AI-Assisted Dossier Drafting: Time and Quality Study

Lindsay Mateo
CCO

This summary shares final, unpublished data from a collaborative study led by Weave Bio and a Top 20 global pharma company. The study compares AI-assisted content generation with traditionally authored content from two previously submitted IND studies. The goal of the study was to evaluate both preparation time and the quality of content using the two approaches.

To ensure a consistent and meaningful comparison, the study focused on IND sections 2.6.2 (Pharmacology), 2.6.4 (Pharmacokinetics), and 2.6.6 (Toxicology)—sections known for their analytical depth and narrative complexity, making them ideal for the assessment.

The final study results reinforce the significant time saving and quality boost found with platform-based, AI-assisted content preparation—especially when paired with expert oversight. The Weave Platform not only reduced preparation time, but also enabled rapid, real-time refinement of content. Users of the Platform were able to instantly generate first drafts, eliminate repetitive tasks like data formatting and rapidly iterate. While the study demonstrates how AI can increase speed and offer a collaborative space for data management, human oversight remains essential for strategic decision making, program planning, and incorporation of organization-specific preferences.

Productivity at Scale: Time Impact

At the start of the study, the pharma team shared that drafting similar IND content typically takes ~100 FTE hours. To measure comparable performance in The Weave Platform, preparation time was tracked for two dedicated pharma users, and content was prepared in The Weave Platform in under 4 hours—**resulting in ~97% time savings**.


Quality Scoring Framework

A Quality Scoring Framework was used to compare the first draft of AI-assisted content from The Weave Platform to the final draft of traditionally prepared content. Six key focus areas were assessed:

- Correctness
- Completeness
- Redundancy
- Conciseness
- Clarity
- Emphasis

Each area was rated by an unbiased evaluator on a scale of 0 to 3, with 3 representing the highest possible quality score. The scores were then aggregated to calculate an overall quality percentage for each drafted IND summary. This framework enabled a structured, side-by-side comparison of draft quality across both methods.
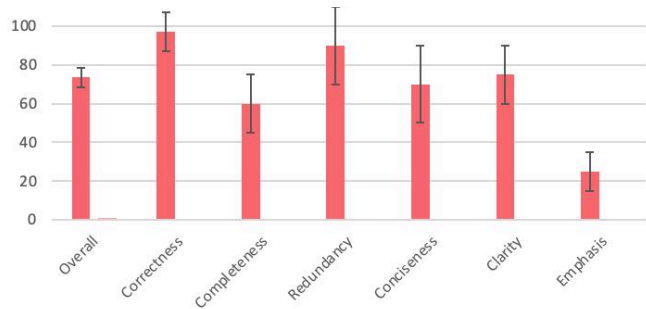
Content quality results, when aggregated across the six focus areas for the two fully scored study summaries, were as follows:

- Asset 1: The Weave Platform–generated **first draft content received an overall score of 89.5%.**
- Asset 2: The Weave Platform–generated **first draft content received an overall score of 66.7%.**

Across both IND studies, clear patterns emerged—revealing where AI-assisted drafting with The Weave Platform consistently performs well and where human input plays a critical role in shaping high-quality regulatory content. Examples include:

Focus Area: Correctness

In The Weave Platform, AI-assisted content consistently scores high where it matters most: accuracy and faithfulness to source documents.

Focus Area: Completeness

When prompted correctly in the AutoIND template, requested information is consistently included. For example, asking to "describe all endpoints" results in all endpoints being described.

Focus Areas: Redundancy & Clarity

AI-assisted content in The Weave Platform can be too wordy or too brief if not guided properly, resulting in inconsistent scores.

Focus Area: Conciseness

Structure, tone, and level of detail are highly consistent in AI-assisted content within The Weave Platform, leading to a high score.

Focus Area: Emphasis

AI-assisted content in The Weave Platform struggles with emphasis—human judgment remains essential to ensure a clear, focused narrative.

AI's Growing Role in the Regulatory Lifecycle

These findings highlight the value of combining AI-native tools with human expertise. In the study, The Weave Platform streamlined the drafting process and gave teams flexibility to refine content in real time—reducing manual effort and accelerating review cycles without compromising quality.

While AI boosts speed and consistency, expert oversight remains essential to account for organizational context and nuance. Together, a robust AI platform guided by expert users creates a more efficient, adaptable model for regulatory content development.