

ADVANCING CLINICAL TRIALS THROUGH DIGITAL HEALTH TECHNOLOGY

Key Insights from a Remote Cardiac Monitoring Partnership

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Remote cardiac monitoring devices are rapidly becoming an essential part of modern clinical trials and patient care. Unlike traditional in-clinic ECG assessments, these technologies enable continuous, real-time monitoring of cardiac activity as patients go about their daily lives. This approach provides a more comprehensive view of heart health, capturing events that are often missed during periodic site visits. This is essential for asymptomatic arrhythmias or transient abnormal physiological parameters that can be hard to capture during in-clinic checkups. Regulatory agencies such as the FDA and EMA are increasingly advocating for the use of digital health technologies, including remote cardiac monitoring devices, to enhance data quality and patient safety.^{1,2} These devices support a more patient-centric approach by minimizing the need for frequent site visits, while also generating large, continuous datasets that offer more comprehensive insights into safety and treatment effects. For Sponsors, this translates into fewer missed cardiac events, improved patient compliance, and streamlined data collection, ultimately leading to more efficient and reliable trial outcomes.

Other key advantages include improved patient convenience and reduced patient burden, both of which can enhance patient engagement and retention. By allowing patients to remain at home with minimal physical involvement in data collection, these technologies also promote greater patient population diversity. Patient safety is strengthened through real-time monitoring, enabling timely alerts to healthcare providers and facilitating quick intervention to minimize risk. Collectively, these benefits are critical to the success of clinical trials.

While remote cardiac monitoring devices offer significant advantages, their adoption in clinical trials also presents a unique set of challenges. Sponsors must navigate evolving global regulatory requirements, coordinate complex device logistics

for global distribution and technical support, and manage the integration and quality control of large, continuous data streams into trial databases—all while ensuring patient and site compliance. These complexities underscore the need for strategic partnerships between Clinical Research Organizations (CROs) and technology vendors to combine operational expertise with technical innovation to deliver reliable, compliant, and patient-friendly solutions at scale. When effectively executed, such partnerships can unlock the full potential of remote cardiac monitoring.

This whitepaper aims to demonstrate how remote cardiac monitoring devices can enhance the design and execution of large-scale clinical trials through effective collaboration between Medpace and Vivalink. We will explore key applications of remote cardiac monitoring devices in clinical research and share lessons learned and key takeaways from clinical trials involving these technologies.

APPLICATIONS OF REMOTE CARDIAC MONITORING DEVICES IN CLINICAL TRIALS

Remote cardiac monitoring devices range from smartwatches to chest straps and patches. These devices use sensors to monitor heart rate, electrocardiogram (ECG) signals, and physical activity, providing comprehensive insights into cardiovascular health. The sensors are typically connected to a smartphone app via Bluetooth. Devices vary by form factor, accuracy and performance (consumer-grade vs. medical-grade with FDA clearance), battery life, reusability, and data-sharing capabilities.

Initially adopted in hospital settings to shorten inpatient stays and enable proactive patient management via notifications triggered before a deteriorating event³, this technology is now also used in cardiology clinical trials for heart failure⁴ or arrhythmias such as atrial fibrillation^{5,6}.

Arrhythmia monitoring is a primary application because these events are either nonsustaining or asymptomatic, making them difficult to capture with a standard 12 lead ECG or traditional Holter monitor. Arrhythmias can also lead to significant complications such as stroke, heart failure, and cardiac arrest.

Applications now extend well beyond cardiology, encompassing clinical trials in COVID-19, oncology, COPD, and mental health. Remote monitoring has supported fully remote COVID-19 trials. This demonstrates applications in rigorous, safe, and entirely remote clinical trial conduction.⁷ In oncology, cardiac safety is critical for post-chemo patients to capture early arrhythmias and enable timely intervention to avoid hospitalization. In COPD studies, continuous remote cardiac monitoring of respiratory rate, activity levels, heart rate variability, and patient-reported symptoms offers significant benefits. Wearables can support a 6-minute walk test (6MWT) that is routinely performed for cardiopulmonary function assessment. Beyond the above mentioned conditions, mental health issues such as stress and anxiety can also be detected in the data from remote cardiac devices. This facilitates remote observations of cardiac patterns that may serve as early indicators of depression and anxiety adolescents.⁸

In addition to its efficacy and safety benefits, remote monitoring plays a significant role in decentralized clinical trial (DCT) solutions. The Industry Standard Research (ISR) surveyed employees at biopharmaceutical companies who have leveraged DCTs within the year and reported that about 42% of respondents are currently utilizing remote monitoring, while 55% of respondents expect their remote monitoring use to increase in the next two years⁹. As DCT solutions are commonly used to support study visits, they reduce the number of investigative sites while supporting more patients per site and shorter timelines¹⁰, offering both operational and economic benefits for trials.

Overall, the usefulness and versatility of remote cardiac monitoring in various types of clinical trials highlights the growing benefits across clinical research.

THE CRITICAL ROLE OF CRO-VENDOR COLLABORATION IN TRIALS WITH REMOTE CARDIAC MONITORING

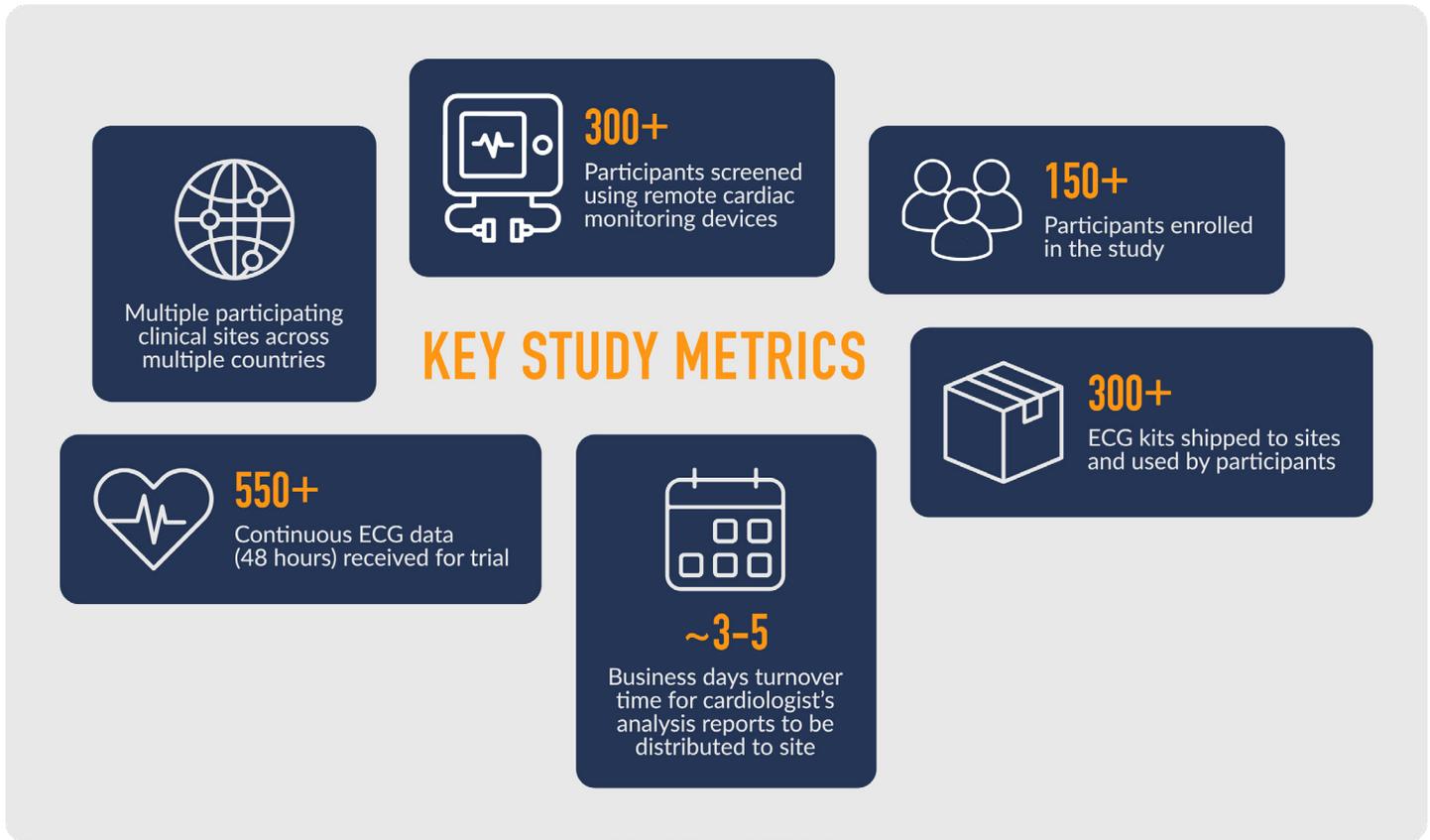
Incorporating remote cardiac monitoring through wearable technologies in clinical trials offers significant advantages for patients, sites, Sponsors, and regulatory agencies alike. However, realizing their full potential requires more than the hardware and software technology; it necessitates rigorous scientific oversight, regulatory depth, operational readiness, and technical expertise. Consequently, strategic collaboration between an experienced CRO and vendor specialized with digital healthcare solutions is essential to navigate this complex landscape.

To successfully implement remote cardiac monitoring, Sponsors can partner with an experienced CRO and a technology vendor with proven success in clinical trials. Enlisting the support of a vendor with the experience and infrastructure to manage biosensor-enabled clinical trials mitigates challenges and positions Sponsors to reap the benefits. Equally important is the CRO's ability to fully understand the complexities of the study protocol and regulatory requirements, manage data workflows, and ensure the remote monitoring data aligns with the study objectives.

To illustrate how a strong CRO and vendor partnership can effectively support the integration of remote cardiac monitoring devices into a clinical trial, a case study is presented in the following section.



CASE STUDY: COLLABORATIVE TRIAL INVOLVING PATIENTS WITH PULMONARY HYPERTENSION AND HEART FAILURE



A clinical trial across multiple countries targeted individuals diagnosed with pulmonary hypertension and heart failure, two conditions that require close cardiac monitoring to assess disease progression and IP safety. To ensure continuous and reliable cardiac data collection outside of the clinical setting, the study implemented Vivalink's remote continuous ECG monitoring device. This lightweight FDA-cleared remote ECG recording device enabled continuous cardiac rhythm monitoring while allowing study participants to maintain their normal daily activities. The continuous ECG kit that was provided to participants includes one rechargeable wireless ECG patch, charger, and one mobile phone with internet and Bluetooth connection. The ECG patch was applied close to the participant's heart on their upper left chest.

Recorded continuous ECG data were transmitted in near real time via Vivalink cloud-based platform, providing central cardiologist readers with high-quality and un-interrupted ECG signals.

The collaboration between Medpace, a global full-service CRO, and Vivalink, a leading provider of digital health solutions, ensured reliable implementation of remote cardiac monitoring in a large, multicenter clinical trial. Medpace led the operational and regulatory aspects of the study, overseeing site coordination, data management, and regulatory compliance; while Vivalink provided a validated technology platform, device logistics, and technical support. Together, the team established a robust governance framework to ensure seamless data flow, real-time issue resolution, and consistent training across all participating sites.



STRATEGIES FOR OVERCOMING CHALLENGES OF REMOTE CARDIAC MONITORING IMPLEMENTATION

Throughout the duration of the clinical trial, both Medpace and Vivalink encountered some operational and technical challenges inherent to conducting remote continuous ECG monitoring in real-world, home-based settings. In response, Medpace and Vivalink collaborated to implement targeted solutions to ensure data completeness and maintain study integrity.

Study Population Demographic, Accessibility, and Lifestyle

The study population primarily consisted of older adults diagnosed with pulmonary hypertension and heart failure, a demographic that presented unique challenges in the use of remote cardiac monitoring devices. Some participants had limited experience with wearable technology, and age-related factors such as reduced dexterity, cognitive limitations, and comorbid conditions occasionally impacted compliance, data completeness, and device care and maintenance. During this trial, participant-reported operational issues were observed in 3.2% of assigned ECG kits. To address these challenges, Medpace and Vivalink implemented steps for proactive adherence monitoring, simplified training, and remote troubleshooting strategies to streamline site coordination and ensure high quality data collection.

Another operational challenge arose among participants living in remote or rural areas with limited or no access to Wi-Fi or cellular connectivity, which disrupted the real-time transmission of ECG data from the wearable device to the study platform. Although the remote cardiac monitoring device is designed to store the ECG data locally until a connection becomes available, prolonged absence of network access increased the risk of delayed uploads and required additional oversight. To mitigate this issue, Medpace and Vivalink implemented alternative data recovery solutions for these instances. Participants were advised to intermittently travel to areas with stable internet access so that the device could transmit accumulated data.

In cases where traveling wasn't feasible, participants were instructed to return the device at the end of the recording period, allowing the site or the Vivalink technical team to recover and transmit the recorded data.

Another source of variability in data quality stemmed from participants' daily lifestyles, which could sometimes interfere with the performance of the remote ECG recording device. In a few cases, participants traveled during active recording periods to locations with different time zones which affected the timestamp alignment during data processing. Other times, participants engaged in vigorous physical activities that caused the ECG patch to loosen or shift, resulting in excessive motion artifacts and noisy data sections or extended data gaps. In some cases, the participants worked night-shift schedules, which altered their expected nighttime cardiac rhythm and required the study team to interpret ECG patterns within an atypical daily cycle. To address these challenges, Medpace and Vivalink provided targeted reminders on proper patch placements, reinforced guidance on maintaining secure adhesion during activity, and clarified the importance of notifying staff about travel schedules. In instances where the data quality was impacted, re-recording was requested if it was still within the study-specific recording window. These measures helped preserve data quality while accommodating the natural variability in participants' daily lives.

ECG Patch Operation, Training, and Compliance Monitoring

Despite comprehensive training and relevant study-specific documentations, some participants encountered difficulties in operating the device at home, leading to recording or transmission delays. To resolve this, Medpace and Vivalink provided ongoing support to site staff, ensuring they remained proficient with the units and understood the escalation path for real-time technical assistance.

Given the large scale of the trial and multiple recording timepoints, maintaining strict adherence was vital to prevent data loss. Medpace proactively sent reminders to site personnel before each collection window to ensure participants were prepared. Additionally, they reviewed the incoming data on an ongoing basis and notified the site for



interrupted transmission or poor data quality with needed site assistance during the data collection. If the issue was still unsolved, the Medpace team would escalate to the Vivalink support team. In some cases, a replacement kit was provided to the participant to re-record the expected session, or the used ECG kit was shipped back to Vivalink so the support team could recover the missing data.

Deployment of ECG Kits, Resupply, and Data Recovery

Given the high volumes of patient screening and consequently ECG kit shipment requests by clinical sites, the Medpace and Vivalink teams developed a fast-paced workflow to ensure supplying sites had enough ECG kits to provide to the study participants at screening and follow up timepoints. In some instances, the sites required expedited shipment as they could not always accurately predict the number of patients that would qualify for study participation. In those cases, the team ensured timely shipment of ECG kits to the sites. In other instances, the participants were located in suburbs or remote areas that would require additional shipping arrangements to ensure participants could access the ECG kits in a timely manner.

One of the challenges encountered during the trial was loss or misplacement of ECG kit components including the wearable patch, the mobile phone used for data transmission, or both. Some participants—particularly those unfamiliar with wearable technology—accidentally discarded the patch after removal or misplaced the phone between monitoring periods, which required device replacements. Over the course of the trial, 7.2% of the ECG kits issued to participants experienced partial or complete loss of kit components. To address the recurring instances, Medpace requested the site staff to complete additional online training and participate in virtual refresher sessions to reinforce proper patient/caregiver instruction and accountability procedures.

Meanwhile, Vivalink supported the remediation process by providing clear, simplified device-handling guidelines, assisting with replacement logistics, and offering technical clarifications during troubleshooting sessions. This approach reduced further device loss and ensured more consistent device management across study locations. Due to the cloud-based storage design of these remote monitoring devices, device losses did not lead to data loss in the trial.

CONCLUSION

Incorporating remote cardiac monitoring through wearable technologies in clinical trials offers significant advantages, from continuous real-time data capture to improved patient convenience and retention. New remote cardiac monitoring technology is expected as the capabilities and applications of DCTs continue to expand, driven by advancements in sensor accuracy, data connectivity, and analytics.

A strong partnership between a CRO and a digital healthcare solution vendor is essential to fully realize these benefits. In large clinical trials, it is critical for the technology vendor to provide a tiered global technical support with seamless CRO workflow integration and compliance reporting to the CRO, while the CRO provides end-to-end study coordination and works closely with the vendor and sites for prompt issue solvencies. Close collaboration streamlines operations, reduces site and Sponsor burden, and supports faster, more reliable endpoints—ultimately accelerating development timelines and regulatory success.

Looking ahead, the future of remote cardiac monitoring devices will play a pivotal role in shaping the next generation of clinical research. By embracing these technologies and fostering effective collaboration, clinical development will continue to advance to enhance patient outcomes and quality of life.



ABOUT MEDPACE

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, neuroscience, ophthalmology, immunology, and infectious diseases and vaccines.

Medpace Core Labs provides an end-to-end suite of global imaging and cardiac safety services to enhance and expedite biopharmaceutical and medical device development. As part of our full-service offering Medpace seamlessly collects, harmonizes, and integrates data from wearables and remote devices—such as ECGs, blood glucose, cardiac output, actigraphy, volume status, and vital signs—into your clinical study to present strong regulatory cases.

ABOUT VIVALINK

Vivalink is a Medtech company providing end-to-end digital healthcare solutions for continuous remote patient monitoring in healthcare and clinical trials, with extensive training, technical support and services, from the patient side wearables to the clinician side web portal. Its turnkey remote data capture services for human vitals and biometrics helps ensure optimal data integrity and patient adherence. Its platform captures rich “real-world” data directly from patients outside of traditional care settings to offer insights into a patient's health.

Vivalinks wearables are very flexible to optimize user wearing experience, which include an armpit temperature sensor for continuous body temperature monitoring and a multi-vital patch for continuous monitoring of the heart rate, heart rate variability, respiratory rate, activity and arrhythmias. The same platform also incorporates varieties of third-party devices from pulse oximeters and blood pressure cuffs to scales and spirometers to ensure all data in a centralized place. In addition, this platform has been used in a wide variety of clinical studies including general vital sign monitoring, atrial fibrillation, heart failure, pulmonary hypertension, neurology, COPD, and oncology.



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