical and data needs.

Data & Query Management

Building on this aligned, partner-focused foundation, Stiris implemented a structured, proactive workflow to address aging queries and EDC completion. Weekly updates with clearly categorized, actionable priorities enabled faster resolution, reduced backlog, and improved overall data quality.

On-Site Support

Extending this approach during IMVs, Stiris worked alongside the coordinator to resolve complex data issues in real time while supporting administrative and regulatory tasks—maintaining momentum without impacting patient-focused activities.

Implementation

→ IA Readiness & Planning

Stiris reviewed open queries, EDC status, and source documents to build a prioritized plan aligned with the interim analysis timeline.

→ Ongoing Monitoring & Data Management

Weekly communications focused on query triage, progress tracking, and hands-on support, preventing further data backlog.

→ IMV Execution & Database Lock Preparation

IMVs were used to resolve complex issues in real time and reinforce protocol adherence. Data were validated to GCP standards, documentation kept audit-ready, and PI sign-off coordinated for timely database lock.

Results

Resolved **100+ open queries**, including all aging queries (>30 days)

Achieved **100% data cleaning** aligned with interim analysis requirements

Delivered **query resolution 2 days ahead** of schedule

Secured early **Principal Investigator (PI) sign-off**

Sponsor Impact

- Re-engaged a critical site and restored operational performance
- Ensured high-quality, inspection-ready data while protecting IA timelines
- Enabled a clean, on-schedule data review
- Avoided database lock delays and maintained development velocity
- Preserved the Phase IIb timeline and strengthened regulatory positioning

Key Takeaways

- Strong site engagement improves ALS trial data quality and timelines
- Proactive query management accelerates database readiness
- Embedded operational support stabilizes underperforming sites quickly
- On-site collaboration resolves complex data issues faster than remote escalation
- Targeted intervention recovers performance without protocol changes or delays
- Measurable impact: 100+ aging queries resolved and PI sign-off achieved ahead of IA deadline

Facing site issues, data delays, or an upcoming interim analysis or database lock? **Stiris Research helps keep your trial on track and inspection-ready.**

Partner with us to re-engage sites, accelerate data readiness, and hit your next milestone.

Contact us

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