eCOA vs ePRO Vendor Comparison: Costs, Migration & Compliance

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Executive Summary

Electronic Clinical Outcome Assessment (**eCOA**) and electronic Patient-Reported Outcome (**ePRO**) systems have become the default data-capture layer for clinical trials, but the vendor market supporting them remains fragmented, opaque on pricing, and increasingly reshaped by private-equity consolidation. This report compares the six vendors that dominate procurement shortlists as of August 2026: **Signant Health**, **Medidata** (a Dassault Systèmes company), **Clario**, **YPrime**, **Suvoda**, and **Veeva Systems'** eCOA product line, and answers the practical questions sponsors and clinical operations teams raise when building a request for proposal (RFP).

Commercial market-research estimates vary and are not independently auditable market facts. **MarketsandMarkets** estimates the global eCOA solutions market at **$1.94 billion in 2024**, projected to reach **$4.13 billion by 2029** at a **16.3% CAGR**; its methodology is described as secondary research, expert interviews, and its own analysis (Source: marketsandmarkets.com). The same publisher estimates ePRO, the subset of eCOA data reported directly by patients rather than clinicians or observers, at **57.1% of segment share in 2024** (Source: marketsandmarkets.com). Separately, Castor-sponsored content hosted by Clinical Leader cites a **$2.27 billion** 2025 estimate and a **16.1% CAGR** (Source: clinicalleader.com). These estimates should be treated as directional because their definitions, inputs, and methodologies differ.

Consolidation has redrawn the competitive map twice in the past five years. **ERT** and **Bioclinica** merged to form Clario in 2021 (Source: prnewswire.com), and on **October 29, 2025**, private-equity owners Nordic Capital, Astorg, Novo Holdings, and Cinven agreed to sell Clario to **Thermo Fisher Scientific**, a deal an independent legal analysis values at **$8.875 billion** in cash at close (Source: mnawatch.com). Suvoda, historically an Interactive Response Technology (IRT) specialist, completed its merger with payments platform Greenphire on **April 24, 2025** under lead investor Thoma Bravo (Source: suvoda.com). Meanwhile, **Veeva Systems** (NYSE: VEEV) entered the category from an adjacent position, launching **Veeva ePRO** on **October 18, 2022** as part of its unified Vault Clinical Suite (Source: veeva.com), positioning platform unification against the point-solution model of incumbent eCOA vendors.

Regulatory expectations tightened materially in the same window. The **U.S. Food and Drug Administration** (FDA) issued its final guidance, "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers," on **October 1, 2024**; the Federal Register published the notice of availability on **October 2, 2024**. The guidance superseded 2007-era guidance (Source: federalregister.gov), and the European Medicines Agency (EMA) finalized its "Guideline on computerised systems and electronic data in clinical trials" on **March 7, 2023**, explicitly naming eCOA in its scope (Source: ema.europa.eu). The stakes of non-compliance were illustrated starkly on December 3, 2024, when the FDA issued a warning letter to Applied Therapeutics after a third-party vendor deleted eCOA source data and audit trails for all 47 subjects in a pivotal trial (Source: fda.gov).

The public materials reviewed for the six vendors did not provide verifiable list prices or a common published pricing basis. Sponsors should obtain vendor-specific quotes and confirm whether pricing is study-, enterprise-, bundle-, or usage-based. What sponsors can benchmark instead is the cost of getting it wrong: Tufts Center for the Study of Drug Development found the median direct cost of a substantial Phase III protocol amendment, a frequent trigger for eCOA rebuilds, was **$535,000**, with 45% of such amendments judged avoidable (Source: pubmed.ncbi.nlm.nih.gov), and a Medidata case study puts the cost of legacy Data Clarification Form (DCF) processes at **$80,000 to $100,000 per study** (Source: medidata.com). This report's core conclusion is that eCOA vendor selection is less a software-feature exercise than a regulatory, licensing, and change-management decision, one where IntuitionLabs, a life-sciences and AI consultancy and Veeva Vault CRM X-Pages partner, advises sponsors to evaluate device strategy, instrument licensing, and platform integration together rather than in isolation (Source: intuitionlabs.ai).

Introduction and Background

Clinical trials increasingly rely on two overlapping but distinct categories of electronic data capture: **eCOA** and **ePRO**. Getting the terminology right matters for procurement, because the two terms are frequently used interchangeably in marketing copy despite denoting different scopes of data. eCOA is the umbrella term covering any Clinical Outcome Assessment collected in electronic form, spanning four assessment types: Clinician-Reported Outcomes (ClinRO), Observer-Reported Outcomes (ObsRO), Performance Outcomes (PerfO), and Patient-Reported Outcomes (PRO). ePRO refers specifically to the patient-reported subset of that data, collected electronically rather than on paper. The peer-reviewed literature makes this hierarchy explicit: a Value in Health paper on ePRO dataset standardization describes the "electronic patient-reported outcome (ePRO) Dataset Structure and Standardization Project" as a joint initiative of the Critical Path Institute's (C-Path) PRO Consortium and its Electronic Clinical Outcome Assessment (eCOA) Consortium (Source: ispor.org), naming eCOA as the parent category that contains ePRO. C-Path's own "Getting Better Together" initiative maintains a shared industry lexicon precisely to reduce this kind of ambiguity across sponsors and vendors (Source: media.c-path.org). This is not merely semantic housekeeping: sponsors who conflate the two terms in an RFP risk receiving vendor responses calibrated to the narrower ePRO scope when the protocol actually requires broader eCOA functionality, such as clinician-administered rating scales or performance-based outcome capture, a mismatch that typically only surfaces after contracts are signed and site training has already begun.

Practically, this distinction shapes vendor evaluation. A platform marketed as "ePRO software" may only address the patient-facing diary and questionnaire workflow, while an "eCOA platform" typically also handles clinician and observer assessments, site-based rating scales, and often adjacent workflows like electronic informed consent (eConsent) and, in some vendor portfolios, Interactive Response Technology (IRT) for randomization and drug supply. All six vendors profiled in this report brand their core offering as "eCOA," reflecting the market's consolidation toward broader platforms rather than single-purpose ePRO tools.

The regulatory backdrop for both categories rests on **21 CFR Part 11**, the FDA regulation governing electronic records and electronic signatures. Part 11 establishes that electronic records and signatures meeting its criteria are "trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper" (Source: ecfr.gov), and specifically requires closed systems to maintain "secure, computer-generated, time-stamped audit trails" of every record creation, modification, or deletion (Source: ecfr.gov). Public materials cite compliance-related assurances for some vendors' systems or modules, but they do not establish a uniform, eCOA-product-specific Part 11 claim across all six vendors. As the Applied Therapeutics warning letter shows, compliance claims and operational reality can diverge when a vendor's audit trail is deleted rather than merely unmonitored.

This report evaluates the six leading platforms across capability, adoption scale, and independently sourced strengths and limitations; presents a feature comparison matrix; reviews performance and compliance benchmarks from peer-reviewed literature; quantifies the market and pricing landscape; walks through named case studies including a regulatory enforcement action and two controlled compliance studies; and closes with guidance on vendor selection criteria and migration planning. Figures are anchored to August 2026 unless a source explicitly states an earlier "as of" date.

Signant Health

Capabilities

Signant Health was formed in 2019 when **CRF Health** (founded 2000) and **Bracket** (whose predecessor PharmaStar was founded 2001) merged under Genstar Capital ownership, rebranding as a single "unified patient technology organization" (Source: signanthealth.com) (Source: signanthealth.com). Since the merger, Signant has continued to expand its evidence-generation footprint through acquisition, adding **VirTrial** (2020), **DSG** (2023), and **Ametris**, formerly known as ActiGraph, in 2026 (Source: signanthealth.com). The core eCOA product supports flexible hardware deployment: sponsors can choose provisioned devices, a web browser, or the patient's own smartphone under a **bring your own device (BYOD)** model (Source: signanthealth.com). Signant also markets a supply-chain module, GxP Inventory, that it describes as "fully 21 CFR part 11 compliant" with a real-time transaction history (Source: signanthealth.com).

Adoption

Signant states that its technology and services supported **25% of novel drug approvals across FDA and EMA between 2020 and 2025** (Source: signanthealth.com). This vendor-reported footprint claim is not directly comparable with Medidata's FDA-only 2022 claim or Clario's FDA-approval claim since 2012, because the geography, period, and reported denominator differ. A published Signant case study describes a Phase 2 oncology trial that added 350 patients, 50 sites, and 5 countries mid-study on Signant's eCOA platform without a vendor switch; the therapy went on to receive **FDA approval in spring 2021** and **EMA approval in January 2022**, after which Signant was retained for the Phase 3 follow-on study (Source: signanthealth.com).

Strengths and Limitations

Signant's principal strength, according to its own materials, is elasticity: the ability to absorb substantial protocol amendments (additional sites, countries, and patients) without a platform migration, which directly mitigates the kind of $535,000 amendment costs identified by Tufts CSDD. Independent, non-vendor sentiment is more mixed. On a clinical-research practitioner forum, sponsor-side commenters described Signant's tablet interface as "ridiculously overcomplicated," citing workflow rigidity and elevated Data Clarification Form volumes, with at least one commenter reporting they cancelled a Signant contract and reverted to paper collection (Source: reddit.com). Because this is a single, unverified community thread rather than a peer-reviewed or independently audited benchmark, it should be read as anecdotal sentiment rather than a quantified performance finding, but it is consistent with a broader pattern in eCOA trade press: legacy platforms with complex configuration options can trade flexibility for usability.

Medidata

Capabilities

Medidata was founded in June 1999 by Tarek Sherif, Glen de Vries, and Ed Ikeguchi (Source: medidata.com) and became a wholly owned subsidiary of French software group **Dassault Systèmes** on **October 29, 2019**, in a deal valued at **$92.25 per share**, or approximately **$5.8 billion** in total enterprise value (Source: 3ds.com). Medidata's eCOA product, Rave eCOA, is architected as a mobile application usable in either BYOD or provisioned-device mode, unified with the company's Rave Electronic Data Capture (EDC) system to avoid duplicate data entry between the two systems (Source: medidata.com). On compliance, Medidata states it was among the first life sciences companies to achieve independent ISO 27701 privacy certification and SOC 2 Type II attestation over privacy controls (Source: medidata.com).

Adoption

By March 2023, Medidata reported having supported more than **30,000 clinical trials** and **9 million study participants** across more than **2,100 global customers**, with studies conducted in over **140 countries**; the same release stated that more than **70% of novel drugs approved by the FDA in 2022** were developed using Medidata software (Source: medidata.com).

Strengths and Limitations

Medidata's chief differentiator is unification with Rave EDC, which a Medidata-published case study credits with cutting a sponsor's average eCOA system build time to roughly six weeks and eliminating Data Clarification Forms entirely for that program (Source: medidata.com), directly targeting the $80,000 to $100,000 per-study DCF cost the same case study attributes to legacy multi-vendor setups. The limitation is the flip side of that integration: sponsors already committed to a non-Medidata EDC may find the unification argument less compelling, and as with all vendors in this comparison, no independent, published head-to-head benchmark of Rave eCOA against competing platforms was located during this research.

Clario

Capabilities

Clario was created in November 2021 when **ERT** (eResearchTechnology) and **Bioclinica** completed their 2021 merger and rebranded under a single name (Source: prnewswire.com), combining ERT's eCOA, cardiac safety, respiratory, and wearables business with Bioclinica's medical imaging and eClinical software under then-CEO Joe Eazor (Source: astorg.com). Clario's eCOA platform supports BYOD, web, and provisioned-device modalities across more than **120 countries** and **100-plus languages** (Source: clario.com), with stated therapeutic-area experience spanning **560 indications**, including neuroscience, oncology, and immunology (Source: clario.com). Clario further expanded eCOA depth by completing its acquisition of **WCG's** eCOA business on **May 6, 2025**, aimed at strengthening neuroscience trial support under CEO Chris Fikry (Source: clario.com).

Adoption

Post-WCG acquisition materials state Clario's endpoint data solutions have been deployed more than **26,000 times** and that the company has supported over **60% of all FDA drug approvals since 2012** (Source: clario.com). At the time of the 2021 rebrand, the combined ERT-Bioclinica lineage had completed more than **19,000 clinical trials** and contributed to **870 regulatory approvals** since 1990 (Source: prnewswire.com).

Strengths and Limitations

On **October 29, 2025**, Clario's private-equity owners (Nordic Capital, Astorg, Novo Holdings, and Cinven) agreed to sell the Philadelphia-headquartered company to **Thermo Fisher Scientific**; Nordic Capital's own release states Clario "doubled its revenue to approximately USD 1.2 billion" under PE ownership and now serves more than 600 life sciences customers (Source: nordiccapital.com). An independent legal and M&A analysis puts the transaction at **$8.875 billion** in cash at close, rising to as much as **$9.4 billion** with earnouts, which closed **March 24, 2026** following unconditional EU antitrust clearance (Source: mnawatch.com). Clario offers eCOA alongside medical imaging, cardiac safety, and respiratory endpoint services; its imaging tool "SMART Submit" is described as supporting 21 CFR Part 11 and EU General Data Protection Regulation (GDPR) compliance when sharing de-identified images (Source: clario.com). Public materials do not support a finding that this breadth is unmatched among competitors. The Thermo Fisher acquisition is a limitation to watch: sponsors evaluating Clario for multi-year programs should factor in integration risk as ownership transitions from a PE consortium to a strategic acquirer with a much broader life-sciences tools portfolio.

YPrime

Capabilities

YPrime was co-founded in 2006 by Shawn Blackburn and grew from what its own materials describe as "a two-person consultancy" into a global clinical trial technology provider (Source: yprime.com), now headquartered in Malvern, Pennsylvania, after opening a new headquarters there in **September 2019** following an investment from private equity firm **Flexpoint Ford** (Source: prnewswire.com). YPrime's eCOA platform has been deployed in nearly **1,000 clinical trials** across more than **100 countries** and **19 therapeutic areas**, with AI-assisted localization supporting more than 250 languages (Source: yprime.com). YPrime's IRT (Randomization and Trial Supply Management, RTSM) product maintains compliance with Part 11, GDPR, and the U.S. Health Insurance Portability and Accountability Act (HIPAA), with live dashboards and 24/7/365 protocol-trained helpdesk support (Source: yprime.com).

Adoption

In **October 2025**, YPrime launched "Advanced eCOA Oversight," a feature explicitly aligned with EMA's Guideline on Computerised Systems and ICH E6(R3) expectations for documented investigator review, tying each electronic sign-off to a specific investigator to maintain Part 11 compliance (Source: globenewswire.com). The same release states YPrime was named a Leader in Everest Group's 2025 eCOA PEAK Matrix Assessment, following a 2024 recognition as a Trailblazer in Patient Engagement (Source: globenewswire.com).

Strengths and Limitations

YPrime's strength is its dual eCOA and IRT portfolio combined with a mid-market position: smaller than Clario, Medidata, or Signant by trial volume, but positioned by analyst recognition as competitive on oversight tooling. Because the Everest Group PEAK Matrix result is cited only through YPrime's own press release rather than a directly fetched analyst report, this report treats it as a vendor-reported, third-party-sourced claim rather than an independently verified ranking. No public pricing, per-patient cost, or independent compliance-rate benchmark for YPrime's eCOA product was located during this research.

Suvoda

Capabilities

Suvoda was founded in 2013 and built its early reputation on IRT and Randomization and Trial Supply Management (RTSM) before expanding into eCOA (Source: prnewswire.com). Its eCOA product supports BYOD, sponsor-provisioned devices, and hybrid deployment models within the same study (Source: suvoda.com), and the company undergoes an annual SOC 2 Type 2 audit covering its RTSM, eCOA, and eConsent services, while self-certifying to the EU-U.S. Data Privacy Framework (Source: suvoda.com).

Adoption

Suvoda's current company profile claims support for more than **6,000 trials** across **115-plus countries**, with **65% concentrated in oncology, rare disease, and central nervous system (CNS)** indications (Source: suvoda.com). Growth has been funded by successive institutional investment: LLR Partners' **$40 million** December 2019 investment was described as Suvoda's first institutional capital (Source: suvoda.com), followed by the **April 24, 2025** completion of its merger with Greenphire, with **Thoma Bravo** as lead strategic investor and Bain Capital Tech Opportunities and LLR Partners as minority investors (Source: suvoda.com).

Strengths and Limitations

Suvoda's differentiator is combining eCOA with its established IRT franchise, and a Suvoda-published customer case study describes **Cara Therapeutics** using Suvoda's unified eCOA/IRT platform across two pruritus studies (chronic kidney disease pruritus and notalgia paresthetica), reporting a vendor-published claim of a "dramatic increase in patient eCOA compliance" versus prior studies run with other vendors (Source: suvoda.com), with Cara's VP of Biometrics noting all study languages, including Xhosa and Setswana for South African sites, were certified before go-live for the first time in any Cara study (Source: suvoda.com). That case study reports qualitative rather than quantified compliance improvement, and this report could not locate a non-paywalled version with specific percentage figures, so the claim should be read as vendor-published testimony rather than an independently audited result. The Greenphire merger integration, still relatively recent as of this report, is a factor sponsors evaluating multi-year Suvoda contracts should monitor.

Veeva eCOA

Capabilities

Veeva Systems (NYSE: VEEV) entered the eCOA and ePRO category from its existing position as a life-sciences cloud software provider, launching **Veeva ePRO** on **October 18, 2022**, as part of the Veeva Vault Clinical Suite (Source: veeva.com). Veeva's own product page now classifies the offering as "**Veeva eCOA**," describing its status as "Mature" with **51 to 100 customers** as of its most recent listing (Source: veeva.com). The Veeva

eCOA Library contains more than **200 fully reusable, validated assessment instruments** intended to speed study setup (Source: veeva.com), and Veeva has joined the Critical Path Institute's eCOA Consortium to participate in industry-wide standards work (Source: veeva.com).

Adoption

Veeva cites a **2025 ISR Market Research** report, a vendor-cited third-party claim, that recent users rated Veeva eCOA highest on three of four critical performance categories and described it as the "gold standard in the market" (Source: veeva.com). This report was unable to independently retrieve the underlying ISR report, which was bot-blocked at the source, so the finding should be treated as a vendor-cited third-party claim pending independent verification, the same caveat applied to YPrime's Everest Group citation above.

Strengths and Limitations

Veeva's strength is architectural: because Veeva eCOA sits inside the same Vault Clinical platform as the company's electronic Trial Master File (eTMF), Clinical Trial Management System (CTMS), and Study Data Tabulation Model (SDTM) tooling, sponsors already standardized on Veeva can, in principle, avoid the system-to-system integration work that a best-of-breed eCOA vendor requires. This is the same unification argument Medidata makes for Rave eCOA, applied to a broader platform. The limitation is relative newness: at "51 to 100 customers" and a 2022 launch date, Veeva eCOA has materially less trial-volume history than the five incumbents above, none of which publish a comparable customer count for direct comparison, making an apples-to-apples adoption comparison currently impossible from public data.

Feature Comparison

Table 1 below summarizes the six platforms across the axes sponsors most frequently cite in RFPs: device strategy, compliance posture, ownership structure, and claimed regulatory-approval support. Because the public materials reviewed did not provide comparable list prices or a common published pricing basis, the final column records the availability of public pricing information rather than inferring a uniform contract model.

Vendor	**Device Strategy**	**Ownership (2026)**	**Compliance Claims**	**Vendor-Reported Regulatory Footprint (not comparable across vendors)**	**Analyst Recognition**	**Public Pricing Information**
Signant Health	BYOD, provisioned, web (Source: signanthealth.com)	Genstar Capital (private equity)	Part 11 (GxP Inventory module) (Source: signanthealth.com)	Vendor-reported: 25% of FDA/EMA novel approvals, 2020 to 2025 (Source: signanthealth.com)	—	No comparable public list price identified
Medidata	BYOD, provisioned (Source: medidata.com)	Dassault Systèmes (public parent) (Source: 3ds.com)	ISO 27701, SOC 2 Type II (privacy) (Source: medidata.com)	Vendor-reported: 70%+ of 2022 FDA novel drug approvals (Source: medidata.com)	—	No comparable public list price identified
Clario	BYOD, web, provisioned (Source: clario.com)	**Acquired by Thermo Fisher Scientific**, deal announced Oct. 2025 (Source: mnawatch.com)	Part 11, EU GDPR (imaging module) (Source: clario.com)	Vendor-reported: 60%+ of FDA approvals since 2012 (Source: clario.com)	—	Quote-based, per study
YPrime	BYOD, provisioned (Source: yprime.com)	Flexpoint Ford (private equity) (Source: prnewswire.com)	Part 11, GDPR, HIPAA (IRT) (Source: yprime.com)	Not separately disclosed	Everest Group 2025 PEAK Matrix Leader (vendor-cited) (Source: globenewswire.com)	No comparable public list price identified
Suvoda	BYOD, provisioned, hybrid (Source: suvoda.com)	Thoma Bravo (lead, private equity) (Source: suvoda.com)	Annual SOC 2 Type 2, EU-U.S. DPF (Source: suvoda.com)	Not separately disclosed (vendor reports 6,000+ trials across all products) (Source: suvoda.com)	—	No comparable public list price identified
Veeva eCOA	BYOD, provisioned (Vault Clinical) (Source: veeva.com)	Veeva Systems, publicly traded (NYSE: VEEV)	Not separately published on eCOA product pages	Not separately disclosed	2025 ISR ranking cited by Veeva (vendor-cited) (Source: veeva.com)	No comparable public list price identified

The matrix surfaces a structural pattern rather than a single winner: the approval-support figures are vendor-reported footprint claims, not a common adoption measure. Signant reports FDA and EMA approvals for 2020 to 2025, Medidata reports FDA approvals for 2022, and Clario reports FDA approvals since 2012; their differing geography, time period, and definitions preclude relative adoption or vendor-ranking inferences. Ownership structure is not cosmetic: Clario, YPrime, and Suvoda have undergone a major ownership change, investment, or merger since 2019. Genstar's acquisition and combination of CRF Health and Bracket occurred in 2018; the combined company launched as Signant Health in 2019. Sponsors signing multi-year eCOA contracts should ask directly about contract-continuity commitments and post-transaction operating plans; Thermo Fisher reports that Clario is now part of its Laboratory Products and Biopharma Services segment (Thermo Fisher Scientific. The comparison also underscores that headline trial-volume and approval-support statistics, while useful as a first screen, measure a vendor's aggregate footprint rather than its fit for any single protocol; a sponsor running a rare-disease trial with fewer than 50 patients gains comparatively little from a vendor's claim of supporting tens of thousands of trials if that vendor's therapeutic-area experience in the relevant indication is thin, which is why the RFP criteria discussed later in this report emphasize indication-specific and population-specific vendor experience over aggregate scale alone.

Performance and Benchmarks

Independent, peer-reviewed performance data on named eCOA vendors is scarce; the literature instead benchmarks electronic versus paper collection modes and device strategies (BYOD versus provisioned devices) generically, which is nonetheless directly relevant to vendor evaluation since every vendor above supports multiple device modes. The seminal finding in this literature is a controlled study of chronic pain patients (Stone et al., 2003) in which reported paper-diary compliance was **90%**, but electronic monitoring embedded in the paper binder revealed actual compliance of only **11%**; the same patients achieved **94% actual compliance** using an electronic diary (Source: pubmed.ncbi.nlm.nih.gov). The paper diary binder was, remarkably, never opened on **32% of study days** even though reported compliance for those days exceeded 90% (Source: pubmed.ncbi.nlm.nih.gov). This finding, now more than two decades old, remains the foundational evidence cited industry-wide for why regulators and sponsors moved away from paper diaries toward eCOA.

More recent data refines the device-strategy question specifically. In Eli Lilly's Phase 3 baricitinib trials for rheumatoid arthritis, RA-BEAM (n equals 1,305) and RA-BUILD (n equals 684), electronic PRO diary compliance through Week 12 reached **94%** and **93%** respectively, using a handheld electronic diary from Invivodata (Source: pubmed.ncbi.nlm.nih.gov). A peer-reviewed crossover study of 64 chronic obstructive pulmonary disease (COPD) patients comparing BYOD against provisioned devices found weekly eCOA compliance of **89.7% to 100% for BYOD** versus **76.9% to 100% for provisioned devices**, with strong score equivalence between modes (intraclass correlation coefficient of 0.863 to 0.908) (Source: pmc.ncbi.nlm.nih.gov), and **79.7%** of participants reported being "quite a bit" or "very" comfortable using their own device for data collection (Source: pmc.ncbi.nlm.nih.gov).

Site staff, however, are not uniformly enthusiastic about BYOD. A survey of 67 clinical trial site staff affiliated with the PRO Consortium and eCOA Consortium found **37.3%** preferred BYOD versus **31.3%** who preferred provisioned devices, with the remainder reporting no preference; among staff who had actually trained participants on BYOD apps, preference for BYOD rose to **57.5%** (Source: pmc.ncbi.nlm.nih.gov). The same survey found sites had far more hands-on experience with provisioned devices (**79.1%** had entered eCOA data via provisioned device) than with training participants on BYOD apps (**60.0%**) (Source: pmc.ncbi.nlm.nih.gov), a gap that speaks to operational readiness rather than pure preference and suggests vendor helpdesk and site-training quality, an area where the Signant Reddit criticism above is directly relevant, is as much a performance variable as the underlying software.

On measurement equivalence, ISPOR's ePRO Good Research Practices Task Force, whose original report dates to 2009 (Source: ispor.org, issued updated guidance in **May 2023** concluding that additional equivalence testing is "no longer needed for many questionnaires" migrating between paper and electronic modes, and explicitly extending that conclusion to BYOD scenarios (Source: ispor.org) (Source: ispor.org). A separate peer-reviewed meta-analytic review corroborates this, finding "high overall levels of agreement between paper and computerized measures" and concluding that for minor-change migrations of instruments with standard response-scale types, no additional quantitative or qualitative equivalence studies are needed if ePRO design best practices were followed (Source: rtihs.org). This is directly relevant to migration cost, discussed further below: the regulatory and scientific bar for switching modes has fallen over the past fifteen years, even as vendor switching itself remains operationally complex. Taken together, these findings suggest that measurement performance is now a largely solved problem for well-designed eCOA and ePRO instruments, while operational performance, site training quality, helpdesk responsiveness, and device provisioning logistics, remains the more variable and vendor-dependent factor, consistent with the split between vendor-published compliance statistics and the more critical independent sentiment found in trade forums.

Data Analysis and Evidence

Market-sizing data on eCOA diverges by research firm, a pattern this report treats as an honest finding rather than resolving artificially into a single number. **MarketsandMarkets** values the eCOA solutions market at **$1.94 billion in 2024**, forecasting growth to **$4.13 billion by 2029** at a **16.3% CAGR**, with Asia Pacific identified as the fastest-growing region at a **16.8% CAGR** (Source: marketsandmarkets.com). A separate trade-press figure, attributed to Castor-sponsored content on Clinical Leader, states the market reached **$2.27 billion in 2025** at a **16.1% CAGR**, and explicitly segments the competitive field into "enterprise leaders" (Medidata, Signant, Clario) and "specialized vendors" (Suvoda, Kayentis, Clinical Ink) (Source: clinicalleader.com). The $2.27 billion 2025 figure is approximately 17% higher than the $1.94 billion 2024 figure, which is broadly consistent with the cited annual growth rates. Because the sources use different methodologies, their estimates should still be treated as directional rather than directly comparable.

Within the eCOA category, ePRO is the largest single product segment, accounting for **57.1% of market share in 2024** per MarketsandMarkets (Source: marketsandmarkets.com), consistent with patient-reported data being the most common eCOA use case across therapeutic areas. *Table 2* below summarizes clinical-trial technology adoption trends drawn from a 2023 industry tracker.

Table 2 contextualizes eCOA and ePRO adoption against other clinical trial digital tools, drawing on DT Consulting's Clinical Trial Digital Tracker as reported by OpenClinica.

METRIC	DECEMBER 2020	2023	SOURCE
Sites using no digital tools	43%	20%	(Source: openclinica.com)
Trials using Electronic Data Capture (EDC)	not reported	approximately 80%	(Source: openclinica.com)
Sites using ePRO	not reported	approximately 45%	(Source: openclinica.com)
Trials with decentralized components started (annual)	approximately 674 (2020, implied by 93% jump to 2022)	approximately 1,300 (2022)	(Source: openclinica.com)

The table shows ePRO penetration (45% of sites) trailing EDC penetration (80% of trials) by a wide margin, indicating substantial headroom for further eCOA and ePRO adoption even as overall digital-tool usage has become near-universal. Separately, a Veeva-sponsored survey of 280 global clinical leaders found **87%** were using some form of decentralized trial technology in 2021, up from **28%** in pre-pandemic conditions, though **99%** of sponsors and Contract Research Organizations (CROs) reported significant challenges from fragmented decentralized-trial technology stacks, having added an average of four new clinical applications (Source: acrpnet.org) (Source: acrpnet.org). That fragmentation finding is directly relevant to the Medidata and Veeva unification arguments discussed above.

On licensing costs specifically, the public materials reviewed for the six vendors did not provide comparable per-patient or per-study list prices, and this report could not trace any single "$X per patient" industry benchmark to a citable originator; aggregated figures circulating informally in procurement circles should not be relied upon absent vendor-specific quotes. What can be benchmarked is instrument licensing, a cost stream entirely separate from the eCOA software contract: standard clinical outcome assessment instruments like the **EQ-5D** require their own commercial-use license from the copyright holder, EuroQol, governed by a dedicated fee-and-procedure document (Source: euroqol-domain.ams3.digitaloceanspaces.com) independent of whichever eCOA vendor hosts the instrument. Trade sources report typical instrument-licensing negotiation timelines of around 30 days, with roughly **5% to 10% of licensors** adjusting fees or terms in any given year (Source: lifesciences.transperfect.com), a variable cost sponsors frequently underweight relative to the eCOA software fee itself when budgeting. Sponsors budgeting for an eCOA program should therefore treat the software license, the instrument copyright license, and translation and linguistic validation spend as three separate line items with three separate negotiation timelines, rather than assuming a single vendor quote captures the full cost of deployment.

Finally, on the cost of change mid-trial, Tufts CSDD's analysis of 836 protocols found **57%** had at least one substantial global amendment, with a median direct cost of **$141,000** for Phase II amendments and **$535,000** for Phase III amendments, of which **45%** were judged avoidable (Source: pubmed.ncbi.nlm.nih.gov). Because eCOA rebuilds (new instruments, translations, device reconfiguration) are a common component of substantial amendments, this figure is one of the closest available proxies for the true cost of an unplanned, mid-study eCOA change, even though it is not eCOA-specific.

Case Studies and Real-World Examples

Applied Therapeutics: An eCOA Data Integrity Enforcement Action

On December 3, 2024, the FDA issued a warning letter to **Applied Therapeutics** after a third-party vendor contracted by the company deleted electronic data captured in Pearson's Q-global system, along with the associated audit trails, for all **47 subjects** enrolled in a pivotal study (Source: fda.gov) (Source: fda.gov). The deletion occurred days after the FDA announced a site inspection, a timeline the agency's letter treats as significant. This case is the clearest publicly documented illustration of why 21 CFR Part 11's audit-trail requirement is not a procedural formality: when an eCOA-adjacent data source loses its audit trail, the underlying clinical endpoint data becomes functionally unverifiable, regardless of which primary eCOA vendor the sponsor used for the rest of the study.

Eli Lilly's RA-BEAM and RA-BUILD Trials: Quantified ePRO Compliance at Phase 3 Scale

Eli Lilly's Phase 3 baricitinib rheumatoid arthritis program provides one of the largest published, named examples of ePRO compliance at scale. Across RA-BEAM (n equals 1,305) and RA-BUILD (n equals 684), electronic diary compliance through Week 12 reached 94% and 93% respectively, using a handheld electronic diary supplied by Invivodata (Source: pubmed.ncbi.nlm.nih.gov). The published analysis explicitly frames this as evidence supporting the FDA's broader endorsement of electronic PRO capture, noting that ePRO systems "may lead to more accurate and complete data capture, improved compliance" relative to paper alternatives (Source: pubmed.ncbi.nlm.nih.gov).

Cara Therapeutics: Multilingual eCOA Deployment on Suvoda's Unified Platform

Cara Therapeutics used Suvoda's combined eCOA/IRT platform across two pruritus indications, chronic kidney disease pruritus and notalgia paresthetica, reporting what the published case study calls a "dramatic increase in patient eCOA compliance" relative to the sponsor's prior studies with other vendors (Source: suvoda.com). Cara's VP of Biometrics, Catherine Munera, is quoted stating that all study languages, including Xhosa and Setswana for South African trial sites, were certified before go-live for the first time in the sponsor's history (Source: suvoda.com), illustrating the translation and linguistic-validation workload that sits underneath any eCOA vendor's device and software layer.

Signant Health: Absorbing a Mid-Study Protocol Amendment Without a Platform Switch

A published Signant Health case study describes a Phase 2 oncology trial that expanded by 350 patients, 50 sites, and 5 countries mid-study while remaining on Signant's eCOA platform throughout (Source: signanthealth.com). The therapy subsequently received FDA approval in spring 2021 and EMA approval in January 2022, and the sponsor retained Signant for the follow-on Phase 3 study, an outcome directly relevant to the Tufts CSDD finding that substantial amendments carry a median cost of $535,000 at Phase III: absorbing scale changes on the existing platform, as this case describes, is one concrete way sponsors avoid that cost.

Clario's WCG eCOA Acquisition and the Thermo Fisher Deal: Consolidation as Market Structure

Clario's **May 6, 2025** completion of its acquisition of WCG's eCOA business, explicitly framed as strengthening neuroscience trial support (Source: clario.com), and the subsequent **October 2025** announcement that Clario itself would be sold to Thermo Fisher Scientific for approximately $8.875 billion (Source: mnawatch.com), together illustrate that vendor consolidation is not a background trend in this market but an active, ongoing feature sponsors must plan around. Recent consolidation among these vendors is a planning consideration for sponsors signing multi-year eCOA contracts. They should assess contract-continuity commitments and post-transaction operating plans, rather than infer a probability of a future ownership change from past transactions.

Read together, these five cases span the full lifecycle of risk a sponsor faces with an eCOA vendor relationship: data integrity failure, compliance performance at scale, multilingual deployment complexity, mid-study platform resilience, and vendor ownership churn. No single vendor in this comparison has a public track record demonstrating strength across all five simultaneously, which is itself a reason to treat vendor selection as a portfolio-risk decision rather than a single-feature purchase.

Implications and Future Directions

Vendor Selection Criteria and Migration Checklist

Sponsors evaluating eCOA vendors should structure their RFP around criteria that go beyond feature checklists. Guidance published in the Journal of the Society for Clinical Data Management (JSCDM) recommends asking vendors to state their experience with **provisioned devices versus BYOD versus hybrid** models broken down by patient population, country, and therapeutic area (Source: jscdm.org), to require vendors to describe their 21 CFR Part 11 compliance approach explicitly rather than accepting a general assurance (Source: jscdm.org), and to confirm end-of-trial device disposition planning up front (Source: jscdm.org). The same guidance notes that BYOD's principal cost advantage is structural: "reduced costs as no device needs to be provided and shipped" (Source: jscdm.org), a savings that must be weighed against the lower site-staff comfort with training participants on BYOD found in the performance data above.

A practical eCOA migration or new-implementation checklist, synthesized from peer-reviewed and industry guidance, should include the following steps:

- **Confirm instrument licensing before any build work begins.** Peer-reviewed clinical data management guidance stresses ensuring "the license is in place before any build activity starts" (Source: jscdm.org), since instrument copyright holders like EuroQol license separately from the eCOA software vendor.
- **Secure copyright-holder license agreements** for every COA and its derivatives, a distinct contractual track from the eCOA vendor Master Service Agreement (Source: mapi-trust.org).
- **Run conceptual harmonization analysis before translation**, listing the concepts that must be preserved across languages prior to linguistic validation (Source: mapi-trust.org).
- **Assign a single accountable project manager** across the eCOA workstream, since best-practice guidance recommends treating implementation as "a single project across the multiple stakeholders that are involved" rather than as parallel, uncoordinated tracks (Source: mapi-trust.org).
- **Assess whether additional comparability evidence is required.** Per the 2023 ISPOR update, the decision is instrument- and migration-specific: it depends on the available supporting evidence and on whether the change from paper to electronic affects the questionnaire's meaning. Additional testing is not needed for many questionnaires, but this is not a blanket exemption for minor changes or BYOD (Source: ispor.org).
- **Evaluate device strategy against operational readiness**, not just cost. The survey measured different types of experience: 79.1% of respondents had entered eCOA data using a provisioned device, while 60.0% had trained participants on BYOD apps; neither figure alone measures comparative comfort with the two models (Source: pmc.ncbi.nlm.nih.gov).
- **Question vendors about ownership and contract continuity directly**, given how frequently the vendors in this comparison have changed hands: Clario became part of Thermo Fisher on March 24, 2026 (Thermo Fisher Scientific; Suvoda merged with Greenphire under Thoma Bravo in April 2025; Medidata joined Dassault Systèmes in 2019; and YPrime received Flexpoint Ford investment in 2019.

A vendor-neutral criteria framework published by consultancy Delve Health similarly frames the evaluation as extending beyond basic functionality to include protocol flexibility, patient usability, support model, and audit readiness (Source: delvehealth.com), a framing consistent with the JSCDM RFP guidance above. In IntuitionLabs' advisory work with pharmaceutical and life-sciences clients on digital transformation and technology assessment, the firm similarly emphasizes evaluating vendor and platform choices as an integrated decision rather than a checklist exercise, stating that its assessments help clients "make informed decisions about technology investments and implementations" (Source: intuitionlabs.ai) rather than optimizing any single feature in isolation; this framing is consistent with the JSCDM and Delve Health guidance above, and reflects a general vendor-technology-assessment practice rather than an eCOA-specific product offering.

Regulatory Trajectory

The regulatory environment governing eCOA and ePRO systems has moved toward greater specificity in the past three years. The FDA's October 2024 final guidance on electronic systems, records, and signatures explicitly updates audit-trail and data-integrity expectations and adds recommendations on data collected via digital health technologies (Source: federalregister.gov), while the EMA's March 2023 computerised-systems guideline formally replaced a 2010-era reflection paper and named eCOA in its explicit scope for the first time (Source: ema.europa.eu). The EMA also opened public consultation on a draft "Reflection paper on patient experience data" on **September 29, 2025**, running through **January 31, 2026**, signaling continued regulatory attention to patient-generated data broadly, not just eCOA specifically (Source: ema.europa.eu). On the standards side, ePRO data still lacks a mandatory structural data model: the ISPOR paper on ePRO dataset standardization notes plainly that "ePRO data are not required to follow a standard model, and the data models used often vary by eCOA provider and sponsor" (Source: ispor.org), a gap that CDISC's CDASH standard partially addresses by establishing consistent data-collection formats that trace cleanly into the Study Data Tabulation Model for regulatory submission (Source: cdisc.org). Sponsors should expect this data-model gap to narrow over time as regulators and standards bodies converge, but as of August 2026 it remains a live source of vendor-to-vendor data interoperability friction.

Looking forward, three trends are likely to shape vendor selection over the next 24 months. First, further consolidation is probable given the pace of the past five years; sponsors should build contract-continuity language into new agreements regardless of a vendor's current ownership status. Second, platform-native entrants like Veeva will likely continue pushing the "unification" argument against point-solution incumbents, a dynamic that mirrors the same argument Medidata already makes with Rave eCOA against non-Medidata rivals. Third, the narrowing regulatory bar for equivalence testing, combined with tightening audit-trail and data-integrity guidance, means the compliance differentiator among vendors is shifting away from "can you validate an instrument" toward "can you prove, with an unbroken audit trail, exactly what happened to every data point," a bar the Applied

Therapeutics warning letter shows some organizations still fail to clear. Sponsors that have historically evaluated eCOA vendors primarily on instrument library breadth and device catalog should expect procurement scorecards to weight audit-trail architecture and data-deletion safeguards more heavily going forward, mirroring the shift in emphasis regulators have already made in guidance text.

Frequently Asked Questions (FAQs)

What is the difference between eCOA and ePRO? eCOA is the umbrella term for any Clinical Outcome Assessment, covering clinician-reported, observer-reported, performance, and patient-reported data, collected electronically. ePRO is specifically the patient-reported subset of that data, collected electronically rather than on paper; C-Path's PRO Consortium and eCOA Consortium jointly maintain the ePRO data-standardization work that formalizes this hierarchy (Source: ispor.org).

How much does eCOA or ePRO software cost? The public materials reviewed for Signant Health, Medidata, Clario, YPrime, Suvoda, and Veeva did not provide comparable list prices. Sponsors should request vendor-specific quotes and confirm the proposed contract structure, then budget separately for instrument copyright licensing (governed by holders like EuroQol independent of the software vendor) (Source: euroqol-domain.ams3.digitaloceanspaces.com) and for the downstream cost of avoidable protocol amendments, which Tufts CSDD priced at a median of $535,000 for Phase III (Source: pubmed.ncbi.nlm.nih.gov).

Is eCOA data automatically FDA-compliant? No. Compliance depends on meeting 21 CFR Part 11's audit-trail and record-integrity requirements in practice, not just in vendor marketing claims (Source: ecfr.gov). The December 3, 2024, Applied Therapeutics warning letter shows that even a well-established data vendor's system can fail this bar when audit trails are deleted (Source: fda.gov).

Can eCOA vendors be switched mid-study? Yes, though it is operationally complex. Signant Health's own case study describes absorbing a mid-study expansion of 350 patients, 50 sites, and 5 countries without switching platforms (Source: signanthealth.com), which is generally easier than a true vendor switch. The 2023 ISPOR update supports deciding whether additional comparability evidence is needed based on the instrument, the migration, the available supporting evidence, and whether the change affects questionnaire meaning; it does not create a blanket exemption from testing (Source: ispor.org).

Should sponsors choose BYOD or provisioned devices? The performance data is mixed by design intent: BYOD showed higher weekly compliance (89.7% to 100%) than provisioned devices (76.9% to 100%) in one COPD crossover study (Source: pmc.ncbi.nlm.nih.gov). In a separate site-staff survey, 79.1% of respondents had entered eCOA data using a provisioned device and 60.0% had trained participants on BYOD apps; these are different activities and do not compare training experience across both device models (Source: pmc.ncbi.nlm.nih.gov). The appropriate choice depends on site readiness and patient population as much as raw compliance data.

Conclusion

This comparison of Signant Health, Medidata, Clario, YPrime, Suvoda, and Veeva eCOA finds substantial overlap in documented device options and deployment capabilities, but the public evidence does not establish that every platform supports a hybrid model within the same study. Four of the six vendors profiled have changed hands or completed major mergers since 2019; most recently, Thermo Fisher Scientific completed its acquisition of Clario on March 24, 2026, and Clario became part of Thermo Fisher's Laboratory Products and Biopharma Services segment (Thermo Fisher Scientific. Comparable public list prices were not identified in the reviewed materials, so sponsors should obtain vendor-specific quotes and evaluate the proposed contract structure alongside scope and implementation requirements. Published evidence also indicates that instrument licensing, translation, and protocol-amendment planning can create material downstream costs.

The regulatory bar has tightened on data integrity, as the Applied Therapeutics warning letter demonstrates. Separately, ISPOR's 2023 Good Practices guidance supports an evidence-based, case-specific approach to measurement comparability; it does not create a regulatory exemption from testing. This combination rewards vendors and sponsors who maintain audit-trail discipline and document whether the evidence for a particular instrument and migration supports dispensing with further comparability testing. Sponsors selecting an eCOA or ePRO vendor in 2026 should weight device strategy against site operational readiness rather than compliance claims alone, treat instrument and translation licensing as a parallel workstream with its own timeline, and build ownership-continuity protections into any multi-year contract given the sector's consolidation pace. Ultimately, the vendors compared in this report are converging on similar feature sets while differing in ownership structures and integration histories. Ownership continuity is one procurement consideration among several, alongside protocol fit, instrument licensing, device strategy, integration requirements, service quality, and contractual protections; the public evidence reviewed does not establish which factor will be decisive for a given sponsor. For organizations without in-house capacity to run this evaluation, independent advisory support, distinct from any single eCOA vendor's own sales process, can help translate the criteria in this report into a defensible, audit-ready vendor decision.

Tags: ecoa, epro, clinical outcome assessment, patient reported outcomes, clinical trial technology, signant health, medidata, clario, yprime, suvoda

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