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AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 07

THE SAFETY PILLAR GOES AGENTIC — AI IN PHARMACOVIGILANCE & DRUG SAFETY

ArisGlobal
Enterprise safety + NavaX gen-AI

Oracle Argus
PV system-of-record + AI intake

Veeva Vault Safety
Cloud-native unified safety

Saama
AI safety analytics + surveillance

Clinevo OnePV
AI-native unified PV platform

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

The safety pillar is going agentic — AI moves from signal detection to the whole PV workflow

Pharmacovigilance is the compliance-critical backbone of drug development — every individual case safety report (ICSR), every signal, every aggregate report. Case volumes keep climbing while regulatory requirements tighten, and the manual "case factory" doesn't scale. In 2025–26 the safety stack crossed a line: incumbents embedded generative AI in case processing, analytics players pushed active surveillance into real-world data, and AI-native challengers unified the whole PV lifecycle. This issue maps five vendors rebuilding drug safety with AI — from the system-of-record to the challenger.

WHAT SENIOR LEADERS SHOULD WATCH

01

From case factory to agents. AI now automates ICSR intake, coding and narrative writing — vendors report 50–65% case-processing efficiency gains (company-stated). The human job shifts from data entry to oversight.

02

Signals move upstream and outward. Detection is expanding from spontaneous-report databases (FAERS, EudraVigilance) into real-world data and active surveillance (FDA Sentinel / TreeScan) — earlier, broader, continuous.

03

Incumbents and challengers converge. System-of-record leaders are adding gen-AI while AI-native challengers unify the stack. Both are courting design partners now — before agentic PV becomes table stakes.

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. This issue's safety cohort clusters in the **execution-to-evidence** stages (P06–P10), where adverse events are captured, monitored, processed and surveilled. 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.

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 safety vendor plays across the trial lifecycle

Vendor	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	Footprint
ArisGlobal Enterprise safety + gen-AI							■	■	■	■	4 /10
Oracle Argus PV system-of-record + AI						■	■	■	■	■	5 /10
Veeva Vault Safety Cloud-native unified safety						■	■	■		■	4 /10
Saama AI safety analytics + RWD						■	■	■		■	4 /10
Clinevo OnePV AI-native unified PV						■		■	■	■	4 /10

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

The cohort clusters in execution-to-evidence (P06–P10), where adverse events are captured, monitored, processed and surveilled. Footprint counts the stages a vendor is positioned to touch; a directional, point-in-time read, not a ranking.

THE SENIOR-LEADER VIEW

Executive market map

VENDOR	PRIMARY CATEGORY	PROBLEM(S) TARGETED	PUBLIC EVIDENCE SIGNAL
ArisGlobal	Enterprise safety + gen-AI	ICSR case processing, coding, narratives, aggregate reports & signal management at scale.	**Market leader.** 300+ customers, >12M cases/yr; NavaX gen-AI; Dassault to acquire (Jul 2026).
Oracle Argus	PV system-of-record + AI	End-to-end ICSR capture, reporting & signal detection across trials and post-market.	**IDC MarketScape 2025 Leader.** Most FDA drug/vaccine ICSRs run through Argus (co-stated); QPS win (Jan 2026).
Veeva Vault Safety	Cloud-native unified safety	Scaling ICSR intake, coding & submission without legacy infrastructure.	**Cloud momentum.** Case Intake & Narrative agents live; full Safety agents Apr 2026; Veeva FY26 $3.2B.
Saama	AI safety analytics + surveillance	Slow in-trial safety data review; passive post-market surveillance.	**Documented.** Pfizer vaccine review weeks→<24h; ASAP surveillance with Gilead; $430M Carlyle-led.
Clinevo OnePV	AI-native unified PV	Fragmented PV run on separate intake, database, signal & literature systems.	**Challenger.** Unifies intake→signal→literature; gen-AI; ~50% case-processing cut (co-stated); integrates with incumbents.

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

Prepared for market education; not a buying recommendation.

ArisGlobal

LIFECYCLE FOOTPRINT
4 /10

ENTERPRISE SAFETY + NAVAX GEN-AI

Targets: *The cost, speed and manual-labor bottleneck of processing exploding ICSR volumes — intake, coding, narratives, aggregate reports and signal detection — under rising regulatory complexity.*

WHAT THEY DO

- LifeSphere Safety / MultiVigilance is an end-to-end drug-safety suite — case intake through processing, reporting, aggregate reports and signal management — positioned as the most widely used safety product worldwide.[1]
- The NavaX gen-AI engine is embedded in case processing — dynamic data extraction, automated narratives, native Japanese and handwritten-record parsing — with 2025's NavaX Insights adding agentic sourcing and auto-drafted PSMFs / PSURs.[2]

COMPANY & BACKING

- Founded 1989 (Waltham, MA); majority-owned by Nordic Capital since 2020 — and on Jul 23, 2026 Nordic Capital agreed to sell ArisGlobal to Dassault Systèmes (~$175M revenue).[3]
- 300+ customers including named regulator deployments — the FDA's FAERS II, Health Canada and China's NMPA — plus pharma safety databases such as Santen's LifeSphere MultiVigilance.[4]
- Recognized as a Leader in the IDC MarketScape: Worldwide Life Science R&D Pharmacovigilance Solutions vendor assessment.[5]

LIFECYCLE FOOTPRINT — POST-MARKET SAFETY CORE

P07 · P08 · P09 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

12M+[3]
Safety cases processed on the platform each year

up to 65%[2]
NavaX case-processing efficiency gain (company-stated)

90%[2]
NavaX intake data accuracy (company-stated)

SENIOR-LEADER READOUT

The category's system-of-record leader, now moving generative and agentic AI into the heart of case processing — at a scale (300+ customers, 12M+ cases/yr) regulators and top-25 pharma already rely on.

The pending Dassault Systèmes acquisition signals where enterprise safety is heading — an anchor conversation for any gen-AI safety roadmap.

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

Oracle Argus

PV SYSTEM-OF-RECORD + AI INTAKE

LIFECYCLE FOOTPRINT
5/10

Targets: *The end-to-end burden of adverse-event collection, processing, regulatory reporting and signal detection across clinical trials and post-market surveillance — PV's compliance-critical bottleneck.*

WHAT THEY DO

- The Argus Safety database is the market-standard PV system for capturing, processing and reporting adverse-event cases across drugs, biologics, vaccines, devices and combination products.[6]
- Safety One Intake automates ICSR ingestion straight into Argus,[7] and Empirica adds quantitative signal detection — frequentist, Bayesian and regression-enhanced algorithms — across FAERS, VAERS, WHO VigiBase and PMDA JADER.[8]

COMPANY & BACKING

- Oracle Life Sciences was named a Leader in the 2025 IDC MarketScape for Worldwide Life Science R&D Pharmacovigilance; company-stated, >70% of drug and >90% of vaccine ICSRs to the FDA since 2017 originate in Argus.[9]
- QPS Holdings, a global full-service CRO, selected Oracle Argus Safety in January 2026 for oversight and traceability across all phases of clinical trials.[10]
- ~400 direct PV customers, with a gen-AI layer — OCI AI Services over the Safety One platform plus Oracle Real-World Data — driving a "precision PV" strategy.[9]

LIFECYCLE FOOTPRINT — SAFETY ACROSS TRIALS + POST-MARKET

P06 · P07 · P08 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

>70%[9]
of FDA drug ICSRs since 2017 originate in Argus (co-stated)

~400[9]
Direct pharmacovigilance customers (company-stated)

Jan 2026[10]
QPS Holdings selects Argus (named CRO)

SENIOR-LEADER READOUT

The PV system-of-record — the database most of the industry's and regulators' adverse-event reporting already runs through — now layering AI intake and RWD signal detection on top.

The proven backbone to benchmark against before adding agents — and the fresh QPS win shows the base still growing.

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

Veeva Vault Safety

CLOUD-NATIVE UNIFIED SAFETY + AI AGENTS

LIFECYCLE FOOTPRINT

4 /10

Targets: *The manual, high-volume burden of ICSR case management — intake, entry, narratives, coding and submission — that safety teams struggle to scale on legacy infrastructure as global reporting grows.*

WHAT THEY DO

- Vault Safety is a cloud-native, unified ICSR system — global and domestic adverse events in one platform with built-in health-authority gateways and automated MedDRA / WHODrug / EDQM coding — connected to Veeva's clinical, quality and regulatory Vaults.[11]
- New AI agents target the case factory — a Case Intake Agent for faster, more accurate extraction and a Case Narrative Agent for cleaner narratives[12] — with full agentic Safety slated for April 2026.[13]

COMPANY & BACKING

- Named Vault Safety users span emerging and large pharma — Camurus, CRISPR Therapeutics, Merck, UCB and LEO Pharma among them.[14]
- Built by Veeva Systems (NYSE: VEEV), whose FY2026 revenue reached $3.20B (up ~16%) — deep resources behind the safety roadmap.[15]
- A self-reported 51–100 Vault Safety customers, with early adopters citing 30+ minutes saved per case on the base platform, before the new agents land.[11]

LIFECYCLE FOOTPRINT — UNIFIED CLOUD SAFETY

P06 · P07 · P08 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

$3.20B[15]
Veeva FY2026 revenue backing the roadmap (documented)

51–100[11]
Vault Safety customers (self-reported band)

Apr 2026[13]
Agentic Safety AI agents scheduled (company-stated)

SENIOR-LEADER READOUT

The cloud-native challenger to the safety incumbents — one connected platform for case management, now adding AI intake and narrative agents ahead of full agentic safety in 2026.

For teams already on Veeva's clinical and quality Vaults, Safety is the natural extension — a strong design-partner window as the agents ship.

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

Saama

LIFECYCLE FOOTPRINT

4 /10

AI SAFETY ANALYTICS + ACTIVE SURVEILLANCE

Targets: *The limits of passive spontaneous-report surveillance and slow manual clinical-safety data review — met with FDA-grade active surveillance on real-world data and AI-accelerated trial data review.*

WHAT THEY DO

- ASAP (Active Safety Analytics for Pharma) was the first validated solution to apply the FDA Sentinel Common Data Model and TreeScan method to real-world-data signal detection — co-built with Gilead.[16]
- Its AI data-review platform (Smart Data Query) automates query generation and cleaning to speed in-trial safety and DSMB review;[17] Sept-2025 Clinical AI Agents extend it to submission.[18]

COMPANY & BACKING

- Founded 1997 (Campbell, CA); its AI ran the data review on Pfizer's COVID-19 vaccine trial, and the two firms expanded a multi-year R&D agreement in Feb 2024.[19]
- Backed by a $430M strategic investment led by Carlyle — with Amgen Ventures, Merck GHI, Pfizer Ventures, McKesson and Northpond among the syndicate.[20]

LIFECYCLE FOOTPRINT — IN-TRIAL SAFETY + RWD SURVEILLANCE (AN A&R READ)

P06 · P07 · P08 · P10

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

$430M[20]
Carlyle-led strategic investment (documented)

weeks→<24h[17]
Pfizer vaccine trial safety data review (company-stated)

40,000+[17]
Trial participants' data AI-reviewed (company-stated)

SENIOR-LEADER READOUT

An Avery & Riley read: safety intelligence is moving upstream into the trial and outward into real-world data — and Saama sits on that edge, pairing documented in-trial data review with ASAP surveillance.

For sponsors wanting signal detection earlier and broader than spontaneous reports allow, Saama is a strong first conversation.

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

Clinevo OnePV

AI-NATIVE UNIFIED PV CHALLENGER

LIFECYCLE FOOTPRINT
4 /10

Targets: *Fragmented PV — where intake, safety database, signal detection and literature run on separate systems with manual handoffs — unified into one automation-driven platform to cut cost, cycle time and reconciliation errors.*

WHAT THEY DO

- OnePV unifies the four core PV functions — case intake (MICC), safety database with E2B submission, signal detection and literature management — in one environment.[21]
- Gen-AI runs intake and detection — voice intake via AWS Connect with live form population and serious-AE routing, NLP parsing of MedWatch / CIOMS PDFs, and disproportionality signal detection (PRR, ROR, EBGM).[22] Clinevo reports ~50% case-processing reduction.[23]

COMPANY & BACKING

- Founded 2016 (US front office; engineering in Bengaluru) — a lean, bootstrapped PV specialist suited to a design-partner engagement.[24]
- One US CRO on OnePV processes 25,000+ adverse events/yr to FDA, EMA, MHRA, Health Canada and TGA; OnePV integrates with — not replaces — incumbent databases (company-stated).[21]

LIFECYCLE FOOTPRINT — AI-NATIVE UNIFIED PV (COMPANY-STATED)

P06 · P08 · P09 · P10

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

~50%[23]
Case-processing time & cost reduction (company-stated)

2–3 days[22]
Signal investigation, from 2–3 weeks (company-stated)

25,000+[21]
Adverse events/yr on OnePV at one CRO (company-stated)

SENIOR-LEADER READOUT

The AI-native challenger of the cohort — one unified, automation-first PV platform that integrates with the incumbents rather than replacing them, so a pilot needn't rip out the safety database.

Company-stated metrics and an early-stage team — the ideal design-partner profile, shaping an agentic PV product while it's still moving fast.

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 case factory is going agentic

Intake, coding and narratives — PV's most manual work — are being handed to AI agents across the cohort, with 50–65% efficiency gains reported (company-stated). Oversight, not data entry, becomes the human job.

02

Signals move upstream and outward

Detection is expanding beyond spontaneous-report databases into real-world data and active surveillance (FDA Sentinel / TreeScan), and earlier into the trial — broader, faster, continuous.

03

Incumbents and challengers converge

System-of-record leaders are embedding gen-AI while AI-native challengers unify the stack and integrate with the incumbents. Both are courting design partners now, before agentic PV is table stakes.

THE BOTTOM LINE FOR ADOPTION

"Drug safety is being rebuilt agent-first. Safety leaders who engage this cohort now — incumbent backbone and AI-native challenger alike — shape how automation enters their most compliance-critical workflow, before the category standardizes."

HOW TO USE THIS ISSUE

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- Which safety workflows most need leverage first — ICSR intake and coding, narrative writing, aggregate reporting, or signal detection?
- What engagement fits — a design partnership on agentic capabilities, a module pilot, or a full safety-database migration?
- How are AI actions governed for GxP / 21 CFR Part 11 — validation, audit trails, human-in-the-loop review, and inspection readiness for a regulated safety system?
- Does the platform integrate with your existing safety database and health-authority gateways, or require replacing them?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- AI in regulatory affairs & submissions (RIM)
- Real-world evidence & HEOR platforms
- AI medical information & call-center (MICC)
- Clinical data management & EDC automation
- 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 & SOURCES

References

Reference numbers are assigned by first appearance in the body and shown as sequential superscripts throughout this issue.

1 ArisGlobal — LifeSphere Pharmacovigilance & Drug Safety software (product scope). arisglobal.com/pharmacovigilance-drug-safety-software

2 PRNewswire — "Launched at Breakthrough 2025: ArisGlobal announces LifeSphere Unify, NavaX Insights & Advanced Compliance Docs" (2025) — gen-AI capabilities; up to 65% efficiency, 90% intake accuracy (company-stated).

3 PRNewswire — "Nordic Capital agreement to sell ArisGlobal to Dassault Systèmes" (Jul 23, 2026) — ownership change; ~$175M revenue; >12M safety cases/yr.

4 ArisGlobal — "LifeSphere Safety surpasses 300 customers & 7M+ cases processed annually"; FDA FAERS II, Health Canada, China NMPA; Santen MultiVigilance deployment (BioSpace).

5 ArisGlobal — Recognized as a Leader, IDC MarketScape: Worldwide Life Science R&D Pharmacovigilance Solutions vendor assessment.

6 Oracle Life Sciences — Pharmacovigilance / Argus Safety database (product scope). oracle.com/life-sciences/pharmacovigilance

7 Oracle — Safety One Intake: automated ICSR ingestion into Argus Safety (product documentation).

8 PRNewswire (Dec 2, 2024) — "New updates in Oracle Life Sciences Empirica streamline safety signal management" — algorithms & multisource signaling (FAERS/VAERS/VigiBase/JADER).

9 Oracle (Sep 30, 2025) — "Oracle recognized as a Leader in the 2025 IDC MarketScape for Worldwide Life Science R&D Pharmacovigilance"; install-base & market-share figures (company-stated).

10 QPS / BusinessWire (Jan 15, 2026) — "QPS selects Oracle Argus Safety database."

11 Veeva — Vault Safety product page: scope, AI agents, named customers, self-reported 51–100 customer band. veeva.com/products/veeva-safety

12 Veeva — Case Intake Agent & Case Narrative Agent (product resource).

13 Veeva (Oct 14, 2025) — "Veeva AI Agents to be released across all Veeva applications" — Safety agents targeted April 2026.

14 Veeva — "Companies transforming pharmacovigilance with Vault Safety" — named customers; Camurus 30+ min/case (company-stated testimonial).

15 Veeva Investor Relations — Q4 & FY2026 results: total revenue $3.20B, up ~16% YoY (SEC-filed).

16 BusinessWire (Oct 26, 2020) — "Saama launches Active Safety Analytics for Pharma (ASAP), co-built with Gilead" — FDA Sentinel Common Data Model + TreeScan.

17 Saama — "AI & the Pfizer vaccine success" — trial safety data review cut from weeks to <24h; 40,000+ participants (company-stated).

18 PRNewswire (Sep 2025) — "Saama introduces modular & adaptive AI agents for clinical innovation."

19 BusinessWire (Feb 12, 2024) — "Saama and Pfizer expand agreement to integrate AI-driven data solutions across R&D portfolio."

20 Carlyle (Oct 20, 2021) — "$430M strategic investment in Saama led by Carlyle" (Amgen Ventures, Merck GHI, Pfizer Ventures, McKesson, Northpond among syndicate).

21 Clinevo Technologies — OnePV product page: unified 4-module PV platform; incumbent-database integration; 25,000+ AEs/yr at a CRO (company-stated). clinevotech.com/products/clinevo-onepv

22 Clinevo — "GenAI in pharmacovigilance" — AI/NLP intake & signal detection (PRR, ROR, EBGM); signal investigation 2–3 weeks → 2–3 days (company-stated).

23 Clinevo — "AI pharmacovigilance case-intake automation" — ~50% case-processing time & cost reduction (company-stated).

24 Inc42 — Clinevo Technologies company profile: founded 2016, Bengaluru base, bootstrapped (third-party).

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 as 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.