THE LOOM

A QUARTERLY NEWSLETTER FROM WEAVE BIO

Weaving the Future

Ruminations from our CPO, Brandon Rice

A new era for regulatory submissions

2024 was a big year for Weave. We launched AutoIND, welcomed our first customers, and together generated our first INDs (submission pending...). In doing so, we turned months into minutes, transformed tedium into delight, and began defining a new paradigm for regulatory submissions.

The shift is simple but profound: submissions are no longer written—they are generated. AI now handles tasks like data extraction, table construction, and summarization, allowing teams to focus on strategy, interpretation, and narrative.

The experience is now closer to design and engineering than drafting and editing—though humans remain firmly in the driver's seat. With AutoIND, we've built an end-to-end platform for IND submissions—organizing source data, drafting and refining content, reviewing and QC'ing documents, and publishing—all with AI support at every step. The result? High-quality submissions in half the time and effort.

What's next in 2025?

The IND was just the beginning. Every regulatory submission follows the same core workflow—upload, draft, refine, review, QC, publish—so we need not build a new platform for each document, we will simply extend the Weave Platform to support the entire regulatory lifecycle.

This year, we're expanding into clinical-phase filings—starting with clinical study reports, protocols, and amendments. These will be followed by safety reports, annual reports, and improved IBs. By year-end, we aim to move beyond the clinic toward NDAs and BLAs—check in mid-year for an update on that plan. Human expertise in drug development is irreplaceable, but the roles themselves are evolving.

Join us in shaping the next era of regulatory submissions.

In this newsletter you will find:

Latest news, product updates, resources, and more. Keep Reading!

AutoIND

New threads of functionality

WE'RE EXCITED TO BRING YOU THE FIRST RELEASE OF THE YEAR, FILLED WITH ENHANCEMENTS DESIGNED TO MEET YOUR EVOLVING NEEDS.

Data tags

To more effectively categorize and use source data for generation, each file in the Data Room now contains data tags. Instead of generating entire sections with many source files, data tags enable content generation of individual parts of a section using only the most appropriate files or source sections as inputs. This offers greater flexibility when using content templates and providing greater control over the type and length of generated content.

Data room exploration

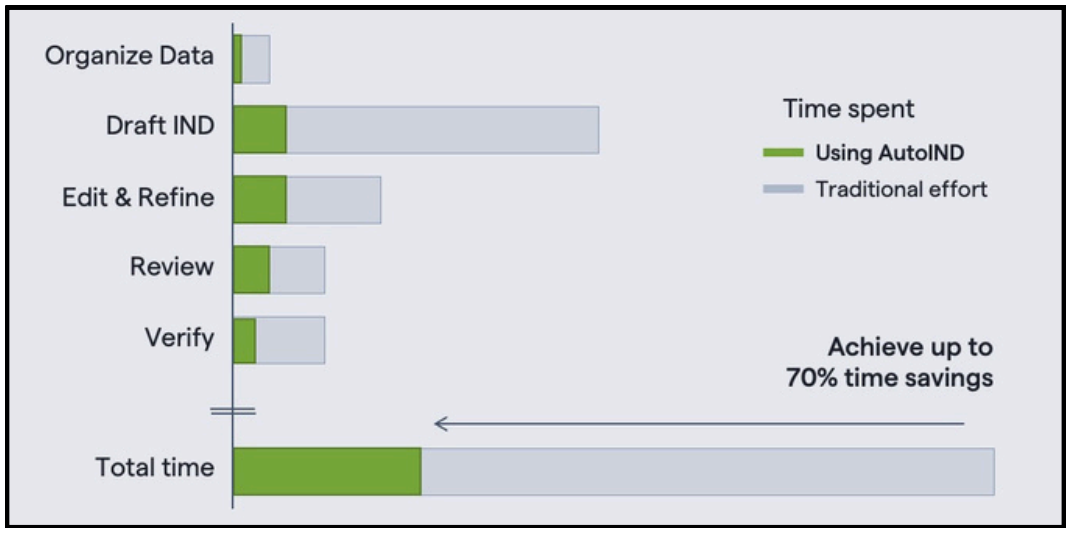
Data Room now has two new tabs in addition to Files Overview and Explore. The Overview tab shows a customizable tabular view of all the files in the Data Room with the ability to add custom columns. The Explore tab allows users to describe the data they want to see or ask open-ended questions about a selection of their files.

Publishing v1

An important and required feature of every IND submission is the hyperlinks that connect content in one section of the IND to another (either within the same document, in other parts of the dossier, or to source files in Modules 4 & 5). Now those hyperlinks can be created while drafting each document. Additionally, these links are automatically updated when the content to which they link is updated (e.g. the relative numbering) which reduces time needed for link validation immediately prior to submission.

SEE FULL RELEASE NOTES

Reclaim your time with AutoIND



AutoCT

The next strand of innovation

COMING SOON: THE WEAVE PLATFORM WILL ALSO SUPPORT THE CLINICAL PHASE OF REGULATORY.

Building on the success of AutoIND, Weave will soon launch AutoCT. AutoCT streamlines and accelerates the drafting, refinement, and review of critical documents, including clinical study reports, protocols, amendments, safety reports, annual reports, and Investigator's Brochures (IBs).

By eliminating redundant work and ensuring consistency across filings, AutoCT empowers regulatory teams to focus on high-value strategic activities.

SIGN UP FOR UPDATES

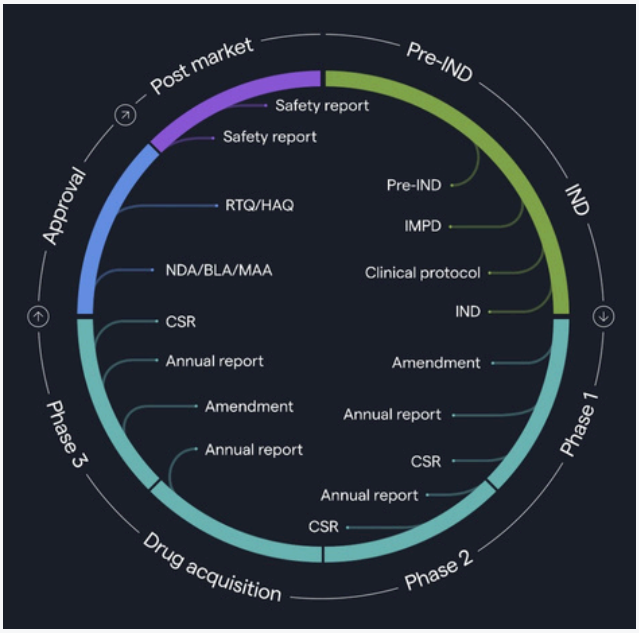
Threading the Path

Your full lifecycle, unified

WEAVE SETS A NEW STANDARD WITH OUR AI-NATIVE REGULATORY AUTOMATION MANAGEMENT PLATFORM

Our platform provides a single source of truth for your therapeutic candidate, enabling seamless collaboration, faster timelines, and high-quality, submission-ready content.

We are engaging a limited number of Design Partners to shape core functionality for our full regulatory lifecycle support launching in 2025. Design Partners inform, test, and become the first users of enhanced features.



INTERESTED IN DESIGN PARTNERS

Weaver Spotlight

Meet the Team

Wes Galliher

Staff Product Manager

WITH A CAREER SHAPED BY SCIENTIFIC RIGOR, PROBLEM-SOLVING, AND A PASSION FOR MAKING REGULATORY PROCESSES SEAMLESS, WES IS AN INTEGRAL PART OF THE WEAVE TEAM.

Threading it all together

With 20 years of experience spanning pharma, biotech, and software, Wes plays a key role on our team. His background in bioorganic chemistry, consulting, and product management helps drive cutting-edge regulatory automation for Weave's customers.

The fabric of his life

Family man: married to Crystal with two amazing kids, Grant and Serena.
BBQ enthusiast: currently perfecting smoked pork before moving to brisket.
Must haves: a good cup of coffee, his faith, and something to fidget with.

Weaving insights

"I thrive in Weave's culture of trust, innovation, and rapid experimentation. Working with a team that's both customer-driven and forward-thinking keeps things exciting, and having the freedom to solve complex problems makes every day rewarding."

MEET MORE OF OUR TEAM AT THESE UPCOMING EVENTS:

RAPS GRSC
March 11-12, 2025 | Baltimore, MD

Stanford Drug Discovery Symposium
April 28-29, 2025 | Stanford, CA

FIND MORE EVENTS