

Your North Star for Regulatory Submissions

koneksa | **LODESTAR**

Introducing the first intelligent submission software guiding your team through every step to filing, under *one AI-assisted, auditable workflow*.

Most biometrics teams spend the majority of their time on mechanical work scattered across disconnected tools with no single source of truth. Lodestar™ changes that. It is the first software to connect every step of the submission pipeline in one continuously validated, 21 CFR Part 11 workflow, from EDC ingest through eTMF push.

80%
Less Programming Time

16X
Faster QC Cycles

Validated using data from the completed LEARNS clinical study. Outputs compared against a traditional submission workflow.



65%
Lower Biometrics Costs

100%
Audit-ready Outputs

Koneksa built Lodestar™ to power its own biometric operations, and the results speak for themselves. Every database build and biometrics program Koneksa delivers runs on Lodestar™.

Every Step of the Pipeline, in One Place

	Validation	Medidata	TLF + Packaging	Submission	LODESTAR
EDC Ingest	✓				✓
SDTM Mapping	✓	✓			✓
ADaM Generation	✓				✓
Protocol + SAP Overread					✓
TLG Shells + Render			✓		✓
QC + Sign-off					✓
SDRG / ADRG					✓
eCTD Assembly					✓
BIMO Package					✓
eTMF Push				✓	✓

Find Your Path to Submission



Let Koneksa run a Lodestar™-powered biometrics program for your study, from database build through eCTD submission. Faster delivery, lower cost, full accountability.
Our team. Our tools. Your data.



License Lodestar™ to run your own biometrics operations. The same validated pipeline, configurable for your study protocols, regulatory standards, and team workflows.
Your team. Your environment. Our pipeline.

Reach FDA + EMA submission faster and with more confidence with Lodestar™ through Koneksa, or licensed for your own team.

Contact us at: hello@koneksahealth.com
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