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A pharma sponsor stopped an AI-drafted submission error before it reached the regulator

Verification against the source data caught 214 proposed statements that the trial record did not support — before any of them were filed.

Scenario	Published	Orcher components
Global pharmaceutical sponsor · 9 active submissions	2026-08-12	Logic Scrubber, Immutable Audit Ledger, Role Identity Fabric

Summary

A pharmaceutical sponsor used agents to draft sections of regulatory submissions from trial data. Fluency was never the problem; unsupported assertion was. The Logic Scrubber verified each proposed statement against the source dataset before it could enter the document, and recorded both the check and its result.

214
unsupported statements refused before filing
across nine submissions

3.7%
of generated assertions failed verification

58%
reduction in medical-writer review hours per section

0
post-filing corrections attributable to drafted text
over the engagement period

The situation

- Agents drafted narrative sections from locked trial datasets, and medical writers reviewed the output line by line.
- Review was the bottleneck and the risk: a plausible sentence that overstated a secondary endpoint reads exactly like a correct one.
- The sponsor needed to show its inspectors what verification had occurred, not merely that a human had signed.

What Orcher enforced

- Every proposed statement was decomposed into checkable assertions and tested against the locked dataset before it could enter the document.
- Statements the data did not support were refused with the specific contradiction attached, rather than flagged for a reviewer to find.
- Role Identity Fabric bound each drafted section to the medical writer and the responsible medical monitor.

- The ledger holds the assertion, the check, the dataset version and the outcome — the artefact an inspector asks for.

The data

Submission section	Assertions generated	Refused	Refusal reason (most common)
Efficacy narrative	3,180	97	Effect size overstated vs dataset
Safety narrative	2,410	64	Adverse event count mismatch
Population description	1,120	18	Inclusion criteria drift
Statistical summary	1,860	31	Rounded value not reproducible
Discussion	970	4	Unsourced causal claim

Assertion-level verification results across nine active submissions.

Outcomes

- Medical writers moved from line-by-line checking to reviewing refusals and edge cases.
- The sponsor's inspection-readiness pack now includes verification evidence generated automatically.
- Two agent-drafted section types that had been prohibited internally were approved for use.
- The refusal log became a quality signal in its own right, surfacing two data-entry problems upstream in the trial record.

> “The model was never wrong in a way that looked wrong. That is precisely why the check has to be mechanical.”
>
> — Head of Regulatory Operations, global pharmaceutical sponsor (composite, modelled scenario)

Read further

- The Verified Execution Cycle — dippai.com/news/verified-execution-cycle
- The trust gap — dippai.com/research/the-trust-gap
- Full case study — dippai.com/case-studies/pharma-submission-verification

Disclosure. Modelled reference scenario. The organisation is representative of the sector and scale described, not a named customer. Figures are produced by Orcher's own observability and ledger instrumentation for this configuration over the stated period and have not been independently audited. Market figures carry their own source line.