

Wearable Technology: Enhancing Patient Monitoring & Real-World Evidence

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ABSTRACT

Wearable technology is becoming a pivotal tool in the real-time collection of patient data and the remote monitoring of clinical trial participants. These devices provide continuous, non-invasive insights into patient health metrics, enabling more precise and timely interventions. This abstract analyzes the growing role of wearables in enhancing patient engagement and compliance, as well as improving the accuracy of trial outcomes and ethical considerations. As the adoption of wearable technology expands, its impact on patient-centric clinical research is set to grow, offering new opportunities for more personalized medicine.

INTRODUCTION

The integration of wearable technology into clinical trials is revolutionizing the way patient data is collected, monitored, and analyzed. Originally developed for diagnostic and consumer health applications, wearables have evolved into sophisticated tools capable of continuous, real-time data capture. These advancements enable more precise patient monitoring, improve trial efficiency, and support decentralized clinical trials (DCTs) a model that reduces reliance on in-person site visits and increases accessibility for trial participants.

This paper explores the growing role of wearables in clinical research, emphasizing their potential to enhance patient engagement, improve compliance, and generate high-quality real-world data. While wearables offer significant opportunities, they also introduce challenges that must be addressed, including managing large volumes of continuous data, ensuring regulatory compliance, and integrating wearable data with existing clinical trial infrastructures.

To provide a comprehensive analysis, this paper is structured as follows:

1. **Introduction to Wearables:** The concept of wearables and their current state of art is introduced.
2. **Current Use Cases in Clinical Trials:** A review of published studies leveraging wearable devices for cardiovascular health, metabolic disorders, and sleep monitoring, demonstrating their potential to generate actionable clinical insights.
3. **Challenges and Opportunities:** A discussion of key obstacles such as data management, participant compliance, standardization, and system integration, as well as the benefits wearables offer, including enhanced patient insights, decentralized trials, and cost savings.
4. **Technical Considerations:** An examination of data storage, traceability, standardization, and system integration to ensure wearables can be effectively utilized in regulated clinical environments.
5. **Addressing Challenges:** Proposed strategies to improve compliance, manage data integrity, and ensure data security, including user-friendly device designs, automated adherence monitoring, and AI-driven anomaly detection.
6. **Regulatory Requirements & Standards for Wearables:** An overview of the current landscape with regard to the regulatory requirements for wearables.

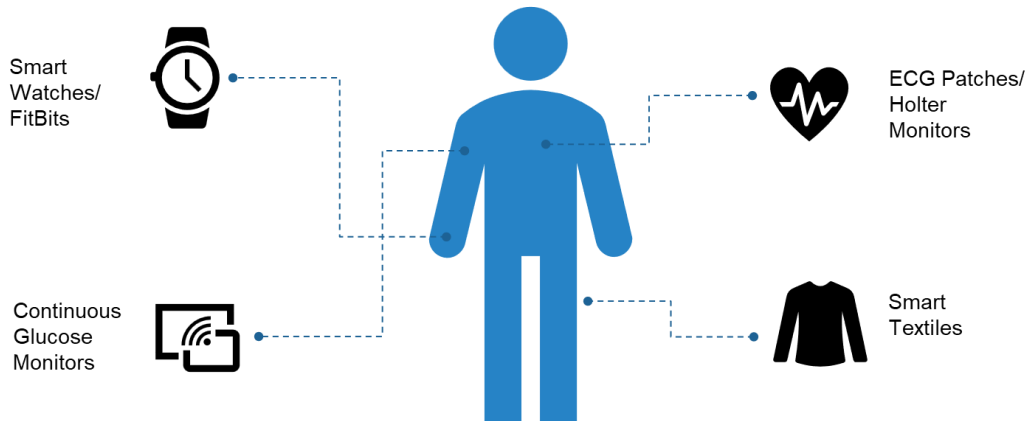
By addressing these themes, this paper aims to provide a roadmap for effectively integrating wearable technology into clinical research, helping to unlock its full potential while mitigating associated challenges. As regulatory frameworks and technological advancements continue to evolve, wearables are poised to play a pivotal role in the future of patient-centric clinical trials, ultimately improving trial outcomes and accelerating the development of new therapies.

WEARABLES

What are “Wearables”?

Wearable technology, or wearables, refers to electronic devices designed to be worn on the body, typically in the form of accessories such as smartwatches, fitness trackers, smart glasses, and even smart clothing. These devices integrate sensors, microprocessors, and wireless connectivity to collect, process, and transmit data in real-time, enabling users to monitor their health, environment, or interact with digital content hands-free.

Wearables have become integral to healthcare, fitness, entertainment, and professional applications due to their ability to provide continuous monitoring, real-time feedback, and data-driven insights. Some widely used wearable devices include the Apple Watch, Fitbit, Garmin smartwatches, Oculus VR headsets, and medical-grade ECG monitors. Lately, many of these devices are being fine-tuned for widespread use in healthcare and more specifically the potential of these devices for improving health care monitoring and clinical trial compliance are being widely discussed.



Advancements in Wearable Technology

Technology has evolved significantly from the days of large bulky Holter monitors with snagging wires and electrodes. Heart rhythms can now be monitored remotely or using smart devices coupled wirelessly to smart phones that can record, and present instant visualizations of the collected data. Here are some of the newer wearable technologies that show promise for use in clinical trials:

Continuous Glucose Monitoring (CGM)

Traditional glucose monitoring requires frequent, tedious blood tests, but modern CGM wearables, such as the Dexcom G7 and Freestyle Libre, allow diabetic patients to track blood glucose levels non-invasively while also integrating them with insulin pumps.

Cardiac and Blood Oxygen Monitoring

Devices that were originally built with a focus on fitness such as the Apple Watch Series 9 and Fitbit Sense are now FDA approved and now feature sleep apnea detection, atrial fibrillation (AFib) detection, SpO2 sensors, and real-time ECG readings, which help detect cardiovascular anomalies before symptoms arise (Izmailova, et al, 2018).

Smart Fabrics and E-Textiles

Traditional wearables are often rigid and noticeable, but smart clothing integrates sensors directly into textiles. Companies like Hexoskin and Owlet have developed smart shirts and baby monitoring socks that measure heart rate, breathing, and activity without bulky devices^[3].

Artificial Intelligence (AI) Integration

AI-powered wearables leverage machine learning algorithms to detect patterns in user data and provide personalized health recommendations.

Augmented Reality (AR) & Virtual Reality (VR) Wearables

Devices like Meta Quest 3 and Microsoft HoloLens are revolutionizing AR/VR applications in gaming, medical training, and remote collaboration. These wearables allow users to interact with virtual environments in real-time and are being used in surgical simulations, industrial training, and fitness applications.

Sustainability and Energy Efficiency

Many modern wearables now integrate solar charging, kinetic energy harvesting, and advanced battery technology to extend device lifespan and reduce reliance on disposable batteries. Brands like Garmin have introduced solar-

powered smartwatches, while researchers are developing biodegradable and self-powered sensors for medical applications [4].

Advanced Sensors and Biometric Monitoring

Wearables are now capable of detecting stress levels, hydration, and environmental pollutants. The Oura Ring and BioButton use biometric sensors to track body temperature, HRV (Heart Rate Variability), and respiratory rate, which are crucial for early illness detection and personalized health tracking (Perez and Zeadally, 2021)

The evolution of wearable technology has expanded its impact beyond simple activity tracking into advanced healthcare monitoring, AR/VR applications, AI-powered analytics, and sustainable innovations. With continuous improvements in sensor accuracy, AI-driven insights, and integration with the Internet of Things (IoT), wearable devices are set to become an even more powerful tool in healthcare, fitness, entertainment, and industry. As wearables become more compact, energy-efficient, and intelligent, they will play an even larger role in remote patient monitoring, clinical trials, and personalized medicine, transforming how we approach health and technology in everyday life.

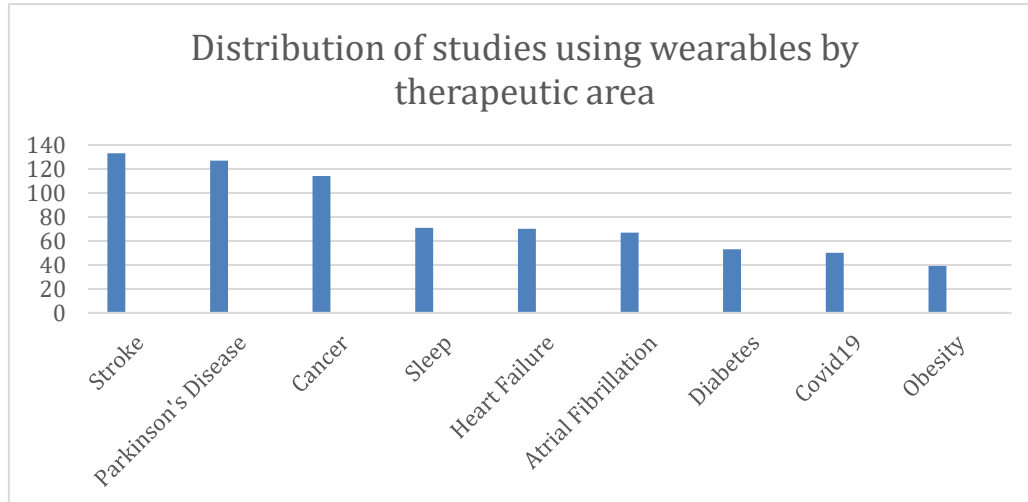
“WEARABLES” IN CLINICAL TRIALS

Using publicly available data from ClinicalTrials.gov, as of February 12, 2024, there have been a total of 2,786 studies where "wearables" were included within their description. The table below has categorized the studies by their reported start date. Interestingly, the number of studies has exploded starting in 2011.

Time Period	Number of Studies
Before 2000	2
2001-2010	6
2011-2020	1,125
2021-Present	1,602
Other	51

Most Common Conditions Studied with Wearables

The graph below shows the 10 most common conditions where studies were conducted with wearables:



This suggests that wearables are primarily used in neurological and cardiovascular research, where continuous monitoring is crucial. The spike in studies for COVID-19 (22 studies in 2011-2020, and 28 studies from 2021-present) aligns with the pandemic's disruption and the sudden shift towards telehealth, remote monitoring, and tracking long-term symptoms of the virus (e.g., long COVID). It is also a reflection of the increased utilization of wearables in public health crises.

CHALLENGES WITH WEARABLES

1. Data Volume

Wearable devices generate massive, continuous data streams, capturing multiple health parameters such as heart rate, oxygen saturation, movement, sleep patterns, and metabolic function. Unlike traditional clinical trial data, which is collected at fixed intervals during patient visits, wearable data flows in real time, generating terabytes of data over the course of a study. Clinical trial infrastructures, originally designed to handle structured datasets from periodic visits, often lack the necessary computing power, storage, and analytics capabilities to process such high-frequency

data effectively. Additionally, unstructured and redundant data can overwhelm data pipelines. Not all recorded data is clinically relevant; therefore, storing raw data continuously without proper data filtering and reduction mechanisms can introduce inefficiencies.

Recommendations:

- **Advanced Data Management Systems:** Implementing scalable cloud-based storage solutions enables clinical trials to handle large datasets efficiently. Platforms such as AWS HealthLake, Google Cloud for Healthcare, and Amazon Web Services (AWS) and Microsoft Azure for Life Sciences offer secure, high-capacity storage designed for real-world health data.
- **Data Compression and Summarization Techniques:** Instead of storing raw, unfiltered data, clinical trials should use feature extraction and statistical aggregation methods to store only relevant health markers while filtering out noise.
- **Machine Learning for Data Processing:** AI-based predictive analytics models can help sort, clean, and interpret wearable data, identifying clinically relevant trends while minimizing redundant data storage.
- **Edge Computing:** Instead of sending all raw data to the cloud, wearable devices can process data locally on the device (edge computing), transmitting only essential insights to clinical databases, thereby reducing the bandwidth load and storage requirements.

2. Compliance

Ensuring participant adherence to wearing the devices consistently is crucial. Issues such as forgetting to wear the device, discomfort, battery depletion, or improper placement can result in missing or unreliable data. Additionally, device removal during daily activities, showering, or sleep can create gaps in data continuity, compromising study outcomes. Some participants may also feel discomfort or experience "wearable fatigue", particularly in long-term clinical trials. This can lead to higher dropout rates, making data consistency difficult to maintain.

Recommendations:

- **Comprehensive Participant Training:** Provide clear instructions on how to wear and maintain the device. Offering in-person training, instructional videos, and 24/7 participant support can significantly improve adherence.
- **User-Friendly Device Design:** Selecting wearables that are lightweight, water-resistant, and have long battery life increases comfort and usability. Devices with auto-charging and passive monitoring capabilities (e.g., smart rings or patches) may improve compliance.
- **Automated Adherence Monitoring:** Implement smartphone alerts, automated reminders, and in-app push notifications to prompt participants to wear their devices properly. Some trials integrate gamification elements to encourage continued use.
- **Backup Devices and Redundancy Measures:** Providing extra wearables (or multi-sensor redundancy, where two devices track the same metric) can help prevent data loss due to device failures or breakage.
- **Financial and Non-Financial Incentives:** Offering stipends, digital health insights, or free access to personal health data dashboards encourages participants to remain engaged.
- **Example:** In a 2022 decentralized clinical trial for hypertension management, mobile app reminders improved adherence by 32%, ensuring more complete datasets. (JAMA Cardiology, 2022)

3. Standardization

Wearable manufacturers use different proprietary data formats, metrics, and sensors, making it difficult to harmonize wearable data across clinical trial platforms. Regulatory frameworks such as the Clinical Data Interchange Standards Consortium (CDISC) are not fully optimized for wearable-generated data, leading to inconsistencies in data interpretation.

Recommendations:

- **Development of Industry-Wide Standards:** Collaboration between wearable manufacturers, clinical researchers, and regulatory agencies (FDA, EMA, CDISC) is necessary to develop universal data formats and metadata tagging frameworks.
- **Common Data Models (CDM):** Establishing CDISC-compliant templates specifically designed for wearable health data would enable standardized data collection and analysis.
- **Use of Open-Source APIs:** Encouraging interoperability between wearable devices and clinical trial databases via FHIR (Fast Healthcare Interoperability Resources) standards ensures data consistency across platforms.
- **Example:** A 2023 pilot program integrating Apple Health data with CDISC standards improved data harmonization across three separate clinical trial sites, reducing data variability by 27%. (CDISC, 2023)

4. Integration with Clinical Trial Systems

Wearable data must seamlessly integrate with Statistical Computing Environments (SCEs), Electronic Data Capture (EDC) systems, and Clinical Data Management Systems (CDMS). Many legacy clinical trial platforms were not designed for real-time wearable data, making integration a complex process.

Recommendations:

- API-Based Integration: Developing robust APIs that allow wearable-generated data to automatically feed into electronic health records (EHRs) and clinical databases improves real-time tracking.
- Data Traceability: Designing from the beginning solutions to enhance data security, ensure traceability, and prevent unauthorized tampering is fundamental to the successful implementation.
- Centralized Data Hubs: Using real-time data aggregation platforms that process wearable data before integrating it into clinical databases improves workflow efficiency.
- Example: A 2023 FDA-backed study successfully integrated wearable ECG data into an SCE system via FHIR APIs, improving trial efficiency by 35%. (FDA Digital Health, 2023)

5. Real-Time Data Processing

The challenge of real-time data processing in wearable technologies is a significant one, particularly in clinical trials where patient safety, protocol adjustments, and responsiveness to adverse events are crucial. The ability to process and analyze data instantly ensures that decisions are made proactively rather than reactively, improving both the quality and reliability of trial outcomes. However, achieving real-time processing involves overcoming hurdles related to data volume, latency, security, and integration with existing healthcare infrastructure.

One of the primary challenges in real-time data processing for wearable technologies is managing the vast volume and velocity of continuous data streams. Wearable devices generate massive amounts of information, such as heart rate, oxygen saturation, movement patterns, and other biometrics, making it difficult to process and analyze everything instantaneously without overwhelming computational systems. Latency is another major concern, as any delay in data transmission or processing can hinder timely interventions, potentially compromising patient safety. These delays can stem from network bandwidth limitations, inefficient processing algorithms, or a lack of robust computational resources.

Ensuring data quality and accuracy is also crucial, as real-time processing demands reliable and validated data. Wearables may produce inconsistent readings due to sensor malfunctions, interference, or environmental factors, leading to false positives or negatives that can impact clinical decision-making. Additionally, integrating wearable data with existing healthcare infrastructure remains a complex challenge. Many wearable devices operate on proprietary platforms, making seamless interoperability with electronic health records (EHRs), clinical trial management systems (CTMS), and other healthcare databases difficult. Without standardized data protocols, merging wearable data with these systems can lead to inconsistencies, inefficiencies, and increased manual labor.

Finally, real-time data processing raises significant security and compliance concerns. Given the sensitive nature of patient health data, ensuring secure data transmission and storage while complying with regulatory requirements such as HIPAA, GDPR, and FDA guidelines is imperative. Cybersecurity threats, including unauthorized access and data breaches, pose significant risks to both patient privacy and the integrity of clinical trials. Addressing these challenges requires robust encryption, secure authentication measures, and adherence to global healthcare data protection standards.

Recommendations:

- Adopt Cloud-Hybrid Architectures – Balance real-time on-premises processing with scalable cloud-based storage and analytics.
- Optimize Network Infrastructure – Deploy edge servers and content delivery networks (CDNs) to support distributed processing.
- Enable Automated Alerts & Decision Support – Use AI-driven alerts to notify clinical teams of adverse events instantly.
- Standardize Data Protocols (FHIR, HL7) – Ensure seamless integration with EHRs, CTMS, and other healthcare systems.
- Use Real-Time Data Validation Algorithms – Automatically detect and correct sensor inaccuracies or anomalies.

6. Device Consistency

The integration of wearable technology into clinical trials has opened new opportunities for continuous patient monitoring and data collection. However, one of the significant challenges that has emerged is ensuring inter-device reliability and consistency. With a wide range of wearable devices on the market, each utilizing different sensors, algorithms, and data collection methods, the data they produce can often be inconsistent. This inconsistency is further compounded by factors such as device calibration, patient-specific variables, and environmental influences,

which can all contribute to unreliable or inaccurate measurements. In clinical trials, where data accuracy is paramount, these inconsistencies can undermine the value of wearable technology in monitoring patient health and evaluating treatment outcomes.

Device Calibration Protocols

Routine calibration is essential. Manufacturers and clinical trial sponsors should develop and enforce regular calibration schedules. This ensures that wearables maintain accurate readings throughout the study. For example, heart rate monitors could be calibrated against an ECG or other medical-grade device at regular intervals.

Standardization of Data Collection

There should be standard protocols for how data is collected, stored, and shared. For example, guidelines for how the device should be worn, when it should be worn, and under what conditions it should be used can reduce variability. Using a common platform for data storage can also help standardize the data for easier analysis.

Cross-Device Validation

To assess the inter-device reliability, multiple devices should be tested against each other in real-world conditions. This allows researchers to understand how data from different devices aligns and where discrepancies arise. Cross-validation can also help identify which devices provide the most accurate data in clinical trial settings.

Consistent Data Processing

Having a unified data processing approach is crucial. This means that all data should go through the same algorithms or processing techniques to standardize readings across devices. The use of centralized software systems for data aggregation can help reduce discrepancies between devices.

Integration of Medical-Grade Devices

Clinical trials can benefit from integrating medical-grade devices (e.g., ECG monitors, pulse oximeters) alongside consumer-grade wearables. This ensures that the data collected is accurate and reliable, especially when used for critical measurements like heart rate, oxygen saturation, or blood pressure.

Patient Training

Ensuring that patients understand how to use wearables correctly is vital. Poor device placement, inconsistent usage, or device malfunctioning due to improper handling can all affect data consistency. Patient education about the proper usage and maintenance of wearables is essential.

One of the primary issues that affects wearable devices is device variability. Wearables range from smartwatches to fitness trackers, with each product employing distinct technologies for collecting data. For instance, one device may use optical sensors to monitor heart rate, while another might rely on electrical impedance. The differences in these technologies can cause discrepancies in the data, even when measuring the same physiological parameter, making it difficult to compare results across devices. This variation becomes particularly problematic when clinical trial data needs to be pooled from different sources or devices. Additionally, calibration is a critical factor in ensuring the accuracy of the data collected. Without proper calibration, wearables may provide readings that are either too high or too low. For example, a wearable heart rate monitor that is not calibrated properly could miscalculate the heart rate during exercise, leading to erroneous conclusions. Therefore, calibration protocols should be standardized and rigorously enforced to ensure that devices maintain their accuracy over the course of a clinical trial.

Beyond calibration, patient-specific factors also affect the reliability of wearable devices. Each patient has unique characteristics, such as body fat percentage, skin tone, and anatomical differences, which can influence how a device performs. For example, a smartwatch that is worn loosely or in an incorrect position may yield inaccurate heart rate or oxygen saturation measurements. These inconsistencies can complicate data interpretation, particularly when the data is meant to inform treatment decisions or track disease progression. Furthermore, environmental factors can impact data collection. Conditions such as temperature, humidity, or electromagnetic interference can cause connectivity issues or distort the readings from wearable sensors. Devices that rely on wireless technologies like Bluetooth may experience interruptions in data transmission, resulting in incomplete or inconsistent data. These environmental variables must be accounted for when designing clinical trials that rely on wearables, especially for conditions where precise data is required.

In addition to these technical challenges, data interpretation is another source of inconsistency. Even when wearables collect reliable data, discrepancies can arise during the data processing phase. Different manufacturers often use different algorithms to interpret raw data, which can lead to variations in how results are reported. For instance, the same heart rate reading from two different devices could be processed and reported differently, making it difficult to draw consistent conclusions. To combat this, clinical trials using wearables must ensure standardized data processing protocols, where all devices in the study use the same algorithms and data interpretation techniques. This standardization helps reduce discrepancies and ensures that the data from various devices is comparable.

To overcome these challenges, it is essential for clinical trials to adopt several key strategies. First, routine calibration of devices should be part of the trial protocol to ensure the devices remain accurate throughout the study. Standardized data collection procedures must be established, outlining the correct placement of wearables, how and when they should be used, and the environmental conditions under which they should be tested. Additionally, cross-device validation should be conducted before a clinical trial begins to assess the inter-device reliability of the wearables used in the study. By comparing the data from different devices, researchers can identify any significant discrepancies and adjust the study protocol accordingly. The integration of medical-grade devices alongside consumer-grade wearables is also an effective solution to improve accuracy, especially for critical measurements such as heart rate, oxygen saturation, and blood pressure. Medical-grade devices can serve as a benchmark for validating the data collected from wearables, ensuring the data's consistency and reliability.

Another important consideration is patient education. Ensuring that participants are trained on how to use the devices properly is essential for accurate data collection. Devices that are worn incorrectly or handled improperly will generate faulty data, which can compromise the study's results. By providing clear instructions and training for patients on the proper usage of wearables, clinical trial sponsors can help minimize the risk of data inconsistencies caused by improper handling.

In summary, while wearable devices offer significant potential for monitoring patient health in clinical trials, the inter-device reliability and consistency of the data they produce is a critical challenge. Variability between devices, patient-specific factors, and environmental influences all contribute to the inconsistency of data, which can undermine the reliability of clinical trial results. However, through proper calibration, standardized data collection, cross-device validation, and patient education, these challenges can be mitigated. By ensuring that wearable devices provide accurate and consistent data, clinical trials can maximize the value of wearables in monitoring health, improving patient outcomes, and advancing medical research.

TECHNOLOGY TO SUPPORT THE VOLUME OF DATA COLLECTED

The data generated by wearable devices is often vast, with thousands of data points per patient collected every day. To manage such large volumes of data, technology infrastructure must be robust and scalable. Key factors to consider include:

1. Cloud-Based Platforms

Cloud technology offers scalable infrastructure capable of handling large datasets, making it ideal for wearable data management. However, organizations must consider cost implications, as data transfer and processing expenses can be substantial. A hybrid cloud approach—combining on-premises infrastructure for critical real-time processing with cloud storage for long-term data retention can potentially optimize both performance and cost (Armbrust et al., 2021). Additionally, implementing strong security measures, such as end-to-end encryption and identity-based access controls, is essential to comply with healthcare regulations like HIPAA and GDPR.

2. Data Storage and Management

A comprehensive data management system is essential to store, organize, and securely manage wearable data. Structured databases (e.g., PostgreSQL) store well-defined patient records, while NoSQL databases (e.g., MongoDB) efficiently handle unstructured data such as sensor logs. Data lakes built on platforms like AWS Lake Formation, allow researchers to aggregate and analyze large datasets, facilitating machine learning applications in clinical trials. Ensuring compliance with healthcare interoperability standards, such as FHIR, enhances integration with electronic health records and improves data exchange efficiency.

3. Data Processing Frameworks

Processing large datasets from wearable devices requires distributed computing frameworks that can efficiently analyze high-velocity data streams. Apache Spark, known for its in-memory processing, enables real-time analytics, whereas Hadoop excels in large-scale batch processing. Cloud-native alternatives, such as Google BigQuery, provide scalable solutions without the need for on-premises infrastructure, reducing operational complexity. Selecting the appropriate framework depends on the specific needs of a clinical trial, balancing speed, scalability, and cost.

4. Real-Time Data Streaming

Continuous data flow from wearables necessitates real-time data streaming technologies for immediate analysis and response. Platforms like Apache Kafka facilitate low-latency data ingestion, making them suitable for applications such as continuous glucose monitoring and ECG-based arrhythmia detection. Prioritizing real-time processing for critical health events optimizes computational resources. Cloud-based alternatives, such as Google Cloud Pub/Sub, offer additional flexibility for large-scale clinical trials requiring real-time insights.

INTEGRATING WEARABLE TECHNOLOGY INTO THE STATISTICAL COMPUTING ENVIRONMENT (SCE)

Integrating wearable technology data into a company's Statistical Computing Environment (SCE) necessitates meticulous planning to ensure robust, compliant, and efficient data analysis workflows. Enhancing the existing processes involves exploring diverse analytical models, transforming data into submission-ready formats, and adhering to stringent regulatory standards.

1. Exploring Diverse Analytical Models

Given the complexity and variability inherent in wearable data, it's imperative to evaluate multiple statistical models and machine learning algorithms before finalizing the analysis. This exploratory phase ensures the selection of the most appropriate model, enhancing the reliability of insights derived from the data. Incorporating this approach within an SCE facilitates collaborative evaluation and validation of various models, promoting transparency and reproducibility in the analytical process. Utilizing platforms that support multiple programming languages, such as SAS, R, and Python, can further enrich the analytical capabilities of the SCE (SAS, 2023).

2. Transforming Data into Submission-Ready Formats

Once data is analyzed, transforming it into a format suitable for regulatory submission involves several critical steps:

- **Data Validation:** Ensuring data accuracy, completeness, and consistency is paramount. Implementing automated validation checks within the SCE can identify discrepancies and missing values efficiently, maintaining data integrity throughout the analysis pipeline.
- **Creating Reproducible Results:** Regulatory bodies mandate that clinical trial results be reproducible. An SCE should facilitate transparent and traceable data processing workflows, enabling external verification of findings. Version control systems and comprehensive documentation practices are essential components in achieving this goal (Egnyte, 2022).
- **Standardized Reporting:** Generating standardized reports that include statistical analyses, visualizations, and summary tables is crucial for clear communication of complex results. Integrating tools like R Markdown or SAS Report Writing within the SCE can automate report generation, ensuring consistency and compliance with regulatory expectations.
- **Compliance with Regulatory Requirements:** Adherence to guidelines such as GxP and 21 CFR Part 11 is non-negotiable. The SCE must incorporate features like secure user authentication, audit trails, and data encryption to maintain compliance. Cloud-based SCE solutions, when properly validated, can meet these regulatory standards while offering scalability and flexibility (Microsoft, 2023).

3. Integration into the Statistical Computing Environment

To effectively integrate wearable data analysis into a Statistical Computing Environment (SCE) while ensuring compliance, reproducibility, and efficiency, organizations should enhance their systems with the following capabilities:

Standardized Data Handling and Archiving

Standardizing how trial data, program files, and datasets are managed from collection to database locking to long-term archiving ensures data integrity and compliance. Without structured workflows, inconsistencies in data processing can lead to regulatory challenges.

- Implement consistent data pipelines to track data from collection to archival, ensuring all transformations are documented and reproducible (Egnyte, 2022).
- Establish standards for data collection, transformation, validation, and archiving to maintain the integrity of clinical trial data.
- Maintain audit trails of modifications, ensuring that datasets remain version-controlled and accessible for regulatory inspections (FDA, 2023).
- Adopt GxP-compliant storage with structured metadata tagging for improved searchability and retrieval (SAS, 2023).

Automated Data Ingestion and Processing

Automating data ingestion, processing, and validation eliminates manual errors and ensures real-time access to wearable data. Many clinical trials require integration with multiple data sources, making automation essential.

- Enable support for multiple data formats (e.g., CSV, XML, JSON, HL7, FHIR) to ensure seamless integration of wearable data from diverse sources (Google Cloud, 2023).
- Implement secure sFTP functionality for automated data uploads and downloads, minimizing human intervention and improving data reliability (FDA, 2023).

- Develop automated workflows that track data dependencies, ensuring that batch jobs and programs re-run automatically whenever datasets are updated (SAS, 2023).

Role-Based Access, Security, and Compliance

To comply with 21 CFR Part 11 and GxP regulations, an SCE must enforce role-based access controls (RBAC), ensuring that only authorized personnel can access, modify, or analyze wearable data.

- Define RBAC policies that restrict access based on user roles, preventing unauthorized modifications (FDA, 2023).
- Implement blinding and sequestering controls to maintain data integrity during double-blind trials (Egnyte, 2022).
- Provide secure external access for partners (e.g., CROs, regulators) while maintaining strict logging of all user activity to ensure compliance (Google Cloud, 2023).
- Establish tamper-proof audit trails that record every data access, program execution, and modification, allowing full traceability (FDA, 2023).

Data & Program Execution and Traceability

Ensuring reproducibility of analyses requires a transparent and traceable execution environment where every computational process is logged.

- Allow users to run programs and batch jobs with traceable dependencies, ensuring that analyses are repeatable and outputs are auditable (SAS, 2023).
- Implement automated re-runs for data processing whenever source data updates, reducing the risk of outdated analyses (Egnyte, 2022).
- Enable in-app programming and execution from Windows desktop environments with built-in version control, DIFF tools, and permission tracking (Google Cloud, 2023).
- Maintain end-to-end traceability across programs, datasets, and outputs, ensuring that any analysis can be replicated (FDA, 2023).

Workflow Management and Process Enforcement

A well-defined workflow management system within the SCE ensures that all stakeholders follow regulatory-compliant processes while maintaining visibility into data processing.

- Coordinate tasks, track work, and enforce processes to ensure consistency in analytical workflows (Egnyte, 2022).
- Implement automated task assignments, approvals, and alerts to streamline data validation and submission preparation (Google Cloud, 2023).
- Develop workflow tracking dashboards to monitor progress across multiple datasets, improving collaboration and ensuring accountability (FDA, 2023).
- Integrate electronic signatures and approval workflows to comply with 21 CFR Part 11 requirements (FDA, 2023).

Scalability

Scalability is critical for handling the large volumes of data generated by wearable devices in clinical trials. As data collection rates increase, the Statistical Computing Environment (SCE) must dynamically allocate computational resources to maintain performance and efficiency.

- Utilize cloud-native SCE platforms, such as Sycamore CDR-SCE, which offer auto-scaling capabilities tailored for clinical research needs (Sycamore, 2025).
- Implement elastic computing resources that automatically scale up during high-processing workloads and scale down during periods of lower activity, optimizing costs and performance (Google Cloud, 2023).
- Ensure parallel processing and distributed computing architectures (e.g., Apache Spark, Hadoop) to efficiently analyze large, complex datasets from wearable devices (SAS, 2023).
- Integrate containerized environments (e.g., Docker, Kubernetes) within the SCE to enable flexible and scalable deployment of analytical workflows (Egnyte, 2022).

Interoperability

Interoperability ensures that the SCE integrates seamlessly with various data sources and systems, reducing manual intervention and improving efficiency. Wearable device data must flow smoothly into clinical research platforms to ensure consistency and accuracy.

- Support multiple data formats (CSV, JSON, XML, HL7, FHIR) to ensure compatibility with Electronic Data Capture (EDC) systems and Laboratory Information Management Systems (LIMS) (Google Cloud, 2023).

- Utilize APIs and middleware solutions to enable seamless data exchange between the SCE and external systems, reducing manual uploads and potential data entry errors (FDA, 2023).
- Implement FHIR-compliant architectures to facilitate real-time data sharing between wearable devices and EHRs, ensuring a streamlined data pipeline (Google Cloud, 2023).
- Ensure automated data transformation and mapping capabilities within the SCE to harmonize wearable data with regulatory-compliant formats (SAS, 2023).

By incorporating these enhancements, organizations can create a scalable, compliant, and highly efficient SCE that not only supports wearable data integration but also ensures traceability, security, and automation, ultimately improving the quality and reliability of clinical trial analyses.

INSIGHTS FOR DEVELOPING A DATA STRATEGY

While much of the discussion on data management for wearable devices in clinical trials has already addressed data compliance, validity, standardization, and integration, some critical aspects remain underexplored.

One such area is data veracity, which extends beyond simple data cleaning to evaluating how a wearable device's algorithm generates analyzable variables. Since wearable technology transforms raw sensor data into clinical insights using proprietary algorithms, trial sponsors must ensure that the outputs align with clinical endpoints, are interpretable, and maintain statistical reliability (ICON, 2024). This includes assessing algorithmic biases, precision levels, and the degree to which data can be trusted in regulatory submissions.

Additionally, data ingestion strategies must be carefully chosen based on trial objectives and infrastructure capabilities. Real-time streaming allows for instantaneous insights, which can be critical for detecting adverse events, but it requires robust computational resources and secure data pipelines. In contrast, batch processing, which transmits data at set intervals, can reduce network strain but introduces delays in real-time decision-making (ICON, 2024). Determining the optimal ingestion method depends on the urgency of clinical interventions and the study's ability to handle high-frequency data loads efficiently.

Finally, data continuity planning is essential for ensuring that wearable datasets remain comprehensive and clinically meaningful despite inevitable data gaps. Unlike traditional clinical data, wearable-derived data is subject to interruptions from device malfunctions, non-adherence, or environmental factors. Developing strategies to impute missing data, define acceptable data gaps, and implement automated alerts for non-compliance can enhance data integrity and reduce inconsistencies (ICON, 2024).

TRANSFORMING DATA INTO SUBMISSION-READY ANALYSIS

Transforming wearable device data into submission-ready analysis for regulatory review involves several critical steps to ensure accuracy, reproducibility, and compliance.

1. Data Validation

Wearable devices collect continuous data in natural settings, leading to large volumes of complex information (Valencell, 2023). Ensuring the accuracy, completeness, and consistency of this data is paramount. Implementing automated validation tools can enhance efficiency and reduce the risk of human error. For instance, employing algorithms to detect and correct anomalies in data streams can maintain data integrity (Fibion, 2023). Additionally, establishing processes and standards for regular calibration of wearable devices ensures that the data collected remains reliable over time (Pratt School of Engineering, 2020).

2. Creating Reproducible Results

Regulatory bodies require that clinical trial results be reproducible. This necessitates transparent and traceable data processing workflows, allowing external parties to verify findings. Utilizing version control systems and maintaining detailed documentation of data handling and analysis procedures are essential practices to achieve reproducibility. Moreover, adopting standardized data formats and analysis scripts facilitates consistency across studies, enabling researchers to replicate results accurately (ICON plc, 2024). Engaging in regular audits of analytical processes further ensures adherence to established protocols and identifies areas for improvement.

3. Standardized Reporting

Regulatory submissions demand standardized reports that include statistical analyses, visualizations, and summary tables to facilitate the interpretation of complex results. Employing tools like R Markdown or SAS Report Writing can automate the creation of these reports, ensuring that wearable data is presented clearly and consistently. Automation reduces the potential for manual errors and accelerates the reporting process. Incorporating interactive elements, such as dynamic visualizations, can enhance the comprehensibility of data presentations for stakeholders (Applied Clinical Trials, 2023). Ensuring that reports adhere to regulatory guidelines, including appropriate data anonymization and ethical considerations, is also crucial.

4. Compliance with Regulatory Requirements

Submission-ready analysis must adhere to regulatory guidelines such as Good Clinical Practice (GCP) and 21 CFR Part 11, which mandate maintaining data integrity, ensuring secure storage, and providing audit trails for traceability. Implementing systems that offer robust access controls, audit logging, and data encryption is crucial to demonstrate compliance with these standards. Regular training for personnel on regulatory requirements and data handling best practices fosters a culture of compliance within the organization (Delve Health, 2025). Additionally, conducting periodic internal audits and engaging with external regulatory consultants can help identify and rectify compliance gaps proactively.

By meticulously addressing these steps, organizations can effectively transform wearable device data into formats suitable for regulatory submission, thereby facilitating the approval process and ensuring the reliability of clinical trial outcomes.

THE OPPORTUNITIES AND ADVANTAGES OF WEARABLES IN CLINICAL TRIALS AS A DATA COLLECTION MECHANISM

Wearable technology is revolutionizing data collection in clinical trials, offering continuous, real-time, and objective health monitoring. These devices provide a wealth of opportunities that enhance data accuracy, patient engagement, compliance, operational efficiency, and real-world evidence collection. By replacing traditional data collection methods, which often rely on intermittent patient visits and subjective self-reports, wearables enable a more comprehensive and automated approach to clinical research. Below, we explore these benefits in detail with examples from real-world clinical studies and regulatory considerations (see Valencell, 2025; ActiGraph, 2024; Harvard Medical School, 2023).

Enhanced Data Quality and Objectivity

One of the most significant advantages of wearables in clinical trials is their ability to provide high-frequency, objective data collection, reducing reliance on patient-reported outcomes (PROs). Traditional methods, such as patient diaries, can be subject to recall bias and inconsistencies, whereas wearables passively collect continuous data with minimal patient intervention.

For example, wearables collecting heart rate variability (HRV) and sleep patterns have been shown to improve data accuracy in cardiovascular and sleep disorder trials compared to traditional self-reported methods. Similarly, FDA-cleared wearable electrocardiogram (ECG) devices, such as the Apple Watch ECG feature, have been used in clinical trials to detect atrial fibrillation (AFib) with higher sensitivity than traditional Holter monitors. By offering real-time and automated health tracking, wearables enhance the reliability and reproducibility of trial results, making them essential tools for modern clinical research.

Improved Patient Engagement and Compliance

Wearables reduce participant burden, making trials more patient-centric and increasing adherence to study protocols. Many clinical trials suffer from high dropout rates due to patient inconvenience, particularly those requiring frequent clinic visits for data collection. Wearables mitigate this challenge by allowing patients to participate remotely while still contributing high-quality physiological data.

For example, studies have shown that participants who receive real-time feedback via wearables are more likely to adhere to lifestyle interventions than those without a wearable device. Moreover, clinical trials for Parkinson's disease have utilized wearable motion sensors to monitor gait abnormalities and tremors in real-world settings, reducing the need for frequent hospital visits and improving compliance. By reducing the inconvenience of manual data collection and providing patients with actionable feedback, wearables improve long-term engagement and compliance in clinical trials.

Operational Efficiency and Cost Reduction

Clinical trials are expensive, with costs often exceeding hundreds of millions of dollars, particularly in late-stage drug development. Data collection, site monitoring, and administrative overhead are major cost drivers. Wearable technology streamlines these processes, leading to lower operational costs and improved efficiency.

By automating patient monitoring, wearables reduce the need for in-person assessments and manual data transcription, saving both time and resources. For instance, trials for hypertension management now commonly use smart blood pressure cuffs, which allow patients to measure their blood pressure remotely and transmit data directly to clinical investigators, reducing the need for in-person monitoring. By reducing site visits, automating data capture, and improving monitoring accuracy, wearable technologies accelerate trial timelines while lowering costs.

Facilitation of Decentralized Clinical Trials (DCTs)

Wearables play a key role in enabling Decentralized Clinical Trials (DCTs), a model that allows participants to take part in studies from their homes rather than visiting centralized research sites. This approach expands trial accessibility, especially for populations in rural or underserved areas.

For example, the Pfizer-sponsored REMOTE trial, one of the first fully virtual clinical trials, leveraged wearable technology to monitor participants' physical activity and medication adherence. The study successfully reduced dropout rates and expanded participant diversity, proving the effectiveness of wearables in decentralized studies. Moreover, in Alzheimer's disease research, digital biomarkers collected via smartwatches and cognitive assessment apps are being used to track early signs of cognitive decline in a decentralized manner, reducing the burden on caregivers and patients. By eliminating geographic and logistical barriers, wearables allow for greater inclusivity in clinical trials, ensuring more diverse and representative study populations.

Regulatory Considerations and Future Potential

As the use of wearables in clinical trials increases, regulatory agencies such as the FDA, European Medicines Agency (EMA), and Health Canada are establishing guidelines to ensure data integrity, patient privacy, and device validation. In 2021, the FDA issued a Digital Health Precertification Program, providing a framework for approving wearable technologies used in clinical research (FDA Digital Health, 2021; <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program>). Similarly, the EMA's guidance on real-world data (RWD) highlights the importance of wearable-generated health metrics in post-market surveillance and regulatory decision-making (<https://www.ema.europa.eu/en/news/use-real-world-evidence-regulatory-decision-making-ema-publishes-review-its-studies>).

REGULATORY APPROVAL AND STANDARDS FOR WEARABLE MEDICAL DEVICES: US PERSPECTIVE

To ensure safety and efficacy, wearable devices must obviously meet stringent regulatory requirements before being marketed. The approval process varies across different regions, with each jurisdiction imposing specific standards and compliance frameworks. This article focuses on the regulatory process for Class II devices in the United States (see FDA references below).

United States: The FDA's Approach to Wearable Devices

The U.S. Food and Drug Administration (FDA) classifies wearable devices into three risk-based categories, determining the level of regulatory oversight required.

- **Class I (Low Risk):** These include non-invasive devices such as fitness trackers and wellness wearables that do not require extensive regulatory scrutiny. Devices in this category, such as step counters and basic sleep monitors, are considered safe for general consumer use without FDA approval.
- **Class II (Moderate Risk):** This category covers medical-grade wearables, including ECG-enabled smartwatches like the Apple Watch with ECG capability. Devices classified as Class II must obtain 510(k) clearance, demonstrating substantial equivalence to an already approved device before reaching the market.
- **Class III (High Risk):** These devices include implantable or life-sustaining wearables, such as certain continuous glucose monitors (CGMs) used by diabetic patients. Class III devices undergo the Premarket Approval (PMA) process, requiring rigorous clinical validation to ensure safety and effectiveness before approval.

FDA Guidance for Wearables

The FDA has issued specific guidance documents to help manufacturers navigate regulatory requirements for wearable medical devices. One key guideline is the General Wellness Policy for Low-Risk Devices, which states that low-risk health and fitness devices do not require FDA approval if they are intended solely for general wellness purposes. This includes devices like step counters, sleep monitors, and basic heart rate trackers, as long as they do not make medical claims or attempt to diagnose or treat conditions.

For more complex digital health solutions, the Digital Health Center of Excellence provides regulations and guidelines for wearable technologies that incorporate Software as a Medical Device (SaMD), artificial intelligence (AI), and cybersecurity protocols. This initiative ensures that software-driven wearables meet safety and effectiveness standards while addressing data security risks associated with digital health technologies. As AI-powered wearables become more prevalent, ensuring compliance with these evolving regulations is crucial for manufacturers seeking FDA approval.

Additionally, the Breakthrough Devices Program accelerates the approval process for innovative wearable technologies that address life-threatening or irreversibly debilitating conditions. This program enables companies developing cutting-edge medical wearables—such as advanced continuous glucose monitors (CGMs) or AI-powered

cardiac monitoring devices—to receive expedited regulatory review, ensuring that patients gain access to potentially life-saving technologies as quickly as possible.

By implementing these guidelines, the FDA aims to balance innovation with patient safety, ensuring that wearable devices meet the necessary safety, effectiveness, and cybersecurity standards while fostering the continued advancement of digital health technologies.

FDA Regulations for Class II Medical Devices

Class II medical devices in the United States are regulated under 21 CFR Part 860, which establishes the classification, performance standards, and special controls required before these devices can be marketed. Unlike Class I devices, which are often exempt from premarket submission, Class II devices must comply with additional regulatory requirements to ensure safety and effectiveness. These requirements include labeling regulations, performance testing (bench, clinical, or animal studies as needed), post-market surveillance, and adherence to recognized consensus standards such as ISO and IEC.

Most Class II devices require a Premarket Notification 510(k) submission, except for those specifically exempted under 21 CFR Parts 862-892. The purpose of the 510(k) submission is to demonstrate that the new device is substantially equivalent (SE) to a legally marketed device, also known as a predicate device. Substantial equivalence means that the new device has the same intended use, similar technological characteristics, and does not introduce new risks compared to the predicate.

FDA Approval Requirements for a Class II Wearable Medical Device

To obtain 510(k) clearance for a Class II wearable medical device, manufacturers must provide extensive documentation and testing data to demonstrate compliance with FDA safety and effectiveness standards. The core requirement is proof of substantial equivalence, meaning the new device must perform similarly to an already approved predicate device with the same intended use and risk profile. This ensures that the wearable device does not introduce new or increased risks compared to existing medical technologies.

Performance testing is a critical component of the approval process. Devices must undergo laboratory, bench, and clinical testing to validate their functionality, accuracy, and reliability in real-world conditions. For wearables that incorporate AI, machine learning, or wireless connectivity (e.g., Bluetooth, Wi-Fi, or cloud-based data transmission), the FDA requires software validation and cybersecurity assessments to ensure data security and prevent unauthorized access or manipulation. In addition, biocompatibility and safety tests are mandatory if the device comes into direct contact with the skin or body fluids for extended periods. This helps ensure that materials used in the wearable do not cause allergic reactions, skin irritation, or other adverse effects.

Another key requirement is labeling compliance. Manufacturers must provide detailed instructions for use, warnings, and intended applications, ensuring that healthcare providers and consumers can safely and effectively operate the device. Failure to meet these labeling standards may lead to FDA rejection or mandatory modifications before market clearance.

Examples of FDA-Cleared Class II Wearable Devices

Several Class II wearable medical devices have received 510(k) clearance from the FDA, demonstrating substantial equivalence to previously approved medical technologies.

One notable example is the Apple Watch ECG & Atrial Fibrillation (AFib) Detection feature (510(k) Clearance: K183319), which was the first smartwatch to be FDA-cleared for ECG monitoring. This feature uses AI-driven algorithms to detect irregular heart rhythms, specifically AFib, and was approved based on equivalence to traditional ECG monitors.

Another FDA-cleared device is the Garmin ECG App (510(k) Clearance: K221774), classified under 21 CFR 870.2345 (Electrocardiograph Software for Over-the-Counter Use). This application enables certain Garmin smartwatches to record ECG signals and detect potential heart abnormalities, providing users with medically relevant cardiovascular insights.

For diabetes management, the Dexcom G6 Continuous Glucose Monitor (CGM) (510(k) Clearance: K181939) is a wearable glucose monitoring system that continuously tracks blood glucose levels through a skin sensor, eliminating the need for frequent fingerstick testing. Similarly, the Fitbit Sense SpO2 & Heart Rate Variability (HRV) Monitor (510(k) Clearance: K201876) was FDA-cleared as a medical-grade wearable capable of tracking oxygen saturation levels (SpO2) and HRV, making it useful for cardiovascular health monitoring.

Class II medical devices, including wearables designed for moderate-risk applications, must undergo strict FDA oversight through the 510(k) clearance process. Manufacturers must demonstrate substantial equivalence to an

existing FDA-cleared device and provide comprehensive data on safety, performance, and usability. While the FDA review process typically takes 90 days, delays can occur if additional testing, modifications, or further documentation is required. By meeting these stringent regulatory standards, Class II wearable medical devices can be safely introduced into the market, offering patients and healthcare providers advanced digital health solutions.

CONCLUSION

Wearable technology is transforming clinical trials by providing real-time, continuous, and objective health data that enhances patient monitoring, improves trial efficiency, and supports decentralized clinical trials. The integration of wearables into clinical research has demonstrated significant benefits, including increased patient engagement, improved compliance, enhanced data accuracy, and reduced operational costs. Moreover, these devices facilitate personalized medicine and real-world evidence generation, enabling researchers to collect more meaningful insights while reducing reliance on traditional, intermittent data collection methods.

Despite the advantages, challenges such as data volume management, regulatory compliance, device standardization, and interoperability must be addressed to fully integrate wearables into the clinical trial ecosystem. The adoption of advanced data management systems, AI-driven analytics, standardized regulatory frameworks, and robust cybersecurity measures will be essential in ensuring the reliability, security, and usability of wearable-generated data in clinical research.

As technological advancements continue to evolve, wearable devices will play an increasingly pivotal role in patient-centric clinical trials. Innovations in AI, cloud computing, remote monitoring, and digital biomarkers will further enhance the capabilities of wearables, making them indispensable tools for accelerating drug development, improving patient outcomes, and advancing healthcare research. Regulatory agencies are actively adapting to this shift, ensuring that wearable technology meets the necessary safety, accuracy, and compliance standards.

By embracing these advancements while addressing the associated challenges, clinical researchers, healthcare professionals, and regulatory bodies can unlock the full potential of wearable technology in clinical trials. This will not only streamline research processes but also bring life-saving treatments to market faster, ultimately shaping the future of precision medicine and digital health innovation.

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