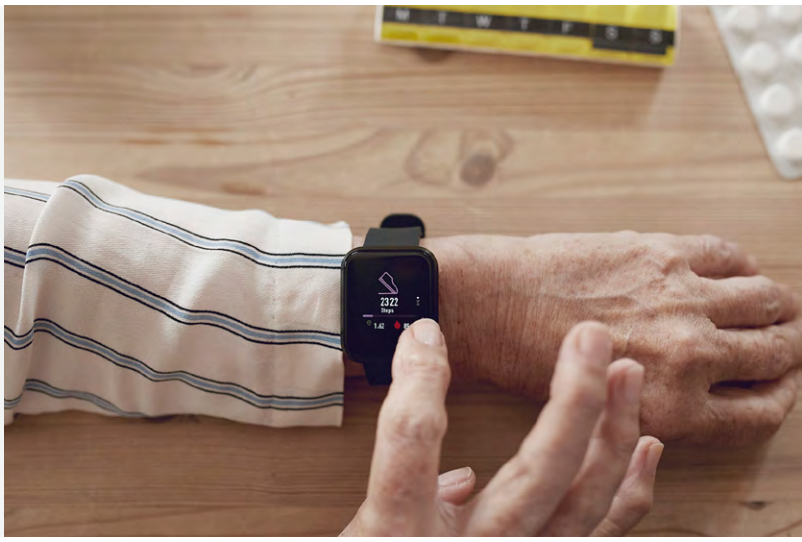
Leveraging digital measurements in clinical trials

ZS Digital Evidence Generation



Entering a new era in drug development and validation via digital measurement inclusion

The adoption of digital measurements derived from digital sensors and devices in clinical trials has been steadily increasing. These measurements improve clinical trials by capturing novel or more granular data, which is often more objective and representative of real-world outcomes. At the same time, device-supported decentralized trials can reduce the need for data collection at in-person visits, thus reducing the participant burden of travel.

While digital sensor and device-derived measurements have yet to be included in label claims, regulatory and industry indicators point to a high likelihood of that happening in the next three to five years. We are seeing good momentum of that happening here due to:

- Digital endpoints (primary and secondary) were used in 14 phase 3 pivotal trials since 2015[1]
- There is a 14% year-over-year average increase in the use of sensors in clinical study settings[2]

[1]DiME Society — Endpoint Library, [2]CTTI Feasibility Study (2013-2019)
[3]ZS-Tufts survey, [4]Clinical Leader

An unsustainable approach

Despite the previously mentioned tailwinds, the life sciences industry still contends with speedbumps in utilizing these digital measurements.

32%

Of participants in clinical trials find digital technology too difficult to manage[3]

10+

Systems or sources that sponsors and CROs are required to manage or oversee, on average, for phase 3 or 4 studies[4]

Current approaches to device and sensor inclusion often fall short of mitigating the associated risks to ensure successful remote monitoring technology in clinical programs.

Modernizing the paradigm of conducting clinical research

ZS Digital Evidence Generation improves outcomes for clinical trials by connecting a fragmented digital landscape.

Our solution

ZS's Digital Evidence Generation consulting and strategy services and ZS Connected Research™ — a compliant and configurable platform that is purpose-built to advance patient data capture and help clinical study teams incorporate novel digital measures into their studies and research initiatives.

Simplified participant experience

- Integrations with a curated portfolio of validated devices with proven usability and clinical value
- A seamless and engaging digital onboarding experience for participants
- Logistical and technical support for participants and clinical research staff

Device and biosensor data ingestion and conversion

- Ingestion and transformation of device-generated data for measurements, such as activity and sleep monitoring
- Compliant data standardization and harmonization for both regulatory submissions and exploratory analysis
- Capability to directly pass sensor data through to client data environments

Publication and regulatory submission support

- Seamless extraction of study data for analysis in your statistical computing environment
- Advisory services on peer-reviewed journal publication pathways, exploratory analyses and regulatory pathways

Value to you

Human-centric

Integrated

Quick to deploy

Out-of-the-box analytics

Learn more: zs.com

About ZS

ZS is a management consulting and technology firm focused on transforming global healthcare and beyond. We leverage our leading-edge analytics, plus the power of data, science and products, to help our clients make more intelligent decisions, deliver innovative solutions and improve outcomes for all. Founded in 1983, ZS has more than 12,000 employees in 35 offices worldwide.