SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

With Sensors and Wearables, It's Not All About the Hardware

The rapid adoption and incorporation of technology into many aspects of clinical research enables new opportunities to improve drug development. For instance, utilizing sensors and wearable digital health technologies (DHTs) such as activity monitors, spirometers, inhalers, glucose monitors, and pulse oximeters offers sponsors the opportunity to measure new or complementary digital endpoints that previously were not attainable, or able to be collected remotely, prior to the advent and maturation of these technologies. We also see growing regulatory interest in the use of DHTs, evidenced by the registration of research programs to develop several new sensor-based endpoints into the U.S. FDA's Clinical Outcome Assessment Qualification program, for example. However, to effectively incorporate sensor-based or wearable DHTs into research, it requires expertise and careful considerations that go beyond just the hardware.

What are digital endpoints?

"A 'digital endpoint' is defined by its use of sensor-generated data often collected outside of a clinical setting such as in a patient's free-living environment" (Landers et al, 2021). Digital endpoints in clinical trials hold great promise for driving innovation, reducing costs of drug development, and incorporating participants' perspectives. More specifically, leveraging DHTs to capture data for digital endpoints helps sponsors:

- Measure concepts that are more meaningful to patients
- Capture objective data, accurately and more frequently
- Enable continuous, remote monitoring of a participant's disease state or the impact of treatment between clinic visits
- Reduce burdens of trial participation and increase protocol adherence by enabling more measurement away from site
- Facilitate earlier and better-informed decision-making by collecting richer insights
- Support decentralized trial designs

While there seems to be consensus on the value of digital endpoints, industry adoption of DHTs has been relatively slow, which may be indicative of challenges and knowledge gaps related to implementation. Many industry consortia and organizations offer resources for developing meaningful outcome measures from DHT data such as the Digital Medicine

Society's 3Ps of Digital Endpoint Value. Signant's experience with over fifty studies that utilized integrated sensor data informs how our science and medicine experts approach advising customers on endpoint development and device selection.

What do you need to consider when selecting DHTs?

Although the benefits are clear, designing and executing trials involving devices and digital endpoints can be less straight-forward. When working with customers, Signant leverages **experience, evidence, and expertise** to help sponsors develop effective frameworks for incorporating digital health technologies and digital endpoints into a protocol. Our science and medicine team recommends considering the following when selecting devices:

- Identify and define the data endpoint the study is trying to collect
- Determine if a device aligns with the collection of that data and has satisfactory evidence of data validity and reliability
- Discern if the participant population is appropriate (user friendliness, safety, patient burden, adherence, etc)
- Data security and privacy
- Contingency planning for missing data (e.g. device data transmission and storage properties)

In its recent draft guidance, the U.S. FDA offers additional details on many of these considerations. We offer interpretation and opinion of the guidance in this whitepaper. Additionally, industry organizations such as DIA, DiMe, and C-Path, also offer detailed guidance on digital health technology best practices including device selection and validation.

What technologies are available to incorporate into my study?

At Signant, all decisions we make about device selection are rooted in science and evidence. Signant SmartSignals eCOA offers native integration with several sensors and wearable devices that have **proven clinical validity** to make it easier for sponsors to incorporate digital health technologies into research.

In addition to integrated activity monitors, glucose meters, spirometers, and inhalers, Signant recently launched our newest integrated digital health technology: the Masimo MightyStat Rx Finger Pulse Oximeter. This hospital- and clinical-grade finger probe device measures oxygen saturation, pulse rate, respiration rate, and other domains during integrated performance tests delivered via our eCOA platform. Sample applications include respiratory indications

such interstitial lung disease, asthma, COPD, or cystic fibrosis for which pulse oximetry can provide critical measures on deterioration of a patient's health and other endpoints.

A single reporting interface provides study teams with near real-time access to outcomes data that is color-coded according to pre-determined thresholds to allow for easy visual identification by study teams of possible participant deterioration. This information can be viewed alongside data from other assessments, making it easier to draw conclusions about the impact of a disease or treatment while minimizing disruptions to site workflows. Displaying COA data together in this manner also provides investigative staff with an overview of participant adherence to study requirements.

The carefully designed participant interface promotes protocol adherence as well with features including:

- Notifications that help participants discern which type of performance test they are required to complete at that time
- Clear, easy-to-follow instructions on how to configure their mobile device and pulse oximeter in preparation for an assessment
- Simple visual cues confirming device connectivity status
- A countdown to the start of the test, countdown during each test, and tactile or audio alerts confirming the beginning and end of each assessment
- Confirmation that the test has been completed and data sent successfully as well as a reporting mechanism to alert investigative staff if not completed successfully

As with all solutions we offer, the new pulse oximeter is supported by dozens of full-time clinical science and medicine experts as well as clinical operations specialists – all of whom collaborate with sponsors to ensure the highest quality data are collected for existing or novel digital endpoints.

To learn more or discuss your protocol with digital health technology experts, contact us.

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