ALIVECOR® BIOPHARMA

Beyond the Checkbox:

How Rethinking Your Cardiac Monitoring Approach Can Dramatically Improve Trial Outcomes

Is Standard Cardiac Monitoring Enough?

The FDA states that "drugs are expected to receive a clinical electrocardiographic evaluation beginning early in clinical development…."[1] To check this box, traditional cardiac monitoring methods are often used without a second thought.

While these methods align with regulatory standards, sticking to what's familiar for decades often means settling for limitations in data integration, operational inefficiencies, and reactive strategies that lead to significant trial pitfalls.

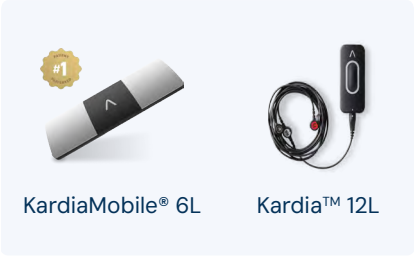
Today's trials demand more. Rethinking your cardiac monitoring strategy can unlock innovative solutions to drive richer, more meaningful data while delivering faster timelines, improved patient safety and engagement, and ensure greater compliance.

Why Change? Why Now? Because Clinical Trials Already Have.

The 12-lead ECG was standardized 70 years ago in 1954. While it remains a vital part of cardiac monitoring, trials have evolved significantly in complexity and scale. Today, trials require greater flexibility, remote capabilities, and real-time data integration—capabilities traditional ECG products alone are still not able to provide. Until now.

AliveCor Reinvents Cardiac Monitoring for BioPharma

Providing an ecosystem of solutions that delivers above and beyond compliance, AliveCor is transforming cardiac monitoring into a forward-thinking cardiac care strategy with new technology. Supporting trials across every therapeutic area and stage, from protocol development to post-market, AliveCor meets patient needs for flexibility and autonomy while delivering AI-powered data and comprehensive insights.



Capture Data Remotely or Onsite

FDA-cleared, medical-grade ECG devices for 6-lead or 12-lead heart data*—available wherever participants and researchers are.

Instantly Record and Review

ECG data is delivered to medical professionals within seconds, streamlining operations and ensuring up-to-date, accurate insights.

Easily Analyze and Manage

ECG data is uploaded to our HIPAA-compliant database and can be shared with partner platforms to be analyzed and interpreted.

Unlocking the Benefits of a Strategic Technology

AliveCor's technology offers a more accessible and innovative alternative to traditional cardiac monitoring. Already widely embraced by consumers worldwide, it goes beyond enhancing cardiac monitoring; it provides sponsors and CROs with a strategic advantage by turning a routine protocol step into a powerful solution that drives better outcomes throughout the clinical trial process.

Patients Empowered Like Never Before

Traditional methods remain effort-intensive and are often cumbersome. They involve medical staff, wiring, and patches and often require in-clinic visits for setup and monitoring. Designed with patients in mind to allow for less invasive onsite or remote ECG monitoring, AliveCor deploys solutions ranging from portable, self-administered capabilities of its KardiaMobile® 6L to its revolutionary Kardia™ 12L devices. Ease in device use and simplicity in data capture deliver greater patient empowerment and data strategy.

Breaking Barriers to Participation and Diversity

Traditional cardiac monitoring typically requires a consistent power supply, specialized equipment, and trained personnel to place leads accurately. The process is outdated and unsuitable for the decentralized clinical trials (DCTs) model that the FDA supports.[2] AliveCor's remote monitoring lets patients and clinicians track cardiac health anytime, anywhere, while researchers collect real-time data on a unified platform. This approach supports DCTs, broadens access for underrepresented groups, improves trial diversity, and simplifies patient participation—allowing sponsors and CROs to accelerate trials, meet regulatory requirements, and generate stronger, more comprehensive data.

More AI-Powered Data Unleashed

Added burdens on trial participants can lead to infrequent data collection, generating more events that raise the risk of data gaps. AliveCor's easy-to-use monitoring solutions reduce these gaps by enabling consistent, frequent data collection. With AI-powered, real-time analysis, potential issues are detected early, allowing sponsors and CROs to take proactive steps, avoid delays, and speed up trial timelines.

Data is Finally Standardized and Consistent

Monitoring across multiple decentralized sites and remote patients can lead to errors and inconsistencies due to staff training and process differences. AliveCor's solutions standardize data collection, ensuring consistent, high-quality data while simplifying operations. This enables sponsors and CROs to meet trial demands without added complexity.

Instant, Data-Driven Decisions Made Easy

Challenges integrating real-time cardiac data for analysis can lead to lost insights and delayed trial outcomes. AliveCor's real-time monitoring gives sponsors, CROs, and sites instant access to actionable data, enabling timely decisions. ECG data is uploaded to our HIPAA-compliant database and can be shared with partner platforms to be analyzed and interpreted. It reduces the risk of missed events and improves trial outcomes through faster, data-driven actions.

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The AliveCor Solution

AliveCor understands that comprehensive monitoring is not just about compliance—especially when cardiac safety concerns are among the top reasons for drug withdrawal from clinical trials and the market.[3]

It's a strategic tool that enhances regulatory trust, data integrity, and trial success. We're the only company integrating innovative 6L and 12L ECGs into a breadth of solutions that meets complex cardiac monitoring requirements both onsite and remotely.

Our innovative solutions redefine what's possible in cardiac monitoring, putting sponsors and CROs in control of their trial data to enable smarter, faster decisions across the entire research life cycle.

Validated and Trusted Globally

Sponsors and CROs that adopt these technologies can gain a competitive edge by improving their trial outcomes and building stakeholder confidence.

5.4M+
lifetime users

250+
million ECGs recorded

25+
countries with clinical studies powered by our ECG solutions

200+
clinical publications validating clinical accuracy and utility

1. "Guidance for Industry: E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs." U.S. Department of Health and Human Services. October 2005.
2. Center for Drug Evaluation and Research. "Conducting Clinical Trials With Decentralized Elements" U.S. Food and Drug Administration, FDA, Sept. 2024.
3. Toward a broader view of mechanisms of drug cardiotoxicity. Mamoshina, Polina et al. Cell Reports Medicine, Volume 2, Issue 3, 100216

* For Kardia™ 12L System: The provisional automated ECG analysis should not be used for clinical action if it has not been reviewed by a healthcare professional qualified to independently interpret the ECG signal. The four synthesized chest leads are not intended for diagnostic use.

Experience the AliveCor impact in your next clinical trial.
Connect with us for a custom integration strategy that sets your research apart.

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AT THE HEART OF CLINICAL RESEARCH

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