

A Sponsor's Guide to Participant Adherence in Remote Data Collection for Clinical Trials

THE GOALS

- Remotely collect participant data for clinical trials using remote patient monitoring technology solutions.
- Monitor participant adherence to clinical trial protocols in order to ensure complete data collection.
- Minimize disruptions and maximize data reliability for efficient trial execution.

THE RESULTS

- Maintained high participant adherence to clinical trial monitoring protocols throughout the study.
- Streamlined trial operations, minimizing disruptions and enhancing efficiency.
- Ensured accurate and reliable data collection, contributing to the overall success of the clinical trial.

NAVIGATING PARTICIPANT ADHERENCE CHALLENGES IN REMOTE DATA COLLECTION FOR CLINICAL TRIALS

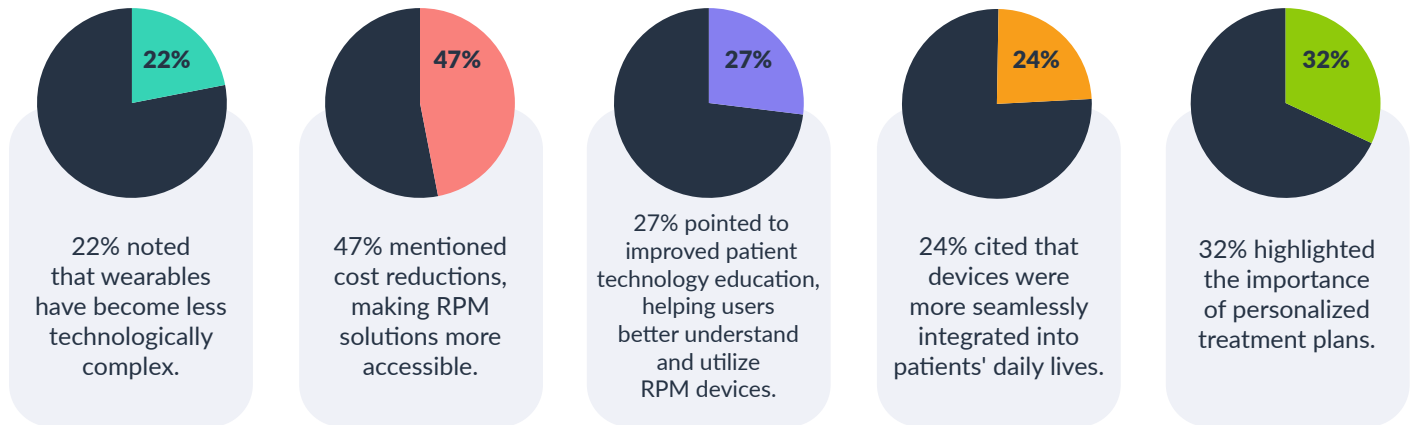
Advancements in digital health technologies are transforming clinical trials and enabling hybrid and remote approaches that enhance participant convenience, broaden participant recruitment, and offer flexible data collection methods. However, challenges persist, notably in ensuring participant adherence to study protocols and data collection.

Participant adherence is imperative in clinical trials, directly influencing outcome assessment and the validity of trial results. Studies indicate that participants in chronic condition trials adhere to protocol requirements between 43% and 78% of the time, highlighting the need for effective adherence strategies.

UNDERSTANDING PARTICIPANT ADHERENCE CHALLENGES

Despite nearly half of surveyed clinicians (44%) identifying patient adherence as a primary obstacle to implementing remote patient monitoring (RPM), those who have adopted RPM report significant improvements. Specifically, 53% of clinicians conducting home-based cardiac rehab noted increased patient adherence due to RPM technology (Source: [Vivalink](#)).

Several factors contributed to the rise in adherence with RPM:



A variety of influences impact participants' adherence to RPM devices, affecting their ability and willingness to follow trial protocols. Understanding these underlying reasons behind adherence challenges is necessary to address them successfully.

● TECHNOLOGY COMPLEXITY

The intricate nature of RPM devices can hinder adherence. Participants, especially older individuals, may struggle navigating complex menus or pairing wearable devices with smartphones. Using simple, preconfigured devices and providing user-friendly interfaces can promote adherence.

● LIFESTYLE FACTORS

Lifestyles heavily influence device usage. Bulky wearables or those needing frequent removal, like during showering or exercise, may inconvenience participants, leading to irregular usage and compromised adherence. Ensuring participants can effortlessly incorporate devices into their daily routines maximizes adherence.

● PHYSICAL LIMITATIONS

Participants undergoing certain treatments may face physical limitations impacting their dexterity, mobility, and overall health. Issues like impaired vision can complicate device use. Complex or cumbersome devices worsen these challenges and hinder adherence.

● FORGETFULNESS AND LACK OF MOTIVATION

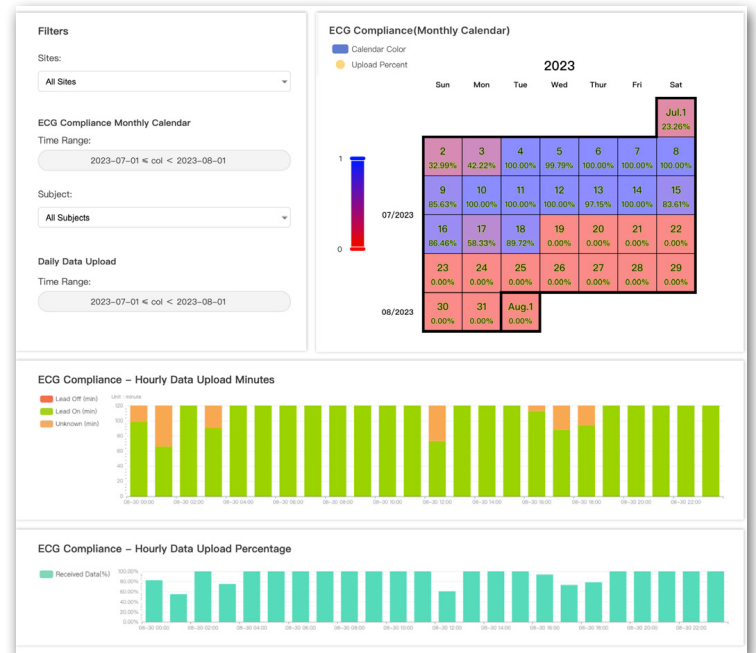
Despite their intentions, participants may forget to use their devices or lose motivation if they do not perceive immediate benefits from using them. Lapses in adherence to monitoring schedules can lead to data collection gaps and compromise treatment outcomes. Using automated “wear and forget” devices is the best option.

EXPLORING THE ADVANTAGES OF REMOTE AND HYBRID TRIALS

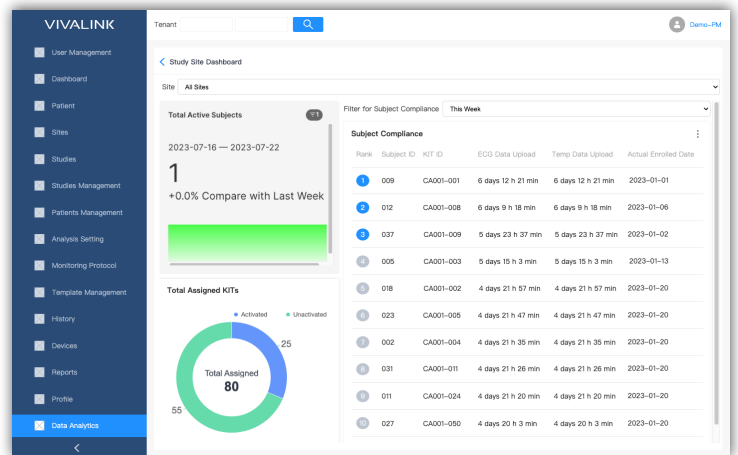
Incorporating remote monitoring solutions into clinical trials yields cost savings compared to traditional methods. Traditional approaches often entail considerable expenses associated with getting participants on-site, including travel costs, provider time, and the logistics of organizing in-person visits.

Relying solely on in-person visits has limitations, as data collection becomes episodic rather than continuous, resulting in monitoring gaps. A well-designed RPM solution includes monitoring and tracking participant adherence remotely, enabling site staff to intervene when needed.

Tracking real-time adherence allows sites to promptly identify potential safety events or deviations from the study protocol. The solutions also empower sites with remote access and support mechanisms, reducing the need for on-site interventions and streamlining trial workflow.



COMPLIANCE DASHBOARD



PARTICIPANT ACTIVITY MONITOR

CASE STUDY

As part of a hybrid trial incorporating remote data collection, a global Clinical Research Organization sought to monitor arrhythmias for cardiac safety using wearable technology. The trial required tailored approaches to ensure participant adherence to device usage, trial coordination, and precise data recording.

Recognizing the importance of accurate data collection and participant adherence, the CRO partnered with Vivalink. Vivalink provided turnkey solutions consisting of RPM technologies, data services, and logistical support that enabled the CRO to effectively maintain trial guidelines, minimize interruptions, and ensure accurate data collection.

THE CRO'S REQUIREMENTS FOR REMOTE MONITORING

REMOTE MONITORING CAPABILITY	The CRO needed a solution for remote monitoring of vital signs, including arrhythmia detection, and ensuring adherence to study-specific monitoring protocol. The solution minimized on-site visits and eliminated the need for home health nurses during data collection.
REAL-TIME DATA INSIGHTS	The CRO needed access to real-time data insights to track adherence to device use, medication diaries, or surveys and promptly detect deviations from the study protocol. Real-time monitoring capabilities enabled the CRO to intervene as needed and ensure data integrity throughout the trial.
CUSTOMIZED TRAINING AND SUPPORT	The CRO sought customized digital training materials, videos, images, and support to educate participants and site staff on remote monitoring technology and troubleshooting procedures. Customized training empowered participants to use the device correctly and resolve issues independently, reducing the burden for on-site staff.
REMOTE TROUBLESHOOTING MECHANISMS	The CRO needed to address technical issues efficiently. Remote troubleshooting capabilities minimized disruptions to data collection, ensuring smooth trial operations at scale.
ADHERENCE TRACKING TOOLS	Tools for tracking adherence and data recording were necessary. Adherence tracking tools enabled the CRO to monitor usage trends, identify potential data issues, and optimize their clinical trial management processes accordingly.
INTEGRATION WITH TRIAL PROTOCOL	Integration into the trial protocol and workflow was a priority for the CRO. This included ensuring that the technology accommodated the study's specific requirements such as data parameters, and the duration of data collection periods.

HOW DID THE CRO ENSURE PARTICIPANT ADHERENCE IN A HYBRID TRIAL?

For this particular study, the CRO employed Vivalink's multi-function wearable ECG and Biometrics Data Platform. Participant ECG and vitals data were collected over three continuous 48-hour periods. Vivalink also implemented targeted tools to enhance adherence and optimize trial management processes.

The Vivalink solution offered a comprehensive platform for automated, continuous data collection and analysis with minimal participant intervention required. The platform featured real-time monitoring capabilities, customizable dashboards, and alerts for detecting adherence issues. Unlike trials requiring home health nurses for data collection, the Vivalink solution allowed participants to manage the recording process with minimal disruptions to their daily routine. From there, site staff remotely monitored the data, ensuring proper functionality throughout the study.

Vivalink provided turnkey solutions consisting of RPM technologies, data services, and logistical support.

Vivalink also provided tailored training and support services for participants and site staff. This included personalized onboarding kits, educational materials, and technical support to ensure seamless integration and optimal usage of the devices, assisting in troubleshooting when issues arise.

IMPACT OF REMOTE MONITORING SOLUTIONS ON PARTICIPANT ADHERENCE AND TRIAL OUTCOMES

IMPROVED DATA COLLECTION

- Alerts, triggered by missed data uploads or irregular usage patterns in Vivalink's platform, provided timely reminders to participants and trial operators, which reinforced device usage and data upload.
- Regular check-ins sent through Vivalink's platform were customized to study requirements and each participant's progress, ensuring engagement throughout the trial duration.
- Vivalink's participant education materials, featuring interactive videos and step-by-step tutorials, emphasized device usage, maintenance, and troubleshooting, encouraging participants to remain committed to proper usage.

ENHANCED TECHNOLOGICAL ACCESSIBILITY

- Vivalink tailored study dashboards to accommodate specific device types and data streams, providing site staff with comprehensive insights into participant adherence and ensuring data integrity.
- Each device, phone, and application, all provided by Vivalink, arrived turnkey and pre-configured. This streamlined the onboarding process, eliminated setup hurdles, and encouraged immediate device usage.
- Vivalink included essential accessories, such as charging cables and alcohol wipes, that ensured participants had all the tools readily available, enhancing convenience and promoting adherence to device usage protocols.

TIMELY ISSUE IDENTIFICATION

- Participants and site staff benefited from personalized assistance from Vivalink's dedicated support team, allowing them to articulate and address any challenges effectively.
- Site staff promptly identified and resolved adherence issues with Vivalink's remote troubleshooting, saving time and minimizing disruptions to the study protocol.
- For example, Vivalink's platform detected that data had not been properly collected. The platform alerted the CRO and enabled them to request the participant to reapply the patch, ensuring accurate data collection.

TRIAL EFFICIENCY

- Vivalink's educational materials equipped site staff with detailed instructions on proper device usage, troubleshooting procedures, and effective participant assistance. The materials enhanced adherence and minimized the need for frequent on-site interventions.
- Personalized onboarding kits with clear instructions and convenient packaging ensured ease of use and encouraged better adherence. Vivalink's kits expedited setup, being ready for use within 15 minutes, and optimized site training and activation processes.

REDUCED COSTS

- Vivalink's reusable and rechargeable sensors eliminated the need to continuously replace one-time use devices, thereby reducing ongoing device procurement costs.
- User-friendly technology and comprehensive support materials reduced the time and resources required for sites to become familiar with Vivalink's technology, ultimately enhancing adherence and decreasing training expenses.

By leveraging Vivalink's technologies and expertise, clinical professionals can benefit from remote trials through reduced expenses, improved participant adherence, and enhanced data collection.

For more information about Vivalink, visit [Vivalink.com](https://vivalink.com).