

## Integrated platform for digitally monitoring health

### About Empatica

[Empatica](#) is redefining clinical research and remote patient monitoring through medical wearables and digital biomarkers. With 5 FDA clearances and over 100,000 devices deployed, Empatica's tools are designed to seamlessly collect and monitor health data from daily life, providing the world's largest selection of gold-standard digital measures from a single, versatile wearable. Empatica's flagship product is the [Empatica Health Monitoring Platform](#), which consists of:

- [EmbracePlus](#) wearable
- [Empatica Care](#) software suite
- Clinically validated biomarkers for monitoring physiologic parameters



### The opportunity

Following the [FDA clearance of multiple condition-specific product solutions](#), Empatica saw an opportunity to **develop a full-stack condition-agnostic platform** that could be deployed for both research or clinical care and would **support integration with third-party algorithms**.

### The challenge

- Novel digital health platforms, particularly those that span multiple clinical domain areas, **pose challenges in the regulatory review process**. Medical devices with cross-cutting clinical applications and multiple potential use cases typically require engagement with multiple FDA review divisions.
- Complexities like these can impact the submission processes for innovators and affect **product development strategies** and **time-to-market**.

### The approach

- Through [early engagement](#) with FDA, Empatica was able to iteratively **clarify regulatory requirements and expectations for multifunctional products**, enabling effective market positioning of the Empatica Health Monitoring Product, as well as proactive planning for the clinical studies required to validate the digital biomarkers available on the platform.
- The [Empatica Health Monitoring Platform](#) received [510\(k\) clearances](#) in 2022 and 2023 for the platform and its integrated biomarkers. The wearable device and paired software platform are intended to be used by trained healthcare professionals or researchers for **remote monitoring of physiologic parameters in ambulatory individuals** 18 years of age and older **in home-healthcare environments**.

### The success

- ✓ The full-stack platform conducts research **integrating multiple devices and featuring over 100 digital clinical measurement capabilities**.
- ✓ The platform's capabilities have led to **numerous successful implementations**, with a recent example being the [co-development of a rare disease digital biomarker with Takeda Pharmaceuticals](#).

“We learned a lot from engaging with multiple FDA divisions over several years to obtain clearance of the Empatica Health Monitoring Platform, and we look forward to ongoing interaction with the Agency to continue streamlining the regulatory submission process for condition-agnostic platforms.”

— **Dr. Marisa Cruz**

Chief Medical Officer, Empatica