Using sensors to bring the future of clinical trials to patients, today

PATIENT SENSORS SOLUTION

The Patient Sensors Solution utilizes Parexel's broad services and eClinical expertise to enable an end-to-end solution that captures, transmits and visualizes connected sensor and device data – built to support the volumes of data collected by modern sensors. This collection of patient sensor data is coordinated by Parexel's Scientific Data Organization, providing:

- Unified project management, delivering proactive client communication and management of all third-party vendors
- Device selection advice and validation services
- Sourcing, testing and distribution of sensors
- Fully validated and compliant with GDPR, HIPAA, 21 CFR Part 11 and Annex 11 regulations
- Analysis and delivery of sensor data sets
- Development of easy-to-read instructions for study subjects and sites
- Comprehensive site training
- 24x7 Help Desk support for sites and subjects

Parexel's Scientific Data Organization develops agile access to real-world data (RWD) via essential technologies, such as connected devices, to support best-in-class digital solutions for clinical research sponsors. We partner with leading, regulatory grade platforms to house, manage, combine and interpret RWD to ensure that processes and technologies used in research are reliable, repeatable and rapid to deploy. We work with our clients so that connected sensors and wearables are fit-for-purpose and delivered with effective technologies, proven scientific expertise and comprehensive wraparound services.

Regulatory Compliant System Architecture

Parexel's Patient Sensors Solution enables the capture of sensor data through a secure communications network. To provide the reliable and accurate collection, secure transmission and storage of connected device data, Parexel has partnered with leading sensor network providers. Our end-to-end solution provides multiple layers of authentication, encryption protocols and algorithms to protect the data and make sure data in transit via cellular and internet channels securely reaches its destination.

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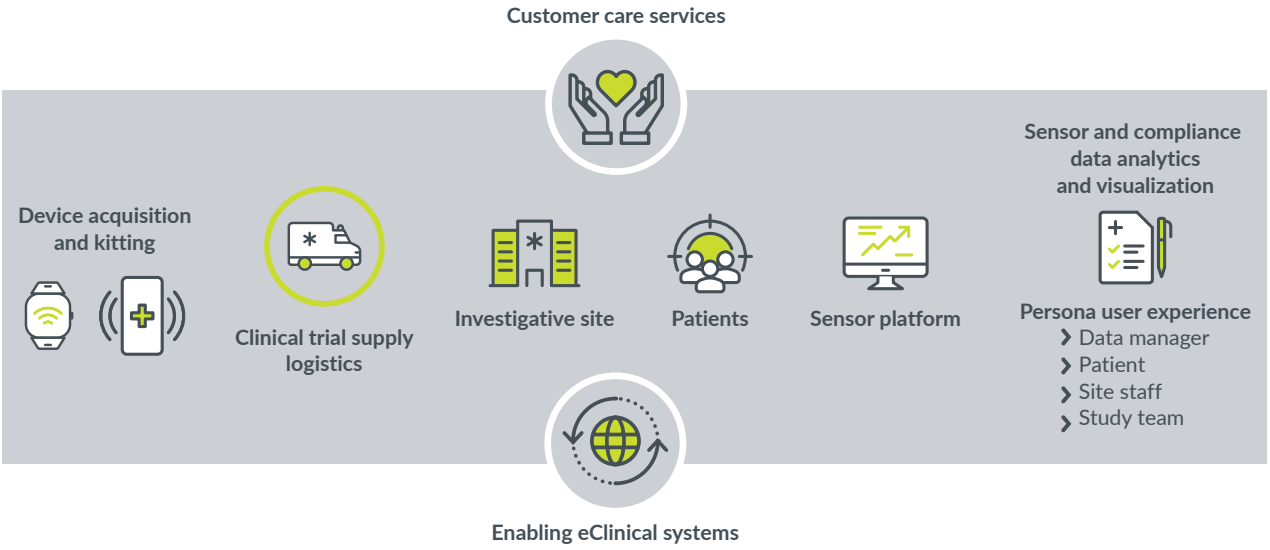
End-to-end sensor-based solution



Connected device data flow

Sensors and connected devices transfer data as secure messages to a processing service which associates the readings to a specific study subject using the established device allocation methodologies. Data is transferred from the sensor device via apps or communication hubs to the sensor data center, with the data then being transmitted to a regulatory grade RWD platform designed to ingest, analyze and visualize connected device data. Parexel's Patient Sensors Solution visualizes device data and monitors subject compliance in a variety of reports including the ability to compare remote device data to in-clinic assessment data. The results are stored in a results repository data structure prepared for the device and the subject (storage technology for large volumes/time series/streaming data). From there, device readings and compliance data are aggregated and made available via persona-based dashboards in the sensor platform or via enabled eClinical systems, such as electronic data capture (EDC).

The right device for the right patient

Devices and sensors must be easy to use by the patient and are typically non-invasive with passive data capture. In a typical device dataflow model, such as actigraphy or Constant Glucose Monitors (CGMs), the sensing device automatically detects, captures and transfers data readings to an app or a cellular hub within the patient's home via Bluetooth connection for transmission of data to a central cloud for storage and onward data analysis. Other devices, such as oximeters or blood pressure readings may require the patient to perform a daily activity with the device in order to capture the reading and trigger the data flow. With all devices, it is always important to ensure that any burden on the patient is minimized as much as possible.

Summary

Parexel has extensive experience integrating commercial FDA- and EMA-approved devices for clinical trial use. Our streamlined offering of clinical trial expertise and the ability to collect sensor-based data creates efficiencies for sponsors and eliminates the need to contract separately. Not only is Parexel ready to support the inclusion of sensors and wearables in clinical trials, for example pilots, Phase I-IV and other observational and post-marketing studies, Parexel is also able to provide wraparound clinical research services, including consulting for device-related protocol design, device validation, informed consent authoring, data management and analysis.

With Heart

Offices across Europe, Asia, and the Americas
www.parexel.com