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AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 06 THE WRITING LAYER — AI THAT AUTHORS THE REGULATORY RECORD

Yseop
GenAI regulatory medical writing

Narrativa
Agentic AI medical-writing automation

Certara
Biosimulation + AI regulatory writing

Freyr
AI-first regulatory cloud (RIM)

Glemser
AI-assisted regulatory document management

Companies featured in this issue may include current or prospective advisory relationships of Avery & Riley. All data is publicly sourced unless otherwise noted; company-stated claims are labeled as such throughout.

WHY THIS ISSUE EXISTS

Every trial ends in a stack of documents. AI is learning to author them.

Regulatory and medical writing is one of drug development's largest, most templated, and most deadline-bound workloads — clinical study reports, patient narratives, submission modules, labeling. This issue looks at five vendors bringing AI to that **writing layer**, each from a different origin: a generative-AI pure-play (Yseop), an agentic document platform (Narrativa), a biosimulation leader adding AI authoring (Certara), an AI-first regulatory-operations cloud (Freyr), and a structured-content specialist for regulatory labeling (Glemser). The common thread is a shift from AI that *summarizes* a trial to AI that *drafts the record the trial produces.*

WHAT SENIOR LEADERS SHOULD WATCH

01

First-draft authoring is the wedge. These tools now generate compliant first drafts of CSRs, narratives, and submission modules — not just summaries — compressing the slowest step in the submission timeline.

02

Provenance and control are the differentiators. Deterministic rules, source traceability, GxP validation, and human-in-the-loop separate regulated-grade tools from a generic chatbot.

03

Evidence maturity varies widely. Proof ranges from named third-party deployments to company-stated adoption — match the level of evidence to your own risk tolerance.

THE MEASURING STICK

The Avery & Riley 10-stage clinical-development taxonomy

Coverage bars throughout this issue map each vendor against the ten trial-lifecycle stages below — a **directional, point-in-time read** of where a vendor appears to operate. Each lit stage is colored by **source class** — **teal** where coverage is publicly documented (named customers or third-party sources), **gold** where coverage is company-stated. This issue's cohort clusters toward the documentation and submission end of the lifecycle (P09–P10), with reach upstream into protocol and regulatory writing.

P01
Portfolio / indication strategy

P02
Protocol design / feasibility

P03
Site identification / selection

P04
Study startup

P05
Recruitment / enrollment

P06
Study conduct / execution

P07
Monitoring / oversight

P08
Data management / cleaning / DBL

P09
Close-out / TMF / inspection readiness

P10
Post-trial insights / evidence



Directional reads from public materials & directory review — a snapshot, not vendor-reported metrics.

LIFECYCLE FOOTPRINT SNAPSHOT

Where each vendor plays across the trial lifecycle

Vendor	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	Footprint
Yseop GenAI regulatory medical writing		■							■	■	3 /10
Narrativa Agentic AI medical-writing automation		■				■		■	■	■	5 /10
Certara Biosimulation + AI regulatory writing	■	■						■		■	4 /10
Freyr AI-first regulatory cloud (RIM)		■		■					■	■	4 /10
Glemser AI-assisted regulatory document management		■						■	■	■	4 /10

■ Publicly documented (named customer / third-party) ■ Company-stated positioning

Footprint counts the trial-lifecycle stages a vendor is positioned to touch — a directional, point-in-time read, not a ranking or a measure of quality. A larger footprint reflects breadth of documentation scope, not superiority. Each vendor's writing tools naturally concentrate at the close-out and submission stages (P09–P10).

THE SENIOR-LEADER VIEW

Executive market map

VENDOR	PRIMARY CATEGORY	PROBLEM(S) TARGETED	PUBLIC EVIDENCE SIGNAL
Yseop	GenAI regulatory medical writing	First-draft CSRs, patient narratives, CTD & CMC submission documents; the manual authoring bottleneck	**Named users, third-party recognition.** TIME Best Inventions 2025 cites Lilly, Novartis, GSK & AstraZeneca as users; 165+ trials supported in 2024 (company-stated).
Narrativa	Agentic AI medical-writing automation	Patient narratives, CSRs, TLFs, eCTD submission docs; end-to-end drafting with validation	**Named third-party deployment.** Powers Blood Cancer United's Beat AML master trial (AWS-funded); president appointed to the CDISC board (2026).
Certara	Biosimulation + AI regulatory writing	Dose/trial simulation that shapes the submission, plus CoAuthor generative-AI regulatory writing	**FDA-licensed, public company.** FDA renewed/expanded biosimulation licenses (400+, 11 divisions); NASDAQ: CERT, $418.8M FY2025 revenue.
Freyr	AI-first regulatory cloud (RIM)	eCTD submissions, registrations, labeling, regulatory intelligence, post-approval variations	**Analyst-recognized platform.** Everest Group PEAK Matrix Leader 2024; freya fusion AI regulatory cloud launched July 2025.
Glemser	AI-assisted regulatory document management	Global & clinical labeling, structured/component content, SPL/ePI, submission-ready regulatory documents	**Named partners, industry recognition.** Quark & Navitas alliances embed/integrate its

Prepared for market education; not a buying recommendation.

Yseop

GENAI REGULATORY MEDICAL WRITING

LIFECYCLE FOOTPRINT
3/10

Targets: *medical writing, regulatory affairs and CMC teams at large biopharma — CSRs, patient narratives, safety summaries and CTD submission modules.*

WHAT THEY DO

- Yseop Copilot drafts first-draft CSRs, patient narratives, safety summaries and CTD/CMC submission documents inside Microsoft Word, integrated with Veeva Vault.[1]
- Its "Composite AI" pairs LLMs with symbolic rules, structured templates and RAG for deterministic, GxP-grade regulated content; hosted per customer on AWS.[1]

COMPANY & BACKING

- Paris-based; strategic backers include Novartis (dRx Capital) and Eli Lilly; €10M growth round led by Claret Capital Partners in September 2025.[2]
- Named to TIME's Best Inventions of 2025; the feature cites Eli Lilly, Novartis, GSK and AstraZeneca among its users.[3]
- Partnership with Cognizant to scale medical writing; 2026 BIG Innovation Award for regulatory writing.[4]

LIFECYCLE FOOTPRINT — WRITING & SUBMISSION

P02 · P09 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

165+[5]
Clinical trials supported in 2024 (company-stated)

>50%[6]
Cut in document-creation time, per customers (company-stated)

€10M[2]
Growth funding, Claret Capital, Sept 2025

SENIOR-LEADER READOUT

Yseop is among the most established generative-AI pure-plays aimed squarely at regulated medical writing, with document authoring — from CSRs to CMC modules — as its center of gravity.

For a senior leader it is a natural design partner where the goal is to compress first-draft cycle time on high-volume submission documents under GxP controls.

Company-stated claims summarized from public materials; not a buying recommendation.

Narrativa

LIFECYCLE FOOTPRINT
5 /10

AGENTIC AI MEDICAL-WRITING AUTOMATION

Targets: *sponsors, biotechs and CROs — patient safety narratives, CSRs, tables/listings/figures (TLFs) and eCTD submission documents.*

WHAT THEY DO

- Narrativa Navigator uses specialized regulatory AI agents to draft and validate patient narratives, CSRs, TLFs and eCTD submission documents with source traceability.[7]
- Built on generative models plus a proprietary knowledge graph; the architecture is positioned as GxP-validation-ready and HIPAA-ready.[7]

COMPANY & BACKING

- Founded 2015; moved to an agentic platform in 2025; president Jennifer Bittinger joined the CDISC board of directors in January 2026 — its first AI-vendor representative.[8]
- Blood Cancer United's Beat AML master trial uses Narrativa's generative AI (funded by an AWS grant) to automate narratives, TLFs and CSRs.[9]
- Published customer work includes Insud Pharma via its CSR Atlas module.[10]

LIFECYCLE FOOTPRINT — CONDUCT THROUGH SUBMISSION

P02 · P06 · P08 · P09 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

65,000+[11]
Regulatory documents generated in 2025 (company-stated)

76%[12]
Narrative time cut, top-3-pharma case (company-stated)

1[9]
Named master-trial deployment (Beat AML)

SENIOR-LEADER READOUT

Narrativa pairs an agentic document platform with the strongest third-party proof point in this cohort — a named, AWS-funded deployment on an active master trial — plus a seat on the CDISC board.

It suits leaders who want breadth across the documentation lifecycle, from in-trial safety narratives to submission-ready CSRs, with a partner already visible in the standards community.

Company-stated claims summarized from public materials; not a buying recommendation.

Certara

LIFECYCLE FOOTPRINT

4 /10

BIOSIMULATION + AI REGULATORY WRITING

Targets: *clinical pharmacology, regulatory and medical-writing teams — model-informed dose selection, trial simulation and generative-AI regulatory writing.*

WHAT THEY DO

- CoAuthor is a life-science-specialized generative-AI tool for regulatory and medical writing — CSRs, protocols and submission documents — with human-in-the-loop drafting inside Word.[13]
- Simcyp and Phoenix biosimulation drive dose selection, drug-interaction prediction and trial simulation — the modeling science that feeds the submission.[14]

COMPANY & BACKING

- NASDAQ: CERT; founded 2008, headquartered in Radnor, PA; FY2025 revenue of $418.8M, up 9%, with software up 18%.[15]
- The FDA renewed and expanded its Certara biosimulation licenses — 400+ Simcyp/Phoenix licenses used across 11 FDA divisions.[16]
- Joined the Veeva AI Partner Program (Oct 2025) and integrated NVIDIA's BioNeMo Agent Toolkit (2026).[17]

LIFECYCLE FOOTPRINT — STRATEGY, DESIGN & SUBMISSION

P01 · P02 · P08 · P10



~90%[18]

Of FDA novel approvals used its customers (company-stated)

$418.8M[15]

FY2025 revenue, up 9% year over year

≥30%[13]

Faster time-to-first-draft with CoAuthor (company-stated)

SENIOR-LEADER READOUT

Certara is the incumbent of the group — a public biosimulation leader whose tools the FDA itself licenses — now extending into generative-AI regulatory writing with CoAuthor.

For senior leaders it offers the reassurance of scale and regulatory familiarity, with AI authoring layered onto model-informed drug development already embedded in submissions.

Company-stated claims summarized from public materials; not a buying recommendation.

Freyr

AI-FIRST REGULATORY CLOUD (RIM)

LIFECYCLE FOOTPRINT
4 /10

Targets: *regulatory affairs and RIM leaders across pharma, biotech, generics and devices — submissions, labeling, intelligence and post-approval change.*

WHAT THEY DO

- freya fusion is an AI-first regulatory cloud (RIM) spanning eCTD v4.0 submissions, product registrations, labeling, regulatory intelligence and post-approval change management.[19]
- A Freya AI copilot sits over a regulatory-intelligence base (~100,000 regulations, 1,598+ health authorities), with a "Via" agent for variation management; delivered by 2,200+ regulatory experts across 120+ countries.[20]

COMPANY & BACKING

- Princeton, NJ; founder-led; states 1,800+ clients including 6 of the Forbes Global Top 10 pharma companies.[21]
- freya fusion launched in July 2025 as the flagship AI-first regulatory platform.[22]
- Named a Leader in Everest Group's PEAK Matrix for regulatory & medical affairs operations, 2024 (among 20+ providers assessed).[23]

LIFECYCLE FOOTPRINT — STARTUP, CLOSE-OUT & SUBMISSION

P02 · P04 · P09 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

200,000+[19]
Submissions processed across 120+ countries (company-stated)

60%[24]
Claimed FDA submission-timeline cut, freya fusion (company-stated)

Leader[23]
Everest Group PEAK Matrix, reg & med-affairs 2024

SENIOR-LEADER READOUT

Freyr blends a large global regulatory-services organization with an AI-first software platform, aimed at the operational machinery of submissions, labeling and variations.

It fits leaders who want AI embedded in end-to-end regulatory operations at global scale rather than a point solution for a single document type.

Company-stated claims summarized from public materials; not a buying recommendation.

Glemser

LIFECYCLE FOOTPRINT
4 /10

AI-ASSISTED REGULATORY DOCUMENT MANAGEMENT

Targets: *regulatory affairs, global labeling and CMC teams — labeling, structured/component content, SPL/ePI and submission-ready regulatory documents.*

WHAT THEY DO

- ComplianceAuthor AI is a GxP-compliant structured content management system with Word-based authoring and a central component repository, automating conversion to health-authority formats including SPL/ePI and HL7 FHIR.[25]
- Uses NLP and generative-AI models trained on customer data behind the firewall for component authoring and continuous regulatory-update monitoring.[26]

COMPANY & BACKING

- Founded 1987 in Bethlehem, PA; founder-led (Dr. Ray Glemser); roughly 38 years serving life-sciences regulatory content.[27]
- Technology alliance embeds Quark's structured-authoring platform in ComplianceAuthor, alongside integrations with Veeva, SAP and Documentum.[28]
- Partnership with Navitas Life Sciences integrates labelREADY with ComplianceAuthor.[29]

LIFECYCLE FOOTPRINT — CONTENT, QUALITY & LABELING

P02 · P08 · P09 · P10

P01	**P02**	P03	P04	P05	P06	P07	**P08**	**P09**	**P10**

1987[27]

Founded; ~38 years in life-sciences content (company-stated)

~50%[25]

Labeling-timeline reduction, ComplianceAuthor (company-stated)

2024[30]

Life Sciences Review Company of the Year

SENIOR-LEADER READOUT

Glemser brings AI to one of regulation's most change-heavy corners — global and clinical labeling — with a structured-content platform and a multi-decade track record in the space.

For a senior leader it fits where the priority is controlled, component-based labeling and regulatory content at scale, with generative AI layered onto an established compliance backbone.

Company-stated claims summarized from public materials; not a buying recommendation.

CROSS-VENDOR PATTERNS FOR SENIOR LEADERS

Three patterns to carry into your diligence

01

The document is the product

In regulatory work the deliverable *is* the written record. Each of these vendors automates the highest-volume, most-templated writing first — narratives, CSRs, submission modules — where the return on first-draft automation is largest.

02

Control beats fluency

Deterministic rules, source traceability, GxP validation and human-in-the-loop are what make a language model usable on a regulated document. The differentiator is provenance, not prose.

03

Proof is uneven — and that's the opening

Evidence ranges from named third-party deployments to company-stated adoption. Early-mover design-partner windows exist to shape roadmaps before these tools become standard equipment.

THE BOTTOM LINE FOR ADOPTION

"The winners in the writing layer won't be the models with the best prose — they'll be the systems that can prove every sentence back to its source."

HOW TO USE THIS ISSUE

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Which documents does the tool draft end-to-end today, and which still require heavy human authoring?
- How is regulated-content provenance handled — can every generated sentence be traced back to source data and locked templates?
- What is the GxP / 21 CFR Part 11 / validation posture, and is the deployment (private hosting, audit trails, role-based access) inspection-ready?
- Is the evidence a named third-party deployment or company-stated adoption — and does that match your risk tolerance?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- Clinical data management & database-lock automation
- Pharmacovigilance & safety-signal AI
- AI for regulatory intelligence & labeling
- Trial master file & inspection-readiness AI
- Real-world evidence & post-market surveillance

Source standard. *All data is publicly sourced unless otherwise noted. Company-stated claims are labeled as such and summarized from public materials; they are not independently validated performance guarantees.*

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