Parexel Announces AI Partnership with Weave Bio to Accelerate Regulatory Submission Processes

September 30, 2025

Collaboration leverages Parexel's proven regulatory expertise and Weave Bio's AI-native platform, aims to speed up market introduction of new therapies

RALEIGH, N.C., Sept. 30, 2025 (GLOBE NEWSWIRE) -- Parexel, a leading global clinical research organization (CRO) providing insights-driven Clinical and Consulting solutions to the world's life sciences industry today announced a partnership with Weave Bio, a pioneer in AI-native regulatory automation management solutions, aimed to accelerate regulatory submission processes and the time to market for new therapies. Under the agreement, Parexel will serve as Weave's CRO design partner and will leverage Parexel's extensive regulatory consulting expertise across clinical, non-clinical, clinical pharmacology and chemistry, manufacturing, and controls (CMC) to enhance Weave's AI platform and product pipeline. In addition, Parexel will maintain a period of exclusivity as the only CRO licensed to use Weave's innovative solutions after new products launch.

"This partnership represents a significant advancement in Parexel's vision to leverage AI to speed clinical research processes, enhance first-time quality and accelerate the delivery of life-changing therapies to patients," said Paul Bridges, President, Consulting, Parexel. "We're beginning this partnership by addressing an area where sponsors feel extreme urgency – early regulatory authoring and submission preparation. By combining Weave's cutting-edge AI technology with the human-in-the-lead expertise of Parexel Consulting, we're helping teams move faster and with greater confidence while maintaining the highest levels of quality and compliance."

Parexel has already leveraged Weave's flagship offering, AutoIND, to support Investigational New Drug (IND) applications, and has been able to complete them 50% faster than traditional IND authoring timelines. These scalable efficiency gains enable high quality INDs to be developed at a transformative pace, supporting sponsors with the time-sensitive step of initiating new clinical trials sooner than current industry timelines. Weave's AutoIND functionality is now part of Weave's comprehensive regulatory workflow solution, The Weave Platform, that spans the entire regulatory lifecycle.

"AI tools are only as strong as the people behind them. Human experts provide the context that guides our platform and help translate its findings into action," said Lindsay Mateo, Chief Commercial Officer at Weave. "Through this partnership, Weave will tap into Parexel's deep regulatory expertise to refine and expand our solutions across the drug development industry."

Parexel and Weave are presenting at the Regulatory Affairs Professionals Society (RAPS) Convergence on October 7-9 in Pittsburgh, Pennsylvania and will discuss the partnership during presentations and at their booths.

Parexel Booth: #606

Weave Bio Booth: #421

Thought leadership session: *Speed Without Shortcuts: Navigating Regulatory Boundaries for AI Applications in Clinical Trials* featuring

- Tala Fakhouri, Vice President Consulting, AI & Digital Policy, Real-World Research, Parexel
- Ryan Zettle, Head of Regulatory Submissions, Americas, Regulatory Consulting, Parexel

Sponsored Presentation: *Lessons from a comparative analysis of old and new AI-infused regulatory processes*

- Brandon Rice, CEO & Co-Founder

About Parexel
Parexel is a leading global clinical research organization (CRO) 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 24,000+ professionals 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 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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About Weave Bio
Weave Bio is an **AI-native**, cloud-based, software company that is **redesigning regulatory workflows** — transforming how novel therapies navigate the complex path from lab to clinic. The Weave Platform is an end-to-end solution that streamlines regulatory content preparation and lifecycle management for pharmaceutical companies, biotech firms, CROs, and regulatory consultants. Weave infuses AI into every step of the workflow, from data extraction to authoring to review and data verification, yielding compliant, submission-ready regulatory dossiers with speed.

The Weave Platform has been **widely adopted** for preclinical IND preparation and earned industry recognition as the "Biotech AI Innovation of the Year" award winner. Weave has since expanded capabilities across the platform to encompass clinical and approval-stage submissions, delivering a comprehensive AI workbench that **accelerates regulatory timelines by over 50%** while improving review **quality** and ensuring **compliance** with FDA, EMA, and global regulatory standards.

Founded in 2022 and headquartered in San Francisco, Weave bridges life sciences, regulatory expertise, AI innovation, and enterprise software to solve critical bottlenecks in drug development. For more information, visit weave.bio and follow us on LinkedIn.

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