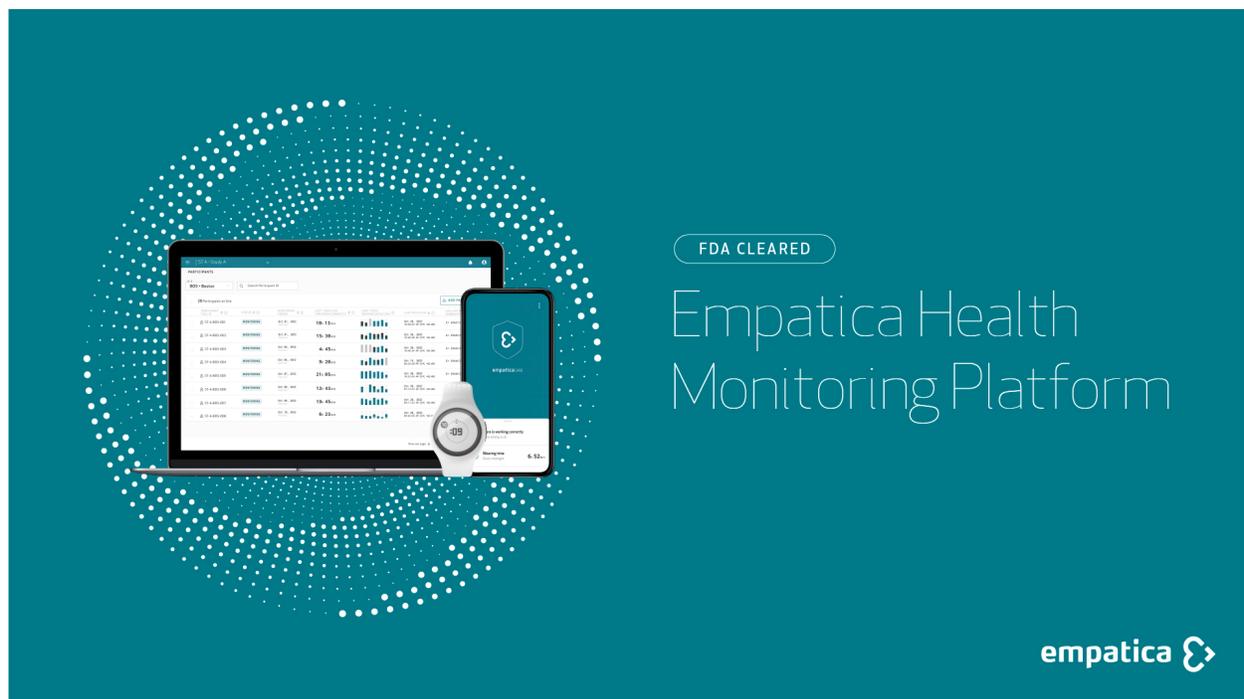


# FDA Clearance Press Release

Empatica receives new FDA clearance for its Health Monitoring Platform and announces Series B financing



***The Empatica Health Monitoring Platform can accelerate the development of novel therapeutics and the adoption of digital endpoints in patient care and clinical trials. The FDA clearance includes data collection for the continuous monitoring of SpO2, Electrodermal Activity, Skin Temperature and activity associated with movement during sleep.***

Boston, MA — Empatica, a digital health and AI company developing medical-grade wearables and algorithms for health monitoring and diagnostics, today announced the clearance of its Empatica Health Monitoring Platform by the U.S. Food and Drug Administration (FDA).

The Empatica Health Monitoring Platform is a full-stack remote health monitoring and data collection solution for research and healthcare professionals, built on data collected by Empatica's medical-grade, CE-certified EmbracePlus wearable. In addition, the Platform includes Empatica's proprietary Care software suite, secure cloud infrastructure, and clinically validated digital biomarkers.

Empatica's Platform has been cleared for continuous data collection to monitor blood oxygen saturation (SpO2)

during rest, peripheral skin temperature, activity associated with movement during sleep, and Electrodermal Activity (EDA). Each of Empatica's digital biomarkers is based on trained algorithms that analyze sensor data in one-minute intervals, and have been rigorously validated in clinical studies conducted with diverse groups of participants. Platform users can also access raw data collected by EmbracePlus' five sensors, and research-grade digital biomarkers such as Pulse Rate, Pulse Rate Variability, and Respiratory Rate.

The Empatica Health Monitoring Platform is being used globally by major pharmaceutical companies to continuously gather and analyze physiological data for clinical trials evaluating the impact of novel therapeutics, with Empatica collaborating to develop digital biomarkers for use as endpoints. Researchers also have the possibility to develop their own digital biomarkers, which they can implement in their digital health applications or infrastructure using the Platform's Software Development Kit.

"This clearance represents a significant step forward for our scientific community," said Dr. Marisa Cruz, Chief Medical Officer of Empatica. "Patients, healthcare providers, and researchers deserve digital health products that are accurate, validated in diverse populations, and intuitive to use. We are proud to have built a solution that accomplishes these goals, offering a high-quality and reliable digital health tool to scientists working to improve patient outcomes through research and clinical care."

Today Empatica also announced the recent closing of its Series B financing, led by Sanofi Ventures and RA Capital, and participation by Black Opal Ventures. The investment will enable Empatica to expand its suite of digital biomarkers, for use in patient care and as digital endpoints in clinical trials.

"We are excited to team up with Empatica, their investors and partners on this journey," said Cris De Luca, Partner at Sanofi Ventures and newly-appointed Empatica board member. "By gaining higher resolution into disease symptomology through novel digital measures and digital biomarkers in clinical and real-world settings, Empatica is unlocking the possibilities of early disease detection, enhanced treatment decisions, and improving quality of life for patients around the world".

**Empatica** – [www.empatica.com](http://www.empatica.com)

Empatica Inc is a pioneer in continuous, unobtrusive remote health monitoring driven by AI. Empatica's platform and technology are used by thousands of institutional partners for research purposes, in studies examining stress, sleep, epilepsy, migraine, depression, addiction, and other conditions. Its flagship medical wearable, EmbracePlus, has been developed with key partners including HHS, USAMRDC, and the NASA-funded TRISH.