Life Sciences Case Study

PROJECT OVERVIEW

Conducting a Data Quality and Integrity Audit for a Biopharmaceutical Company

This client is a biopharmaceutical company seeking to identify and develop innovative drugs for the treatment of conditions such as anemia, idiopathic pulmonary fibrosis (IPF), Duchenne muscular dystrophy (DMD), and locally advanced pancreatic cancer (LAPC).

In preparation for upcoming clinical trials data readouts, the client leveraged Clarkston Consulting's Quality and Compliance experts to evaluate their data quality and integrity processes, procedures, and technologies specific to the database lock to topline results process.

Clarkston utilized leading practices and regulatory guidance to identify improvement opportunities and outline recommendations. Clarkston completed its assessment by reviewing Standard Operating Procedures (SOPs), forms, templates, and executed documentation from a recent database lock, as well as documentation associated with vendor oversight, cybersecurity, data migration, and system validation. Clarkston also facilitated interviews with subject matter experts to verify an understanding of existing processes and their operating effectiveness.

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INDUSTRY:

Biopharmaceutical

PRODUCTS AND SERVICES :

Innovative Drug Treatments

PRIMARY OBJECTIVES:

- Review the role, authority, and scope of the Clinical Data Integrity team and assess effectiveness of the team's collaboration with the Clinical function
- Review eight data quality and integrity-related SOPs against industry-leading practices to understand if they completely address the risks inherent to the processes and their adoption by the organization
- Review preparations for and executed documents from the Clinical Trial Topline Results process during recent clinical trial readouts, including folder and access settings, vendor oversight, database lock readiness, and external and internal communications
- Verify the executed database lock and data release to ensure they follow the designed process and controls
- Identify any gaps in the database lock to topline clinical results process design and controls' operating effectiveness and provide recommendations for improvement

RESOLUTION:

- Evaluated SOPs, forms, templates, executed documentation from the recent database lock, as well as additional vendor oversight, cybersecurity, data migration, and system validation documentation for compliance with external requirements and best practices
- Conducted interviews with subject matter experts to verify an understanding of existing processes and assess their operating effectiveness alongside any gaps
- Created key deliverables including an audit plan, audit checklist, and data quality and integrity audit report
- Provided risk evaluations for observations and recommended solutions informed by leading practices

KEY BENEFITS:

- Provided insights on key areas for improvement ahead of the next database lock across 13 categories informed by data quality and integrity best practices
- Provided specific solutions prioritized by risk and effort to implement to bolster the security and reliability of the company's data
- Enabled and facilitated discussions with teams involved in the database lock to topline results process to determine quick wins and long-term initiatives based on audit recommendations

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KPIs

- **Reviewed 60+ clinical operations and quality documents to inform the audit**
- **Conducted 22 interviews with stakeholders across nine functional areas**
- **Evaluated processes, procedures, and technologies across 13 data quality and integrity categories informed by best practices and industry guidance**

CONTACT US

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