AVERY & RILEY

Prepared for market education · not a buying recommendation

AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 03 DIGITAL BIOMARKERS & REMOTE MONITORING

Koneksa
Validated digital-biomarker endpoints

Empatica
FDA-cleared wearable biosensor platform

Aural Analytics
Speech biomarkers for CNS (Linus Health)

Altoida
AR motor-cognitive neuro biomarkers

AiCure
Computer-vision adherence & biomarkers

Some companies referenced may be current, former, or prospective advisory relationships of Avery & Riley; others are included independently for informational purposes. All data is publicly sourced unless otherwise noted.

WHY THIS ISSUE EXISTS

AI is moving to the edge of the trial — the sensors that generate the endpoints.

Issue 01 mapped AI across the trial workflow; Issue 02 covered the GxP backbone. This issue goes to the **data-generating edge** — the wearables, smartphones, speech, and computer vision that produce **novel, objective digital biomarkers** and enable decentralized, lower-burden trials. The promise is new endpoints; the bar is whether they hold up as regulatory-grade.

WHAT SENIOR LEADERS SHOULD WATCH

01

AI is generating **new endpoints** — continuous, objective digital biomarkers from sensors, speech, and vision enable decentralized, lower-burden trials.

02

AI centrality varies. For some it is the product (Native); for others it augments a sensor or assessment (Augmented / Peripheral). Know what you are actually buying.

03

Regulatory grade is the bar. A digital measure only matters if it is validated or qualified — look for FDA clearances, biomarker qualification, and peer-reviewed evidence.

THE MEASURING STICK

The Avery & Riley 10-stage clinical-development taxonomy

Coverage bars throughout this issue map each vendor against the ten stages below — a **directional, point-in-time read** of how many stages a vendor appears to touch, based on the latest publicly known data. These are not vendor-reported metrics and not a buying recommendation.

P01
Portfolio / indication strategy

P02
Protocol design / feasibility

P03
Site identification / selection

P04
Study startup

P05
Recruitment / enrollment

P06
Study conduct / execution

P07
Monitoring / oversight

P08
Data management / cleaning / DBL

P09
Close-out / TMF / inspection readiness

P10
Post-trial insights / evidence



LIFECYCLE COVERAGE SNAPSHOT

Where each vendor appears to play across the lifecycle

Vendor	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	Coverage
Koneksa Validated digital-biomarker endpoints · Native					■	■				■	3 /10
Empatica Wearable biosensor platform · Augmented						■					1 /10
Aural Analytics Speech biomarkers · Augmented		■	■	■							3 /10
Altoida AR neuro-cognitive biomarkers · Peripheral			■	■				■			3 /10
AiCure Computer-vision adherence & biomarkers · Native					■	■	■				3 /10

Digital-biomarker vendors are deliberately focused — they touch fewer lifecycle stages than platform players, but go deep on the ones they own. ■ P10 evidence stage shown in gold. This is a snapshot of the latest publicly known data and Avery & Riley database records available during preparation.

THE SENIOR-LEADER VIEW

Executive market map

VENDOR	CATEGORY & AI ROLE	PROBLEM(S) TARGETED	PUBLIC OUTCOME SIGNAL
Koneksa	Validated digital-biomarker endpoint platform NATIVE AI	Lack of novel, objective endpoints; episodic in-clinic visits; oversized trials; endpoint validation to regulatory grade.	**68%** fewer patients per arm (at-home sim); **15** biomarker programs / 20+ papers; **$45M** Series C (Novartis, Takeda, Merck).
Empatica	FDA-cleared wearable biosensor platform AUGMENTED AI	Episodic in-clinic snapshots; site-visit burden; need for continuous, passive physiological monitoring outside the clinic.	**6** FDA-cleared digital biomarkers / 300+ measures; **120+** trials, >90% compliance; **~98%** seizure-detection accuracy.
Aural Analytics	Speech / language biomarkers for CNS · Linus Health AUGMENTED AI	Subjective neuro rating scales; rater/site variability; insensitive CNS endpoints; need for remote bulbar/cognitive measures.	**FDA Breakthrough** Device (Speech Vitals-ALS); **1st** speech biomarker to signal efficacy in a major interventional trial; **30+** studies.
Altoida	AR motor-cognitive neuro digital biomarker PERIPHERAL AI	Slow, subjective cognitive batteries; weak screening / stratification for CNS & dementia trials; need to enrich populations.	**FDA Breakthrough** Device (2021); **94% / 82%** prognostic accuracy / specificity; **780+** biomarkers across 11 domains.
AiCure	Computer-vision adherence + digital biomarkers NATIVE AI	Unverified dosing / adherence; patient dropout; weak self-report data; central monitoring of adherence risk across sites.	**89.7% vs 71.9%** adherence vs mDOT (AbbVie Ph2); **92%** retention / 1.5M+ doses; **28** trials, 43 countries.

Koneksa

LIFECYCLE COVERAGE
3/10

VALIDATED DIGITAL-BIOMARKER ENDPOINTS | NATIVE AI

Targets: *Lack of novel, objective endpoints; episodic in-clinic visits; oversized trials; endpoint validation to regulatory grade.*

WHAT THEY DO

- End-to-end platform turning at-home wearable / sensor data (spirometry, actigraphy, gait, speech, vitals) into validated, regulatory-grade endpoints.[1]
- ML model development for feature selection, risk scoring, and endpoint optimization, aligned to FDA biomarker / DHT frameworks.[2]

OPERATIONAL PROBLEMS ADDRESSED

- Developing and qualifying novel digital endpoints to regulatory standards.
- Decentralized, at-home capture replacing episodic clinic visits.
- Endpoint validation versus the current standard of care.
- Reducing sample size and trial burden via denser measurement.

LIFECYCLE COVERAGE — AVERY & RILEY SNAPSHOT

P05 · P06 · P10

P01	P02	P03	P04	**P05**	**P06**	P07	P08	P09	**P10**

68%[3]
Fewer patients per arm, at-home vs in-clinic (peer-reviewed simulation)

15[1]
Digital-biomarker programs; 20+ peer-reviewed papers

$45M[4]
Series C with Novartis, Takeda & Merck (named investors)

SENIOR-LEADER READOUT

Coverage centers on enrollment, study conduct, and post-trial endpoint evidence — three of ten stages; AI is native, with endpoint derivation as the core product.

Strongest proof is the peer-reviewed sample-size simulation and named pharma partnerships (Takeda, Regeneron, Sanofi, Merck); absolute sensitivity figures are described qualitatively.

Empatica

LIFECYCLE COVERAGE
1/10

FDA-CLEARED WEARABLE BIOSENSOR PLATFORM AUGMENTED AI

Targets: *Episodic in-clinic snapshots; site-visit burden; need for continuous, passive physiological monitoring outside the clinic.*

WHAT THEY DO

- EmbracePlus medical-grade wrist biosensor plus the Empatica Health Monitoring Platform for continuous remote physiological data.[5]
- Care software and cloud delivering clinically validated digital biomarkers; AI layered on the sensor platform, incl. seizure detection and forecasting.[6]

OPERATIONAL PROBLEMS ADDRESSED

- Continuous, passive remote physiological data outside the clinic.
- Reducing site visits and patient burden — one wearable, many parameters.
- Objective continuous endpoints versus episodic snapshots.
- Fast study standup and multilingual global deployment.

LIFECYCLE COVERAGE — AVERY & RILEY SNAPSHOT

P06

P01	P02	P03	P04	P05	**P06**	P07	P08	P09	P10

6 FDA-cleared[5]
Digital biomarkers; 300+ digital measures on platform

120+[5]
Industry-sponsored trials; >90% compliance reported

~98%[6]
Tonic-clonic seizure-detection accuracy (vendor / third-party)

SENIOR-LEADER READOUT

The most focused vendor here — study conduct / data collection only (one of ten stages); AI is augmented, enhancing an FDA-cleared sensor platform rather than being the product.

Regulatory footprint is strong (clearances 2022–2023); named pharma sponsors are not publicly disclosed on company materials.[7]

Public claims; not independently validated. Not a buying recommendation.

LIFECYCLE COVERAGE
3/10

Aural Analytics

SPEECH BIOMARKERS FOR CNS · LINUS HEALTH

AUGMENTED AI

Targets: *Subjective neuro rating scales; rater / site variability; insensitive CNS endpoints; need for remote bulbar & cognitive measures.*

WHAT THEY DO

- Speech Vitals platform turning minutes of recorded speech into objective brain-health metrics — speaking rate, articulatory precision, phonatory duration.[8]
- ML / NLP on acoustic and cognitive-linguistic features; FDA-registered as an assessment aid. Acquired by and now operating within Linus Health (March 2024).[9]

OPERATIONAL PROBLEMS ADDRESSED

- Objective, repeatable remote neuro assessment from a smartphone.
- Sensitive digital endpoints for CNS trials (ALS, AD, MS, PD, HD).
- Reduced rater and site variability versus subjective scales.
- Earlier detection of bulbar and cognitive decline.

LIFECYCLE COVERAGE — AVERY & RILEY SNAPSHOT

P02 · P03 · P04

P01	**P02**	**P03**	**P04**	P05	P06	P07	P08	P09	P10

FDA Breakthrough[10]

Device designation for Speech Vitals-ALS (2023)

1st[11]

Speech biomarker to signal therapeutic efficacy in a major interventional trial (HEALEY ALS)

30+[9]

Clinical studies, including the Bio-Hermes Alzheimer's trial

SENIOR-LEADER READOUT

Coverage concentrates in protocol / endpoint design, feasibility, and study startup — three of ten stages; AI is augmented, with speech biomarkers aiding rather than replacing clinical assessment.

Now operating within Linus Health (acquired March 2024); exact effect sizes from the pridopidine arm are not publicly disclosed.

Altoida

LIFECYCLE COVERAGE
3/10

AR MOTOR-COGNITIVE NEURO BIOMARKERS | PERIPHERAL AI

Targets: *Slow, subjective cognitive batteries; weak screening / stratification for CNS & dementia trials; need to enrich trial populations.*

WHAT THEY DO

- NeuroMarker platform — a ~10-minute self-administered smartphone / tablet test using augmented-reality motor-cognitive tasks; sensors feed ML "Digital Neuro Signatures."[12]
- Produces neurological composite scores predicting cognitive decline / Alzheimer's risk; validated in-clinic and at home (investigational use).[13]

OPERATIONAL PROBLEMS ADDRESSED

- Early, objective cognitive assessment versus 2–4 hour pen-and-paper batteries.
- Screening, stratification, and enrichment for CNS & dementia trials.
- Remote, at-home cognitive endpoints.
- Predicting MCI-to-Alzheimer's conversion to enrich populations.

LIFECYCLE COVERAGE — AVERY & RILEY SNAPSHOT

P03 · P04 · P08

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

FDA Breakthrough[14]
Device designation (2021) — predicting MCI→AD within 12 months

94% / 82%[15]
Prognostic accuracy / specificity (vendor / media claim)

780+[12]
Digital biomarkers across 11 cognitive domains

SENIOR-LEADER READOUT

Coverage centers on site / participant selection, study startup, and data / endpoints — three of ten stages; the model is AI-driven, but the platform is investigational-use-only.

The 94% / 82% figures trace to vendor study claims, not independent peer review; notable pharma partner is Eisai.[16]

Public claims; not independently validated. Not a buying recommendation.

AiCure

LIFECYCLE COVERAGE
3/10

COMPUTER-VISION ADHERENCE + DIGITAL BIOMARKERS | NATIVE AI

Targets: *Unverified dosing / adherence; patient dropout; weak self-report data; central monitoring of adherence risk across sites.*

WHAT THEY DO

- H.Code platform uses the patient's smartphone camera and computer-vision AI to visually confirm medication ingestion and verify dosing remotely.[17]
- Captures digital biomarkers (facial, voice, motor) and predictive analytics flagging early-termination risk across sites.[18]

OPERATIONAL PROBLEMS ADDRESSED

- Confirming dosing / ingestion remotely without in-person observed therapy.
- Capturing behavioral / digital biomarkers at scale.
- Improving patient engagement and retention; reducing dropout.
- Central monitoring of adherence risk across multinational sites.

LIFECYCLE COVERAGE — AVERY & RILEY SNAPSHOT

P05 · P06 · P07

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

89.7% vs 71.9%[19]

Adherence vs modified-DOT over 24 weeks (AbbVie Ph2, peer-reviewed)

92%[17]

Participant retention; 1.5M+ doses captured

28[18]

Phase I–IV trials; 4,000+ patients across 43 countries

SENIOR-LEADER READOUT

Coverage spans enrollment retention, study conduct, and monitoring / oversight — three of ten stages; AI is native, with computer vision at the core of dosing verification and biomarkers.

Strongest proof is the peer-reviewed AbbVie adherence result; retention and dose-capture figures are vendor-reported across its trial base.

CROSS-VENDOR PATTERNS FOR SENIOR LEADERS

Three patterns to carry into your diligence

01

New endpoints, narrow footprints

These vendors touch fewer lifecycle stages than platforms — but they create novel, objective measures (speech, gait, vision, physiology) that didn't exist before.

02

AI centrality is a buying question

Native vs augmented vs peripheral changes the risk and the moat. Ask whether AI is the product or a feature on a sensor or assessment.

03

Regulatory grade separates the field

FDA clearances, Breakthrough designations, qualification, and peer-reviewed evidence — not demos — decide whether a measure can carry a label claim.

THE BOTTOM LINE FOR ADOPTION

"Which endpoint is hard to measure, valuable enough to matter, and validated enough to trust?" — that question, not sensor novelty, should drive the next conversation.

HOW TO USE THIS ISSUE

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Which endpoint is being measured, and is it novel, valuable, and hard to capture any other way?
- Is the measure validated or qualified — FDA clearance, Breakthrough, biomarker qualification, peer-reviewed evidence?
- How central is the AI — is it the product (Native), or a feature on a sensor or assessment (Augmented / Peripheral)?
- What is the data-integrity, patient-burden, and decentralized-deployment story across sites and geographies?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- eCOA / ePRO & patient-reported outcomes
- Imaging & digital pathology biomarkers
- Decentralized-trial orchestration platforms
- Wearable & sensor data infrastructure
- Biomarker qualification & regulatory strategy

Source standard. *All data is publicly sourced unless otherwise noted. Public claims are summarized from vendor websites, customer stories, peer-reviewed papers, regulatory actions, or industry-publication summaries and should not be treated as independently validated performance guarantees.*

REFERENCES & SOURCES

References

Reference numbers are assigned by first appearance in the body and shown as sequential superscripts throughout this issue.

1 Koneksa, company website & clinical-pipeline materials (digital-biomarker programs).

2 Koneksa, "Advanced Modeling & Analysis Services," company website.

3 Koneksa, "Digital Biomarkers FAQ," citing Lavine et al. (2024) at-home vs in-clinic sample-size simulation.

4 Fierce Biotech, "Novartis and Takeda join $45M Series C funding for Koneksa Health."

5 Empatica, "Clinical Trials" / platform page (FDA-cleared biomarkers; 120+ trials; compliance).

6 Empatica seizure-detection accuracy & AI seizure-forecasting (NeurologyLive; BusinessWire, 2024).

7 Empatica, FDA-clearance announcements (2022–2023), company blog & PR Newswire.

8 Aural Analytics, company website (Speech Vitals platform).

9 Linus Health, "Linus Health acquires Aural Analytics" press release (March 2024); 30+ studies.

10 BioSpace / Business Wire, FDA Breakthrough Device designation for Speech Vitals-ALS (2023).

11 Business Wire, HEALEY ALS Platform Trial — pridopidine arm speech-biomarker result (Feb 2023).

12 Altoida, "Our Science" / NeuroMarker platform (digital-biomarker count, domains).

13 Altoida, peer-reviewed AR validation study (npj Digital Medicine) & company materials.

14 Altoida, "FDA Breakthrough Designation" announcement (2021).

15 Being Patient / OpenMinds coverage of Altoida prognostic-accuracy claims (94% / 82%).

16 MedGadget, Altoida–Eisai Innovation funding & research partnership (2021).

17 AiCure, company website (H.Code platform; retention & dose-capture statistics).

18 AiCure / PR Newswire, computer-vision digital-biomarker platform launch (28 trials; 4,000+ patients).

19 Bain et al., peer-reviewed schizophrenia adherence study (AbbVie ABT-126), NCBI / PMC.

Disclosure: Some companies referenced may be current, former, or prospective advisory relationships of Avery & Riley; others are included independently for informational purposes. Lifecycle-coverage and AI-centrality reads use Avery & Riley's vendor framework compiled from public materials and directory review; they are a snapshot as of the latest publicly known data and may change as vendors add, discontinue, or reposition capabilities. Aural Analytics is now part of Linus Health (acquired March 2024).