

BREAKING BARRIERS

Remote ECG Solution Enables a Fully Decentralized ME/CFS Phase 2 Clinical Trial

Lindus Health conducted a fully decentralized Phase 2 trial for myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and aimed to remove traditional site visit barriers and improve accessibility.

The trial required a secure, flexible, and patient-centric ECG monitoring solution for seamless at-home data collection, compliance, and real-time insights.



THE CHALLENGE

Barriers to Patient Participation

ME/CFS affects 0.9% of the population worldwide, with symptoms such as severe fatigue, cognitive impairment, and mobility limitations making travel to trial sites difficult. This significantly restricted recruitment and participation, requiring a solution that could bring the trial directly to the patient's home.

Ensuring ECG Data Integrity

Given the sensitive nature of ECG data and the strict regulatory environment, Lindus Health needed a cardiac monitoring solution that ensured:

Data privacy and security in compliance with GDPR and HIPAA

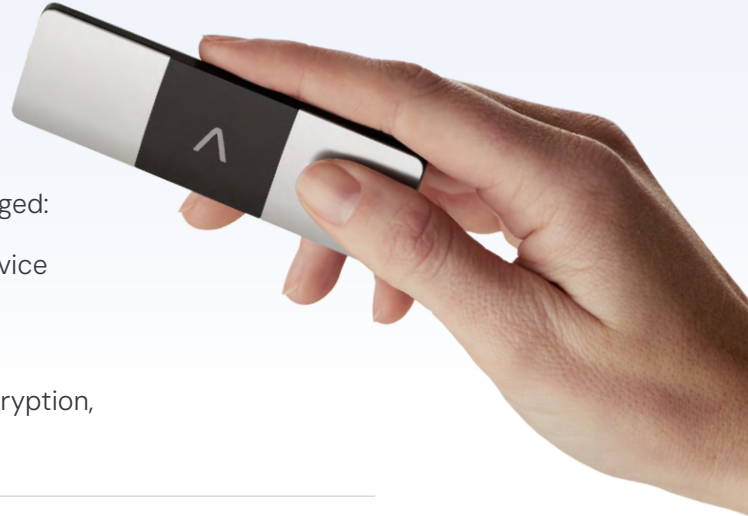
Reliable, high-quality ECG data to support trial outcomes

Seamless remote data collection without compromising integrity

THE SOLUTION

To address these challenges, Lindus Health selected AliveCor's secure, remote cardiac safety monitoring solution, enabling a fully decentralized approach while maintaining clinical integrity and regulatory compliance. The solution leveraged:

- AliveCor's KardiaMobile[®] 6L, an FDA-cleared portable ECG device
- Full-service management and CoreLab physician review to ensure high-quality cardiac data
- A GDPR- and HIPAA-compliant infrastructure with robust encryption, secure data storage, and controlled access



✓ FDA-Cleared
Portable ECG Device

✓ Streamlined,
Patient-Centric Design

✓ Cutting-Edge,
Compliant Infrastructure

"This fully decentralized trial represents a significant milestone in our mission to make clinical research more accessible and patient-centric. By leveraging AliveCor's innovative cardiac monitoring solution and prioritizing data security, we've proven that we can conduct clinical trials remotely, without compromising on quality or compliance."

Meri Beckwith
CEO, Lindus Health

THE RESULTS

By overcoming traditional site visit barriers and ensuring secure, remote data collection, Lindus Health successfully:

Expanded Trial Accessibility

The decentralized approach enabled participation for patients who would otherwise have been excluded due to mobility limitations. This significantly broadened recruitment reach, allowing for a more diverse and representative patient population.

Optimized Remote Data Collection

AliveCor's solution delivered high-quality ECG data in real time, allowing researchers to monitor patients remotely and address any issues promptly. The full-service management and CoreLab physician review ensured that trial integrity and compliance were maintained without requiring in-person site visits.

Enhanced Regulatory Confidence

By maintaining strict data security and adhering to global compliance standards, Lindus Health demonstrated the feasibility of fully decentralized clinical trials. This success reinforced regulatory confidence in remote cardiac monitoring and set a precedent for future decentralized research.

Experience the AliveCor Impact

Connect with us to discover how AliveCor can support your clinical trial today.
Discover more at alivecor.com/clinical-trials.