

Company background & expertise

Weave was started in 2022 and has since developed the only AI-native cloud platform that supports the entire regulatory lifecycle. Customers span all segments of the ecosystem - from start ups and small biotechs to large pharmaceutical companies and global CROs. References are available upon request.

Product capabilities

• AI drafting

- Auto-draft and AI refine
 - + All of M1 (incl. IB)
 - + All of M2
 - + All of M3
 - + All of M5
- Insert and manage always-current links
 - + Intra-document
 - + Inter-document
 - + Literature citations
- Customize AI templates
- Dynamically fill in variables
- Manually edit and format all content
- Auto-extract and insert figures
- Automatically create Table of Contents, List of Tables, and List of Figures
- View version history and restore
- AutoUpdate dossier content (beta)
- Export to Word (DOCX)

• Dossier management

- Dossier section status tracking
- Built-in eCTD
- General purpose documents (outside the eCTD)
- Dossier content expansion (clinical study or additional drug substance or drug product)

• AI data room

- File types supported: PDF, RTF, DOCX, XLSX
- Custom tabulation of data automatically extracted from source files
- Instant Q&A of files in data room
- Simple search by keyword or deep search by description
- Automatic tagging/classification of source files
- Automatic summarization of source files
- Preview of source files
- Uploaded folders and maintenance of folder structure

• Review & data verification

- Sentence-level reference tracing
- Data verification mode with sentence-level tracking
- In-platform review and commenting
- AutoReview of content (beta)

• Organization management

- Parent and child organizations
- Controlled user roles and permissions
- Configurable dossier visibility

Infrastructure & data security

- The Weave Platform is hosted on AWS and uses commercial providers for LLMs, namely OpenAI.
- Weave has Zero Data Retention agreements in place with all LLM providers that may contact customer data.
- Weave does not permit machine learning/training on any customer data, nor does it permit its vendors to.
- Weave follows industry-best security and privacy practices. Details are available upon request and Weave is happy to complete customer IT questionnaires and vendor approval processes.
- Role-based permissions and access control are available in the Weave platform.

Implementation & support

- Onboarding can be up to 4 weeks, to ensure all users are trained and proficient within the platform. Users can then independently upload files, generate content, and customize AI templates to suit unique organizational needs.
- Training is delivered during hands-on sessions over 2 weeks depending on user availability.
- Customer Success maintains regular engagement after onboarding so key milestones are met and all questions are addressed promptly.
- Ongoing customer support is available via email with guaranteed response times.
- Additional support for template customization beyond initial onboarding is available.

Regulatory has one home.

In today's fast-paced environment, staying ahead requires speed, precision, and adaptability throughout the regulatory lifecycle. Weave sets a new standard with a software platform that has AI-infused throughout the workflow to simplify complex processes from data organization to content creation, submission, and beyond.

The Weave Platform provides a single source of truth for the life of your therapeutic candidate, enabling teams to seamlessly collaborate, accelerate project timelines, and deliver high quality, submission-ready content for each required document or report.

Visit our website for more information.

