AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 10 THE PAPER TRAIL GOES AGENTIC — AI IN ETMF, EISF & INSPECTION READINESS

Florence Healthcare

Site network + agent-ready eISF / eTMF

PhlexTMF

TMF specialist inside Cencora PharmaLex

Ennov

Unified regulated-content platform

Trial Interactive

eTMF + AutoMate AI (TransPerfect)

Advarra

eReg + AI inspection readiness

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

Inspection readiness is going agentic — from static filing to continuous compliance

The trial master file is the record an inspector actually opens — and for most of its history it has been a filing exercise, reconciled late. Three shifts are changing that. ICH E6(R3) took effect in the EU on 23 July 2025 and FDA published its final guidance on 9 September 2025.[1] FDA launched its agency-wide AI tool, Elsa, on 2 June 2025, with identifying high-priority inspection targets among its stated uses.[2] And the TMF Reference Model — used by 96% of eligible respondents in a 2022 survey — is being rebuilt as a CDISC standard.[3] This issue maps five vendors moving the paper trail from filing to always-on readiness.

WHAT SENIOR LEADERS SHOULD WATCH

01

From static binder to living record. Expected-document lists, completeness and misfile checks are being recalculated continuously rather than at milestones — readiness becomes a state, not an event.

02

The regulator has AI too. With Elsa in the inspector's toolkit, vendors are building products that review a whole quality system the way an AI-enabled agency could.

03

Documents become agent-accessible. Open protocols and read-only APIs let a sponsor's own agents query site and TMF data directly — a design-partner window is open now.

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 at study startup (P04), oversight (P07) and close-out / TMF (P09).

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 TMF vendor plays across the trial lifecycle

VENDOR	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	FOOTPRINT
Florence Healthcare Site network + agent-ready eISF / eTMF			■	■		■	■		■		5/10
PhlexTMF TMF specialist inside Cencora PharmaLex				■			■		■		3/10
Ennov Unified regulated-content platform				■		■	■	■	■		5/10
Trial Interactive eTMF + AutoMate AI (TransPerfect)			■	■		■	■		■		5/10
Advarra eReg + AI inspection readiness		■		■		■	■		■		5/10

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

The cohort clusters at startup (P04), oversight (P07) and close-out / TMF (P09) — where essential documents are created, checked and defended. Footprint counts the stages a vendor is positioned to touch; a directional, point-in-time read, not a ranking.

Executive market map

VENDOR	PRIMARY CATEGORY	PROBLEM(S) TARGETED	PUBLIC EVIDENCE SIGNAL
Florence Healthcare	Site network + agent-ready eISF / eTMF	Document burden between sponsors and sites; late eISF-to-eTMF reconciliation.	**Agent-ready.** MCP access across 11 tools (Jun 2026); 65,000+ sites (co-stated).[4]
PhlexTMF	TMF specialist + AI at upload	Misfiles and metadata errors caught at the moment of filing, not at audit.	**Enterprise parent.** Inside Cencora PharmaLex, a €1.28B acquisition.[5]
Ennov	Unified regulated-content platform	Fragmented point systems across quality, clinical, regulatory and PV.	**Fresh capital.** Bregal Sagemount + Ardian investment (May 2026) aimed at AI.[6]
Trial Interactive	eTMF + AutoMate AI	Manual indexing and QC; expected-document lists that go stale.	**Living EDL.** First native LiveTMF integration; GA expected Q4 2026 (co-stated).[7]
Advarra	eReg + AI inspection readiness	Sample-based readiness in an era of AI-enabled regulators.	**Regulator-aware.** GxP AI tool launched Mar 2026, framed around FDA's Elsa.[8]

Signals summarize public materials as of the cited profiles that follow; company-stated claims are labeled as such.

Florence Healthcare

LIFECYCLE FOOTPRINT 5/10

SITE NETWORK + AGENT-READY EISF / ETMF

Targets: *The administrative document burden between sponsors and sites — startup packets, regulatory binders, remote monitoring and eISF-to-eTMF reconciliation.*

WHAT THEY DO

- In June 2026 Florence opened Model Context Protocol access across all 11 workflow tools, so sponsor or site agents can find missing documents and automate eTMF reconciliation.[4]
- AI-assisted workflows (Sept 2025) cover feasibility surveys, contract exchange in startup and remote-monitoring progress reports.[9]

COMPANY & BACKING

- Atlanta-based; closed an $80M Series C led by Insight Partners in May 2021.[10]
- Named deployment: supported Revolution Medicines' daraxonrasib program across 200+ sites, 41 of them in the pivotal Phase 3 (company release).[11]

LIFECYCLE FOOTPRINT — SITE STARTUP THROUGH TMF

P03 · P04 · P06 · P07 · P09

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

65,000+[4]
Research sites on the network (company-stated)

11[4]
Workflow tools opened to AI agents via MCP

98.7%[12]
eTMF QA pass rate, up from 65% (company-stated)

SENIOR-LEADER READOUT

Florence has turned a very large site network into agent-accessible infrastructure — site document reality becomes something a sponsor's own agents can query rather than chase.

The MCP release is an early reference point for agentic eISF-to-eTMF reconciliation, and a design-partner opening.

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

PhlexTMF

TMF SPECIALIST INSIDE CENCORA PHARMALEX

Targets: *Misfiles and metadata errors at the moment of upload — the quiet source of TMF quality findings — plus the expert capacity to keep a file inspection-ready.*

WHAT THEY DO

- PhlexTMF Enterprise pairs an eTMF with TMF services across the study — planning and startup through quality review, close-out and archival.[13]
- AI pre-trained on millions of TMF documents gives classification and metadata tips at upload, announced with PhlexTMF v21 in March 2023.[14]

COMPANY & BACKING

- Founded 1997; merged into PharmaLex in January 2022 with 400+ TMF staff (company-stated).[15]
- AmerisourceBergen — now Cencora — agreed to acquire PharmaLex for €1.28B in cash; the deal closed 3 January 2023.[5,16]

LIFECYCLE FOOTPRINT — THE TMF CORE

P04 · P07 · P09

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

€1.28B[5]
Cash price paid for parent PharmaLex

98%[17]
Right-first-time indexing accuracy (company-stated)

1997[15]
Founded — a long-standing TMF expert bench

SENIOR-LEADER READOUT

One of the longest-standing TMF expert benches, paired with AI trained on TMF documents and now housed in an enterprise-scale parent.

For sponsors who want TMF technology and managed services under one roof, the AI roadmap beyond upload-time classification is an opening to shape directly.

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

Ennov

LIFECYCLE FOOTPRINT 5/10

UNIFIED REGULATED-CONTENT PLATFORM

Targets: *Fragmented point systems for regulated content — one platform where a document moves from quality to clinical to regulatory without re-filing.*

WHAT THEY DO

- Ennov eTMF is preconfigured to the TMF Reference Model, with risk-based sampled QC, auto-generated expected-document placeholders and completeness dashboards.[18]
- Ennov 11.0 (Dec 2025) added a built-in AI chatbot, eCTD auto-classification and PV narrative summarization, alongside integrated EDC and RTSM.[19]

COMPANY & BACKING

- Founded 1999 in Paris; Bregal Sagemount led a strategic growth investment with Ardian in May 2026, focused on AI innovation (amount undisclosed).[6]
- Oxana Pickeral, former CEO of Sparta Systems, became CEO on 9 Sept 2026; the platform is positioned for agentic workflows.[20]

LIFECYCLE FOOTPRINT — ONE PLATFORM, STARTUP TO TMF

P04 · P06 · P07 · P08 · P09

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

~650[6]
Life-science customers (company-stated)

500,000+[6]
Platform users (company-stated)

98.5%[18]
On-time project delivery rate (company-stated)

SENIOR-LEADER READOUT

Fresh growth capital and a new CEO with a quality-software pedigree, both pointed at embedding agentic AI across one regulated-content platform.

For teams that want eTMF on the same data model as quality, regulatory and PV, eTMF-specific AI is an early-stage opportunity to shape.

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

Trial Interactive

ETMF + AUTOMATE AI · TRANSPERFECT LIFE SCIENCES

Targets: *Manual TMF indexing and QC, and static expected-document lists that drift away from what the study actually requires.*

WHAT THEY DO

- TI AutoMate classifies records, extracts 35+ metadata fields and runs completeness checks with human-in-the-loop review, in 40+ languages (company-stated).[21]
- In Aug 2026 it partnered with Virtual Data Corp to natively integrate LiveTMF, which keeps the expected document list current; GA anticipated Q4 2026.[7]

COMPANY & BACKING

- A division of TransPerfect, which reported 2025 billed revenue of $1.32B, up 7% (company-stated).[22]
- Named customer: AO Foundation selected its eISF, Study Collaborate and eTMF in May 2025.[23]

LIFECYCLE FOOTPRINT — SITE ACTIVATION THROUGH TMF

P03 · P04 · P06 · P07 · P09

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

70%[21]
Less document handling time (company-stated)

1,079[21]
Record types auto-classified (company-stated)

$1.32B[22]
Parent 2025 billed revenue (company-stated)

SENIOR-LEADER READOUT

Trial Interactive is moving the eTMF from a filing system to a continuously computed compliance state, with multilingual depth suited to global programs. The Q4 2026 LiveTMF availability is an early-adopter opening for sponsors rethinking completeness.

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

Advarra

EREG + AI INSPECTION READINESS

Targets: *Sample-based inspection readiness in an era when regulators can analyze a whole quality system with AI — plus the site regulatory binder itself.*

WHAT THEY DO

- GxP Compliance Intelligence (Mar 2026) connects by read-only API to any QMS and detects compliance gaps continuously, with consultants in the loop.[8]
- eReg is a Part 11 electronic regulatory binder integrated with OnCore, Clinical Conductor, IRB review and eSource, with remote-monitor access.[24]

COMPANY & BACKING

- Columbia, Maryland; Blackstone and CPP Investments took a majority stake in June 2022, with Genstar and Linden retaining equity.[25]
- ICON and Advarra announced a connected, research-ready site network built on eReg and OnCore in March 2026.[26]

LIFECYCLE FOOTPRINT — PROTOCOL TO INSPECTION READINESS

P02 · P04 · P06 · P07 · P09

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

50,000+[26]
Investigators on Advarra systems (company-stated)

<5%[8]
Of documents sampled in a traditional inspection (company-stated)

45%[24]
Fewer documentation audit findings with eReg (company-stated)

SENIOR-LEADER READOUT

Advarra has built a product around the fact that regulators now use AI — continuous, QMS-wide gap detection in place of periodic mock inspections. With its site reach and the ICON partnership, it offers a credible path to always-on readiness.

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

Three patterns to carry into your diligence

01

Filing gives way to computed compliance

A living expected-document list, continuous QMS gap detection, agents that surface missing documents, misfile prevention at upload — readiness is recalculated, not reconciled.

02

The stack is opening to agents

MCP access, read-only QMS APIs and system-agnostic engines mean a sponsor's own agents can work across vendors. Ask what is exposed, and how each action is governed.

03

Capital is backing the content layer

Cencora, Blackstone and CPP, Bregal Sagemount and Ardian, Insight Partners and TransPerfect all stand behind this cohort — funding the AI roadmaps buyers can now help shape.

THE BOTTOM LINE FOR ADOPTION

"The inspector's view of your trial is becoming continuous and machine-readable. Leaders who engage this cohort now decide how AI enters their most scrutinized record — before always-on readiness becomes the expectation."

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Where does TMF risk actually sit today — misfiles at upload, stale expected-document lists, site-to-sponsor reconciliation, or QMS-wide gaps?
- What engagement fits — a design partnership on agentic features, an overlay on the current eTMF or QMS, or a platform migration?
- How are AI actions governed for GxP / 21 CFR Part 11 — validation, audit trails, confidence thresholds and human-in-the-loop review?
- What can your own agents reach — MCP, APIs, read-only connectors — and who controls that access?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- AI in regulatory affairs & submissions (RIM)
- Clinical data management & EDC automation
- Study startup, contracts & site payments
- Real-world evidence & HEOR platforms
- Manufacturing, CMC & supply-chain AI (Pharma 4.0)

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.

References

Reference numbers are assigned by first appearance in the body and shown as sequential superscripts throughout this issue. Each entry links to its source.

1 ACRP (Sep 16, 2025) — "FDA Publishes ICH E6(R3): What it Means for U.S. Clinical Trials" — EU effective date and FDA final guidance.

2 U.S. FDA (Jun 2, 2025) — "FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People" — Elsa launch and stated uses.

3 CDISC — Trial Master File (TMF) Reference Model / TMF Standard Model page — move to CDISC; 2022 usage survey.

4 PR Newswire (Jun 16, 2026) — "Florence Healthcare Unlocks Agentic AI Across Global Site Network at DIA 2026" — MCP across 11 tools; 65,000+ sites (company-stated).

5 AmerisourceBergen Investor Relations (Sep 12, 2022) — agreement to acquire PharmaLex for €1.28B in cash.

6 Ennov (May 20, 2026) — "Ennov Welcomes Strategic Growth Investment from Bregal Sagemount and Ardian Growth" — customer and user counts (company-stated).

7 GlobeNewswire (Aug 13, 2026) — "TransPerfect's Trial Interactive Partners with Virtual Data Corp" — native LiveTMF integration; GA anticipated Q4 2026.

8 Advarra (Mar 18, 2026) — "Advarra Launches AI-Powered GxP Technology to Strengthen Inspection Readiness in the Era of FDA's Elsa" (company-stated).

9 Florence Healthcare (Sep 2, 2025) — "Florence Announces AI-Assisted Workflows to Transform Clinical Trials."

10 Florence Healthcare (May 6, 2021) — "Florence Announces $80 Million Series C Led by Insight Partners."

11 Florence Healthcare (Aug 31, 2026) — release on supporting Revolution Medicines' daraxonrasib program (company-stated; named customer).

12 Florence Healthcare (Oct 23, 2025) — "Florence Connects 65,000+ Study Sites and 600+ Sponsors Worldwide" — eTMF QA pass rate (company-stated).

13 Cencora — PhlexTMF Enterprise eTMF Solution, product page (company-stated).

14 Clinical Leader (Mar 20, 2023) — "Phlexglobal Announces Industry-First eTMF AI" — PhlexTMF v21 (company-stated).

15 PharmaLex (Jan 25, 2022) — merger with Phlexglobal announced; founded 1997, 400+ staff (company-stated).

16 Cencora Investor Relations (Jan 3, 2023) — "AmerisourceBergen Completes Acquisition of PharmaLex."

17 Cencora — case study, "AI-Assisted Indexing Transforms TMF Management" — unnamed mid-sized pharma (company-stated).

18 Ennov — Ennov eTMF product page — Reference Model configuration, QC, on-time delivery rate (company-stated).

19 Ennov (Dec 1, 2025) — "Introducing Ennov 11.0: AI-Powered Productivity for Regulated Teams" (company-stated).

20 Ennov (Sep 9, 2026) — "Ennov Appoints Oxana Pickeral as Chief Executive Officer."

21 Trial Interactive — "TI AutoMate: AI-powered eTMF" product page (company-stated).

22 TransPerfect (Mar 5, 2026) — "TransPerfect Billed Revenues Increase 7% in 2025 to $1.32 Billion" (company-stated).

23 TransPerfect (May 13, 2025) — "AO Foundation Selects Trial Interactive to Digitize Clinical Trial Operations."

24 Advarra — eReg Solution product page — Part 11 binder, integrations, audit-findings reduction (company-stated).

25 Advarra (Jun 10, 2022) — "Advarra Secures Major Investment from Blackstone and CPP Investments."

26 Advarra / ICON plc (Mar 24, 2026) — "ICON and Advarra Introduce New 'Research-Ready,' Connected Site Network Model."

Disclosure: Companies featured in this issue include current or prospective advisory relationships of Avery & Riley. Lifecycle-footprint and source-class reads use Avery & Riley's vendor framework compiled from public materials and directory review; they are a snapshot of the latest publicly known data and may change as vendors ship or reposition capabilities. This is not a ranking and not a buying recommendation.