Scientific Rigor at Speed: Trace Biosciences' First IND Experience

Preparing a first IND is not a matter of assembling text or compiling reports. It requires constructing a coherent regulatory argument that integrates preclinical evidence, CMC strategy, and clinical intent into a single, defensible narrative that remains internally consistent, traceable to source data, and aligned with regulatory expectations as drafts evolve. For Trace Biosciences, a company developing a nerve-targeted molecular imaging agent, achieving this for its first IND under tight timelines required a drafting approach that could scale faster than headcount while keeping scientific and regulatory judgment firmly human-led.

Execution Snapshot

2
employees at contract start

14 days
contract to first IND draft

50 days
submission-ready IND

FDA approval within 30 days
with limited questions

The Coordination Challenge in a First-Time IND

One of the most time-consuming aspects of Trace's IND preparation was maintaining internal consistency across modules. Technical summaries, narrative sections, and supporting descriptions needed to remain aligned as content evolved. Even small changes—such as updated interpretations of preclinical findings or refinements to CMC descriptions—could cascade across sections if dependencies were not tightly managed.

This risk was compounded by the need to maintain FDA-appropriate language and regulatory logic throughout the submission. As a first-time IND submitter, Trace relied heavily on subject-matter experts and external advisors to ensure that descriptions, justifications, and conclusions were framed correctly. Without a shared drafting structure, teams risked spending more time reconciling drafts than evaluating scientific and regulatory merit.

Establishing Structure and Regulatory Logic

Using the Weave Platform, Trace worked within customizable, structured templates designed around how IND documents are actually reviewed. These AI-assisted templates clarified expectations around scope, level of detail, and cross-section alignment early in the drafting process, allowing contributors to work from a shared framework rather than independent outlines.

This structure proved especially valuable during iteration. As drafts evolved in response to internal review and external feedback, changes could be applied consistently across sections without repeated manual reconciliation. Reviews increasingly focused on scientific interpretation and regulatory positioning rather than document mechanics.

By clarifying expectations upstream, Trace reduced downstream rework and improved predictability across drafting cycles.

Accelerating Drafting Without Losing Oversight

Trace used the Weave Platform as a central environment for drafting and iterating on key IND sections, including technical summaries and narrative components. AI-assisted drafting reduced the time required to generate initial content and apply revisions consistently across sections, while keeping experts in CMC, toxicology, quality, and clinical development fully engaged in review and decision-making.

"What Weave really allowed us to do was work directly with our subject-matter experts instead of spending time coordinating drafts across another layer of writers or consultants," — Connor Barth, Co-founder and CEO of Trace Biosciences. The largest efficiency gains occurred during early drafting, cross-section alignment, and revision.

Across the IND, Trace estimates a 60–75% reduction in drafting and revision time compared to traditional approaches. The team also reduced reliance on outsourced medical writing support by more than 60%, while continuing to use consultants for strategic oversight and final review.

This shift shortened feedback cycles and reduced the friction typically associated with incorporating comments across multiple sections. As a result, Trace was able to iterate more quickly while maintaining clear ownership and accountability for scientific and regulatory decisions.

Submission Outcome

The IND was submitted and cleared within the standard 30-day review window, allowing Trace to initiate first-in-human clinical studies on schedule. During the review period, the agency issued routine requests for information but raised no unexpected or substantive questions.

For the Trace team, the review experience was notable not for its speed, but for its predictability. Feedback aligned with expectations, and responses could be addressed without requiring restructuring of the submission or revisiting core assumptions. This reinforced confidence that the IND was clear, internally consistent, and well aligned with regulatory expectations across sections.

Equally important, the team entered submission with a strong understanding of the content and rationale behind the IND, enabling more efficient interaction during review and positioning the program to move forward without delay.

What This Customer Story Illustrates

Documentation foundations established early scale more effectively through IND execution. When structure, hierarchy, and drafting expectations are set upstream, first-time IND teams can integrate new data and evolving interpretations without repeatedly rebuilding sections or losing alignment across modules.

Consistency reduces operational drag during IND preparation. Clear structure and shared drafting standards limit downstream rework, shorten review cycles, and reduce the coordination burden that often slows lean teams as submissions take shape.

AI adds the most value when it supports expert-led IND workflows. By accelerating early drafting and managing repetitive alignment work, AI-assisted tools allow experienced scientists and regulatory leaders to focus on interpretation, judgment, and regulatory strategy rather than document mechanics.

Structure keeps IND reviews focused on substance, not reconstruction. With a stable drafting foundation in place, internal and external reviews can center on evaluating the science and regulatory rationale, rather than reconciling drafts or reassembling narratives under time pressure.