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Remote Patient Monitoring for Decentralized Clinical Trials

An Effective Way to Remotely Gather Patient Data and Accelerate Trials

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Introduction

Remote Patient Monitoring (RPM) is an integrated approach that employs technology-backed medical devices to gather physiological and biometric data from patients that is then electronically transmitted for remote analysis, review, and, when necessary, interventions and preventive care. Advances in network technologies, connected devices, medical wearables, sensors, data analytics algorithms, and software are paving the way for efficient data collection in remote clinical trials and the delivery of advanced healthcare.

RPM is not a new model of care – in fact, the concept antedates the COVID-19 outbreak. However, the pandemic did provide the necessary push to drive RPM, with lockdowns restricting patients' movements, posing a challenge to data collection and halting clinical trials worldwide. This adversity emerged as a blessing in disguise for RPM solutions. Decentralized Clinical Trials (DCTs), powered by RPM, made it possible for clinical trials to be conducted at patients' homes. RPM helped counter clinical trial disruptions and ensured the continuity of therapeutic developments.

In fact, RPM benefits study participants and clinical trial sponsors as it enables real-time data collection from patients in a natural environment, accelerates trial data collection, and enables participant retention throughout a trial. Thus, we believe that RPM will continue to be instrumental in providing dependable data collection solutions for years to come.

In this report, we:

- Examine the present state of RPM
- Evaluate the drivers and challenges for RPM
- Share the future outlook for RPM
- Provide a road map for the successful implementation of an RPM solution

The report will benefit biopharma enterprises and Contract Research Organizations (CROs) in understanding the benefits of RPM, implementing an RPM solution, and accelerating trials to deliver on the promise of improved healthcare.

The present approach to RPM

Traditionally, patients had to physically arrive at hospitals or research centers to participate in clinical trials. However, the pandemic compelled the industry to come up with innovative ways to collect patient data to counter disruptions to clinical trials. While numerous approaches emerged, RPM was used most frequently.

An Oracle survey[1] of sponsors and clinical trial professionals ranks remote monitoring at the top of newly adopted technologies during the pandemic, as Exhibit 1 shows. The study also found that during the pandemic, 67% of respondents had already implemented RPM in their clinical trials through mobile applications, wearables, and sensors.

EXHIBIT 1

Clinical trial models implemented during the pandemic

Source: Oracle Health Sciences (2021)

RPM-enabled DCTs are allowing sponsors to design clinical trials that are patient- and site-centric. The pandemic significantly accelerated the adoption of DCTs, and the momentum will only increase as sponsors and CROs continue to deploy these models for clinical trials. Notably, a Veeva Systems survey[2] among 289 clinical trial professionals reveals that 95% of the respondents intend to increase their reliance on DCTs in the next two years.

RPM has enabled clinical trial sponsors and CROs to bring in more diversity in the participant population while ensuring that patients stay engaged while participating in trials from the comfort of their homes. Undoubtedly, this approach has helped gather large volumes of data with clinical accuracy – an essential success factor for trials.

> Putting research within the reach of more diverse populations has the potential to advance medical progress and lead to better outcomes for more patients.
>
> – Freda Lewis-Hall, former Chief Patient Officer and Executive VP, Pfizer

1 Clinical Trial Management in a Post-Pandemic World, conducted by Pharma Intelligence on behalf of Oracle, October 2021
2 Veeva Digital Clinical Trials Survey Report, Veeva Systems, 2022

The RPM architecture

To fully appreciate the RPM approach, it is vital to understand the components and technologies that power it. These are:

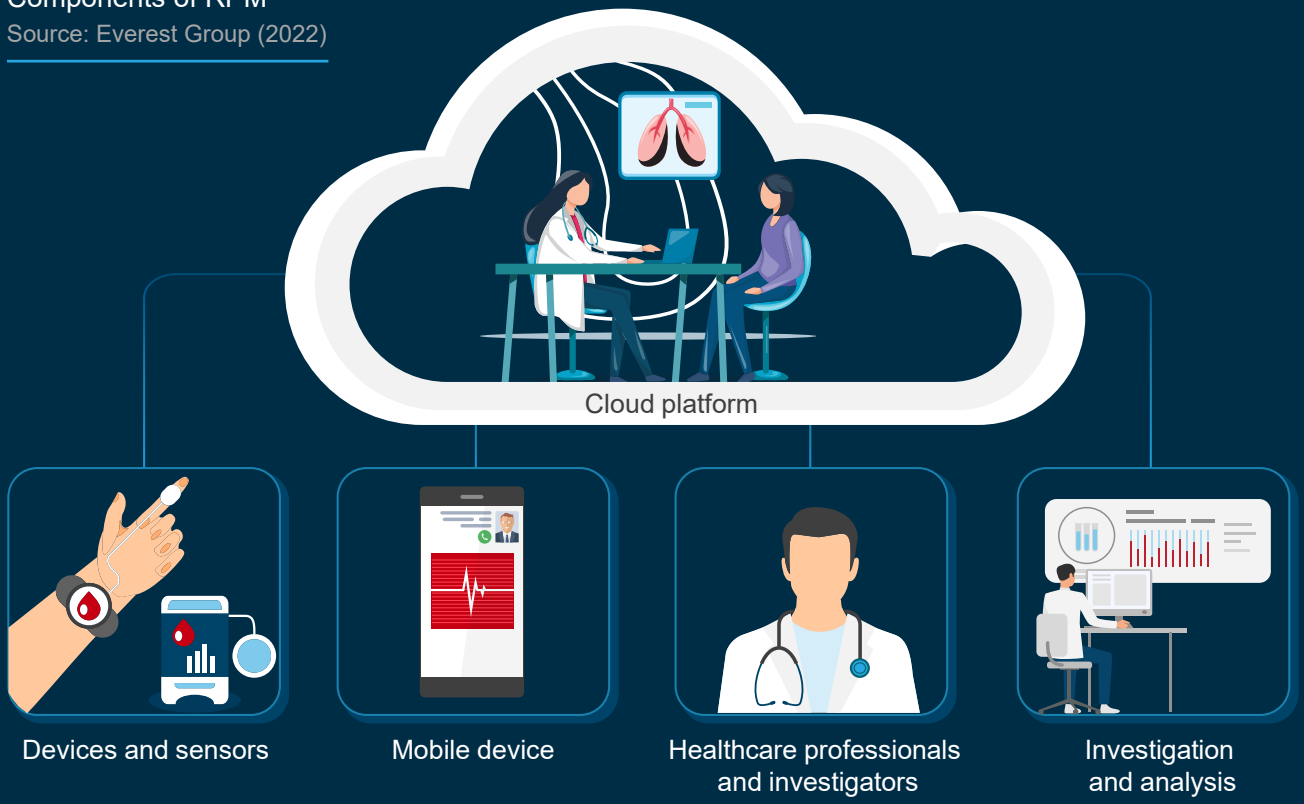
- **Devices and sensors:** These could include medical-grade devices and sensors, such as Vivalink's wearable ECG monitors, Dexcom's glucose meters, or consumer-health devices such as Apple/Fitbit watches, which gather health-related data from patients
- **Communication technology:** Information from wearable devices is transmitted over a cellular, Wi-Fi, or Bluetooth network. Each of these technologies has its own benefits and drawbacks. Organizations must consider factors such as data security, power consumption, network reliability, and range of data transmission when selecting the best-fit communication technology
- **Mobile devices:** These refer to smartphones or tablets, either owned by the patient or provisioned to them by life sciences firms. The data from wearables is typically transmitted to these devices, which also log patient-reported symptoms in a relevant mobile application
- **Cloud platforms:** Real-time data monitoring can result in a deluge of information, which necessitates a data storage platform that can store information securely and grant easy access to relevant individuals. Additionally, a cloud platform provides centralized access to data captured from multiple locations and patients
- **Analytics capabilities:** RPM requires the software and analytics capabilities that investigators and data scientists use to monitor and manage the incoming data

Exhibit 2 depicts how these components work together in an RPM solution.

EXHIBIT 2

Components of RPM

Source: Everest Group (2022)



Benefits of adopting RPM

Sponsors and CROs are adopting RPM to effectively monitor patients in their natural settings from afar without compromising compliance, integrity, and safety. RPM has not only improved patients' access to trials but has also enabled sponsors to reduce their trial costs and timelines, increasing participant retention, data accuracy, and integrity.

An Intel study suggests that up to 70% of clinical trials will adopt sensors by 2025.[1]

Exhibit 3 highlights how patients, sponsors, and sites are reaping the benefits of RPM solutions.

EXHIBIT 3

Benefits of adopting RPM

Source: Everest Group (2022)

Patients	Sponsors/CROs
• Enhanced access to clinical trial participation • Increased comfort and convenience – reduced trips to hospitals and sites • Improved quality of care and better treatment outcomes • Increased access to health and trial information	• Patient-centric clinical trials • Reduced trial costs and time • Enhanced patient safety and efficacy • Improved participant diversity • Higher data integrity and accuracy • Streamlined and unified workflows

Challenges in RPM implementation

New technologies are often accompanied by problems that hinder their adoption, and RPM is no different. Despite its strong prospects for success, there are several challenges that need to be addressed by stakeholders before sponsors and CROs can reap exhaustive benefits from RPM solutions. Some of the key challenges are:

1 Transforming Clinical Trials with the Power of AI, Intel, July 2018

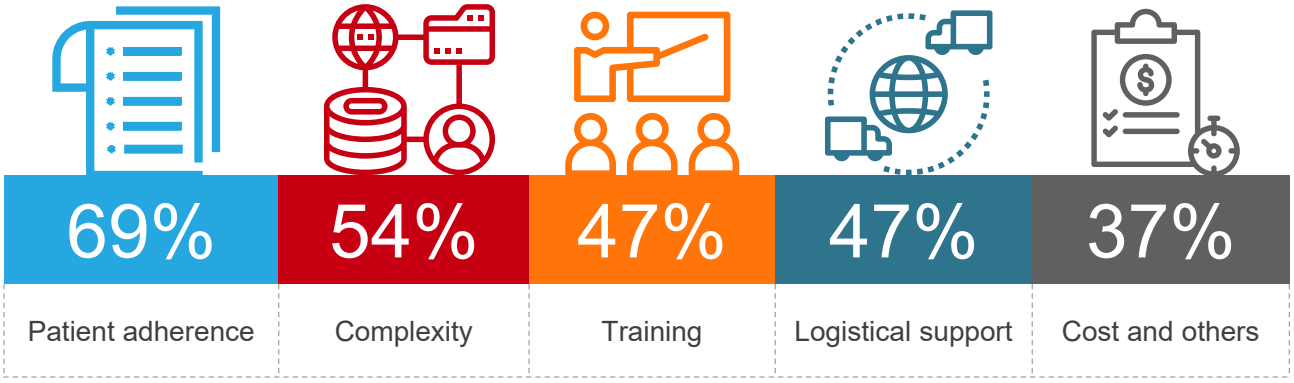
- **Data security:** Different varieties of sensors and the sheer volume of heterogenous data they gather can become overwhelming for investigators. Providers are actively developing analytics algorithms and data mining technologies that can accelerate value generation from this data. However, data collection and transmission over a wireless network makes data vulnerable to power outages, cyberattacks, ransomware, impersonation attacks, and replaying. This warrants the need to design a foolproof system that has ironclad data management practices and strict security protocols
- **Patient adherence:** Under the RPM approach, investigators no longer physically monitor patients. This situation, coupled with limited digital literacy and challenges in operating new sensors, devices, and applications, makes it difficult for investigators to ensure patient adherence. A Vivalink survey[1] among 112 pharma and clinical research professionals shows that 69% of the respondents believe patient adherence to be their biggest concern vis-à-vis RPM adoption

Exhibit 4 depicts the top concerns with RPM in clinical trials

EXHIBIT 4

Top concerns with RPM in clinical trials

Source: Vivalink (2021)



- **Overhead costs:** Every new technology battles with the concern of overhead costs associated with the initial setup and implementation of its programs. Therefore, it is important for enterprises to budget all their requirements, especially those pertaining to new devices; engagement with providers; training sessions for clinicians, investigators, and patients; cloud storage and access; logistics; and initial setup. The burden of these additional costs could impede the adoption of RPM solutions
- **Integration and interoperability:** RPM solutions require a host of different sensors and devices, most of which are manufactured by different organizations. Also, not all data systems operate on the same infrastructure and network, hindering the integration and effective communication between devices. The heterogeneity across devices, networks, and systems makes it difficult for regulatory bodies to design and implement effective interoperability standards for this technology

1 Vivalink survey of pharma and clinical research professionals, May 2021

- **Technical constraints:** Wearable devices and sensors have limited battery capacities and could consume significant power. Even though the latest devices and network protocols such as Bluetooth consume less power, batteries continue to have limited capacities and frequent recharging becomes an additional burden for patients to bear

Although these barriers could impede RPM uptake, the industry is making efforts to overcome them. We believe that RPM has the potential to emerge as a patient-centric, reliable, and powerful healthcare solution, which continuously improves itself to enhance patient experience while making it easy for investigators to accelerate value generation from participant data.

The future of RPM solutions

The COVID-19 pandemic highlighted the immense benefits of RPM solutions and accelerated their adoption. To realize the full potential of this technology, organizations will have to find ways to overcome its associated challenges. We believe that RPM will emerge as an integrated, interoperable, and secure solution in the future that will transcend its traditional metrics and make devices more patient-friendly to improve trial adherence and patient care.

> We are continuing to see clinical trials rapidly shift to a decentralized model with remote patient monitoring. A successful RPM solution needs to keep everyone – the technologists, patients, and clinicians – in mind.
>
> – Jiang Li, CEO, Vivalink

Next-generation RPM solutions will be characterized by the following features:

- **RPM-enabled biometrics data platform:** A broad range of data types is required to enable the diverse kinds of clinical studies that are conducted today. Each data type, such as ECG, blood pressure, or oxygen saturation, may require a different type of medical device or sensor to capture the data. Next-generation RPM platforms need to be able to integrate this heterogeneous data for centralized access
- **Advanced data security measures:** Modern RPM platforms will have data security and privacy measures built in by design and not as an afterthought. Adherence to network security (such as SSL and TSL protocols), device security (such as FDA's medical device cybersecurity guidance), and data security (GDPR guidelines and its regional variations) protocols will be an integral feature of the platform. Established data access policies, data ownership transparencies, and data encryption measures will further secure and strengthen the next generation of RPM solutions

- **Data analytics:** Next-generation RPM will go beyond the traditional metrics and tap into sleep patterns, exercise regimes, and sedentary activities as well. For example, MIT-developed sensors can analyze the breathing patterns of sleeping participants and correctly identify individuals with Parkinson's disease 80% of the time[1]. Coupled with predictive analytics, RPM solutions will accelerate drug development
- **Data compliance:** Ensuring patient adherence to trial protocols for efficient data capture requires the next generation of RPM solutions to be able to monitor the status of data collection across multiple sites and participants. Such monitoring requires a central operational console to detect data interruptions and proactively address any problems to ensure data continuity
- **Integration of clinical systems with RPM solutions:** Data collected from RPM devices should be integrated into a central clinical system to facilitate data standardization and value generation. As such, data interoperability via network protocols, data formats, and system interfaces needs to be ensured

The exhibit below captures the evolution of RPM solutions. The future state of RPM, powered by advanced analytics, is a well-integrated and self-intuitive solution designed to provide a seamless experience to all stakeholders in the ecosystem.

EXHIBIT 5

Evolution of RPM solutions

Source: Everest Group (2022)

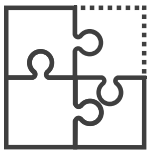
Current RPM solutions		Next-generation RPM solutions
Disparate systems, lack of standardization, and ineffective communication	**Nature of platform** 	Integrated platform-based approach and consolidated data for central access
Gaps in ownership protocols, security measures, and vulnerable to cyber attacks	**Data security** 	Robust data security measures and strict adherence to network protocols, enhancing system resilience
Limited application of predictive analytics, restricted to established measures	**Data analytics** 	Innovative applications (psychological health, exercise, and sleep), coupled with predictive analytics
Inability to monitor data collection across multiple sites and participants	**Data compliance** 	Centralized data monitoring, proactively addressing issues to ensure compliance
Limited integrations between RPM and clinical systems	**Clinical integrations** 	Increased integrations with clinical systems enhancing interoperability

1 MIT researchers track Parkinson's patients using radar as they sleep, August 2022

University of California, San Francisco (UCSF) uses Vivalink ECG sensors for large-scale Atrial Fibrillation (AF) study

Challenge

UCSF wanted to conduct a multi-year study involving more than 1,000 patients to detect biomarkers of early atrial transformation in AF. The need was to continuously monitor ECG for patients for a week every quarter. Devices available in the market were expensive, designed for single use, and did not provide access to real-time patient data. Additionally, ambulatory and remote settings faced network disruptions, and it was thus difficult to ensure accuracy and patient adherence with the available RPM devices. UCSF needed a device that was easy to use, connected directly with its digital research platform, and could continuously stream ECG monitoring data for a week.



Solution

UCSF partnered with Vivalink for continuous ECG recording, enabling direct analysis of real-time patient data. Vivalink's wearable ECG patch, designed for patient self-service, can continuously capture ECG and heart rate, and transmit them in real-time. In the study, each patient was required to wear the ECG patch for a week each quarter, while in an ambulatory setting or at home. The device has Bluetooth connectivity and onboard memory caches and is directly integrated with the clinical patient application. A dedicated cloud consolidates all data captured from the different devices and generates reports that help ensure adherence and compliance.

Outcome

UCSF was able to successfully recruit patients for the study and collect ECG data in real-time. The study reported the following outcomes in particular:

- The reusable ECG patches drove significant cost savings for UCSF as compared with single-use medical diagnostic patches
- Data quality and consistency substantially improved
- The device addressed network connectivity issues as the in-built cache automatically syncs with the cloud
- UCSF was able to enhance patient adherence through data acquisition reports and wearable sensor statuses

> "The capabilities of the Vivalink ECG sensor will enable us to capture a larger continuous dataset to identify imaging, serum, and digital biomarkers of AF risk and progression in the study.
>
> – Jeffrey Olgin, Chief of Cardiology and Principal Investigator of the UCSF project

Executing a successful RPM program

Like any other new technology, the success of an RPM program depends on a rigorous phased implementation approach, as depicted in Exhibit 6.

EXHIBIT 6

A quick start guide to implementing RPM solutions

Source: Everest Group (2022)

Below we take a closer look at each of these steps.

Identify a need

At the very outset, sponsors and CROs should envision situations where the patient and investigator experience can be enhanced using RPM solutions. Such situations could include gathering data from a diverse patient population, monitoring patients with chronic conditions, or simply reducing the site and patient burden while increasing access to therapeutic developments. A strong vision will help lay out a clear roadmap and secure management buy-in.

Choose an RPM vendor

When choosing an RPM provider, enterprises should ask the right questions, basing them on the need identified, along with the therapy area, assessment procedures, and patients' comfort with digital devices. Some of the factors that organizations must consider when sourcing a provider are:

- A unified data platform that supports the interoperability of devices and clinical systems
- Extensive experience with RPM in clinical use
- A broad range of devices and sensors with user-intuitive technologies

- Patient, clinician, and data scientist education and support services
- Logistical support for multi-site, multi-regional trials
- A robust product roadmap and strategies

In addition to the products themselves, the services rendered are equally important. How is RPM implemented? Will the provider support clinical workflows and unique data requirements? Will we receive operational guidance throughout the engagement? These are some additional factors that enterprises should consider as part of their sourcing considerations.

Provision devices and sensors

Wearables should reach the participants on time and should be fit for use. RPM providers can take care of the logistics and supply chain management or simply outsource them to a third-party provider. Sponsors and providers often have their teams/partnerships take care of this process. Irrespective of who's in charge, system protocols should be established well in advance to ensure supply chain transparency and resilience.

Setup and training

Patients and clinicians must have clear instructions on how to set up and use the devices, and who to contact if they need assistance. Difficulties in following instructions while setting up devices can lead to frustration among study participants and pose a challenge in retaining them in the program. An initial discussion on setting up the system over a phone or video call, or maybe in person, can be highly beneficial.

Ensure data compliance

The successful collection of study participants' data depends on factors including patient adherence to the RPM technologies, network integrity for data transmission from remote locations to the cloud, and data security and privacy to ensure that the data is not compromised. The right RPM platform will have requisite measures in place to monitor this at scale.

Conclusion

It is evident that DCTs are indispensable to the clinical research industry. Remote data collection and timely data analysis are the backbone of this model. As the industry emerges from the pandemic, organizations will work to accelerate DCT adoption and convert piecemeal deployments into a comprehensive strategy aimed at enhancing the trial experience for study participants, sponsors, and CROs.

RPM adoption has surged in recent years, with sponsors and CROs actively adopting a digital and remote model for trial operations. As the momentum continues, RPM will become an integral part of clinical R&D in the future. Technological innovations will play a significant role in this journey, as RPM solutions become more patient- and site-friendly. Technology will not only reduce the need for in-person visits, but also simplify trial participation and improve trial accessibility and diversity among the study participant population. Furthermore, efforts around patient education and assistance, coupled with a favorable regulatory landscape, are expected to drive RPM adoption at a steady pace.

To deliver on the promise of improved healthcare, all stakeholders in the ecosystem – sponsors, healthcare providers, RPM platform vendors, and regulatory bodies – need to work together to build a holistic digital framework for remote data collection and analysis.

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