

ENNNOV REGULATORY SUITE

Ennov Dossier

Regulatory Dossier Management & Submission Publishing Software

A complete and scalable dossier management and submission publishing solution that helps regulatory teams create, manage, validate, publish, review, and maintain compliant submissions across global health authority requirements and formats.

The Publishing Challenge

Regulatory operations teams must produce compliant submissions across a growing mix of formats, regions, and lifecycle requirements. Supporting global submissions requires accurate structure, metadata, content, validation, and version control.

When documents, dossier structures, and publishing activities are managed separately, teams spend too much time locating the right files, confirming approved versions, rebuilding content, and tracking submission history. This creates rework, slows publishing, and increases compliance risk.

Organizations need one intuitive and unified publishing platform connected to controlled regulatory content, with the flexibility to support global requirements and the visibility to manage dossiers through every sequence and submission lifecycle.

Efficient and Intuitive Publishing

Ennov Dossier helps teams build, manage, publish, validate, review, and maintain regulatory dossiers using content from Ennov Regulatory Documents or connected third-party DMS systems. Publishers can add approved documents through search, views, or drag-and-drop from local files, while managing hyperlinks and reusable content within a single controlled dossier structure.

Configurable templates support global submission formats. Teams can manage eCTD sequences, lifecycle operations, Study Tagging Files, cumulative views, and submission history while keeping content synchronized with the latest approved document versions.

Interactive viewing, real-time progress tracking, validation, and publishing help teams improve submission quality and efficiency. AI-assisted capabilities further reduce manual work through document classification, AI-assisted translation, conversational AI, and agentic workflows.

> CORE CAPABILITIES

Global submission support, including: eCTD, NeeS, vNeeS, eCopy, & sequence-based support

Integrated validation & real-time progress tracking

Integrated regulatory archive & submission history

Dossier lifecycle, sequence, & operation management

Study Tagging Files & metadata management

Electronic submission & PDF volume publishing

> KEY FEATURES

Native connection with Ennov Regulatory Documents

Connectivity with third-party DMS environments

Intuitive drag-and-drop dossier assembly

Automated hyperlink maintenance

Content synchronization and reuse

AI-supported regulatory workflows and automation

Full-text search and exportable progress reports



**Cloud Based
or On Premises**



**Web-Based
Across Any Device**



Certified

Streamline Global Submissions and Accelerate Regulatory Publishing

Ennov Dossier helps regulatory teams accelerate submission publishing, reduce manual effort, and maintain compliance across global markets. As part of Ennov's unified compliance platform, it connects approved regulatory content with dossier assembly, validation, and publishing. By simplifying content reuse, minimizing rework, and improving visibility throughout the submission lifecycle, organizations can deliver accurate, compliant submissions faster and with greater confidence.



The Ennov Regulatory Suite

**REGULATORY
DOCUMENT
MANAGEMENT**

**SUBMISSION
PUBLISHING**

**REGULATORY
INFORMATION
MANAGEMENT**

**ENNOV
IDMP**

**DOCUMENT
TRANSFORMATION**

**ARTWORK
MANAGEMENT**

Why Choose Ennov?

HUNDREDS OF COMPANIES TRUST ENNOV

Over 25 years' experience, and 650+ Life Science customers, with many more in other industries.

Modern architecture and user interface: 100% web-based. Highly scalable. User-centric design.

Our commitment to your success: Very high customer satisfaction. 98.5% of projects delivered on time and within budget.

PROVIDING YOU FREEDOM OF CHOICE

Available as cloud-based or on-premises deployment: You can switch between deployment options at any time.

No IT skills required for system configuration and management.

Improved security and optimized performance: Data is hosted locally for total flexibility. Single tenancy minimizes business interruptions.

Learn more about our Unified Compliance Platform to support the entire Life Sciences product development continuum at www.ennov.com



REGULATORY

Our world-class Regulatory content and information management software accelerates HA approvals



QUALITY

Our comprehensive QMS improves operational efficiency and ensures regulatory compliance



CLINICAL

Our total solution for capturing and managing Clinical Trial information streamlines clinical operations



COMMERCIAL

Our complete management of professional events ensures DMOS, EFPIA, HCP and COI compliance



PHARMACOVIGILANCE

Our end-to-end solution for collecting, reporting and analyzing human and vet PV data minimizes risk