

The Submission Stack Was Never Designed to Move This Fast. *Until Now.*

Lodestar™ is the first intelligent submission software connecting biometrics, QC, regulatory artifacts, and eCTD assembly into one AI-assisted, auditable workflow.

Despite advances in automation and AI tooling, clinical submissions still rely on fragmented workflows, repeated handoffs, and manual reconciliation across programming, QC, and regulatory operations. Koneksa replaces that stack with *Lodestar™ Intelligent Submission Software*, designed to reduce cycle time, compress operational burden, and accelerate submission readiness.

From Fragmented Submission Workflows to Connected Delivery

A SIDE-BY-SIDE COMPARISON



vs.



Traditional Submission Stack

Disconnected tools, manual handoffs, and repeated reconciliation across biometrics, QC, publishing, and regulatory operations.

Koneksa's Lodestar™ Software

Connected orchestration with human oversight, continuous validation, and end-to-end traceability.

1

EDC INGEST



Manual exports, renamed files, reconciliation checks, and custom import workflows.



Direct ingestion with automated normalization and chain-of-custody validation.



DAYS → MINUTES

Reduced manual reconciliation burden.

2

SDTM MAPPING



Weeks of manual domain mapping and iterative validation cycles.



AI-assisted mapping generation with continuous validation and human approval.



6+ WEEKS → DAYS

Reduced programming workload + review cycles.

4

SAP OVERHEARD



Manual interpretation of endpoints, estimands, and analysis populations.



Structured extraction with review-ready analysis objects.



REVIEW CYCLES REDUCED

Faster downstream analysis preparation.

3

ADaM GENERATION



Independent dataset derivation and duplicate QC programming.



Automated generation from approved specifications and mappings.



REDUCED DUPLICATE PROGRAMMING

Fewer redundant derivation cycles.

5

TLG SHELLS + RENDER



Manual shell formatting followed by sequential rendering, packaging, reruns, and manual classification.



Parallelized execution and automated output organization from auto-generated, SAP-aligned shells.



WEEKS → DAYS, FASTER THROUGHPUT

Lower QC burden and rerun delays.

6

QC + SIGNOFF



Separate validation workflows and fragmented signoff documentation.



Integrated audit-ready approvals and traceability.



ACCELERATED QC REVIEW

Reduced manual tracking overhead.

7

SDRG / ADRG

Hand-authored documentation across disconnected source systems.



Metadata-driven draft generation with reviewer oversight.



DAYS → HOURS

Reduced documentation assembly burden.

8

eCTD ASSEMBLY

Manual file placement, validation, and publishing coordination.



Automated module assembly and manifest generation.



REDUCED PUBLISHING FRICTION

Reduced submission preparation time.

10

eTMF PUSH

Manual uploads and post-placement reconciliation.



Automated artifact routing with logged delivery events.



REDUCED ADMINISTRATIVE OVERHEAD

Improved downstream traceability.

9

BIMO PACKAGE

Cross-functional document gathering under compressed timelines.



Centralized inspection package generation from one source of truth.

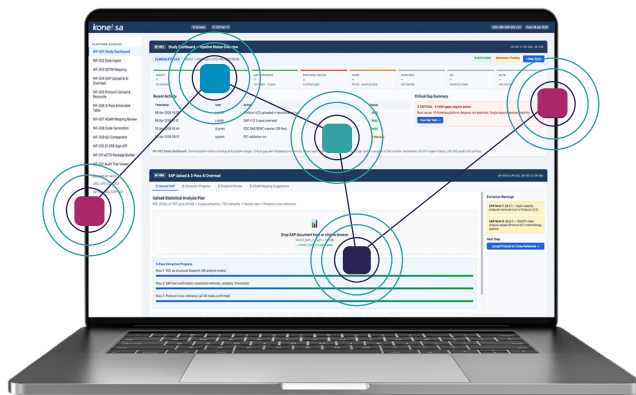


HOURS → MINUTES

Faster inspection readiness.



LODESTAR



The Cumulative Impact

FEWER MANUAL HANDOFFS

Reducing reconciliation across biometrics, QC, publishing, and regulatory operations.

FASTER SUBMISSION READINESS

Compressing downstream preparation timelines.

SCALABLE DELIVERY WITHOUT LINEAR HEADCOUNT GROWTH

Reducing operational burden across the submission lifecycle.

See the Lodestar™ Submission Workflow in Action

Now supporting select pilot engagements with sponsor and CRO partners.

REQUEST EARLY ACCESS

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