George Clinical's Centralized Monitoring

Centralized Monitoring is imperative for regulatory compliance to RBQM (Risk-Based Quality Management). George Clinical has an exceptional record in risk-based Centralized Monitoring for renal studies, which ensures scientific excellence and data integrity across all sites.

Why Centralized Monitoring?

Centralized Monitoring, according to ICH regulatory guidelines *E6(R2)*, *E8(R1)* and upcoming E6(R3), is a remote evaluation carried out by sponsor personnel or representatives at a location other than the sites where the clinical trial is being conducted.

The FDA endorses centralized monitoring as a key component in Risk-Based Quality Management (RBQM). The shift from SDV to SDR is designed to improve data quality and integrity and eliminates site risk attributed to on-site monitoring visits. Centralized Monitoring also improves the identification of data anomalies (*e.g.*, fraud, including fabrication of data and other non-random data distributions) and mitigates them in the early stages.

Key Themes in E6(R2) Addendum

- Quality risk management for sponsors
- Prioritized, risk-based approach to monitoring clinical trials
- Investigator oversight / supervision
- Additional text on use of computerized systems

What does data-focused, Centralized Monitoring entail?

Centralized Data-Driven Monitoring / Focus on Processes & Data

Site Trends	Protocol Compliance	Performance Metrics	Risk-Based Adaptive Monitoring
Examine data trends such as the range, consistency and variability of data within and across sites	Review compliance to study visits and procedures	Analyze site characteristics and performance metrics	Select sites and/or processes for targeted on-site monitoring

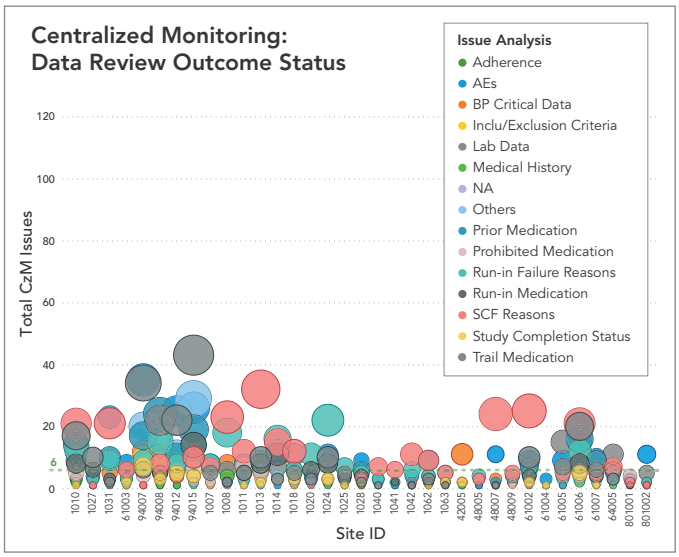
Quicker Detection & Mitigation

Key Critical to Quality (CTQ) Factors for Renal Studies

Critical to Quality (CTQ) factors for renal studies are essential for ensuring the safety of patients, data integrity and the overall success of the study due to the fact that these studies focus on various chronic and acute kidney-related conditions and disorders. Some of CTQ factors George Clinical specifically address in renal studies monitored by remote Centralized Monitoring in an Risk-Based Monitoring (RBM) context include:

- Patient Safety & Adverse Events
- Renal Function Biomarkers
- Fluid & Electrolyte Balance
- Early Biomarker Changes
- eGFR Trends
- Compliance with Medication Regimens
- Protocol Adherence

George Clinical has supported numerous projects with risk-based high quality data. One example was a study with 3,000+ screened subjects, eight regions and 70+ sites globally, where data was generated identifying risk at early stages, trends analysis by issues/issue analysis, protocol compliance issues, protocol deviations, critical data issues and patient safety concerns.



Centralized Monitoring Benefits to Sponsors

Cost-savings:

- Minimizes on-site visits, cutting travel and accommodation costs for clinical research
- Efficient resource allocation maximizes savings by allowing sponsors to redirect funds from travel to vital trial activities

Real-time data access summary:

- Provides near-real-time insights into trial data for timely decision-making
- Swift issue resolution prevents trial delays and ensures study progress remains on schedule

Efficiency & Timeliness:

- Streamlines operations, enhancing trial efficiency for faster, cost-effective clinical studies

Enhanced Oversight:

- Offers a comprehensive view of the entire trial, enabling effective site performance evaluation and trend identification
- Tailored interventions allow sponsors to address specific sites and issues as required, reducing reliance on routine on-site visits

Data-Driven Decision-Making:

- Provides data-driven insights and analytics, empowering sponsors to make informed decisions for more successful clinical trials

In summary, George Clinical offers comprehensive and flexible Centralized Monitoring services that provide sponsors, project management and operations teams with numerous advantages ranging from cost savings and real-time data access to enhanced data quality, risk management and overall efficiency. By adopting this approach, sponsors can optimize their clinical trial operations, reduce costs and increase the likelihood of successful trial outcomes.

George Clinical
Science. Service. Solutions.
20+ years

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