Weave Bio Launches NDA Workflow Designed in Partnership with Parexel; Extending AI-Native Platform Coverage Across the Full Regulatory Lifecycle

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Initial performance data demonstrates 60%+ acceleration in NDA authoring timelines.

SAN FRANCISCO & RALEIGH, N.C.--(BUSINESS WIRE)--Weave Bio, the leader in AI-native regulatory automation for drug development, and strategic partner Parexel, a leading global clinical development partner, today announced that the Weave platform now supports New Drug Application (NDA) submissions, advancing the company's coverage of the full regulatory lifecycle.

Parexel brings more than 40 years of regulatory experience and a track record of successful NDA submissions to the partnership. Through Parexel's active use of the platform for real-world NDA submissions, Weave has delivered more than 60% faster authoring timelines compared to traditional methods—without compromising quality.

Preparing an NDA means synthesizing years of clinical, non-clinical, and manufacturing data into a single, comprehensive package under intense time and quality pressure. Historically, this has meant months of manual work for regulatory teams. The Weave platform applies AI-native data extraction, document authoring, content verification, and workflow automation, freeing regulatory scientists and regulatory writers to focus on the strategic work of narrative design.

"NDA submissions are the highest-stakes moment in a drug's path to approval. Our customers deserve a platform that helps them meet that moment with speed, quality, and confidence," said Brandon Rice, Co-Founder and CEO of Weave Bio. "Today we are delivering exactly that, and having Parexel's expertise as part of this expansion is a clear signal of the standard we are building toward."

As a strategic design partner, Parexel's deep regulatory consulting expertise across clinical, non-clinical, clinical pharmacology and chemistry, manufacturing, and controls (CMC) directly informed how the Weave platform was refined to meet the demands of NDA submissions. The platform has been upgraded to support the scale and collaboration required by NDAs, in addition to new AI templates supporting NDA-specific content. While any sponsor may leverage Weave Bio's new NDA templates, Parexel will maintain a defined period of exclusivity as the only CRO with access to the co-developed templates.

"Parexel has earned its reputation by delivering the highest standard of regulatory quality for sponsors with speed and precision—including critical NDA submissions," said Paul Bridges, President, Consulting, Parexel. "Our partnership with Weave enhances that leadership by pairing our deep regulatory expertise with advanced AI that accelerates authoring and strengthens consistency across submissions."

NDA support is available now on the Weave platform. Learn more at weave.bio.

About Weave Bio

Weave Bio is an AI-native software company transforming how novel therapies navigate the complex path from lab to market. The Weave platform streamlines regulatory content preparation and lifecycle management for pharmaceutical companies, biotech firms, CROs, and regulatory consultants by infusing AI into every step of the workflow, from data extraction and authoring to review and verification, yielding compliant, submission-ready regulatory dossiers with unprecedented speed.

Founded in 2022 and headquartered in San Francisco, Weave is backed by leading investors including USVP, Innovation Endeavors, Magnetic Ventures, Character, TMV, and Serrado Capital, and trusted by innovative biopharma companies worldwide.

For more information, visit weave.bio and follow us on LinkedIn.

About Parexel

Parexel is a leading global clinical development partner providing insights-driven Clinical and Consulting solutions to the world's life sciences industry. Leveraging deep local knowledge and a global breadth of clinical, regulatory and therapeutic expertise, our 22,000+ global employees worldwide work in partnership with biopharmaceutical leaders, emerging innovators and sites to design and deliver clinical trials with patients in mind — broadening access and making clinical research a care option for anyone, anywhere. Our proven track record spans 40+ years and drives us forward, advancing clinical research in healthcare's most complex areas while harnessing innovation to drive efficiencies across every phase of the clinical development process. Our insights-driven approach, proven delivery and trusted execution are accelerating the delivery of life-changing treatments to patients — With Heart®. We continue to earn recognition industrywide, including the 2025 Scrip Award for "Best Contract Research Organization – Full-Service Provider," 2024 Fierce Biotech CRO Award for "Innovative Approaches to Patient-Centric Research" and the 2024 and 2023 Society for Clinical Research Sites (SCRS) Eagle Award for advancing the clinical research profession through strong site partnerships.

For more information, visit parexel.com and follow us on LinkedIn, X, Facebook and Instagram.

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