Koneksa Launches the First Intelligent Submission Software to Unify Clinical Submissions in One Auditable Workflow

Lodestar™ eliminates submission pipeline fragmentation through AI-assisted, auditable workflow, validated in completed LEARNS clinical study.

NEW YORK, NY, UNITED STATES, June 2, 2026 /EINPresswire.com/ -- Koneksa Health (Koneksa), a measurement and data science partner for clinical development, today announced the launch of Lodestar™, the first Intelligent Submission Software for clinical trials. Lodestar™ is a regulated, AI-assisted platform that connects every step of the clinical submission pipeline into a single, continuously validated, 21 CFR Part 11 audit-trailed workflow supporting FDA and EMA submissions. The software is now available in early access with select sponsor and CRO partners.

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>
> *Michael Mendoza, SVP, Biometrics & Data Science, Koneksa*

The need to accelerate clinical development has never been more urgent. Submission delays carry significant financial and competitive consequences, with industry analyses estimating that even a 12-month delay can put more than $400 million in net present value at risk for a single sponsor. Yet across many programs, the path to submission readiness remains fragmented by disconnected tools, sequential handoffs, and review cycles spanning multiple teams, compounding delays when issues are identified late.

Lodestar™ addresses this directly. The software sequences ten connected workflow steps from EDC ingest through eTMF push, each AI-assisted, each requiring explicit human approval before advancing, with regulatory artifacts including Define.xml, SDRG, ADRG, BIMO inspection packages, and eCTD Module 5.3 generated directly from system metadata and staged for FDA and EMA transmission. Conformance checks and double-programming QC run continuously throughout, surfacing issues when they are least expensive to fix. Full workflow detail is available on the Koneksa website.

“The gap between database lock and regulatory filing can stretch months, time that carries real financial and patient consequences for sponsors and for the programs waiting on their data,” said David Lynch, Ph.D., CEO, Koneksa. “Closing that gap reliably, at scale, and in a way that holds up under regulatory scrutiny is exactly the kind of problem Koneksa exists to solve.”

Lodestar™ was validated using data from the completed LEARNS clinical study, Koneksa’s observational Parkinson’s disease program evaluating wearable, mobile, and digital biomarker endpoints. Outputs were compared against a traditional submission workflow, showing an 80% reduction in programming hours, a 65% reduction in biometrics costs, QC cycles completing 16 times faster, and 100% audit-ready outputs end to end. The software is designed for regulated submission environments from the ground up, aligned with the FDA’s January 2025 guidance on AI in regulatory decision-making and built to GAMP 5 standards across more than 20 therapeutic areas.

“We built Lodestar™ because we’ve lived this problem inside the biggest CROs and eClinical platforms in the industry,” said Michael Mendoza, SVP, Biometrics and Data Science, Koneksa. “Every piece of the submission stack existed, but nothing connected it. Sponsors and CROs were spending months doing reconciliation work that the software should have been doing. Lodestar™ is what happens when you stop patching the gap and start engineering the pipeline.”

Lodestar™ is currently available through early access with select sponsor and CRO partners, with broader availability expanding throughout 2026. Koneksa will present Lodestar publicly at an upcoming webinar on Tuesday, July 21, 2026. To request early access or schedule a demo, visit koneksahealth.com or contact hello@koneksahealth.com.

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