CASE STUDY

Accelerated Interim Analysis in a Phase II ALS Trial

How Stiris delivered a rapid operational response to meet an accelerated interim analysis in a Phase II Amyotrophic Lateral Sclerosis (ALS) study, without compromising data quality.

Situation

An amyotrophic lateral sclerosis (ALS) clinical trial faced a compressed interim analysis timeline that placed significant pressure on data cleaning, query resolution, and monitoring activities. The accelerated schedule created risks to data readiness and key study milestones while maintaining regulatory compliance and study integrity.

- Therapeutic area: Neurology
- Indication: Amyotrophic lateral sclerosis
- Phase: II
- Location: Canada (2 clinical sites)

Challenge

A sponsor-driven acceleration of the interim analysis timeline created significant operational pressure, requiring critical study activities to be completed ahead of schedule without compromising quality or compliance.

- Compressed interim analysis timeline
- Accelerated data readiness activities
- Cross-functional coordination across sites and study teams
- Data quality and compliance risks under tight deadlines

Stiris' Solution

Stiris leveraged its agile operating model to quickly mobilize key teams and closely collaborate with sites, executing critical study activities within a compressed timeline while maintaining the required quality and oversight for an interim analysis.

Rapid operational response

Quickly aligned project management and monitoring teams to prioritize interim analysis activities.

Cross-functional coordination

Enabled efficient execution of data cleaning, monitoring, and query resolution through close team collaboration.

Site relationships and collaboration

Maintained strong site communication to accelerate query resolution and data clarification.

Focus on data readiness

Prioritized data quality activities to ensure complete and analysis-ready data within the revised timeline.

Results

Interim analysis delivered on schedule	**Data readiness achieved**	**Data quality and study integrity maintained**	**Strong site coordination sustained**	**Sponsor milestone successfully met**

Sponsor Impact

Stiris enabled the sponsor to accelerate a key clinical development milestone, delivering review-ready data ahead of schedule while maintaining data quality, study integrity, and regulatory compliance. The result was earlier access to critical study insights to support timely program decisions.

Key Takeaways

- Interim analyses require **strong operational coordination**
- **Rapid team alignment is critical** under compressed timelines
- **Strong site partnerships** enable faster execution
- **Data quality must be maintained** under pressure
- **Operational agility** drives study success

Time-sensitive milestones such as interim analyses require precision, agility, and coordinated execution. Stiris Research supports sponsors in delivering complex clinical operations under accelerated timelines while maintaining data integrity and regulatory compliance.

Contact Us

(519) 652-5327 (Ext. 117)
info@stirisresearch.com
https://www.stirisresearch.com

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