

Advanced Compliance Docs

Advanced Compliance Docs, powered by **NavaX AI**, embeds AI-powered capabilities across the creation, management, and maintenance of regulated Safety documentation such as PBRER, DSUR, PADER, as well as Pharmacovigilance Agreements (PVAs) and Pharmacovigilance System Master Files (PSMFs). The solution replaces fragmented and manual process with intelligent automation that orchestrates document authoring, review, approval, and submission.



Regulated Safety Documentation, Powered by NavaX AI



AI-Assisted Report Authoring

Harness AI to automatically gather, synthesize, and contextualize information from multiple sources and pre-populate report templates.



Intelligent Report Reuse

Enable faster, more consistent report creation by intelligently updating sections with the latest information from previously authored reports.



Collaborative Review

Support secure multi-author collaboration with configurable review workflows, version control, electronic approvals, and complete audit trails.



Pharmacovigilance Agreement (PVA) Management

Simplify the creation, review, approval, and maintenance of PVAs using standardized templates and intelligent workflow automation.



Pharmacovigilance System Master File (PSMF) Management

Maintain inspection-ready PSMFs through centralized content management, automated change tracking, and lifecycle controls.



Operational Dashboards

Gain real-time visibility into document status, reporting timelines, submission readiness, and operational performance.

See the value of Advanced Compliance Docs.

Powered by **NavaX™**



Efficiency Gains

Drive faster submissions by automating and augmenting critical workflows, including reducing manual document authoring by up to 70-80%.



Cost Savings

Automate manual processes, including medical writing authoring and management, to reduce labor and error-related expenses.



Audit and Inspection Readiness

Strengthen global compliance with enhanced traceability and inspection readiness via centralized document management and intelligent workflows.



Quality and Consistency

Produce higher-quality regulatory documents through AI-assisted content generation that ensure more consistent, reliable outcomes at scale.

**Ready to take
the next step?**



*Connect with us today to learn more
about Advanced Compliance Docs.*

Let's Talk