propharma

CASE STUDY

Restoring Inspection Readiness and Data Integrity Following a CRO Transition



ProPharma has extensive experience helping sponsors recover studies after CRO transitions by providing targeted remediation, re-monitoring, and quality oversight support. In one example, multiple emerging biotech sponsors identified significant gaps in study oversight, documentation, protocol deviation management, and inspection readiness after transferring monitoring responsibilities from a previous CRO. ProPharma implemented a comprehensive remediation strategy to restore compliance and safeguard data integrity.

Challenge

- Significant gaps in monitoring documentation and essential records limited visibility into study oversight activities.
- Incomplete protocol deviation tracking made it difficult to assess site compliance, participant eligibility, and protocol adherence.
- Missing documentation and unresolved findings increased inspection-readiness and data-integrity risks.
- The sponsor required rapid remediation to restore confidence in study quality and regulatory compliance following the CRO transition.

Solution

- Conducted a comprehensive risk assessment, monitoring quality review, eTMF evaluation, and action plan development.
- Performed targeted re-monitoring visits at active and closed sites to verify compliance, assess risk, and resolve critical findings.
- Reconciled protocol deviations against source documentation, rebuilt and resolved deviation logs, identified and reported previously undocumented events, and aligned site records to produce an inspection-ready study history.
- Implemented a structured eTMF and ISF remediation program to recover missing documents, resolve discrepancies, and align documentation with regulatory requirements.

Result

- Within 16 weeks of study transition, ProPharma restored monitoring oversight, reconciled historical documentation gaps, resolved outstanding compliance issues, and returned the Alzheimer's disease study to an inspection-ready state.
- Achieved audit-ready TMF status within 12 weeks and increased inspection readiness by more than 50%.
- Established a complete and reconciled protocol deviation history, achieving 100% capture of known protocol deviations.
- Restored confidence in study data through comprehensive verification, documentation remediation, and sustainable quality oversight processes.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

www.ProPharmaGroup.com
Info@ProPharmaGroup.com

ProPharma Group, LLC Proprietary and Confidential