

# WHAT PATIENTS SAY. WHAT THEIR BODIES SHOW.



## Clinical Outcome Assessments + Digital Health Technologies

### ONE PARTNER. COMPLETE EVIDENCE.

Clinical trials increasingly require multiple lines of evidence to demonstrate meaningful treatment benefit. Clinical outcome assessments capture what matters most - how patients feel and function in their daily lives. Digital health technologies capture continuous, real-world data on movement, sleep, vital signs, and physiological parameters between clinic visits.

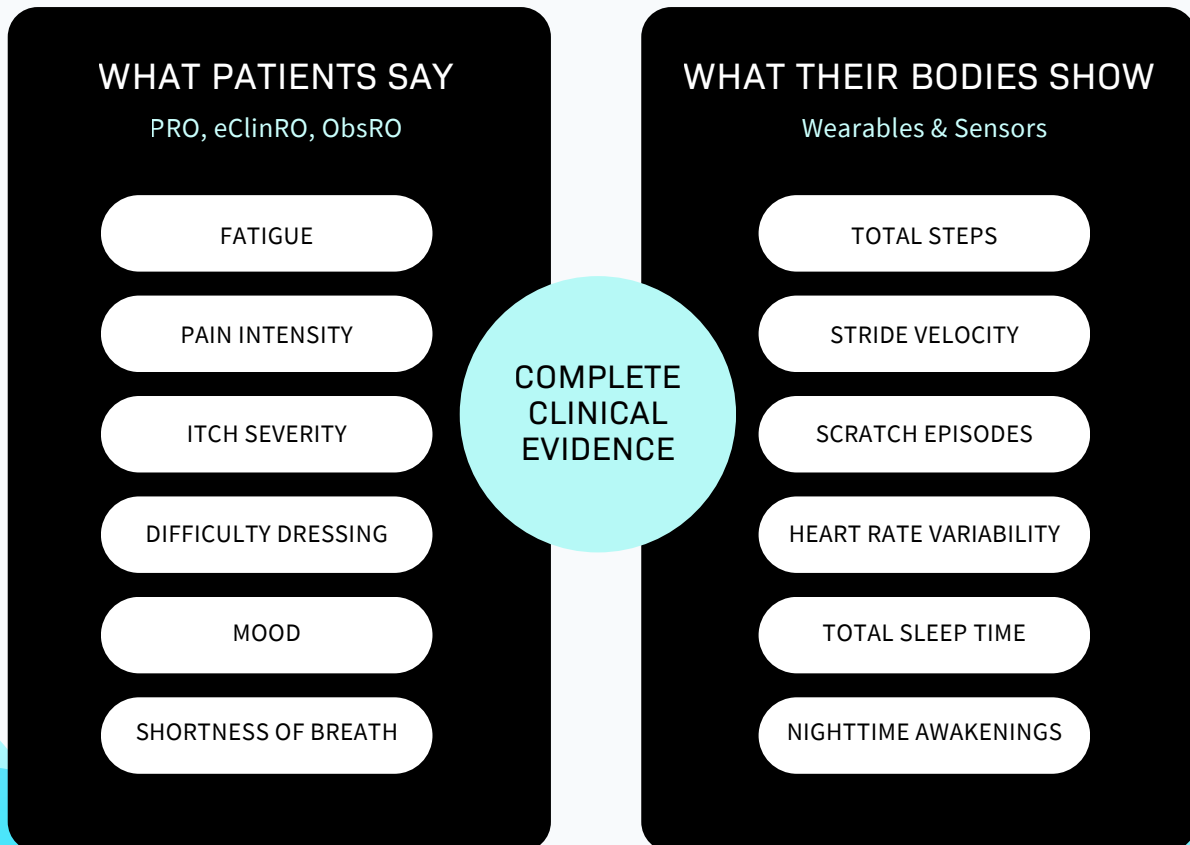
Each provides critical insights. Together, they provide complementary perspectives that build stronger efficacy cases, support more confident decision-making, and strengthen regulatory submissions.



**With Signant Health's acquisition of Ametris (formerly ActiGraph),** you now have one partner for both - coordinated from endpoint strategy through regulatory submission.

# SEEING THE PATIENT FROM EVERY ANGLE

PATIENT VOICE + SENSOR-DRIVEN DATA = COMPLETE CLINICAL EVIDENCE



## WHAT THIS MEANS FOR YOUR TRIALS:

- 01 Single vendor relationship**  
Simplify procurement and account management
- 02 Coordinated endpoint strategy**  
Optimal measure selection across both modalities during study design
- 03 Unified submission packages**  
Coordinated regulatory documentation
- 04 Combined expertise**  
Deep scientific and regulatory guidance across both patient voice and sensor data
- 05 Proven track records**  
Signant: 25% of FDA/EMA novel drug approvals (2021-2024)\*; Ametris: 285+ trials, 30,000+ publications

\*2021-2024. Regulatory authorization for new drug for first indication, defined as Novel Drug Approval by FDA, and Marketing Authorization for New Active Substance by EMA

# THE AMETRIS PLATFORM



## VALIDATED DEVICES

ActiGraph LEAP® multi-sensor wearable plus validated third-party sensors including ECG patches, digital spirometers, blood pressure cuffs, and pulse oximeters. FDA-cleared, medical-grade, clinical-ready.



## SCIENTIFIC SERVICES

World-class team of data scientists, biostatisticians, and clinical scientists supporting endpoint design, algorithm validation, DHT data interpretation, and regulatory strategy.



## AMETRIS CONNECT™

Device-agnostic data collection ecosystem. Ingests data from proprietary and third-party sensors.



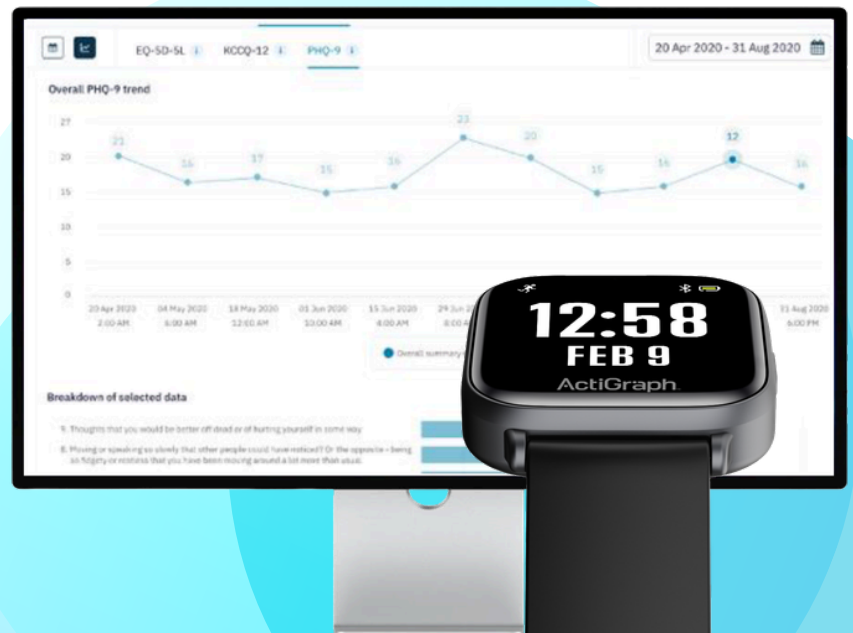
## AI-POWERED ANALYTICS

Algorithm Marketplace with 30+ proprietary, validated algorithms that transform raw sensor data into regulatory-grade digital endpoints across therapeutic areas.



## STUDY OPERATIONS

End-to-end operational support: device provisioning, site training, logistics, data transfer, archiving, and real-time study monitoring across global trials.



**285+ industry-sponsored clinical trials | 30,000+ peer-reviewed publications**  
**Established FDA and EMA regulatory precedent**

# REGULATORY AND SCIENTIFIC EXPERTISE

Regulatory success requires endpoints designed to withstand scrutiny, and partners with established agency precedent.



## SIGNANT HEALTH

Signant has supported hundreds of regulatory submissions with clinical outcome assessment endpoints across diverse therapeutic areas, trusted by all Top 20 pharma and over 600 sponsors globally. Signant's solutions have been used in 25% of novel drug approvals at FDA and EMA from 2021 to 2024.

## AMETRIS

Ametris' DHT data has established regulatory precedent at FDA, EMA, and agencies worldwide, with devices and analytics used in landmark studies and approved submissions. Ametris has deployed solutions in 285+ industry-sponsored clinical trials across 150+ countries globally. Their FDA-cleared, medical-grade devices have generated evidence published in 30,000+ peer-reviewed scientific publications, and supported clinical development submissions across a broad range of therapy areas.

**Our combined regulatory and scientific expertise is available immediately - unified endpoint strategy, coordinated regulatory documentation, and shared insights from successful multimodal trials.**

**Together, we're defining the future standard for clinical evidence.**

## READY TO DESIGN YOUR ENDPOINT STRATEGY?

Talk to us about coordinating clinical outcome assessments and digital health technologies for your next trial.

[GET STARTED](#)