GENBIOCA
Domain Led, Technology Services Company

WE ARE THE TRUSTED



Central Monitoring Partner

Central Monitoring:
A Proactive Approach to Clinical Trial Quality

Beyond On-Site Checks: Real-Time Insights for Smarter, Safer Trials.

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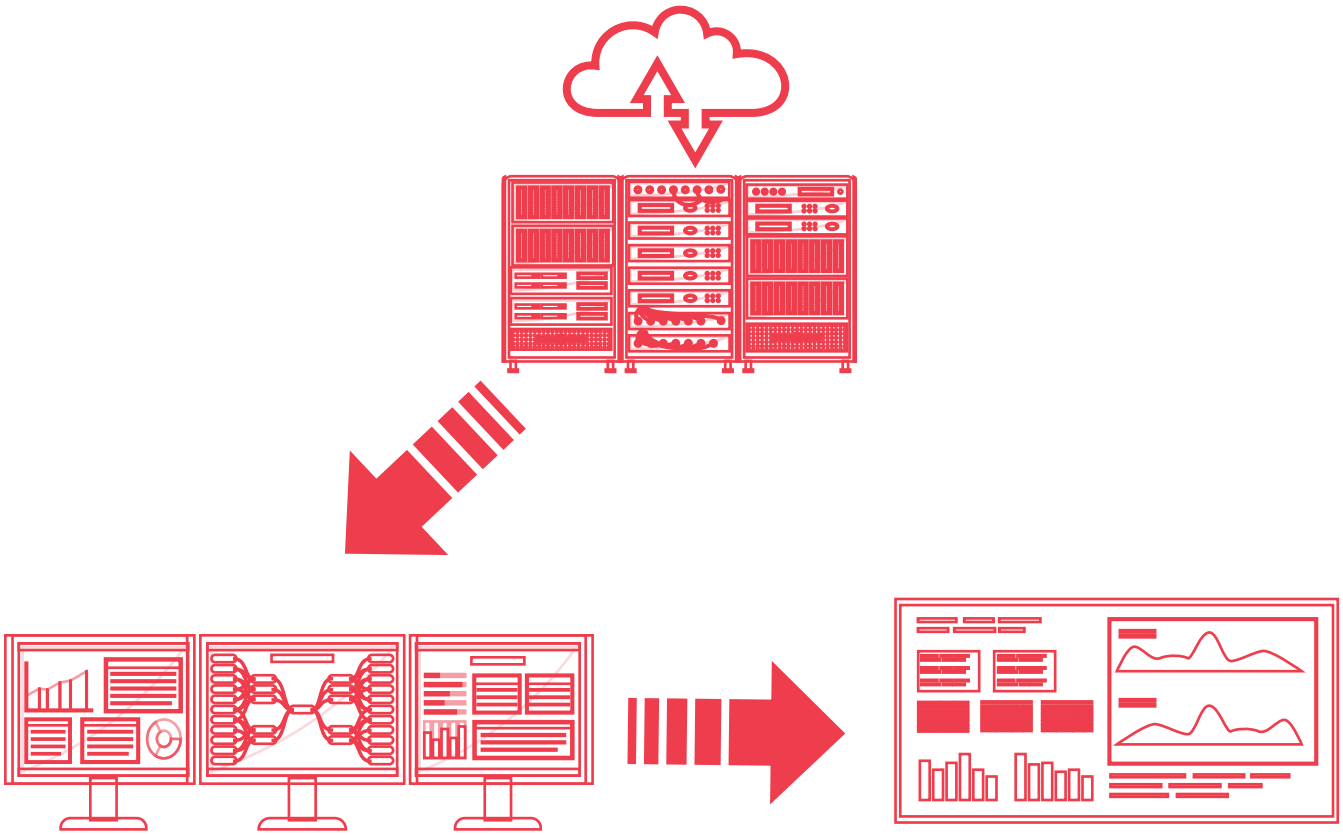
Central Monitoring

Central monitoring is no longer a simple supplement to on-site visits; it's a technology-driven strategy that provides a holistic view of your trial's health. We move beyond traditional, reactive methods by using a blend of advanced statistical modelling, AI-powered analytics, and clear communication protocols to proactively identify risks and ensure data quality.

GenBioCa's approach is the cornerstone of Risk-Based Quality Management (RBQM), shifting focus from exhaustive, resource-intensive on-site checks to efficient, predictive oversight, in line with regulatory guidelines like ICH E6(R3).



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The GenBioCa Advantage: Predictive Quality by Design

We embed quality into the very fabric of your trial. By leveraging data from past studies and applying cutting-edge technology, we create a predictive framework that mitigates risks before they can impact your study.

Statistical Modelling & AI Analytics:
We use sophisticated models and AI to analyse data across sites, identifying atypical patterns that may indicate systemic issues, protocol deviations, or potential fraud. This allows us to direct resources to where they are most needed, ensuring patient safety and data integrity.

Quality by Design (QbD):
We help you define and monitor Key Risk Indicators (KRIs) and Quality Tolerance Limits (QTLs), ensuring continuous compliance and a strong emphasis on data integrity and critical data.

Clear Communication:
Our centralized platforms provide a central, intuitive interface that fosters seamless communication between central monitors, on-site personnel, and study sponsors. Real-time alerts and actionable dashboards ensure swift response to emerging issues.

Real-Time Data Integration:
Our systems seamlessly integrate real-time data from various sources, including EDC systems and wearable devices, providing up-to-date information for proactive risk detection.

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Benefits of Choosing GenBioCa: Your Success Metrics

Proactive Risk Management:

Identify potential issues at acentral level for timely intervention, preventing major problems.

Enhanced Data Quality:

Driven by patient-centric technology and engagement strategies.

Improved Efficiency and Reduced Costs:

Centralized monitoring significantly reduces the need for extensive on-site visits, freeing up resources and lowering overall monitoring costs.

Faster Regulatory Endorsement:

Our methods align directly with the risk-based strategies advocated by regulatory bodies like the FDA and EMA.

Data-Driven Decision Making:

Leveraging advanced analytics and visualization tools to transform data silos into actionable recommendations for effective trial management.

Ready for Smarter, Safer Clinical Trials?

Contact GenBioCa today to implement a proactive central monitoring strategy and elevate your trial quality.

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Website

www.genbioca.com

Enquiry

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