INFOGRAPHIC

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Paper vs electronic ECG capture

Explore the benefits of centralized core lab electrocardiogram (ECG) data in clinical trials

Paper capture	Electronic capture
DATA QUALITY	
⚠ Data variability exists across machines and readers.	✓ Core labs provide standardized machines and expert readers to deliver consistent data.
⚠ Data quality issues are difficult to detect across large paper datasets.	✓ Data quality issues are easier to detect and can be identified quickly.
⚠ There is a risk of manual transcription errors.	✓ Data is automatically transferred into a central database in real time.
⚠ Retrospectively ‘standardizing’ paper data is challenging.	✓ Data is standardized as it is collected and is ready for use.
DATA INTERPRETATION AND ANALYSIS	
⚠ Relying on different site investigators for interpretation creates variability.	✓ Centralized core lab of qualified cardiologists creates consistency and standardization.
⚠ Paper is difficult to analyze in large volumes, leading to blind spots and extended timelines.	✓ Fast analysis of ECGs makes overread data available in as little as 4 hours in a single database.
⚠ Recruitment delays result from false exclusions.	✓ Critical milestones are supported by minimizing false exclusions.
DATA ACCESS	
⚠ Paper records can be lost or damaged (e.g., thermal paper fading), leading to a permanent loss of source data.	✓ Centralized records are stored in safe and secure environments to ensure records are not damaged.
⚠ Data entry and verification delay access.	✓ Near real-time data access is available from any location.
REGULATORY SUPPORT	
⚠ Data may not meet global regulatory standards.	✓ Regulatory-ready data is available in digital XML format with a full audit trail.
⚠ Physical storage and security measures required for compliance can be costly and prone to risks such as document loss or damage.	✓ Direct submission of digital XML files is the preferred regulatory standard for QT assessments.
⚠ Manual entry into electronic data capture (EDC) from paper lacks a direct digital link to the source waveform.	✓ Centralized ECG storage systems track every modification from capture to submission, meeting strict FDA/EMA electronic record requirements.
SAFETY	
⚠ Higher risk of false-negative ECG results enables enrollment of high-risk patients.	✓ False inclusions are minimized, protecting patient safety.
⚠ False negative findings delay insights into safety risks.	✓ Potential cardiotoxicity risks can be detected earlier to protect patient safety.

Digital centralized ECGs improve data quality, enhance participant safety, and support data flexibility. To learn more, please visit **Clario.com** or email **info@clario.com.**