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Digital Biomarkers and Wearable Devices in Clinical Trials: Are We Ready for Continuous Pharmacological Monitoring?

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Perspective
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Abstract

Clinical trials have traditionally relied on measurements collected at predefined visits, creating only brief snapshots of a patient's physiological response to treatment. The rapid development of wearable devices and digital biomarkers is beginning to change this model by allowing researchers to observe patients continuously and in their everyday environments. Smartwatches, activity monitors, continuous glucose monitors, biosensors, and other digital health technologies can capture changes in heart rate, sleep, physical activity, mobility, glucose, rhythm, and other physiological parameters. These data may provide a more detailed picture of drug response than conventional intermittent assessments. Recent clinical trial experience indicates that wearable technologies are increasingly being used not only to measure outcomes but also to understand drug effects, adherence, dosing, and treatment optimization. However, continuous monitoring should not be confused with continuous understanding. Questions concerning analytical validity, clinical relevance, data quality, patient adherence, privacy, interoperability, cybersecurity, and regulatory acceptance remain important. The central challenge is therefore not whether technology can collect more information, but whether clinical research can transform that information into reliable and meaningful evidence about pharmacological effects. This perspective discusses the opportunities and limitations of wearable-derived digital biomarkers and argues that the next stage of pharmacological monitoring should focus on validated, patient-centered and clinically interpretable measurements rather than simply increasing the volume of data.

Keywords: Digital Biomarkers; Wearable Devices; Clinical Trials; Pharmacological Monitoring; Digital Health; Drug Development; Continuous Monitoring

Introduction

For decades, clinical pharmacology has largely depended on measurements obtained at specific points in time. A patient visits a research center, provides a blood sample, undergoes a physiological assessment, completes a questionnaire, and then returns home. These measurements are valuable, but they represent only selected moments in a continuously changing biological system. Drug exposure and drug response, however, rarely follow the schedule of a clinical appointment.

Wearable technologies offer a different possibility. A smartwatch can record heart rate throughout the day, an activity monitor can capture changes in mobility, and a continuous glucose monitor can reveal fluctuations that would remain invisible through occasional measurements. In clinical trials, these technologies can potentially transform

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the observation of drug response from a series of isolated snapshots into a longitudinal picture [1].

This transition is already occurring. A 2026 review examining more than 1,000 interventional trials found that wearable-derived data are being used across several areas of drug development, including assessment of drug effects, dosing optimization and adherence. At the same time, formal regulatory qualification of wearable-derived measures remains limited.

The important question, therefore, is no longer whether wearable devices can collect continuous information. They clearly can. The more difficult question is whether we are ready to interpret continuous physiological information as evidence of pharmacological benefit, toxicity, or treatment failure.

From Intermittent Measurements to Digital Pharmacology

The most attractive feature of wearable monitoring is its ability to capture changes that conventional trial visits may miss. A patient receiving an antihypertensive drug, for example, may experience physiological changes at particular times of the day that are not reflected by a single clinic measurement. Similarly, a neurological treatment may influence mobility or tremor in ways that vary considerably between morning and evening.

Digital biomarkers can potentially reveal these patterns. This does not necessarily mean that every physiological signal should become a biomarker. A useful digital biomarker must have a meaningful relationship with the biological or clinical process being studied. Continuous measurement creates an enormous amount of information, but information alone is not evidence [2].

The distinction is particularly important in pharmacology. Researchers may observe a change in heart rate, sleep duration, activity level, or glucose variability after treatment. The next question is whether that change represents a genuine pharmacodynamic effect, a behavioral response, an environmental influence, device error, or simple biological variation.

The future of digital pharmacology will therefore depend less on collecting data and more on identifying which signals matter, when they matter, and for whom they matter.

Wearables as a Window Into Drug Response

One of the most promising applications is the assessment of pharmacodynamic effects in real-world settings. Traditional pharmacological measurements often occur under controlled conditions, whereas patients take medicines while working, sleeping, exercising, travelling, and performing everyday activities.

Wearables can place treatment response within this real-life context. For example, continuous physiological monitoring may help investigators understand whether a drug produces sustained effects or whether its effects fluctuate during the dosing interval. Similarly, activity and sleep measurements could provide additional information about functional changes that might be difficult to capture through conventional clinical scales.

This approach could also be valuable for identifying early safety signals. A persistent alteration in heart rhythm, sleep pattern, physical activity, or another physiological parameter might provide an additional signal that deserves clinical evaluation [3].

Importantly, wearable data should complement rather than automatically replace established clinical measurements. The strength of a digital biomarker lies in its ability to add information that is clinically meaningful.

The U.S. Food and Drug Administration (FDA) has recognized this potential. Its guidance on digital health technologies describes their ability to acquire data remotely and repeatedly during clinical investigations, while emphasizing that technologies should be appropriately selected and fit for their intended purpose.

The Problem of Too Much Data

Continuous monitoring introduces an unexpected problem: data abundance can become a scientific weakness if it is not accompanied by analytical discipline.

A traditional clinical trial may generate a manageable number of predefined measurements. A wearable device can generate thousands or millions of observations from a single participant. Increasing the frequency of measurement does not automatically increase the quality of evidence.

Researchers must decide which measurements should be analyzed, how missing observations should be handled, and how temporary fluctuations should be distinguished from meaningful changes. Device failure, poor skin contact, battery depletion, inconsistent wearing behavior, software updates, and differences between devices can all influence data quality.

There is also a risk of discovering statistically significant patterns that have little clinical importance. When thousands

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of measurements are analyzed, apparently interesting associations can emerge by chance.

For this reason, digital endpoints should be defined prospectively and linked to a clear clinical question. The emerging regulatory approach emphasizes verification, validation, clinical relevance and fitness for purpose rather than assuming that a technologically sophisticated device automatically produces a valid clinical measure.

Are Patients Ready for Continuous Monitoring?

Technology may be ready before patients are. Wearing a device for several months is not equivalent to wearing one for several days. Participants may forget to charge a device, remove it during exercise, find it uncomfortable during sleep, or simply become tired of continuous monitoring. Such behaviors can produce missing or biased data.

There is also a social dimension. Continuous monitoring changes the relationship between the participant and the clinical trial. Instead of providing information during scheduled visits, participants may feel that they are being observed throughout their daily lives.

This raises legitimate questions about privacy and ownership of health data. Who can access the raw data? How long are they stored? Can information collected for a clinical trial be used for another purpose? What happens when a commercial device manufacturer is involved?

These questions should not be treated as secondary technical issues. Trust is fundamental to research participation. If participants do not understand how their information is collected and used, technological sophistication may actually weaken rather than strengthen clinical research.

The FDA has specifically highlighted the importance of data protection, cybersecurity, participant communication, and appropriate handling of data generated through digital health technologies.

Continuous Monitoring Does Not Mean Continuous Intervention

The phrase "continuous pharmacological monitoring" is attractive, but it requires careful interpretation.

Monitoring a physiological parameter continuously does not mean that clinicians should continuously change medication doses. Drug therapy cannot be safely transformed into an automatic feedback system simply because wearable data are available.

Pharmacological decisions require an understanding of dose, exposure, pharmacokinetics, pharmacodynamics, disease state, comorbidities, concomitant medications, and clinical context. A temporary change in heart rate, for instance, may have several explanations unrelated to the drug under investigation.

The appropriate future model is therefore likely to be continuous measurement combined with selective clinical interpretation. Digital systems can identify patterns and potential signals, while clinicians and validated analytical frameworks determine their significance.

This distinction could prevent one of the major risks of digital medicine: allowing the availability of real-time data to create an expectation that every fluctuation requires an immediate therapeutic response.

Where Do We Go From Here?

The next generation of clinical trials should move beyond the question, "Can we measure it?" and instead ask, "Will measuring it improve the trial?" Three principles should guide this transition. First, clinical meaning should come before technological novelty. A simple sensor measuring a validated endpoint may be more valuable than an advanced device producing dozens of poorly understood signals.

Second, validation must become central to digital biomarker development. Researchers need to establish whether a digitally derived measure is reliable, reproducible and sensitive to meaningful changes caused by treatment. Regulatory agencies are increasingly emphasizing this concept as digital measures move toward clinical use.

Third, patients should be involved in deciding what is worth measuring. A biomarker that is statistically impressive but disconnected from outcomes that matter to patients has limited clinical value.

Ultimately, wearable devices should not be judged by how much data they produce. They should be judged by whether those data improve our ability to understand treatment response, identify harm, and make better decisions.

Conclusion

Wearable devices and digital biomarkers are changing the architecture of clinical trials. They offer something conventional trial designs have struggled to provide: a continuous view of patients in their everyday environments. This creates exciting possibilities for understanding

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pharmacodynamic effects, treatment adherence, functional outcomes and early safety signals. Yet continuous data collection is only the beginning. The field now faces a more difficult scientific task-turning large streams of physiological information into validated and clinically meaningful evidence.

We may therefore be ready for continuous pharmacological monitoring, but not for continuous interpretation of everything a wearable can measure. The future should not be defined by collecting more data; it should be defined by collecting the right data, validating them rigorously, protecting the people who generate them, and translating them into decisions that genuinely improve drug development and patient care.

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