

Optimize cardiac safety in clinical trials with centralized ECG

Centralization of digital electrocardiogram (ECG) data in clinical trials replaces fragmented, site-level assessments with a standardized core laboratory approach. **This process ensures high-precision cardiac safety assessments, which is critical for drug development and regulatory approval.**

Core benefits of centralization

Benefit	Impact on trial quality
Data consistency	Standardized equipment and software across all sites eliminate variability caused by different ECG machine algorithms.
Expert interpretation	Centralized reading by a dedicated team of expert cardiologists ensures uniform, high-precision analysis compared with varying site-level expertise.
Regulatory compliance	Centralization facilitates submission to the FDA ECG Warehouse, speeding up review and ensuring adherence to the E14 guidance.
Operational efficiency	Central labs manage equipment logistics, site training and automated data queries, reducing the burden on CROs and site staff.

Risks and costs of not centralizing

 Incorrect enrollment Relying on site ECG machines can lead to unnecessary exclusion of eligible patients or inclusion of high-risk patients due to inaccurate measurements.	 Inconsistent data Different sites using various machine brands and algorithms make it impossible to scientifically compare results across the entire study.
 Higher long-term costs Although site-level collection seems to reduce cost initially, data cleaning, transcription errors and potential regulatory delays often lead to much higher total study costs and longer timelines.	 Value of digital ECGs As technology evolves, the value of digital ECGs becomes increasingly more important. Digital ECGs allow for the application of innovative tools that support data integrity, advanced data analysis and decentralized trials.

What makes a good ECG centralization partner?

Scientific and clinical expertise	Proven experience in designing cardiac safety protocols and a team of board-certified cardiologists for oversight.
Technology stack	Ability to provide validated, standardized equipment and a cloud-based platform for near real-time data access and secure storage.
Global logistics support	A dedicated team to handle the rental, shipping and maintenance of ECG machines to investigator sites worldwide.
Quality and compliance standards	Adherence to international standards like ISO 9001 and experience with managing data for regulatory submissions.
Diverse capabilities	Platforms that can integrate ECG data with other clinical markers, such as blood pressure or patient-reported outcomes (PROs), to provide a holistic safety profile.

Digital centralized ECGs improve data quality, enhance participant safety, and support data flexibility. To learn more, please visit [Clario.com](https://clario.com) or email info@clario.com.