CASE STUDY

Stiris Stabilizes Site Performance to Protect a Phase IIa ALS Trial Milestone

Targeted site stabilization and operational oversight to deliver on-time interim analysis.

Situation

A Phase IIa Amyotrophic Lateral Sclerosis (ALS) clinical trial faced operational challenges at a high-enrolling site, leading to delays in data query resolution, ethics submissions, and regulatory documentation updates.

- Therapeutic Area: Neurology - ALS
- Phase IIa
- Location: Clinical site within global program

Challenge

The study coordinator was significantly overextended, resulting in operational strain and workflow inefficiencies, including:

- Delays in data query resolution
- Backlog in regulatory documentation updates
- Communication breakdowns across cross-functional study teams

The Stiris Solution

Site Management & Engagement

Stiris transitioned from high-volume email communication to direct, structured phone-based interactions, improving clarity and accelerating decision-making. A personalized communication approach was developed based on the study coordinator's workflow preferences, significantly reducing operational friction.

Structured Prioritization System

Custom tracking tools were implemented to manage open queries, source documentation updates, and outstanding action items were prioritized collaboratively with the site, enabling the coordinator to focus on critical activities while deferring lower-priority work without impacting study progress.

On-Site Monitoring & Operational Support

During each Interim Monitoring Visit (IMV), dedicated time was spent addressing complex data issues directly with the site coordinator, improving data clarity and turnaround. In parallel, Stiris provided hands-on administrative and regulatory support, allowing coordinators to focus on patient-facing activities while maintaining inspection-ready documentation.

Results

Stabilized Site Performance

Targeted support restored stakeholder responsiveness and improved overall trial execution consistency.

Protected Interim Analysis Timeline

The interim milestone was delivered on schedule despite constraints, without impacting recruitment or

Strengthened Operational Alignment

Coordination improved across stakeholders, restoring alignment and ensuring continuity across sites.

Sponsor Impact

Stiris Research successfully stabilized a high-risk site in a time-sensitive Phase IIa ALS clinical trial through hands-on operational support and proactive site engagement. This helped protect critical study milestones, reduce execution risk, and ensure uninterrupted clinical development progress in a highly constrained rare disease program.

Key Takeaways

- Relationship-driven communication outperforms email escalation
- Prioritization reduces burden and improves responsiveness
- Transparency enables proactive risk mitigation
- Hands-on support prevents delays
- Operational agility is critical in rare disease trials
- Regulatory and project management alignment protects timelines

On-time delivery depends on having the right partner. Stiris combines expertise, strong site relationships, and operational agility to protect critical trial timelines.

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