Rave Wearable Sensors - A New Method of Data Capture

Directly capture more frequent, continuous and objective patient data through a variety of integrated wearable and remote biometric sensors. With a robust dashboard and advanced analytics capabilities, Rave Wearable Sensors enables summary and compliance dashboards for monitoring studies in real timeʐwhile securely storing sensitive sensor data.

While regulatory bodies such as the FDA or EMA have not yet provided a formal, prescriptive position on the use of sensors in trials, Medidata actively participates in thought-leading industry consortia and government organizations such as the Clinical Trials Transformation Initiative, ePRO Consortium and the Center for Drug Evaluation and Research focused on the methodology of collecting and using patient mobile health data in clinical trials.

Thought Leadership Participation

Medidata leverages its expertise in digital health technology by partnering with study teams in developing the ideal strategy and best approach for using sensors in a clinical trial. We provide consultation with study teams in establishing goals in the use of sensor data as well as the study design that can adequately capture data from sensors and other feedback mechanisms, e.g., ePRO, in a low-risk setting. Medidata also advises and supports study teams on device provisioning with options that include full provisioning of mobile devices and sensors or "Bring Your Own Device."

Patient Cloud

Single, Unified Clinical Platform
Capture, track, analyze, visualize, and report on all types of patient-centered clinical trial data whether in the clinic or remotely.

Operational Scale
We see a future where the inclusion of mobile technology is no longer a question for operational teams. Sensor-derived data will become a standard part of the vast majority of clinical trials.

Any Study, Anywhere
Global clinical trials require flexible solutions that can meet evolving study requirements, local regulatory guidelines, and can be deployed through a variety of hardware and deployment models.

A Larger Journey
A new set of work flows revolve around the patient, providing profound new experiences for clinical trials of the future.

Patient Cloud Product Line

Medidata's Patient Cloud is a suite of products including: Rave eConsent, Rave eCOA, Rave Wearable Sensors, and Rave Virtual Trials.

One Unified Platform with a Scalable Infrastructure for Integration and Processing of Sensor Data

- Secure Integration of data from select 3rd party sensors

- High volume processing, storage, and auditing of data

- Dashboards for compliance and operational oversight

- Technology to transfer data for external analytics

- Platform services that route and integrate data while protecting clinical record from Personally Identifiable Information
- Signal processing and machine learning for data visualization and analysis

Wearable Sensors Line Up

Medidata has identified select wearable sensor devices most commonly used by patients to collect biosensors and wearables data that will be integrated into the Medidata Rave Clinical Cloud™.

Activity

Garmin vivofit 4
Fitbit Charge 3

Temperature

Withings Thermo
Temporal
Thermometer

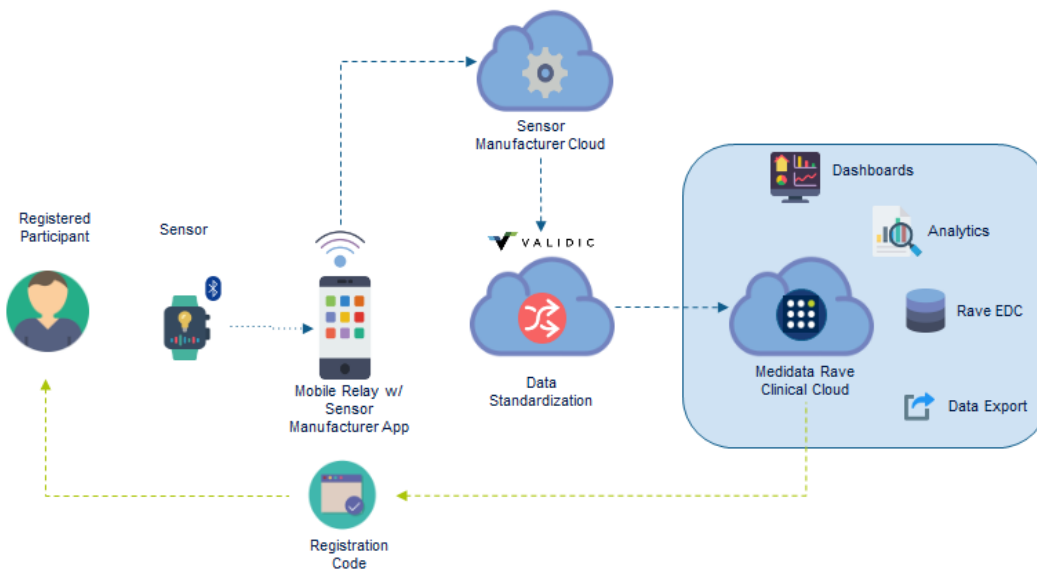**Blood Pressure**

Withings
Blood Pressure Cuff

Weight

Withings
Body+ Scale

Rave Wearable Sensors Data Flow

Registered participants transmit data from their wearable sensors, which is ingested by the sensor manufacturer's cloud. Data from the sensor manufacturer is then sent to Validic, a third-party sensor integrator, for standardization, This data is then transmitted to Rave EDC.

About Medidata

Medidata is leading the digital transformation of life sciences, with the world's most-used platform for clinical development, commercial, and real-world data. Powered by artificial intelligence and delivered by the top ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve more than 1,300 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life science: **www.medidata.com**

**info@medidata.com |
+1 866 515 6044**

The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

Medidata Rave Clinical Cloud™
Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk