AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 09

THE OVERSIGHT LAYER — AI IN RISK-BASED QUALITY MANAGEMENT & CENTRALIZED MONITORING

CluePoints

RBQM specialist + agentic data review

Medidata

Platform incumbent: Detect + Clinical Data Studio

eClinical Solutions

Clinical data cloud with RBQM agents

TRI (OPRA)

Focused RBQM challenger

Lokavant

Trial intelligence, now inside ProofPilot

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

Oversight is moving off the site visit — and AI is becoming the way sponsors see risk

Monitoring is the single largest line in most trial budgets, and for two decades it ran on source-data verification and site visits. ICH E6(R3), finalized in January 2025, formalizes what regulators have been asking for since 2013: risk-proportionate oversight built on critical-to-quality factors, centralized monitoring and quality tolerance limits. Sponsors now need a system that turns trial data into risk signals continuously — and in 2025–26 the vendors selling that system crossed from statistical dashboards into agentic AI that investigates, queries and documents on its own. This issue maps five of them: a specialist leader, a platform incumbent, a data-cloud challenger, a focused RBQM tool and a trial-intelligence startup that was just absorbed.

WHAT SENIOR LEADERS SHOULD WATCH

01

E6(R3) turns RBQM from option to expectation. Risk assessment, CtQ factors and QTLs are now the backbone of GCP. Every vendor in this cohort is re-labeling around R3 — the question is which ones can show it working in an inspection.

02

Central monitoring is absorbing data review. KRIs and statistical surveillance are converging with listing review, medical review and coding. Vendors report 60–80% cycle-time gains from AI-assisted review (company-stated). The buyer's boundary between RBQM and data management is dissolving.

03

The category is consolidating. Private equity owns the specialists (EQT, GI Partners), a platform incumbent is under revenue pressure, and a startup was acquired in 2025. Expect roadmaps, pricing and support to shift with ownership.

Prepared for market education; not a buying recommendation.

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 oversight cohort clusters in Execute & Oversee (P06–P08), with the platform players reaching back into planning and startup.

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 oversight vendor plays across the trial lifecycle

VENDOR	P01	P02	P03	P04	P05	P06	P07	P08	P09	P10	FOOTPRINT
CluePoints RBQM specialist + agentic review						■	■	■	■		4/10
Medidata Detect + Clinical Data Studio		■	■	■	■	■	■	■	■		8/10
eClinical Solutions elluminate data cloud + RBQM		■		■		■	■	■		■	6/10
TRI (OPRA) Focused RBQM platform		■				■	■	■	■		5/10
Lokavant Trial intelligence (ProofPilot)		■	■	■	■	■	■				6/10

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

The cohort's center of gravity is P07 (monitoring / oversight), spilling into conduct and data cleaning (P06, P08). Platform vendors extend upstream into planning and startup; the specialists stay narrow by design. 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
CluePoints	**RBQM specialist + agentic data review**	Detecting site and data anomalies statistically; cutting manual listing review, medical review and coding effort.	**Specialist leader.** EQT majority owner (2024); FDA CRADA lineage; three agentic review tools launched Sep 2026 with a top-10 pharma.
Medidata	**Platform incumbent (Detect + CDS)**	Siloed, retrospective data review across EDC and non-EDC sources; slow database lock; audit-trail interrogation.	**Incumbent under pressure.** ICON fully integrated Clinical Data Studio (Mar 2025); Medidata Plus agentic layer (Jul 2026); Dassault Life Sciences revenue down 6% in FY2025.
eClinical Solutions	**Clinical data cloud + RBQM**	Fragmented trial data slowing review and risk detection; RACT/KRI/QTL workflows; SDTM mapping.	**Documented.** Everest PEAK Matrix highest Leader (Nov 2024); ZS RBQM partnership (Oct 2025); AI agents unveiled Dec 2025; argenx expansion (Mar 2026).
TRI (OPRA)	**Focused RBQM platform**	Data-quality failures that surface at submission; monitoring cost; risk assessment and central monitoring in one tool.	**Challenger.** OPRA-CM overhaul (Jun 2025); Veeva Vault EDC partner (Oct 2024); "450+ trials" (company-stated); no AI/ML claims found.
Lokavant	**Trial intelligence (acquired)**	Harmonizing ~3M data points per trial into real-time risk, enrollment and site-performance forecasts.	**Absorbed.** Acquired by ProofPilot (Sep 2025) after $29M from Roivant, Edison and Mitsui; Spectrum v15 with a Pfizer endorsement (Apr 2025).

CluePoints

RBQM SPECIALIST + AGENTIC DATA REVIEW

Targets: *The cost of finding what is wrong in trial data — on-site monitoring that consumes 40–60% of trial budgets and manual listing review that eats 60–70% of data-management reconciliation effort (company-stated).*

WHAT THEY DO

- Central monitoring built on statistical surveillance — KRIs, QTLs and critical-to-quality tracking — plus SPOT, which turns central signals into site risk scores that drive SDV and visit frequency. [1]
- September 2026: three agentic tools co-innovated with a top-10 pharma — Intelligent Query Detection (80%+ precision, >99% recall), Medical & Safety Review, and Intelligent Medical Coding (company-stated). [2]

COMPANY & BACKING

- Founded 2012 in Louvain-la-Neuve, Belgium; Summit Partners invested 2020; EQT took a majority stake in June 2024. [3]
- Claims "many" top-20 pharma clients (company-stated); an FDA CRADA co-developed its statistical method for targeting anomalous sites for inspection. [3,4]
- Recognition: ACDM 2024 innovation award (Audit Trail Review); SCDM 2025 implementation-excellence award (IQD); Scrip Awards 2025. [4]

LIFECYCLE FOOTPRINT — CONDUCT THROUGH INSPECTION READINESS

P06 · P07 · P08 · P09

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

2,800+[1]
Studies de-risked on the platform (company-stated)

320K+[1]
Data issues detected to date (company-stated)

>99%[2]
IQD recall across 100+ production studies (company-stated)

SENIOR-LEADER READOUT

The pure-play reference point for central statistical monitoring, now pushing into the data-management workflows beside it. The regulator lineage matters: its anomalous-site method was built with FDA.

Engage when you want RBQM run as a discipline rather than a dashboard — and ask how the new agentic review tools are validated before they touch your listings.

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

Medidata

PLATFORM INCUMBENT · DETECT + CLINICAL DATA STUDIO

Targets: *Retrospective, siloed data review across Rave and non-Rave sources — the manual reconciliation that delays database lock and hides safety and quality signals until it is too late to act.*

WHAT THEY DO

- Detect is the RBQM engine — KRIs, QTLs and centralized statistical monitoring wired into Rave EDC; Clinical Data Studio (2024) unifies Medidata and third-party data for AI-assisted review and anomaly detection, claiming up to 80% faster review (company-stated). [5]
- Medidata Plus (July 2026) adds an AI-native layer: proactive enrollment and safety risk flags, and Audit Intelligence — agentic natural-language querying of audit trails (company-stated). [7]

COMPANY & BACKING

- Founded 1999; acquired by Dassault Systèmes for $5.8B in 2019. Dassault Life Sciences posted €1,081M FY2025 revenue, down ~6%, citing Medidata "headwinds with lower study volume." [8]
- ICON was the first large CRO to fully integrate Clinical Data Studio for review and central monitoring (March 2025); Worldwide Clinical Trials embedded Medidata's AI companion (April 2026). [6,7]
- IDC MarketScape Leader for Risk-Based Monitoring Solutions — a 2023 assessment; no newer RBQM-specific placement found. [9]

LIFECYCLE FOOTPRINT — PLATFORM BREADTH, OVERSIGHT CORE

P02 · P03 · P04 · P05 · P06 · P07 · P08 · P09



€1.08B [8]
Dassault Life Sciences FY2025 revenue, down ~6%

up to 80% [5]
Faster data review in Clinical Data Studio (company-stated)

38,000+ [5]
Trials run on the Medidata platform (company-stated)

SENIOR-LEADER READOUT

The default when oversight has to live inside the EDC — and the vendor with the most to prove as study volume softens and AI-native rivals target its data-review franchise. ICON and Worldwide are the deployments to test against.

On Rave already? The question is whether Clinical Data Studio and Medidata Plus replace the point tools around it — or add another layer.

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

eClinical Solutions

CLINICAL DATA CLOUD + RBQM AGENTS

Targets: *Trial data scattered across EDC, labs, eCOA and vendors — and the review, risk-detection and standards work that stalls while someone stitches it together. Phase III studies on its platform averaged 5.9 million data points in 2025 (company-stated).*

WHAT THEY DO

- elluminate maps multi-source trial data into one governed layer and runs RBQM on top — RACT, KRIs, QTLs, central statistical monitoring and deviation tracking, with June 2026 updates positioned to ICH E6(R3). [10]
- elluminate AI Agents (unveiled December 2025, phased release 2026) cover data mapping, data review, RBQM and study operations; elluminate Assist adds gen-AI querying and SDTM mapping. [11]

COMPANY & BACKING

- Founded 2012 in Mansfield, MA; Summit Partners invested 2020; GI Partners took a majority stake in September 2024, founders retaining significant equity. [13]
- Highest-designated Leader of 18 in Everest Group's 2024 Clinical Data & Analytics Platforms PEAK Matrix; SCDM 2025 Innovation Award for elluminate Assist. [14]
- RBQM partnership with ZS (October 2025); argenx expanded elluminate for data oversight (March 2026); 18 of the top-50 biopharma are customers (company-stated). [12,13,15]

LIFECYCLE FOOTPRINT — DATA LAYER WITH OVERSIGHT ON TOP

P02 · P04 · P06 · P07 · P08 · P10

P01	P02	P03	P04	P05	P06	P07	P08	P09	P10

1 of 18[14]
Highest-designated Leader, Everest PEAK Matrix 2024

18 / 50[13]
Top-50 biopharma companies as customers (company-stated)

5.9M[11]
Data points per Phase III study, 2025 (company-stated)

SENIOR-LEADER READOUT

The strongest independent evidence in the cohort — an analyst Leader placement, a named partner in ZS and a named biotech expansion — for a vendor that treats RBQM as a feature of the data layer, not a standalone tool.

Engage when your oversight problem is really a data-integration problem. The agents are new: ask which are generally available and which are still in phased release.

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

TRI (OPRA)

FOCUSED RBQM PLATFORM

Targets: *Data-quality problems that surface at submission or inspection because monitoring was reactive — and the cost of that monitoring, which TRI says OPRA can cut by up to 30% (company-stated).*

WHAT THEY DO

- A modular RBQM suite: OPRA-RAM (protocol risk assessment, KRI/QTL setup), OPRA-CM (centralized monitoring, signal detection) and OPRA-SM (subject-level monitoring); marketed as operationalizing ICH E6(R3). [16]
- A June 2025 overhaul of OPRA-CM added automated workflows and "built-in intelligence" — but no AI, machine-learning or generative feature is documented in TRI's public materials. [17]

COMPANY & BACKING

- Triumph Research Intelligence, Cambridge UK and Raleigh NC; incorporated 2013 (TRI's own materials say 2011 or 2014); founder-CEO Duncan Hall; Octopus Investments growth funding in 2018, no later round on record. [19]
- Veeva Product Partner (October 2024) with Vault EDC "Fast Start" RBQM dashboards; earlier partnerships with Rho and Worldwide Clinical Trials. [18,16]
- Claims 450+ trials and customers incl. IQVIA and Roche (company-stated, undated); no 2025–26 customer announcement, award or analyst placement found. [16]

LIFECYCLE FOOTPRINT — RISK PLAN THROUGH INSPECTION READINESS

P02 · P06 · P07 · P08 · P09

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

450+[16]
Clinical trials run on OPRA (company-stated)

up to 30%[17]
Monitoring-cost reduction claimed for OPRA-CM (company-stated)

85%[17]
Trials now using RBQM frameworks, up from 53% in 2018 (industry figure as relayed by TRI)

SENIOR-LEADER READOUT

A focused RBQM tool with a genuine E6(R3) story and a Veeva EDC hook — and, unusually for this issue, no AI claims to discount. A strength in an inspection; a question mark in a roadmap.

Fits sponsors and mid-size CROs that want risk assessment and central monitoring in one tool. Ask about the AI roadmap and ownership horizon.

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

Lokavant

TRIAL INTELLIGENCE · ACQUIRED BY PROOFPILOT

Targets: *The three-million-plus data points a modern trial generates across a dozen systems, and the lag between an enrollment or site-performance problem appearing in them and a sponsor acting on it (company-stated).*

WHAT THEY DO

- Harmonizes EDC, IRT, eCOA and CTMS feeds into a common data model and layers ML, causal and generative AI on top: real-time risk dashboards for study oversight, positioned to ICH E6(R2) and 21 CFR Part 11. [23]
- Spectrum (v15, April 2025) forecasts enrollment, site performance and budgets from planning through mid-study, trained on 500,000+ historical trials; Pfizer's head of predictive analytics called it "the next generation of intelligent trial design." [21]

COMPANY & BACKING

- Launched by Roivant Sciences in January 2020; raised $21M led by Edison Partners (2022) and $8M from Mitsui & Co. (2023) — about $29M disclosed in total. [22]
- Early enterprise agreements with Parexel and CMIC, Japan's largest CRO. [22]
- Acquired by ProofPilot on September 15, 2025 (terms undisclosed); its analytics now sit as the insight layer on ProofPilot's trial-execution platform. [20]

LIFECYCLE FOOTPRINT — PLANNING THROUGH OVERSIGHT

P02 · P03 · P04 · P05 · P06 · P07

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

$29M[22]
Disclosed funding before the ProofPilot acquisition

70×[20]
Claimed improvement in forecasting accuracy (company-stated)

500K+[21]
Historical trials in Spectrum's training data (company-stated)

SENIOR-LEADER READOUT

The cautionary tale of this cohort: a well-funded, Roivant-born analytics startup with a real Pfizer endorsement that was folded into a trial-execution platform. The technology did not fail — the standalone model did.

If you licensed Lokavant, get the ProofPilot roadmap in writing. If you are evaluating it, evaluate ProofPilot.

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

Three patterns to carry into your diligence

01

RBQM and data management are merging

Central statistical monitoring, listing review, medical review and coding are being sold as one AI-assisted workflow — by the specialist (CluePoints), the incumbent (Medidata) and the data cloud (eClinical). Budget lines and org charts will follow.

02

"Agentic" is a spectrum, not a switch

Three vendors ship named agents with company-stated precision and recall; one claims "built-in intelligence" with no AI at all; one's AI now belongs to someone else. Ask for the validation package, not the demo.

03

Ownership is the hidden risk factor

Two specialists are PE-owned, the platform is a division of a company reporting softer study volume, and the startup was acquired. Roadmap, pricing and support horizons now depend on who owns the vendor — diligence that too.

THE BOTTOM LINE FOR ADOPTION

“E6(R3) made risk-based oversight the expectation. The vendors are racing to make it agentic. Leaders who insist on inspection-grade validation now — and on knowing who will own their vendor in three years — will be the ones whose oversight survives both an audit and an acquisition.”

From market read to executive diligence

EXECUTIVE DILIGENCE QUESTIONS

- How does the platform document risk assessment, critical-to-quality factors and quality tolerance limits in a form an inspector can follow under ICH E6(R3)?
- For any AI-assisted review or query generation: what are the validated precision and recall figures, on whose studies, and who signs off before an agent's output reaches a site?
- What data does the tool actually ingest today — EDC only, or IRT, eCOA, labs and CTMS — and what does harmonization cost in weeks and headcount?
- Who owns the vendor, what is their investment horizon, and what happens to the roadmap, pricing and your data if they are acquired?

SUGGESTED CATEGORIES FOR FUTURE ISSUES

- Study startup & site-activation automation
- Site selection & feasibility intelligence
- Clinical data management & EDC automation
- eTMF, inspection readiness & GCP document AI
- Clinical supply, RTSM & forecasting AI

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

Numbered by first appearance in the body; shown as superscripts throughout.

1 CluePoints — Central Monitoring Platform, SPOT; homepage metrics: 2,800+ studies, 320,000+ issues (company-stated).

2 PRNewswire (Sep 3, 2026) — CluePoints launches IQD, MSR and IMC with a top-10 pharma; IQD page — 80%+ precision, >99% recall (company-stated).

3 EQT / PRNewswire (Jun 12, 2024) — EQT acquires majority of CluePoints; founded 2012; Summit Partners retains minority; "many of the top 20 pharma" (company-stated).

4 CluePoints — FDA CRADA extension; Clinical Research News (Mar 2024) — ACDM 2024 award; SCDM 2025 implementation-excellence award; Scrip Awards 2025.

5 Medidata — Detect product page; Dassault Systèmes (Jun 18, 2024) — Clinical Data Studio launch; up to 80% faster review; 38,000+ trials (company-stated).

6 Dassault Systèmes (Mar 20, 2025) — ICON first large CRO to fully integrate Clinical Data Studio.

7 GlobeNewswire (Jul 23, 2026) — Medidata Plus launch incl. Audit Intelligence; Medidata (Apr 23, 2026) — Worldwide Clinical Trials partnership.

8 Dassault Systèmes Q4/FY2025 results — Life Sciences revenue €1,081.1M, ~6% decline; Medidata "headwinds"; 2019 acquisition, $5.8B.

9 BusinessWire (Feb 2023) — IDC MarketScape: Medidata a Leader, Risk-Based Monitoring Solutions.

10 eClinical Solutions — elluminate RBQM product page; BusinessWire (Jun 29, 2026) — RBQM advances for ICH E6(R3).

11 eClinical Solutions (Dec 10, 2025) — elluminate AI Agents; 5.9M Phase III data points in 2025 (company-stated).

12 BusinessWire (Oct 16, 2025) — eClinical Solutions and ZS strategic partnership for RBQM.

13 BusinessWire (Sep 12, 2024) — GI Partners investment; founded 2012; BusinessWire (Feb 26, 2026) — 18 of top-50 biopharma, 20+ net-new customers (company-stated).

14 Everest Group (Nov 21, 2024) — Clinical Data & Analytics Platforms PEAK Matrix: highest-designated Leader of 18; SCDM Innovation Award (Oct 13, 2025).

15 BusinessWire (Mar 24, 2026) — elluminate supports argenx data oversight.

16 TRI — tritrials.com: OPRA-CM / RAM / SM; "450+ trials"; customers; ICH E6(R3) page (company-stated).

17 BusinessWire (Jun 3, 2025) — TRI overhauls OPRA-CM; up to 30% monitoring-cost cut; 85% of trials use RBQM vs 53% in 2018 (company-stated).

18 TRI (Oct 17, 2024) — TRI joins Veeva Product Partner Program (Vault EDC).

19 PRNewswire (Oct 15, 2018) — Octopus Investments funding for TRI; UK Companies House — incorporated Oct 2013; Preqin.

20 PRNewswire (Sep 15, 2025) — ProofPilot acquires Lokavant; 70× forecasting accuracy, 70% fewer non-conformances (company-stated); Clinical Trial Vanguard interview.

21 BusinessWire (Apr 23, 2025) — Lokavant Spectrum v15; 500,000+ historical trials (company-stated); Pfizer predictive-analytics quote.

22 PRNewswire (Jan 2020) — Roivant launches Lokavant; PRNewswire (Dec 2022) — $21M Edison round; BioSpace (Oct 2023) — $8M Mitsui; Roivant IR (Dec 2021) — CMIC.

23 Lokavant — Study Oversight page: risk dashboards, ICH E6(R2), 21 CFR Part 11 (company-stated).

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