

Empatica Health Monitoring Platform

Category:

Best Digital Health Solution

Company Name:

Empatica

Number of employees:

51-200

Turnover and/or Funding:

N/A

Product/Solution Name:

Empatica Health Monitoring Platform

Corporate Name:

N/A

Date of Approval:

N/A

Indications:

The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers for retrospective remote monitoring of physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments. As the platform does not provide real-time alerts related to variation of physiologic parameters, users should use professional judgment in assessing patient clinical stability and the appropriateness of using a monitoring platform designed for retrospective review.

The device is intended for continuous data collection supporting intermittent retrospective review of the following physiological parameters:

- Pulse Rate

- Blood Oxygen Saturation under no-motion conditions
- Respiratory Rate under no motion conditions
- Peripheral Skin Temperature
- Electrodermal Activity
- Activity associated with movement during sleep

The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

Therapeutic Areas:

Neurology, mental health, physical health, occupational health, sleep, oncology, endocrinology, cardiology, and more.

General Information File Document upload:

[K230457 1.pdf](#)

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[K232915 1.pdf](#)

Background information and need for drug / device:

A pioneer in the development of algorithm-based digital biomarkers and AI-powered continuous health monitoring, Empatica and the Empatica Health Monitoring Platform are providing researchers with the tools they need to seamlessly collect real-world health data while minimizing the burden on patients, caregivers and health professionals.

This is of particular value in clinical research, where \$325 billion is spent yearly in the US alone to develop prescription drugs. However, studies have shown that up to 75% of these drugs don't have the intended use on patients. Traditionally, data collection in clinical trials has been imperfect. Trial results can be impacted by challenges with scale and diversity of their cohorts, while 1 in 3 clinical trial participants will drop out due to patient burden. And while remote monitoring devices have become more popular, many remain less intuitive or less comfortable than patients need.

The clinical trial dropout rate prevents important treatments from going to market and increases costs, as sponsors need to conduct further recruitment to make up the numbers. 85% of all clinical trials experience delays, costing anywhere between \$600k and \$8 million per day. Decentralized trials, achieved through remote data collection through wearable technologies and digital biomarkers, can save up to 3 months in phase 2 studies, bring more effective and diverse treatments to market faster, and open up trial participation to underrepresented groups, expanding clinical research on

rare diseases and diseases affecting populations with reduced mobility or access to traditional trial sites.

The algorithms developed by wearable technology companies such as Empatica also offer non-invasive, objective and continuous measurements in real-world settings, helping to ensure that research is more robust and patient-centric.

Digital biomarkers play a vital role when serving as digital endpoints, reducing bias and enhancing the reliability of results. This is particularly beneficial when a digital biomarker is used to diagnose or detect a specific event that would otherwise rely on subjective self-reporting, such as mental health, autism outburst prediction, seizures and more.

By harnessing the power of digital health technologies, researchers can not only enhance the efficiency and accuracy of clinical studies, but personalize their approaches with effective interventions to improve the overall quality of healthcare they provide.

Background File Document upload:

N/A

History of the development of the solution/product:

The Empatica Health Monitoring Platform has its roots in Embrace2, Empatica's first commercial product which was spun out of the MIT Media Lab in 2013. This smartband received FDA-clearance for its ability to algorithmically detect seizures in people with epilepsy and is used by thousands of people with epilepsy worldwide. Embrace2 alerts caregivers when it detects a seizure and can thus expedite first response, which is crucial in preventing sudden unexpected death in epilepsy (SUDEP), the leading cause of death for people with uncontrolled seizures.

When Empatica released the Empatica E4 wristband in 2014, it fast became the industry-standard for scientific research thanks to its reliability and its unique sensor combination. The E4 provided researchers with raw data and digital biomarkers from multiple participants simultaneously, and in real-time, by streaming it to the Cloud. To date, thousands of papers have been published using data collected with the E4.

In 2021, Empatica introduced its flagship wearable, EmbracePlus, combining the best of Embrace2 and the E4 in a single powerful device. EmbracePlus is a medical-grade smartwatch, developed with the support of NASA, HHS, and the US Army Medical Research and Development Command, and with award-winning design (IDSA, Chicago Atheneum). It is the missing link between medical and consumer devices, and a key component of the Empatica Health Monitoring Platform.

Released and cleared by the FDA in 2022, the Empatica Health Monitoring Platform is a full-stack remote patient monitoring solution that harnesses the data collected by EmbracePlus to enrich medical research and healthcare practices with real-world health insights. The Platform consists of the EmbracePlus wearable, its companion smartphone application the Care App, as well as the Empatica Cloud and the Care Portal. Data is transferred to the Empatica Cloud, where it can be visualized via the online Portal or downloaded for further analysis.

In 2023, the Empatica Health Monitoring Platform received FDA clearance for two new digital biomarkers: pulse and respiratory rate, bringing Empatica's total number of FDA-cleared digital biomarkers to 6, among the most offered for use in clinical trials.

The Empatica Health Monitoring Platform is highly versatile. EmbracePlus' modular design allows it to be worn on the wrist, hip, waist or lumbar position depending on the needs of the study or its participants. And the platform's offering has now been expanded with third-party integration to algorithm developers.

In 2024, we announced a landmark partnership with McRoberts, one of the leaders in ambulatory monitoring of physical activity, opening third-party integration to algorithm developers and incorporating 71 of McRoberts' algorithms into our digital biomarkers portfolio.

This partnership establishes the Empatica Health Monitoring Platform as a one-stop solution for monitoring digital biomarkers in clinical trials, with over 200 digital biomarkers available, and the ability to be fully compatible with validated third-party algorithms.

Development File Document upload:

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Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The Empatica Health Monitoring Platform is available in 160+ countries and over 20 languages, enabling clinicians and researchers worldwide to remotely collect and monitor the health data of thousands of patients and clinical trial participants simultaneously. All data collected by EmbracePlus is done so automatically, objectively, and continuously. Patient burden is minimal, requiring no manual input and instead relying on patients to wear the smartwatch-like device while going about their daily lives. During this time, their health data is constantly analyzed by Empatica's algorithms and streamed to the cloud for further analysis.

The algorithms provide researchers with constant and remote access to over 200 validated digital biomarkers, the largest range of measures in a single solution. These algorithms can monitor a range of parameters and health conditions, from respiratory rate and pulse rate to sleep, gait speed and energy expenditure. Digital biomarkers can serve as digital endpoints in clinical trials, or be used by researchers to develop novel endpoints, expanding the capabilities of decentralized clinical trials by providing continuous and automated remote health assessments, something which is of particular importance for rare diseases and diseases affecting populations with limited mobility or access to traditional trial sites.

Empatica has deployed over 10,000 devices and its technology is already being used in dozens of trials by some of the top 20 pharmaceutical companies to advance treatment development and develop novel digital biomarkers. Some recent projects include Chugai's work on the development of an algorithm to measure pain in endometriosis, Bristol Myers Squibb's study measuring sleep quality in patients with Alzheimer's, Takeda's study using EmbracePlus to assist with Fabry disease diagnosis, and Eli Lilly's master protocol on Digital Health Technologies (DHTs) in chronic pain.

Beyond clinical trials and drug development, our platform is used in other research projects that are leading to new discoveries, including the US Department of Defense, and a better understanding of how the human body adapts in extreme environments, including the South Pole, Mount Everest, and in NASA missions simulating the conditions of space. Our goal is to enable new discoveries in science, especially for conditions that have no established treatments, and to contribute to a world where health monitoring through AI becomes a standard and powerful practice for patients and clinicians alike.

In 2024, Empatica introduced Embrace2's successor in the US, EpiMonitor. EpiMonitor is an FDA-cleared all-in-one wearable and smartphone app solution, powered by EmbracePlus, to detect patterns associated with possible generalized tonic-clonic seizures, alert caregivers during emergencies, and monitor epilepsy. EpiMonitor demonstrates the successful integration of a new algorithm with the existing technology stack of the Empatica Health Monitoring Platform, highlighting its potential to host future SaMD products.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

- <https://pubmed.ncbi.nlm.nih.gov/36539756/>
- Validity of the Empatica E4 wristband to estimate resting-state heart rate variability in a lab-based context <https://pubmed.ncbi.nlm.nih.gov/36252721/>
- <https://www.tandfonline.com/doi/abs/10.1080/07420528.2020.1835942?journalCode=icbi20>
- IMPLEMENTING WEARABLE TECHNOLOGIES FOR IN-HOME ASSESSMENT OF COGNITIVE- AND EVENT-RELATED POTENTIAL RESPONSES AFTER SLEEP AND WAKEFULNESS IN ALZHEIMER'S DISEASE
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9765108/#:~:text=IMPLEMENTING%20WEARABLE%20TECHNOLOGIES%20FOR%20IN%20HOME%20ASSESSMENT%20OF%20COGNITIVE%2D%20AND%20EVENT%2DRELATED%20POTENTIAL%20RESPONSES%20AFTER%20SLEEP%20AND%20WAKEFULNESS%20IN%20ALZHEIMER%E2%80%99S%20DISEASE>
- <https://dimesociety.org/access-resources/digital-measures-physical-activity/>

References File Document upload:

N/A