Case study

Accelerated trial setup & operations: A case study in Cystic Fibrosis to illustrate the ROI of improved data availability

About VivoSense

VivoSense is a wearable sensor contract research organization (CRO) that develops and deploys digital endpoints in clinical trials. From trial design to sensor selection and operationalization, data capture, cleaning, and analysis, the team's deep scientific knowledge and extensive clinical trial experience have been instrumental in helping clinical researchers analyze and interpret wearable sensor data, thereby enhancing patient research and care.

The opportunity

- A pharmaceutical sponsor sought to include digital measures from multiple sensor types in a Phase 3B study for patients with cystic fibrosis (CF).
- Based on insights from similar trials, we know that carefully chosen digital endpoints can capture meaningful aspects of the CF patient experience.

The challenge

- Collecting digital measures in a clinical trial often results in missing data. The sponsor was concerned that data losses would require increasing patient recruitment to ensure the study's power.
- The sponsor needed a single solution provider to manage and deliver the digital measures of cough, physical activity, and sleep while minimizing data loss.

The approach

Sensor-based digital health technologies (sDHTs) were used to measure physical activity (step count, walking bouts, etc.), sleep, and cough frequency, capturing changes in concepts meaningful to CF patients.

- The sponsor received high-quality digital measures from 200 sDHTs across 18 sites globally. VivoSense managed sDHT operationalization, wear compliance, data analysis, data aggregation, and interpretation.

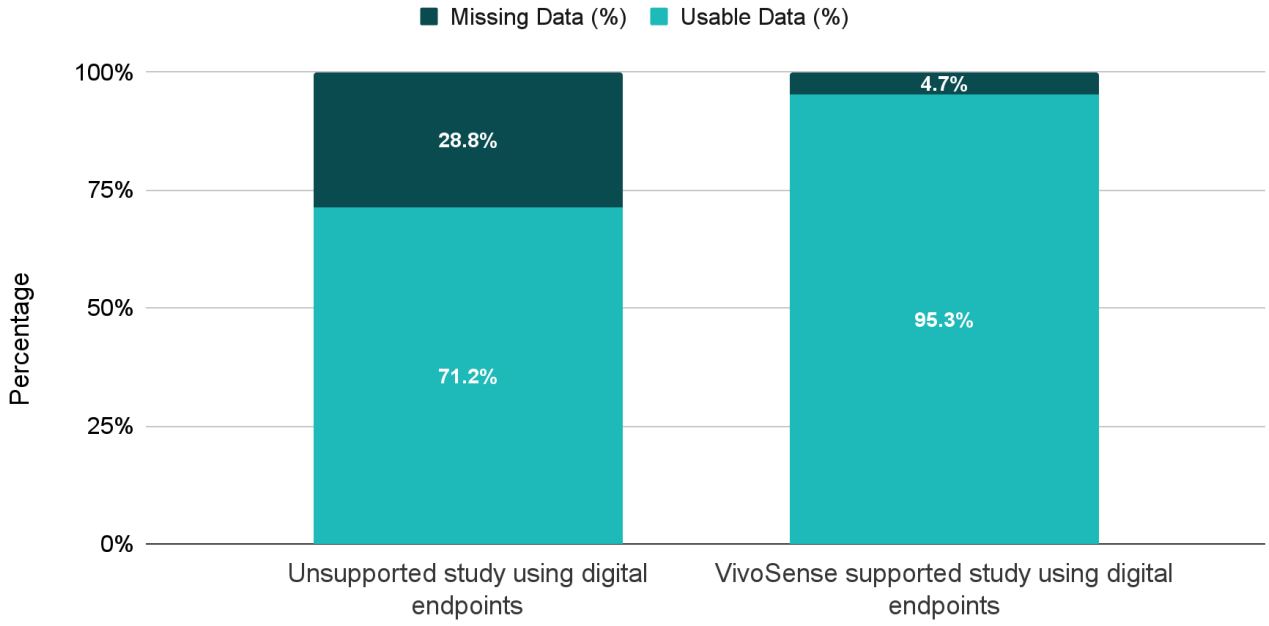
The impact

- ✔ Digital measures enabled the identification of novel endpoints in CF that the Sponsor is considering for future studies in this and other therapeutic areas.
- ✔ 99% data availability and 94% wear compliance were achieved, ensuring no further patient recruitment was required.
- ✔ Clinically meaningful improvements were identified by the digital measures throughout treatment.

> "If the missing data from sensor-based digital health technologies is not managed, the power of the study may be compromised, the results may be too variable, and the output may be misunderstood. Improving data availability directly impacts the cost of delivering a digital measure in a clinical trial."

— Dudley Tabakin
Founder & CEO, VivoSense, Inc.

Comparison of usable and missing data from digital endpoints in an unsupported study vs a VivoSense managed study



You can reference a similar paper on data cleaning and missingness in real-world digital biomarker analysis published by Oakley-Girvan et al., (2025): **Analysis Method of Real-World Digital Biomarkers for Clinical Impact in Cancer Patients**, Digital Biomarkers.