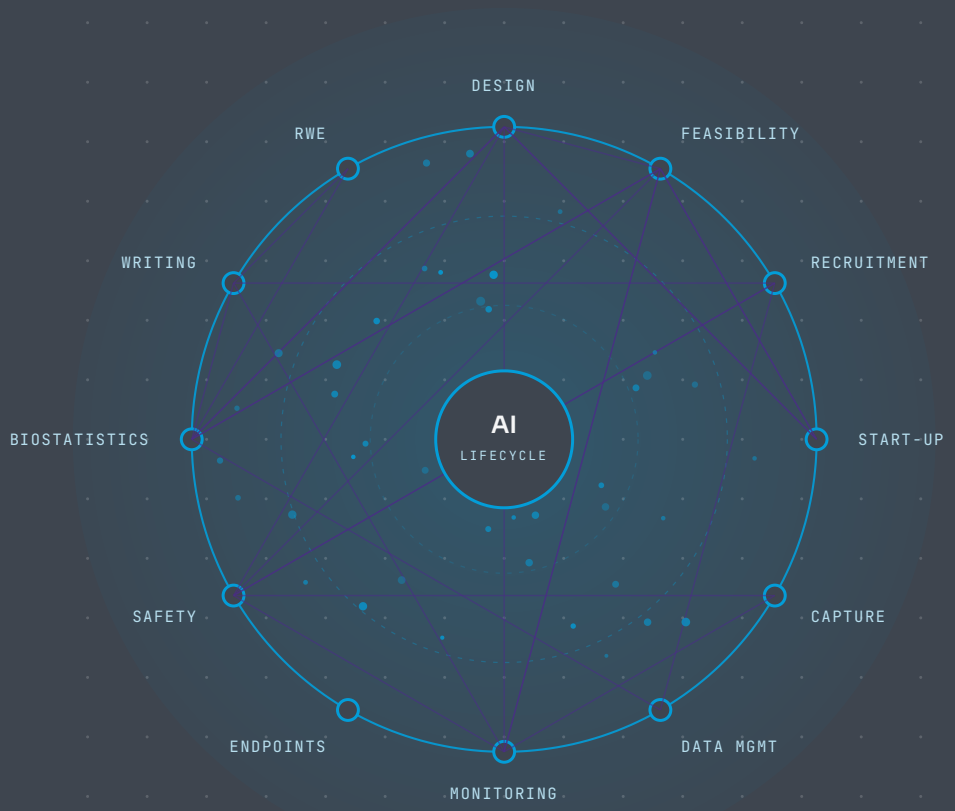
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AI Across the Clinical Development Lifecycle

A review of the tools and services in use and in development, from protocol design to real-world evidence - with the evidence, the regulation and the open questions

Praveg Consultancy Services LLP
AI Domain Intelligence · Biometrics Process Excellence · PMO Consulting
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PRAVEG Consultancy Services
ENHANCING POTENTIAL, ACCELERATING GROWTH

ABOUT THIS REVIEW

Scope, method and how to use this paper

This paper reviews artificial-intelligence tools and services available to, or in development for, the clinical development lifecycle as of November 2026. It covers commercial platforms, CRO and IT-services offerings, regulator-qualified methods and peer-reviewed research across twelve lifecycle stages, together with the regulatory, validation and standards instruments that govern their use in the United States, the European Union and India. Drug discovery is summarised as context only.

Material was compiled from roughly 450 public sources: vendor product pages and press releases, regulator publications, peer-reviewed journals and indexed conference proceedings, industry-body reports and trade press, each cited in the reference list. Vendor-reported metrics are labelled as such throughout and are not independently verified; where a vendor's own documents disagree, the discrepancy is noted. Coverage is deliberately broad but cannot be complete in a market that announced new products weekly through 2026; the catalogue is a structured, non-exhaustive market review, and omissions are not judgements. Statements of the form "the only vendor found" or "not identified in this review" refer to this sample and search method, not to the market as a whole.

Method and evidence grading. Sources were located by web search between October and November 2026, with vendor pages, press releases, regulator publications, peer-reviewed journals, conference abstracts and preprints each read directly where accessible. Every quantitative claim is tagged in the text as vendor-reported, customer-reported, peer-reviewed, conference or preprint, or regulator-recognised; a product announcement is treated as evidence that a product exists, not that its claimed performance has been demonstrated. Where two sources conflict, both figures are given. Regulatory instruments are cited from the issuing body where possible and their legal status (binding, guidance, good practice) is stated in Section 16. Limitations: vendor entries in Appendix A were not verified entry by entry beyond their cited public page; late-2026 launch dates describe announced plans, not confirmed deployments; and the reference list, while large, is not a measure of evidence strength. AI tools, including Anthropic's Claude, were used to assist with source gathering and drafting; cited claims were checked against their sources by the authors, and the structure, analysis and conclusions are Praveg's own.

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The intended reader is a decision-maker in a sponsor, CRO or service organisation who must choose where to invest, what to validate and what to ask vendors. Sections 1–3 give the summary and framing; Figure 1 is the one-page map; Sections 4–15 work through the lifecycle; Sections 16–20 cover regulation, geographies, the market and the provider landscape; Sections 21–23 draw conclusions, map the white space and offer a checklist.

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SECTION 1

01 Executive summary

Artificial intelligence has moved from the margins of clinical development to its operating core. The major eClinical platforms, the large CROs and most of the large Indian IT-services firms now sell AI-labelled capability across the trial lifecycle, and regulators in the United States, the European Union and India have published the frameworks by which that capability will be judged. This review maps what is actually available, what is still in development, and what the evidence says about each.

Three things stand out from the ~450 sources compiled for this paper. First, the maturity of AI varies sharply by lifecycle stage. Patient-to-trial matching, medical coding, safety-case intake and imaging reads have peer-reviewed or regulator-recognised evidence behind them; protocol authoring, statistical programming and clinical-study-report generation have promising pilots but thin independent validation. Second, the regulatory position has clarified quickly: the FDA's January 2025 draft guidance supplies a seven-step credibility framework for any AI output that supports a regulatory decision,[1] the EMA's reflection paper and the joint EMA–FDA principles of January 2026 set expectations for the full product lifecycle,[2,3] and ICH E6(R3) now requires validated, governed data systems whatever technology underlies them.[4] Third, the gap between vendor claims and measured outcomes is wide. A 2025 scoping review of 262 publications on statistical-programming automation (a preprint, not yet peer-reviewed) found that only 16% reported quantitative outcomes and that every one of the 42 quantitative studies was positive, a pattern the authors read as publication bias.[5] Deloitte's 2026 analysis of R&D returns is blunter: the promise that AI would materially cut development time and cost "has not yet been realised at scale."[6]

US$2.67bn

Deloitte's cost-per-asset measure for its cohort of 20 large biopharma companies, 2025 (16th ed.)[6]

~5.9m

Mean data points per Phase III protocol in the TransCelerate–Tufts sample, growing ~11% a year[7]

76%

Protocols with at least one substantial amendment in Tufts CSDD's 2024 cohort (950 protocols, 16 companies); Phase III averages 3.4[8]

22% / 9%

Life-science leaders who have scaled AI, and who report significant ROI (Deloitte 2026 outlook)[9]

For a sponsor or CRO deciding where to invest, the practical conclusion is to buy where the evidence is, pilot where it is not, and treat validation, data governance and skills as the cost of entry rather than an afterthought. Section 23 sets out a decision checklist on that basis. The lifecycle map in Figure 1 (following Section 2) is the organising device for the whole paper: twelve stages from protocol design to real-world evidence, each showing the tools in commercial use and those still emerging, with the platforms and governance instruments that cut across all of them.

How to read the evidence labels in this paper

Throughout, a metric is marked **vendor-reported** when it comes from a supplier's own release or case study and has not been independently audited; **peer-reviewed** when it appears in a peer-reviewed journal; **conference** or **preprint** when it comes from an abstract, proceedings paper or preprint server, whose review standards differ; and **regulator-recognised** when a regulator has qualified, accepted or formally commented on the method for a defined context of use. Appendix A abbreviates these as VR,

PR, Conf/Preprint and RR. Many of the most quoted efficiency figures in this field are in the first category.

SECTION 2

02 Why now: the cost, complexity and data baseline

The economic case for AI in clinical development rests on a set of baseline figures that have been stable in direction, if not in magnitude, for two decades. The Tufts Center for the Study of Drug Development estimated the capitalised pre-approval cost of a new drug at US$2.56 billion in 2013 dollars, a 145% real increase on its 2003 figure.[10] Deloitte's annual tracking of a cohort of 20 large biopharma companies puts its cost-per-asset measure at US$2.67 billion for 2025 and the projected internal rate of return on R&D at 7.0%, or 2.9% once GLP-1 products are excluded; the figure describes that cohort, not every sponsor or every drug.[11]

Much of that cost sits in trial conduct, and much of trial conduct is shaped by protocol complexity. Since 2005, procedures per protocol have risen 139%, endpoints 214% and data points roughly 600%.[12] Tufts counted a mean of 3.56 million data points per Phase III protocol in a sample of 220 protocols from 18 companies and two CROs (2013–2019), about three times the figure a decade earlier,[13] and the TransCelerate–Tufts study of 2025 puts the Phase III mean in its sample at close to 5.9 million, growing around 11% a year, with roughly a third of procedures and data points falling outside the primary and key secondary endpoints; such data may still serve safety, exploratory or compliance purposes, and the figures should not be generalised to early-phase or smaller studies.[14,7]

Protocol amendments are the most expensive symptom. In Tufts' 2024 cohort of 950 protocols from 16 companies, 76% had at least one substantial amendment (as distinct from any amendment); Phase III protocols completing between 2023 and 2025 averaged 3.4, up 48% in a decade, and a typical Phase III amendment carries about three months of delay and, by the most recent WCG estimate, around US$1 million in unbudgeted cost.[8] The earlier Tufts benchmark of US$535,000 median direct cost per Phase III amendment, with roughly 45% judged avoidable, is the figure most vendors still quote.[15]

Enrolment is the other persistent failure. The widely repeated claim that "80% of trials miss enrolment timelines" has no traceable primary source; the measured Tufts figure, from 151 Phase II/III trials across roughly 16,000 sites, is that 47% completed enrolment on time, 11% of activated sites enrolled no patients and 48% under-enrolled or enrolled none.[16] Either way, recruitment typically consumes up to a third of a trial's duration and one in five trials fail to recruit at all.[17]

These are the problems the tools in this paper claim to address: fewer avoidable amendments, faster and more predictable enrolment, data review that keeps pace with data volume, and reporting that does not stall the submission. Whether they do so is the question each of the following sections tries to answer.

AI across the clinical development lifecycle – tools in use and in development (Nov 2026)

In commercial use · Emerging / in development

Twelve lifecycle stages; within each, tools in commercial use (left legend) and tools announced, piloted or published in 2025–26 (right legend). Around 160 providers reviewed; full catalogue in Appendix A, sources in the reference list.

UPSTREAM Discovery & translational AI (context): AlphaFold 3 · Isomorphic Labs · Insilico rentosertib (Phase III, Sep 2026) · Recursion/Exscientia · Chai-2 antibody design · Owkin CE-IVD stratification · Lilly TuneLab · NVIDIA BioNeMo

PLANNING ——— CONDUCT ——— ANALYSIS & REPORTING ——— LIFECYCLE

1 Protocol design & simulation

IN USE
- Medidata Protocol Optimization, SCA
- IQVIA protocol design analytics
- Citeline SmartDesign; Nurocor (USDM)
- Unlearn PROCOVA (EMA-qualified)
- Intelligencia AI; Cytel East Horizon

EMERGING
- Faro Health digital protocols (USDM)
- Phesi digital-twin control arms
- Risklick Protocol AI; Evinova
- Clinion eProtocol; Coforge–Espero

2 Feasibility & site selection

IN USE
- Medidata Intelligent Trials
- IQVIA Connected Intelligence
- TriNetX LIVE (RWD feasibility)
- Citeline SmartSelect; H1 GenosAI
- Reify StudyTeam; Lokavant; Inato

EMERGING
- ICON OneSearch + Claude (Orbis)
- Ryght AI site twins (Accenture)
- Lindus Health 'anti-CRO'
- Syneos–Causaly knowledge graph

3 Recruitment & eligibility screening

IN USE
- Tempus TIME / Deep 6 AI
- Mendel Hypercube (neuro-symbolic)
- Paradigm; Massive Bio; BEKhealth
- Leal Health; Acclinate; Carebox

EMERGING
- TrialGPT (NIH, Nat Commun 2024)
- RECTIFIER (MGB, NEJM AI / JAMA)
- Triomics OncoLLM; Trially AI
- Muse (Sanofi–OpenAI); Grove→Hippocrati

4 Start-up, consent & TMF

IN USE
- Veeva TMF Bot; Trial Interactive
- Suvoda agentic RTSM + Sofia
- Signant RTSM builds; 4G Prancer
- ICON contracts; IQVIA GrantPlan

EMERGING
- LLM-simplified consent; WCG Copilot
- Florence agentic eISF; Medable TMF agen
- Veeva Falcon TMF; CRIO eSource Builder
- endpoint elo; Sitero AI

5 Study build & data capture

IN USE
- Medidata AI Study Build
- Clario AI algorithms; YPrime
- OpenClinica AI Foundry; Medrio
- Castor Catalyst; TrialKit AI

EMERGING
- Veeva Study Builder Agent (2026)
- ClinCapture Captivate; Anju Luminee
- Viedoc Vantage; Medable PI agent
- Veeva eSource; IgniteData Archer

6 Data management & medical coding

IN USE
- Saama Smart Data Quality
- Medidata Coder+, Clinical Data Studio
- WHODrug Koda (peer-reviewed)
- IQVIA CDAS; Clinion agentic CDM
- Castor Catalyst coding

EMERGING
- CluePoints IQD / IMC (GA Sep 2026)
- elluminate IQ agents (2026)
- TCS ADD AgentHub
- LLM-assisted SDTM review

7 Monitoring & RBQM

IN USE
- CluePoints SPOT & CSM
- Medidata Detect
- TRI OPRA (450+ trials)
- Fortrea Xcellerate; Cyntegrity MyRBQM

EMERGING
- TRI RiskIQ (protocol→risk drafting)
- Fortrea Foresight predictive signals
- ICON Orbis agentic monitoring
- elluminate RBQM agent

8 Imaging, pathology & digital endpoints

IN USE
- PathAI AIM-MASH (EMA/FDA qualified)
- Perceptive / Clario imaging AI
- Clario ArtiQ spirometry AI
- ActiGraph, Koneksa wearables
- SV95C wearable endpoint (EMA)

EMERGING
- ai.RECIST (Friends of Cancer Res.)
- Altis Labs IPRO survival prediction
- Qureight imaging biomarkers
- Imaging Endpoints AI review charter

9 Safety & pharmacovigilance

IN USE
- ArisGlobal LifeSphere NavaX
- Oracle Safety One Intake / Argus
- IQVIA Vigilance Detect; Qinecsa
- Genpact PVAI; Vitrana (Parexel)

EMERGING
- Veeva Falcon Safety (Nov 2026)
- Tech Mahindra, Wipro, HCLTech PV AI
- biologit, DrugCards literature AI
- LLM ADE extraction; CIOMS XIV

10 Biostatistics & statistical programming

IN USE
- SAS Viya Copilot / Clinical Accel.
- R submissions (R Consortium–FDA)
- Pinnacle 21 + CDISC CORE
- Cytel East Horizon; Berry FACTS

EMERGING
- Saama ADaM Navigator
- LLM SAS→R; Appsilon Mediforce
- Agentic analysis (JMIR 2026 caution)
- Dataset-JSON; Posit Assistant

11 Medical writing & submissions

IN USE
- Certara CoAuthor; Yseop
- Merck–McKinsey GenAI CSR
- Indegene NEXT; Narrativa; TrialAssure
- Freyr freya fusion; Cortellis AI

EMERGING
- Veeva Agentic Authoring (2027)
- Weave Bio; Celegence; Vivpro
- Claude for Life Sciences; GPT-Rosalind
- Zifo; RegASK; Hexaware

12 Post-marketing & real-world evidence

IN USE
- Flatiron LLM abstraction (VALID)
- Aetion (Datavant); RCT-DUPLICATE
- TriNetX; Komodo; Truveta; OM1
- Verana; PicnicHealth; DARWIN EU

EMERGING
- ConcertAI CARAai; Tempus Lens
- TriNetX conversational AI (2026)
- MDClone synthetic data; Causaly
- FDA Sentinel NLP (Oracle, JSL)

CROSS-CUTTING PLATFORMS, FOUNDATION MODELS AND AGENT FRAMEWORKS

Medidata Plus / Dot · Veeva AI & Falcon · Oracle LS AI Data Platform · IQVIA.ai (NVIDIA) · ICON Orbis (Microsoft, Anthropic) · Parexel–Palantir · Claude for Life Sciences · GPT-Rosalind · TCS ADD AgentHub

GOVERNANCE, VALIDATION AND STANDARDS THAT APPLY ACROSS EVERY STAGE

ICH E6(R3) 2025 + Annex 2 2026 · FDA draft AI guidance (Jan 2025) · EMA reflection paper (Sep 2024) · EMA–FDA GAIP principles (Jan 2026) · EU AI Act (high-risk → 2027) · GAMP 5 2e App. D11
FDA CSA (rev. Feb 2026; device QMS scope) · EU Annex 22 draft (AI) · CIOMS WG XIV (PV) · DPDP Rules 2025 · ICMR AI 2023 · NMPA AI opinions 2026 · MFDS AI guide (Dec 2026) · MHRA 2030 strategy · UK CTR 2026 · EHDS 2027–31

Figure 1 · Praveg Consultancy Services LLP · compiled from public sources, Nov 2026

SECTION 3

03 How this review is organised: a lifecycle map

AI vendors tend to describe their products in their own vocabulary ("connected intelligence", "data experience", "agentic labour"), which makes like-for-like comparison difficult. This paper therefore organises the market by what a trial team actually does, in twelve stages that follow the development lifecycle from protocol design to post-marketing evidence, with discovery and translational science treated as upstream context. For each stage, the paper distinguishes tools in commercial use from those that have been announced, piloted or published in 2025–2026 but are not yet in routine deployment. Two further layers cut across all stages: the platforms and foundation models on which many of the tools are built, and the regulatory, validation and standards instruments that govern their use.

Figure 1, on the preceding page, is the one-page version of that map. It is deliberately dense; the sections that follow supply the detail and the evidence for each entry, and Appendix A gives the full catalogue in tabular form.

A note on terminology

"AI" in this market spans at least four distinct technology families, and the regulatory and validation implications differ for each. **Statistical and machine-learning models** (gradient boosting, random forests, anomaly detection) underpin most risk-based monitoring, site-selection and prognostic tools; they are mature and their validation is well understood. **Natural-language processing** of the pre-LLM kind drives much of the medical coding, safety intake and document classification that has been in production for five to ten years. **Large language models** (GPT-4-class and successors) power the newer protocol-, consent- and report-drafting tools and most patient-matching research since 2023. **Agentic systems**, in which LLMs plan and execute multi-step tasks against enterprise data, are the 2025–2026 wave and are almost entirely in early-adopter status. Where a vendor's technique is not stated publicly, this paper says so.

SECTION 4

04 Upstream context: discovery and translational AI

Discovery is outside the scope of this review, but it sets expectations for the clinical stages and increasingly feeds them with candidates designed, and patients stratified, by AI. Three facts frame the picture. The 2024 Nobel Prize in Chemistry recognised AlphaFold's protein-structure prediction,[18] and AlphaFold 3 extended the approach to protein–ligand, nucleic-acid and antibody–antigen complexes.[19] Isomorphic Labs, DeepMind's drug-design spin-out, raised a US$2.1 billion Series B in May 2026 to move its first programmes toward the clinic; no fully AI-designed drug has yet been approved.[20] Chai Discovery reported in mid-2025 a zero-shot de novo antibody design hit rate of around 20% while testing fewer than 20 designs per target, against historical rates below 0.1%.[21]

The clinical evidence for AI-discovered molecules is encouraging but still early. Jayatunga and colleagues identified 75 AI-discovered molecules that had entered trials since 2015; of 24 that completed Phase I by December 2023, 21 succeeded, an 80–90% rate against a historical 40–65%, while Phase II success (4 of 10) matched industry norms.[22] Insilico Medicine's rentosertib, a generative-AI-discovered TNIK inhibitor for idiopathic pulmonary fibrosis, published randomised Phase IIa results in *Nature Medicine* in June 2025 (71 patients; FVC change +98.4 mL at 60 mg once daily versus −20.3 mL on placebo) and dosed its first Phase III patient in September 2026.[23,24] The

counter-example is Recursion, which halted four clinical programmes in May 2025 after its merger with Exscientia, a reminder that AI-originated assets fail in Phase II at ordinary rates.[25]

Two upstream developments bear directly on trial operations. Lilly's TuneLab offers federated access to models trained on more than US$1 billion of proprietary ADME and safety data, with NVIDIA committing up to US$1 billion over five years to a joint lab,[26,27] and the FDA's April 2025 roadmap to phase out animal-testing requirements for monoclonal antibodies explicitly names AI-based toxicity and pharmacokinetic models among the accepted alternatives.[28] In translational science, Owkin's RlapsRisk BC and MSIntuit CRC were CE-marked in 2022 as AI diagnostics derived from routine histology slides, the kind of tool now used to pre-screen or stratify patients before enrolment.[29]

SECTION 5

05 Protocol design, simulation and digital twins

This is the stage with the highest operational leverage and some of the earliest regulator-recognised statistical approaches. Three distinct product families exist: tools that score and optimise a protocol before it is finalised, tools that simulate operational outcomes, and statistical methods that use historical data to reduce the size or duration of the control arm.

Protocol optimisation and digitisation

Medidata's Protocol Optimization, launched at ASCO in May 2025, uses predictive models over a dataset the company puts at more than 38,000 trials to estimate patient burden, site performance and cost before first patient in; Medidata reports more than 500 studies using its AI over a decade and 120 AI-supported study starts in 2025 alone.[30,31] IQVIA digitises protocols into a de-identified library and scores complexity, patient burden and site burden; its internal review of 105 protocols linked higher patient burden to longer start-up, more amendments and higher screen-failure rates.[32] Citeline's Protocol SmartDesign applies machine learning and LLMs to its Trialtrove database to recommend endpoints and eligibility criteria and to forecast enrolment by country.[33] Faro Health converts unstructured protocols into machine-readable assets aligned to the CDISC Unified Study Definitions Model; it won the CDISC 2025 AI Innovation Challenge and in March 2026 became Bristol Myers Squibb's system of record for structured protocol design.[34,35]

Eligibility-criteria optimisation has the best academic pedigree in this group. Stanford and Genentech's Trial Pathfinder (*Nature*, 2021) analysed the records of 61,094 lung-cancer patients against 22 trials and showed that relaxing criteria roughly doubled the eligible population with virtually unchanged safety; Roche, Genentech and AstraZeneca have since used it.[36]

Simulation and operational forecasting

Phesi's Trial Accelerator draws on data it describes as covering 132 million patients and 400,000 cohorts to score patient access, burden, enrolment rate and diversity; the company's claim of an average US$7 million saving per Phase III trial is vendor-reported.[37] Medidata's AI Simulants generate synthetic datasets from cross-sponsor historical data for scenario modelling of sample size and inclusion criteria.[31] Cytel's East Horizon platform covers dose-escalation, group-sequential and adaptive simulation and now includes an AI assistant that writes R code for custom designs, with the explicit caveat that output must be reviewed by trained coders.[38,39] Berry Consultants' FACTS remains the reference Bayesian adaptive simulator and makes no AI claim.

Digital twins and external controls

Unlearn.AI's PROCOVA received a CHMP qualification opinion in September 2022: a prognostic score derived from historical data and machine learning may be used as a covariate in Phase II/III

randomised trials with continuous endpoints, within linear ANCOVA, provided the model is built on data independent of the trial.[40] The FDA's written comments in 2023 took a narrower view, treating PROCOVA as consistent with existing covariate-adjustment guidance rather than as a new method, and cautioned that power calculations may be optimistic if the covariate–outcome correlation differs between the historical and trial populations.[41] Unlearn reports that a reanalysis of a completed Alzheimer's study would have needed 23% more participants without the method,[42] and *Nature* reports the company's claim of typical control-arm reductions of 20–50%.[17] The qualification covers the method, not any particular reduction: the saving depends on the design, the endpoint and how well the historical data predict the trial population, and should be treated as a potential rather than an expected benefit.

Medidata's Synthetic Control Arm was used as a hybrid external control in Medicenna's Phase III glioblastoma trial with FDA support in 2020,[43] and Phesi published a proof-of-concept digital twin in chronic graft-versus-host disease built from 2,042 patients across 32 cohorts.[44] None of these replaces randomisation in a pivotal trial; their regulatory status is as a sample-size reduction or supplementary evidence.

Tool / method	Vendor	What it does	Evidence status
PROCOVA / TwinRCT	Unlearn.AI	ML prognostic covariate adjustment to cut control-arm size	Regulator-recognised (EMA qualification 2022; FDA comments 2023)
Synthetic Control Arm	Medidata	Matched historical controls as hybrid external arm	Regulator-recognised (FDA support, Medicenna Ph III)
Protocol Optimization	Medidata	Predictive simulation of burden, site performance, cost	Vendor-reported; no public metrics
Protocol design analytics	IQVIA	Complexity and burden scoring, benchmarking	Vendor-reported (105-protocol internal review)
Protocol SmartDesign	Citeline	Endpoint and criteria recommendation, enrolment forecast	Vendor-reported
Digital protocol platform	Faro Health	USDM-aligned structured protocols, amendment-driver flags	CDISC 2025 award; BMS enterprise deployment
Trial Pathfinder	Stanford / Genentech	Data-driven eligibility criteria relaxation	Peer-reviewed (Nature 2021)
Trial Accelerator	Phesi	Digital patient profiles, enrolment and burden scores	Vendor-reported; twin PoC published
East Horizon; FACTS	Cytel; Berry	Adaptive and Bayesian design simulation	Established software; AI assistant is new

SECTION 6

06 Feasibility, site selection and recruitment

Feasibility and site selection

Site selection was the first stage of clinical operations to be industrialised with predictive analytics, and it has the most concrete case evidence. Medidata's Intelligent Trials (formerly Acorn AI) applies predictive models to performance data from tens of thousands of trials; in a published case, it helped PPD reshape a US$60 million rare-disease Phase III bid, doubling the forecast enrolment rate, cutting countries from 27 to 18 and sites from 200 to 120 and shortening the forecast duration by seven months.[45] IQVIA's Connected Intelligence site identification, Citeline's Investigator SmartSelect (which the vendor says builds an investigator pool in minutes rather than four to six weeks) and H1's

GenosAI, a generative interface over 490,000 trials and 10 million clinician profiles, occupy the same space.[33,46] TriNetX LIVE takes the real-world-data route, querying a federated network of more than 300 million patient lives and 14,200 sites to find sites with eligible populations; its claimed 50%-plus improvement in site identification is vendor-reported.[47]

The 2026 announcements are about agents rather than models. ICON's Orbis platform, built with Microsoft and now embedding Anthropic's Claude, is positioned to run site intelligence, predictive enrolment-risk signals and protocol optimisation across the CRO's roughly 40,000 staff.[48,49] Parexel's ParexelAI, launched in May 2026 on Palantir's platform, claims a 50% reduction in site-selection timelines (vendor-reported).[50] Syneos Health's August 2026 partnerships pair Causaly's knowledge graph for protocol strategy and feasibility with Databricks and Microsoft tooling.[51] Lokavant's Spectrum and Inato's site marketplace are the notable independents.[52,53]

Patient recruitment and eligibility screening

This is the stage with the strongest peer-reviewed evidence for LLMs, and the field has moved quickly since 2023. The National Library of Medicine's TrialGPT, published in *Nature Communications* in 2024, reached close to clinician-level accuracy on more than 1,000 patient–criterion pairs and, in a pilot, cut screening time by 40% at the same accuracy.[54] Mass General Brigham's RECTIFIER, a retrieval-augmented GPT-4 pipeline, screened 1,894 heart-failure patients at 97.9–100% accuracy against expert review for about US$0.11 per patient (*NEJM AI*, 2024); in a randomised comparison of 4,476 patients published in *JAMA* in February 2025, the AI arm identified 458 eligible patients against 284 for manual screening and enrolled 35 against 19.[55,56] The PRISM study's fine-tuned oncology model, OncoLLM, matched qualified physicians on real EHRs (*npj Digital Medicine*, 2024),[57] and a 2025 systematic review of 31 LLM matching pipelines found GPT-4 consistently outperforming smaller and fine-tuned models, at higher cost, while flagging hallucination, data leakage and inconsistent metrics as open problems.[58]

Commercially, Tempus acquired Deep 6 AI in March 2025 and reports that its TIME network screened 1.28 million patients in 2024, producing 2.25 million algorithmic matches, 5,034 confirmed-eligible patients and 573 consents across 98 trials; a GPT-4o scoring layer raised match rates for top-scored patients to 67% against a 13% average.[59,60,61] Mendel AI's neuro-symbolic Hypercube combines fine-tuned Llama models with a clinical hypergraph; a nurse-led pre-screening study found human-plus-AI accuracy of 78.7% against 76.7% for humans alone and 63.5% for AI alone.[62,63] Paradigm Health acquired Flatiron's clinical-research business in December 2025, Sanofi, OpenAI and Formation Bio launched the Muse recruitment tool in late 2024, and patient-facing matching services such as Carebox and Antidote continue to operate at scale.[64,65] The historical benchmark is Mayo Clinic's IBM Watson deployment, which reported an 80% rise in monthly breast-cancer trial enrolment over 18 months.[66]

> **What the recruitment evidence actually supports**
>
> A 2022 scoping review of 15 studies found AI identifying 24–50% more correctly eligible patients and cutting screening time by up to 78% with 81–96% agreement against clinicians.[67] The 2025 *JAMA* randomised comparison is the first to show an enrolment effect rather than a screening effect. What no study yet shows is a sustained, multi-site reduction in time to full enrolment attributable to AI alone, which is the metric sponsors are paying for.

SECTION 7

07 Study start-up, consent, contracts and the trial master file

Start-up is document-heavy and rules-heavy, which makes it a natural target for both classic NLP and LLMs. The longest-standing production use is document classification: Veeva's TMF Bot, launched in 2021, auto-classifies trial-master-file documents and extracts study, country and site metadata in more than 30 languages; Veeva reports better than 98% classification accuracy and finalised documents reaching the TMF 30% faster (vendor-reported).[68] Veeva's Falcon platform, announced in May 2026, moves TMF intake and quality control to agents operating outside Vault, with early adopters in late 2026.[69] Florence Healthcare's June 2026 release exposes its network of 65,000 sites to sponsor and site agents through a Model Context Protocol server, with a vendor-reported claim of up to 70% faster start-up.[70]

Budgets and contracts are the newer targets. ICON's Study Start-up Site Contracts tool drafts near-final site contracts from historical agreements, and its iSubmit automates regulatory document management by rule.[71] IQVIA's GrantPlan ingests a protocol, extracts procedures and visit schedules, maps them to standard activity codes and generates an initial site budget.[72]

Randomisation and supply systems are the newest front: Suvoda's agentic RTSM and Sofia assistant, Signant Health's AI-assisted builds and supply-planning agents, endpoint Clinical's elo architecture and 4G Clinical's long-standing NLP-driven Prancer are reviewed in Section 20, as are the site-side builders from CRIO and ClinCapture and Medable's TMF and CRA agents.[73,74,75,76,77,78]

Informed consent

Consent simplification is where LLMs have the clearest published benefit. A 2024 study in *npj Digital Medicine* used GPT-4 to rewrite 15 surgical consent forms, reducing the median reading grade from 13.9 to 8.9 and reading time from 3.3 to 2.4 minutes while physicians judged content comparable and an attorney found legal sufficiency preserved.[79] A 2025 *JMIR Medical Informatics* study found LLM-generated key-information sections rated significantly more understandable than human-written ones (90.6% versus 67.2%) with no difference in accuracy or completeness.[80] These studies measure readability and expert-rated understandability, not whether participants actually understand or consent more freely; they are drafting aids, and ethics-committee approval and site-level review are unchanged.

SECTION 8

08 Study build, data capture and clinical data management

Data capture and data management is the stage where AI is most commercially entrenched, where the evidence is most mixed between peer-reviewed and vendor-reported, and where the 2025–2026 product cycle has been most intense. It is also the stage most exposed to ICH E6(R3)'s data-governance requirements.

Study build from the protocol

The ambition shared by the major platforms is to configure the EDC directly from the protocol. Medidata's AI Study Build in Designer reads the protocol to generate forms, visit schedules, edit checks, synthetic test data and CDASH/SDTM mappings; Medidata reported builds "over 50% faster than manual configuration" in tests and has since described timelines moving from 10–12 weeks to

days (vendor-reported).[81] Veeva's Study Builder Agent, announced in September 2026 and delivered as a Claude Cowork plugin, configures Vault EDC forms, visits and edit checks from a USDM-structured protocol with early adopters in December 2026 and, notably, no licence fee.[82] Viedoc's Vantage roadmap and Castor's Catalyst (a multi-agent platform on Google Cloud that cut a four-week real-world-evidence study process to under four hours in one published example) are the mid-market equivalents.[83,84] Oracle's Life Sciences AI Data Platform, launched in January 2026, unites customer data with 129 million de-identified Oracle Health records under an agentic layer; its Clinical One EDC describes AI-enabled EHR and lab capture without published metrics.[85]

The mid-market followed within months: OpenClinica's AI Foundry build, ClinCapture's Captivate AI, Anju's Luminee and Crucial Data Solutions' TrialKit AI all target protocol-to-build, and Castor's Catalyst extends extraction to scanned and FHIR-retrieved records with the only vendor-published comparative error data in the segment (Section 20).[86,87,88,89,90]

Data review and query management

Saama's Smart Data Quality is the most cited production example. Its models flag discrepancies and draft queries; the vendor's comparison on 2,615 queries shows 130 hours and one FTE with the tool against a manual baseline its own documents give as either 1,177 or 1,777 hours and three FTEs; it separately quotes about 3 minutes per query instead of 30 (the two sets of figures do not reconcile exactly, and all are vendor-reported). Pfizer credited the tool with completing an accelerated data-cleaning step on its 40,000-participant COVID-19 vaccine trial in 22 hours rather than more than 30 days once the efficacy case count was reached; that is one cleaning activity, not full reconciliation or database lock (sponsor-reported).[91,92] Medidata's Clinical Data Studio, launched in June 2024 and adopted by ICON in 2025, merges Medidata and non-Medidata data for AI-assisted reconciliation and natural-language audit-trail review; Medidata reports 465 studies and review cycles up to 80% shorter (vendor-reported).[93] IQVIA's Clinical Data Review module and its NVIDIA-built agents, which the company says cut a review cycle from seven weeks to as little as two, and eClinical Solutions' elluminate agents for mapping, review and RBQM (first release early 2026) round out the field.[94,95]

CluePoints' Intelligent Query Detection and Medical & Safety Review, co-developed with a top-ten pharma and reaching general availability in September 2026, let data managers express check logic in plain language and post queries directly to the EDC; the IQD tool won SCDM's 2025 implementation-excellence award with reported review-time reductions above 50% and accuracy above 90% (vendor-reported).[96,97] TCS's ADD AgentHub, launched in August 2026, packages agents for data review, SDTM transformation, medical monitoring and safety intake with claimed efficiency gains of up to 40% in data management (vendor-reported).[98]

Medical coding

Coding is the one data-management task with peer-reviewed accuracy data. WHODrug Koda, Uppsala Monitoring Centre's AI drug-coding engine, achieved 86.0% overall accuracy against a 60.4% direct-match baseline, coding 89% of terms at high certainty with 97% accuracy (*Drug Safety*, 2022).[99] Medidata's Rave Coder+ is trained on more than 90 million historical coding decisions and reports 93–96% accuracy at high confidence and about 70 hours saved per 1,000 verbatims (vendor-reported).[100] CluePoints' Intelligent Medical Coding runs inside Veeva Vault EDC and claims up to 99% MedDRA accuracy (vendor-reported).[96] Veeva's native Coder, by contrast, is documented as rule-based synonym and dictionary matching with no machine-learning component.[101]

Standards automation

Certara's Pinnacle 21 Enterprise Plus (September 2025) replaces spreadsheet specifications for SDTM and ADaM with a collaborative workspace and claims 50% less time drafting mapping specifications; it makes no AI claim and is used by more than 130 organisations including the FDA and PMDA.[102] LLM-assisted SDTM review is at the experimental stage: a PharmaSUG 2026 paper from PPD describes a 13-prompt library that flagged 23 issues against 7 found manually in an illustrative scenario, 20 of them confirmed by humans.[103]

The profession's own framing

SCDM's reflection papers on the evolution of clinical data management into clinical data science (2019–2020) anticipated most of this: a four-stage progression of data review from automated to supervised, human-in-the-loop as the default, and a sponsor hackathon finding semi-supervised learning best for cross-form discrepancies.[104] Its 2022 topic brief lists critical thinking, risk-based methods, AI concepts and R/Python/SQL as the new core skills.[105] A June 2026 ACRP literature review puts the problem in numbers: an average trial raises 21,104 queries, 36% of them manual at roughly €150 each.[106]

Tool	Vendor	Function	Evidence status
Smart Data Quality	Saama	Discrepancy detection, query drafting, GenAI check authoring	Vendor/sponsor-reported (Pfizer)
Clinical Data Studio	Medidata	Unified review, reconciliation, audit-trail NL review	Vendor-reported; 465 studies
AI Study Build	Medidata	Protocol-to-EDC configuration	Vendor-reported
Study Builder Agent	Veeva	USDM protocol-to-Vault EDC build	Early adopters Dec 2026
IQD / MSR / IMC	CluePoints	Plain-language checks, medical review, coding	Vendor-reported; SCDM award 2025
WHODrug Koda	UMC	AI drug coding	Peer-reviewed (Drug Saf 2022)
Rave Coder+	Medidata	ML MedDRA/WHODrug autocoding	Vendor-reported
elluminate agents	eClinical Solutions	Mapping, review, RBQM, study-ops agents	Announced Dec 2025
ADD AgentHub	TCS	Agents for review, SDTM, safety, monitoring	Vendor-reported (Aug 2026)
Catalyst	Castor	Multi-agent study operations (RWE first)	One published customer example
Pinnacle 21 Enterprise Plus	Certara	SDTM/ADaM specification workspace	Established; no AI claim

SECTION 9

09 Monitoring, RBQM and central statistical monitoring

Risk-based quality management is the clearest case of regulation pulling technology adoption. ICH E8(R1) introduced critical-to-quality factors and proportionate oversight; E6(R3), adopted in January 2025, makes risk-proportionate quality management and validated data governance the expected norm; and the FDA's 2023 question-and-answer guidance elaborated its 2013 position on risk-based monitoring.[4,107] The peer-reviewed adoption data follow that curve: an ACRO analysis in *Therapeutic Innovation & Regulatory Science* found trials using at least one RBQM component rose from under

50% in 2019 to over 75% in 2022 across seven CROs, with about 65% of new starts that used central monitoring also reducing source-data review and verification.[108]

The central statistical monitoring vendors are mature. CluePoints' platform counts more than 1,600 studies and its SPOT tool applies deep learning to adaptive site oversight;[109] Medidata Detect (2020) applies proprietary machine learning and statistical tests without customer programming and has been folded into Clinical Data Studio;[110] TRI's OPRA runs on more than 450 trials and its October 2026 release adds RiskIQ, an agent that reads an uploaded protocol and drafts critical-to-quality factors and risks using the organisation's own taxonomy, with human accept-or-reject and audit logging.[111] Fortrea's Intelligent Technology suite (April 2026) embeds predictive signals in its Xcellerate RBQM and central monitoring tools.[112] A 2025 scoping review in *Clinical Trials* of 24 central-monitoring papers found methods ranging from digit-preference tests to Bayesian mixture models, many validated only on simulated data.[113]

Two cautions apply. The regulator-facing value of central monitoring has been argued from the FDA's own observation that central methods could have detected more than 90% of on-site findings,[108] but no published study yet compares AI-assisted risk identification against conventional risk assessment on inspection outcomes. And the 2026 "agentic monitoring" announcements from ICON, Fortrea and eClinical Solutions are platform roadmaps rather than evaluated products.

SECTION 10

10 Imaging, pathology and digital endpoints

Endpoint assessment is the stage where regulators have been most willing to formally qualify AI, because the question is tractable: does the algorithm measure the thing the endpoint depends on as well as, or more consistently than, human readers?

Pathology: the first qualified AI endpoint tools

PathAI's AIM-MASH AI Assist is the landmark. The EMA's CHMP issued its first qualification opinion on an AI methodology in March 2025, qualifying AI-assisted histological scoring of liver biopsies for use in MASH drug trials (a defined context of use, not a diagnostic marketing authorisation) and finding that scoring, trained on more than 100,000 annotations from 59 pathologists across 5,000 biopsies, produced readings with less variability than the three-pathologist consensus standard when verified by one expert; the model is locked and major changes may require re-qualification.[114] In December 2025 the FDA qualified the same tool under its Drug Development Tool programme for enrolment and endpoint assessment in MASH trials, the first AI tool to receive that status; in both qualifications the pathologist remains responsible for the final read.[115] PathAI's broader algorithm library is now integrated into Precision for Medicine's trial operations.[116]

Imaging and RECIST

Oncology imaging CROs (Perceptive, formerly Calyx; Clario; Median Technologies; Image Analysis Group) all now describe AI-assisted segmentation, radiomics or quality-control pipelines, and Thermo Fisher's US$8.9 billion acquisition of Clario in October 2025 was framed around its 50-plus proprietary AI algorithms across eCOA, imaging, cardiac and respiratory data.[117] The evidence base is building: a multicentre reader study presented at ECR 2026 (23 readers, 212 patients) found AI assistance cut read time by about 36 seconds per patient and reduced the share of inter-reader sum-of-diameter disagreements above 20% from 43.4% to 28.3%, though lesion-level variability rose slightly.[118] Friends of Cancer Research's ai.RECIST project is testing inter-tool agreement across six developers with Amgen, AstraZeneca, BMS, Lilly, Merck, Pfizer, Novartis and the NCI as

partners,[119] and Altis Labs' IPRO survival-prediction model, applied retrospectively to roughly 10,000 scans from Johnson & Johnson's Phase III MARIPOSA trial, signalled treatment benefit from week 16 where RECIST response rate had not anticipated the overall-survival result.[120]

Specialist developers are moving faster than the imaging CROs: Onc.AI's Serial CT Response Score (FDA Breakthrough designation, February 2025), Qynapse's QyPredict enrichment model, Nucleai's spatial-AI biomarker in prospective enrolment, and the foundation-model programmes at Quibim, Proscia, Qureight and Lunit are catalogued in Section 20 and Appendix A.[121,122,123,124]

Digital endpoints and wearables

The EMA qualified Sysnav's stride velocity 95th centile (SV95C), measured by a wearable, as a primary endpoint in ambulant Duchenne muscular dystrophy in 2023, the first regulator-qualified digital primary endpoint.[125] The FDA's December 2023 guidance on digital health technologies for remote data acquisition sets the verification, validation and usability expectations that apply.[126] The Digital Medicine Society's library now lists 636 industry-sponsored digital endpoints from 105 sponsors.[127] On the device side, Clario acquired ArtiQ for AI spirometry quality control and over-reading,[128] and ActiGraph, which cites around 250 industry trials and 30-plus proprietary algorithms, acquired Biofourmis' trial platform in January 2025.[129]

SECTION 11

11 Safety and pharmacovigilance

Pharmacovigilance has used NLP and robotic process automation in production longer than any other clinical function, driven by case volumes growing around 20% a year and case processing consuming roughly 70% of safety budgets.[130] The generative-AI wave since 2024 has concentrated on intake: reading source documents of any layout into structured cases without per-form configuration.

ArisGlobal's LifeSphere NavaX reported early-pilot intake efficiency gains of up to 65% at about 90% extraction accuracy in 2024 and in 2025 described a top-ten pharma processing some 350,000 cases a year going live in five months (vendor-reported).[131,132] Oracle's Safety One Intake automates document and email ingestion into Argus with duplicate search and E2B mapping.[133] IQVIA's Vigilance Detect, now generative-AI-powered, extracts safety events from emails, audio, documents and chat and claims up to 80% fewer false positives in client cases (vendor-reported); the underlying platform runs NLP across 50-plus languages.[130] Veeva's safety agent for case narratives is live and its Falcon Safety product, due for early adopters in November 2026, works with any E2B-compliant database including Argus and LifeSphere.[134] Service-side platforms include Genpact's PVAI (now independent) and Accenture's INTIENT Pharmacovigilance, co-built with UCB.[135,136]

India-based safety technology has become an acquisition target: Parexel bought Vitrana in April 2026 for its AI intake and reconciliation platform, and Tech Mahindra, Wipro and HCLTech each publish PV agents or copilots (Section 19); the specialist literature-monitoring tools biologit, DrugCards and Qinecsa's Reportum are covered in Section 20.[137,138,139,140]

The peer-reviewed literature is specific about where LLMs work and where they do not. FDA scientists found GPT-3.5, GPT-4 and Claude 2 screening abstracts for adverse-event relevance at 97% sensitivity but only 67% specificity, with results highly sensitive to prompt design.[141] A 2026 *Drug Safety* study from UCSF used a two-pass o1 pipeline to extract post-marketing adverse drug events from 372 EHR notes at 94.2% precision and 84.1% recall, with 92.5% correct MedDRA lowest-level terms and 100% correct seriousness, at about US$0.18 per note, while noting occasional

hallucinated drug or event names and run-to-run variability.[142] The FDA's Sentinel Innovation Center has contracted Oracle Health and John Snow Labs to build NLP extraction from unstructured notes.[143]

Governance arrived in December 2025 with the CIOMS Working Group XIV report on AI in pharmacovigilance, a 204-page consensus document built over 12 meetings that centres on human-in-the-loop and intelligence augmentation rather than autonomous decision-making.[144]

SECTION 12

12 Biostatistics, statistical programming and data standards

This is the stage where expectations have run furthest ahead of evidence, and where the evidence that does exist is unusually clear about the limits.

What is in use

SAS's Viya Copilot, previewed with AstraZeneca in 2025 and extended in April 2026 to generate SAS and Python code, is complemented by a Health Clinical Data Discovery Copilot and a Viya MCP server that lets external agents, including Claude, call SAS analytics; SAS Clinical Acceleration is the validated submission environment.[145] The R Consortium's submissions working group has completed pilots with the FDA covering R-generated tables, Shiny applications, ADaM in R, WebAssembly and containers, and its 2026 pilots now explicitly use AI to expand ADaM and display programs and to generate synthetic CDISC datasets.[146] CDISC's open-source CORE engine, which the FDA is helping to populate with its own business rules under a three-year collaboration, and Certara's Pinnacle 21 provide the machine-executable conformance layer.[147,102] The FDA published a Federal Register notice in April 2025 exploring CDISC Dataset-JSON as a replacement for SAS XPT, though no decision has been taken.[148] Saama's ADaM Navigator, launched in August 2025, parses the statistical analysis plan to generate ADaM specifications and SAS or R code, with vendor-reported reductions in specification time from 27 to 9 days.[149]

What the evidence says

The most useful single source is a 2025 scoping review of 262 publications on statistical-programming automation, available as a medRxiv preprint and not yet peer-reviewed. Only 16% reported quantitative outcomes; LLM accuracy on routine programming tasks ranged from 60% to 85% (GRADE: very low); pharmaverse open-source workflows were associated with 15–25% reductions in TFL development time (GRADE: low); reported hallucination rates in clinical contexts ranged from 1% to 65%; and the authors recommend treating LLM code strictly as a first draft requiring full human validation.[5] Merck's PharmaSUG 2025 experience with GPT-4o conversion of SAS pharmacokinetic tables to R reached the same conclusion: outputs reproduced values on dummy data but were "not sufficiently robust" for end-to-end conversion.[150] A September 2026 *JMIR* study of an agent built on Claude Sonnet 4.6 running 27 analyses on a 7,802-eye ophthalmology dataset found statistical-analysis-plan drafting reliable (all nine plans selected the correct Cox and Kaplan–Meier methods) but code execution prone to silent errors, including a cohort-boundary mistake, wrong covariates and inflated concordance statistics.[151]

The implication for a biometrics function is not that these tools are useless but that their value is bounded by the review capacity around them. The functions reporting real gains are those that treat generated code and specifications as inputs to an unchanged validation process.

Standards as the enabling layer

The quiet precondition for most protocol-to-build and protocol-to-analysis automation is a machine-readable protocol. ICH M11's structured protocol template reached Step 4 in November 2025, alongside M14 on real-world data and E20 on adaptive designs entering consultation.[152] TransCelerate's Digital Data Flow initiative, with CDISC's Unified Study Definitions Model as the content standard and HL7 Vulcan's FHIR implementation guide as the exchange standard, is what Faro, Veeva and Ephicacy now build against.[153,154]

SECTION 13

13 Medical writing, submissions and regulatory intelligence

Clinical-study-report generation is the generative-AI use case most often cited by pharma executives, and it has the best-documented in-house implementation. Merck (MSD) and McKinsey co-developed a GenAI authoring tool over 18 months covering 14 CSR sections; Merck reports first drafts in about five minutes, CSR turnaround falling from two to three weeks to three to four days, human-reviewed drafting effort falling from 180 to 80 hours and 50% fewer errors, with the first live CSRs submitted in early 2025.[155] A third-party assurance test of the same tool, run under Singapore's AI Verify programme, examined one trial and identified hallucination (unsupported or omitted protocol and TFL content) as the priority risk without publishing a numeric rate.[156]

The commercial field is crowded. Yseop's Copilot, used by Lilly and Novartis, claims 30–50% less document-creation time, with Lilly writers reporting patient narratives falling from four hours to seconds (vendor- and customer-reported).[157,158] Certara's CoAuthor integrates CDISC data and a generative plugin for protocols, CSRs and narratives and claims more than 20% faster timelines (vendor-reported).[159] Indegene's NEXT platform drafts inside Microsoft Word on a multi-agent orchestration engine,[160] IQVIA pairs drafting agents with a separate checker agent and describes drafts as "70% of the way there",[161] and Parexel's partnership with Weave Bio targets a 60% reduction in IND/NDA authoring timelines (vendor-reported).[50] Veeva's Agentic Authoring application for submissible documents is scheduled for late 2027.[69] In regulatory intelligence, Clarivate's Cortellis Regulatory AI Assistant gives cited conversational answers over its intelligence database.[162]

A specialist regulatory-authoring layer sits beneath these: Weave Bio (deployed across 14 Takeda programmes), Celegence's CAPTIS Copilot, Freyr's freya fusion, Vivpro's REGAIN and RegASK, reviewed in Section 20.[163,164,165,166,167]

The frontier-model vendors have entered directly. Anthropic's Claude for Life Sciences (October 2025) connects to Benchling, PubMed and other tools, scored 0.83 against a 0.79 human baseline on a protocol-QA benchmark, and is used at Sanofi, Novo Nordisk, AbbVie and Genmab; Novo Nordisk's reported reduction of study documentation from more than ten weeks to ten minutes is a customer-reported internal metric.[168] OpenAI's GPT-Rosalind (April 2026) is a life-sciences model series with Amgen, Moderna and Thermo Fisher as early partners.[169]

> **The regulator's own experience is the cautionary tale**
>
> The FDA deployed its agency-wide LLM, Elsa, in June 2025 for protocol review, adverse-event summaries and label comparisons, with the Commissioner describing tasks that took two to three days now taking six minutes.[170] Within two months, six current and former officials told CNN the tool cited non-existent studies and "hallucinates confidently"; the agency acknowledged the risk and said use was optional.[171] In January 2026 a medical journal retracted a letter after only 5 of its 15 references

> could be located, the authors attributing the fabrications to generative AI.[172] For regulatory writing, reference and data provenance checks are not optional.

SECTION 14

14 Post-marketing and real-world evidence

Real-world evidence is where AI's data-extraction capability meets regulators' increasing willingness to accept non-interventional studies, and where the validation question is most explicit. The FDA's 2024 draft guidance on non-interventional studies, the EMA's DARWIN EU network (around 250 million patients, 40 data partners and 110 studies since 2022) and ICH M14 on pharmacoepidemiological studies set the frame.[173,174,152] The FDA-funded RCT-DUPLICATE project emulated 32 selected randomised trials using observational healthcare databases. Across all 32 emulations the investigators reported 66% agreement in effect estimates and 75% agreement in statistical significance; concordance was higher where design and measurements could be closely emulated (the 56% figure often quoted refers to the subgroup where close emulation was not feasible). The findings support carefully designed RWE studies while marking the limits of trial emulation.[175]

LLM abstraction from unstructured records is the new capability. Flatiron Health reported Claude-based extraction of real-world progression events across 14 cancer types with F1 scores comparable to expert abstractors, and in April 2026 published VALID, the first peer-reviewed validation framework for AI-extracted real-world oncology data, in *JCO Clinical Cancer Informatics*: comparison against expert abstraction, logical-consistency tests and reproduction of known clinical findings.[176] TriNetX launched a conversational interface over its federated network in January 2026,[177] Komodo Health's MapAI offers generative querying across what it describes as 330 million patient journeys,[178] ConcertAI's CARAai runs multi-agent oncology analytics on NVIDIA infrastructure,[179] and Tempus expanded its Lens platform collaboration with Gilead in April 2026.[180] Aetion, acquired by Datavant in July 2025, brought synthetic-data capability from Replica Analytics into the largest US health-data exchange.[181] Deloitte's 2025 benchmarking found 96% of biopharma leaders planning to raise RWD investment and 80% expecting generative AI to reshape evidence generation within a year.[182]

SECTION 15

15 Cross-cutting platforms, foundation models and agents

By late 2026 the market has consolidated around a small number of platform strategies, and most stage-specific tools in this paper are features of one of them.

eClinical platforms. Medidata's Medidata Plus (July 2026) is an AI-native layer across its 42,000-trial dataset, with "Dot" as a coordinating agent over domain companions; the company claims its AI supported 80% of FDA novel approvals in 2025.[183,31] Veeva's strategy has two tracks: AI agents inside every Vault application, released in waves from December 2025 with the clinical-data wave scheduled for December 2026, using Anthropic and Amazon models on Amazon Bedrock, and Falcon, a separately priced agentic-labour platform outside Vault.[184,69] Oracle's Life Sciences AI Data Platform adds an agentic layer over Clinical One, Argus and 129 million Oracle Health records.[85]

CRO platforms. IQVIA's IQVIA.ai (NVIDIA Nemotron, LangChain, custom foundation models trained on what it describes as 64 petabytes of data) exposes agents for literature review, cohort building

and data review;[185,186] ICON's Orbis runs on Microsoft Azure with Claude embedded;[48,49] Parexel's platform is built on Palantir Foundry;[187] Thermo Fisher's PPD has embedded OpenAI APIs with clinical research as the first focus;[188] and Syneos, Fortrea and others have announced partner ecosystems rather than proprietary stacks.[51,112]

Frontier-model vendors. Anthropic's Claude for Life Sciences and OpenAI's GPT-Rosalind are the first life-science-specific offerings from the model developers themselves, and both are already inside CRO and sponsor platforms (ICON, Veeva's Study Builder Agent, Genmab's CSR agents, PPD).[168,169,180] NVIDIA's BioNeMo and NIM agent blueprints underpin IQVIA, ConcertAI and the Lilly co-innovation lab.[27]

Enterprise deployments. Published sponsor results remain mostly anecdotal: Moderna built more than 750 custom GPTs with 80% employee adoption within two months of its OpenAI deployment;[189] Novartis cut Leqvio trial site selection from four to six weeks to a two-hour meeting; GSK targets 15% faster trials; and TD Cowen's view, reported by Reuters in January 2026, is that measurable effects are one to three years away.[180]

What the agentic wave changes for buyers is the locus of validation. When a vendor's agent configures an EDC from a protocol or posts queries into a live database, the sponsor's computerised-system validation and E6(R3) data-governance obligations extend to that agent's behaviour, and the vendor's own claims about guardrails and audit trails become part of the qualification evidence.

SECTION 16

16 The regulatory, validation and governance landscape

The governing instruments have multiplied since 2023. They fall into four groups: regulator expectations for AI in regulatory decision-making, good-clinical-practice and data-standards updates, computerised-system validation, and data-protection law. India has its own developments in each.

AI in regulatory decision-making

The FDA's January 2025 draft guidance (non-binding, and still a draft) applies to AI models that produce information intended to support a regulatory decision on a drug's safety, effectiveness or quality, explicitly excluding discovery and purely operational uses; it is not a mandatory process for every AI tool used in study operations. Its seven-step risk-based credibility framework runs: define the question of interest; define the context of use; assess model risk as the product of model influence and decision consequence; develop a credibility assessment plan; execute it, engaging the FDA; document results and deviations; and determine adequacy for the context of use. An AI model that makes final determinations without human intervention, such as deciding which patients need monitoring, is given as an example of higher risk.[1] CDER has counted more than 500 submissions with AI components between 2016 and 2023 and established an AI Council in 2024.[190]

The EMA's reflection paper on AI across the medicinal-product lifecycle was adopted by CHMP and CVMP in September 2024 under the HMA–EMA AI workplan 2023–2028, and the two agencies published ten joint guiding principles of good AI practice in January 2026: human-centric design, risk-based approach, adherence to standards including GxP, clear context of use, multidisciplinary expertise, data governance, model-development practice, risk-based performance assessment, lifecycle management including drift monitoring, and clear information to users and patients.[2,3] The

AIM-NASH and PROCOVA qualifications described earlier are the worked examples of how this framework is applied.

The EU AI Act's stand-alone high-risk obligations, originally due in August 2026, are being delayed to December 2027 under the "Digital Omnibus" agreed in May–June 2026, with AI embedded in medical devices moving to August 2028; prohibited-practice and general-purpose-model obligations applied earlier.[191] Whether a trial tool is high-risk turns on its intended purpose under the Act's annexes, which has to be assessed system by system; most trial-operations tools are unlikely to qualify, but a tool that makes consequential decisions about individuals might.

GCP and data standards

ICH E6(R3) (adopted January 2025; effective in the EU from July 2025; published by the FDA in September 2025) introduces a dedicated data-governance section covering audit trails, metadata and validated systems, replaces "documents" with "records" and CROs with "service providers", and explicitly permits digital tools subject to oversight.[4,192] Annex 2 reached ICH Step 4 on 3 June 2026 and comes into effect in the EU on 15 January 2027; it covers decentralised elements, pragmatic designs and real-world data, and other jurisdictions implement it on their own schedules.[193,194] ICH M11, M14 and E20 were discussed in Section 12.

Computerised-system validation

GAMP 5 second edition (2022) added Appendix D11 on AI and machine learning and a chapter on critical thinking through the lifecycle;[195] the FDA's Computer Software Assurance guidance, finalised in September 2025 and reissued in revised final form in February 2026, is scoped to software used in medical-device production and quality-management systems under 21 CFR 820; its risk-based assurance reasoning is widely borrowed for clinical systems, but it does not itself govern EDC or other trial-system validation, where E6(R3), electronic-records requirements and GAMP 5 remain the operative references;[196] and the European Commission's 2025 consultation on a revised Annex 11 and a new Annex 22 on AI in GMP sets out expectations on training-data quality, performance metrics and human review, while stating that generative AI and LLMs "should not be used in critical GMP applications".[197] Although Annex 22 is a manufacturing instrument, its reasoning on deterministic versus non-deterministic systems is the clearest regulatory statement yet on where LLMs fit in a validated environment.

India

Four instruments matter. The ICMR's 2023 Ethical Guidelines for Application of AI in Biomedical Research and Healthcare set out patient-centric principles including accountability, data privacy, validity and non-discrimination, and address informed consent for AI tools.[198] The Digital Personal Data Protection Rules, notified in November 2025, bring the 2023 Act into force in phases over 18 months, with the Data Protection Board immediate and consent-manager obligations at 12 months; penalties under the Act reach Rs 250 crore.[199] The Act regulates consent, purpose and breach notification rather than imposing blanket data localisation; cross-border transfers are permitted except to countries the government restricts, so whether a cloud deployment is acceptable is a matter of sponsor policy, contract and sector-specific rules, not a general legal bar. CDSCO finalised guidance on medical-device software in July 2026 requiring AI-enabled software to document training, validation and test datasets, bias and generalisability across India-relevant sub-populations.[200] And in September 2026 the DCGI announced an expert committee on AI in drug discovery, without yet a timeline or terms of reference.[201] The IndiaAI Mission (Rs 10,372 crore, 2024) supplies the compute and dataset infrastructure behind many domestic entrants.[202]

Instrument	Issuer	Status / date	Legal status	Relevance to AI in trials
AI to support regulatory decision-making (draft)	FDA	Draft, Jan 2025	Draft guidance; non-binding	Seven-step credibility framework for AI outputs that support regulatory decisions
Reflection paper on AI in product lifecycle	EMA	Adopted Sep 2024	Reflection paper; non-binding	Lifecycle expectations; basis for qualification opinions
Guiding principles of good AI practice	EMA–FDA	Jan 2026	Principles; non-binding	Ten shared principles for developers and applicants
ICH E6(R3) + Annex 2	ICH	Jan 2025; Annex 2 Step 4 Jun 2026, EU effect Jan 2027	Guideline; binding where adopted into law (e.g. EU CTR)	Data governance, validated systems, DCT and RWD
ICH M11 (CeSHarP)	ICH	Step 4, Nov 2025	Guideline; regional implementation	Structured protocol enabling automation
EU AI Act (Reg. 2024/1689)	EU	High-risk delayed to Dec 2027	Regulation; binding	Obligations depend on the system's intended purpose
GAMP 5 2nd ed., App. D11	ISPE	2022	Industry good practice	Validation of AI/ML components
Computer Software Assurance	FDA	Final Sep 2025; revised Feb 2026	Guidance; device production/ QMS software only	Risk-based assurance reasoning borrowed for clinical systems
Annex 11 revision; Annex 22 (AI)	EC / PIC/S	Consultation 2025	Draft GMP annexes; binding when adopted	Generative AI excluded from critical GMP use
CIOMS WG XIV report	CIOMS	Dec 2025	Consensus report; non-binding	AI in pharmacovigilance: human-in-the-loop
DHT remote data acquisition	FDA	Final, Dec 2023	Final guidance; non-binding	Verification and validation of digital endpoints
ICMR AI ethical guidelines	ICMR	Mar 2023	Guidelines; applied by ethics committees	Ethics and consent for AI in biomedical research
DPDP Act 2023 and Rules 2025	MeitY	Phased from Nov 2025	Statute; binding	Consent, purpose and breach notice; no blanket localisation
Medical device software guidance	CDSCO	Final, Jul 2026	Guidance under MDR 2017	Dataset and bias documentation for AI software

SECTION 17

17 Geographies: where trials are going, and how AI adoption and regulation differ

The vendors in this paper are overwhelmingly American, the platforms are global, and the regulatory frameworks that matter most were written in Washington, Amsterdam and Geneva. But trials are not where they were a decade ago. Asia-Pacific overtook the rest of the world in trial starts in 2021 and reached 55% of global starts by 2023, with China accounting for 62% of the APAC total;[203] 39% of trials started in 2023 included a Chinese site, against 25% in 2019, and China-initiated trials rose 46% over a period in which global initiations fell 7%.[204] IQVIA puts China at 15% of all trials at the end of 2023, up 57% since 2019, while Western Europe's share fell 21% and Eastern Europe's 33%.[205] GlobalData's 2025 analysis names China, India, South Korea, Japan and the United States as the five fastest-growing trial countries,[206] and Citeline reports China holding 47% of rare-disease trials.[207] Any review of AI in clinical development therefore has to ask how the tools and the rules differ outside the United States and the EU. The short answer is that regulator-facing AI guidance exists almost nowhere else, that Asia has its own platform vendors, and that in most of the rest of the world the live story is digitisation of regulatory process rather than AI in trials.

China

China's NMPA issued "AI + Drug Regulation" implementation opinions in April 2026 (Guo Yao Jian Zong [2026] No. 6), a lifecycle plan that is mostly about the regulator's own AI use (regulatory datasets, vertical language models with human-in-the-loop review, algorithm filing and audit trails, no autonomous approvals) but which commits to standards for electronic trial records, computerised-system validation and trial-data governance, with capability targets for 2030 and 2035.[208] A review of eight APAC regulators in October 2026 found none with a final, sponsor-facing guideline on AI in drug development; China's CDE guideline on computerised systems and electronic data in trials took effect in September 2026 and NMPA released draft AI medical-device guidelines the same month.[209] A rebuilt GCP with electronic-data and sponsor-TMF provisions came into force in September 2026. L.E.K. estimates China's trial volume at about 80% of the United States and 10% above the EU, with surveyed sponsors and CROs concentrating near-term AI adoption in data management and analysis.[210]

China has its own eClinical platform layer. Taimei Technology (HKEX-listed since October 2024) sells EDC, RTSM, eCOA, CTMS and eTMF alongside AI agents for data management (iDM), trial applications (iCTA) and pharmacovigilance (iPV); it reports 1,600 pharma and CRO customers including 20 of the top 25 global companies, more than 10,000 trials supported, revenue of RMB 512.5 million in FY2025 and, by its own account, involvement in some 60% of NMPA Class 1 new-drug approvals in 2025 and processing of more than half of China's trial adverse-event reports (vendor-reported).[211] In 2026 it signed Korea's C&R Research for AI eCRF generation and Japan's Buzzreach for cross-border recruitment through its Trialnet platform (400,000 patients, 1,800 institutions, vendor-reported).[212,213] Yidu Tech's YiduCore applies AI to feasibility, patient matching, quality control and real-world evidence across a network of 12,000 institutions, reporting 516 clinical research projects and its first full-year profit in FY2026.[214] Tigermed, China's largest CRO (RMB 6.8 billion revenue, 11,130 staff in 42 countries), is rolling out an in-house language-model platform, "YIYa", with AI translation and writing tools;[215] XtalPi has moved from AI discovery into partnered clinical assets with a US$345 million Lilly deal;[216] and a Waterdrop subsidiary patented a BERT-based patient-matching method claiming 92% precision (vendor-reported).[217] WuXi AppTec sold its clinical CRO and SMO units to Hillhouse in 2025.[218]

Japan

Japan's PMDA has an AI action plan for its own operations (October 2025), switched on generative AI internally in April 2026, formed a project team to draft a "basic approach to AI utilisation" for publication by March 2027, and opened consultation on generative-AI medical devices in September 2026, but has no sponsor-facing guideline on AI in trials.[219,209] A 2026 academic survey found 60% of Japanese CROs had AI governance documentation but only 6% had SOPs covering generative AI in clinical studies.[220] Decentralised-trial adoption is slow (18.6% of companies had used any DCT element by 2023), though eCOA use is near-universal.[221] The pharma companies are further ahead than the vendors: Shionogi's AI statistical-programming system generates SAS programs with a reported 30% reduction in standard hours;[222] Astellas uses AI for protocol development, translation across 15–20 trial countries and outreach, and has adopted Evinova's design platform;[223] Chugai's in-house assistant on Amazon Bedrock is used by 7,000 staff for tasks including protocol drafting, while its only AI-designed antibody was dropped from the pipeline in early 2026.[224] CMIC, the largest domestic CRO, signed Bluenote in March 2026 for agentic drafting of protocols, SAPs, CSRs and eCTD modules with an expected (not measured) 75% reduction in documentation time;[225] MICIN's MiROHA supports decentralised oncology trials;[226] and Ubie's symptom-checker, with 13 million monthly users, is now a Medable recruitment channel.[227]

South Korea, Singapore and Taiwan

Korea's MFDS is the most active regulator in the region: a draft guide on AI in drug development (June 2024), the world's first generative-AI medical-device guideline (January 2025), a ₩22.3 billion three-year programme to build an AI review system for drug applications (February 2026), and a final AI considerations document scheduled for December 2026.[228,229,209] The health ministry's "clinical-trial AX" agenda targets AI-driven recruitment, design and remote monitoring.[230] Evidnet's FeederNet federates OMOP-standard records from about 50 hospitals (70 million patients, vendor-reported) and added natural-language cohort feasibility in February 2026.[231] Singapore's HSA announced in October 2026 that its MHRA regulatory-innovation corridor covers AI in drug development and trials, that AI guidance is in development, and that lower-risk Phase III approvals have been halved to 15 days;[232] Oncoshot's AI converts unstructured oncology records into research-ready data (vendor-reported 95% extraction accuracy) and Holmusk's NeuroBlu holds 46 million behavioural-health records for stratification and external-control research.[233,234] Taiwan's TFDA has device-level principles only and mandated electronic trial submissions from October 2026.[235]

United Kingdom

The UK has moved on three fronts at once. New clinical-trial regulations in force from 28 April 2026 introduced risk-proportionate approvals and notifiable trials;[236] the MHRA's AI Airlock device sandbox received £3.6 million through 2029,[237] and its 2030 strategy, announced in October 2026, includes an AI-enabled protocol checker for sponsors, AI safety-signal detection, a Centre for AI and Digital Health, and a halved 14-day timeline for qualifying Phase I trials;[238] the Health Research Authority published a two-year AI plan in May 2026;[239] and NICE's 2024 position statement on AI in evidence generation sets expectations for disclosure, validation and human oversight that reach HTA submissions.[240] NHS DigiTrials' recruitment service became permanent in March 2026 after identifying cohorts of up to 120,000 from national data,[241] and the data layer is consolidating: Akrivia and Arcturis (ex-Sensyne) agreed a £140 million merger covering 40 NHS trusts and 20 million patients,[242] Lifebit's federated platform claims 275 million records across 30 countries,[243] and uMotif launched an NLP study-build assistant.[244] The cautionary cases are British too: BenevolentAI delisted in March 2025 after a pivot and layoffs,[245] Sensyne was recapitalised after near-collapse, and Healx's AI-repurposed candidate is in a 20-patient Phase II.[246]

Continental Europe

Beyond the EMA (Section 16), the European Health Data Space regulation sets the timetable that will matter most for AI: general application and health-data-access bodies from March 2027, most secondary-use provisions from 2029, and clinical-trial, genomic and cohort data from March 2031, with research "including AI systems" an explicitly permitted purpose.[247] Germany's Medical Research Act (October 2024) centralised ethics review for complex trials without AI provisions,[248] and France's ANSM 2026 programme uses AI internally (shortage plans, product-information checks) while piloting a fast track for early-phase trials.[249] The sponsor side is where the evidence sits: Novartis reports that AI site selection over data from 460,000 trials identified investigators who recruited 2.7 times more Black patients in a 1,700-patient US pilot;[250] Bayer's proprietary coding model reaches 96% accuracy under four-eyes review and has saved about 170,000 hours since 2017 (vendor-reported);[251] Boehringer Ingelheim and Microsoft are exploring digital patient twins for trial simulation and hybrid controls;[252] Novo Nordisk's NovoScribe reports 90% less CSR-writing time (customer-reported);[253] and Roche says AI contributed to 40% of its research-portfolio decisions in the three quarters to mid-2026.[254] Specialist vendors include Clinerion (Basel; now part of Citeline), myTomorrows (Amsterdam; LLM eligibility support deployed at Clínica Universidad de Navarra in 2026), Inato and Klineo (Paris), alongside those already covered in Sections 5–19.[255,256,257]

Canada and Australia

Health Canada pre-published risk-based clinical-trial regulations and draft decentralised-trial guidance in December 2025, adopted E6(R3) from April 2026 and finalised machine-learning medical-device guidance the same month, with no AI-in-submissions guidance;[258] Canada's Drug Agency issued guidance on AI-generated RWE for HTA in July 2026.[259] Ontario's open-source pMATCH project targets a 50% rise in precision-oncology trial matching.[260] Australia's TGA has floated "evaluation aids" that would let sponsors draft trial reports with AI, and is building the National One Stop Shop for trial approvals and registration,[261,262] while a 2023 census by the Australian Clinical Trials Alliance catalogued the country's recruitment-technology vendors (Evrima, HealthMatch, Opyl, ClinTrial Refer, Oncoshot among them), all self-reported.[263,264] The Access Consortium (UK, Australia, Canada, Switzerland, Singapore) has approved about 40 new substances through work-sharing and is the likeliest channel for shared AI expectations among mid-size regulators.[265]

Middle East and North Africa

The Gulf is building the data infrastructure for AI-assisted research faster than it is building the AI. The UAE's Federal Decree-Law 28/2023 created the Emirates Drug Establishment as the federal trials authority, a 30–50% refundable R&D tax credit took effect in January 2026, and Abu Dhabi requires raw genomic data to be archived in-emirate;[266] the Department of Health's 2018 AI policy and its 2025 Responsible AI Standard govern anyone using Abu Dhabi patient data for AI, including researchers.[267] On that base, M42 has released Med42, an open 70-billion-parameter clinical language model (vendor-reported 85–87% on USMLE-style questions, without peer review),[268] and in June 2026 launched the UAE's first genomics-driven prevention trial, pre-screening APOE4 carriers from the roughly 900,000-person Emirati Genome Programme and linking clinical data through the Malaffi exchange; the recruitment is genomic, not AI-driven, but the infrastructure is the kind an AI layer needs.[269] In October 2026 the Department of Health opened its Trusted Research Environment to Isomorphic Labs for a 24-month preclinical AI programme and committed, with AstraZeneca and Cleveland Clinic Abu Dhabi, to up to 30 cardio-renal-metabolic trials by 2030.[270] PureHealth's Abu Dhabi Health Research Centre cites more than 100 active studies and 300 investigators, with AI

described only generically.[271] The Emirates Drug Establishment itself announced an "agentic AI" agenda for registration and inspection in June 2026, with no trial-specific provisions.[272]

Saudi Arabia's SFDA has device-level AI guidance (MDS-G010, 2023),[273] reported a 40% rise in trials in 2024 and is building an integrated electronic CTA system linked to the Saudi National Institute for Health Research,[274] announced in January 2026 that it will use AI and digital-twin simulation inside its own regulatory operations,[275] and in October 2026 launched five clinical-trial initiatives including a reliance pathway and a model trial agreement.[276] KAIMRC's partnership with Flagship Pioneering brings early-phase trials of new medicines to Saudi sites, with no AI component,[277] and the HUMAIN–Lean announcement of the "world's largest AI physician trial" has published no design, size or registry entry.[278] Israel is the region's exception in both tooling and regulation: Sheba's ARC adopted Paradigm's AI platform across its oncology trials in 2024,[279] the Innovation Authority and Ministry of Health opened a regulatory sandbox for autonomous clinical AI in 2026,[280] CytoReason's computational disease models carry a US$110 million Pfizer extension,[281] and Ibex Medical Analytics has extended its AI pathology into regulated trial endpoints.[282] Qatar's national AI and health strategies name precision medicine but report no trial-operations AI;[283] Egypt's 2020 trials law and 2025–2030 AI strategy do not intersect;[284] and Turkey regulates software with a medical function under EU-aligned device rules with an AI regulation pending.[285]

Latin America

The Latin American story is regulatory digitisation and timeline reform, not AI. Brazil's Law 14.874/2024 set statutory clocks (30 business days for ethics review, 90 for ANVISA) and replaced the CEP/CONEP system;[286] industry reports Brazil rising from 18th to 12th in global trial rank in the first half of 2026, and Hapvida has built an in-house tool that scans electronic records daily against inclusion criteria, the one concrete AI-recruitment deployment this review could find in the region (participants grew from about 120 to over 1,000 in two years, vendor-reported and not isolated to the tool).[287] Fiocruz launched Rebec@, a generative-AI assistant for the national trial registry, in March 2025 without published performance metrics,[288] and the CFM's 2026 resolution on physicians' use of AI permits research use while keeping final clinical decisions human.[289] Hospital Israelita Albert Einstein joined Mayo Clinic Platform's federated data network in July 2026.[290] Mexico's COFEPRIS cut average protocol approval from 90 to 45 days in early 2025 through digitisation and a reliance agreement, with no AI involved;[291] Argentina aligned its GCP regime with ICH from December 2025 and approved 290 new studies in 2025, with AI discussed only generically;[292,293] and Colombia's INVIMA set a 60-day review target with "predictive analytics" as a medium-term aim.[294] CRO and consultancy commentary on AI in the region names no tools and no figures.[295]

Sub-Saharan Africa

Africa's regulatory architecture is consolidating: NAFDAC and SAHPRA became full ICH members in November 2025,[152] the African Medicines Agency was operationalised in Kigali in October 2025 with 33 ratifications and a clinical-trials technical committee, and no AI mandate,[296] and CEPI funded AVAREF to shorten multi-country emergency trial review from a 6–18-month standard to 10–15 days.[297] SAHPRA issued AI/ML device requirements in September 2025, requiring evidence of generalisability to South African populations and locking algorithms at licensing,[298] and piloted an electronic CTA system the same month.[299] The best-evidenced AI deployment on the continent is clinical rather than trial-operational: Penda Health's GPT-4o-based copilot across 39,849 visits in 15 Nairobi clinics reduced diagnostic errors by 16% and treatment errors by 13% in an OpenAI-funded quality-improvement study, with a PATH-led randomised trial following.[300] The Gates Foundation is funding Wits to evaluate diagnostic AI on LMIC cases,[301] DNDi's AI-guided dengue discovery with BenevolentAI remains preclinical,[302] and the collapse of 54gene in 2023 is a caution on genomics-

for-trials narratives.[303] Rwanda approved a National AI Agency in June 2026 without a research mandate.[304] Open-source data capture (OpenClinica, REDCap) remains the practical backbone of academic trials in the region, without AI augmentation.

Global instruments and the contraction of some markets

The WHO's 2021 ethics principles, 2023 regulatory considerations and 2024 guidance on large multimodal models frame AI for health generally and name drug development among the application areas, without trial-specific rules;[305,306,307] the OECD's 2026 report on scaling AI in health focuses on data foundations, assurance and workforce.[308] ICH's June 2026 assembly adopted E6(R3) Annex 2 and admitted Pakistan and New Zealand as observers, taking membership to 25 members and 43 observers, with no AI topic on the agenda.[309] Russia, by contrast, has largely left the international trial map: international multicentre permits fell roughly fourteen-fold year-on-year after 2022.[310]

What the geographies have in common

Jurisdiction	Sponsor-facing AI-in-trials guidance	Regulator's own AI / digital programme	Notable regional platforms and deployments
United States	Draft guidance Jan 2025; EMA–FDA principles Jan 2026	Elsa (Jun 2025); CSA final; Dataset-JSON exploration	Most global platform vendors; frontier-model vendors
European Union	Reflection paper 2024; joint principles 2026; AI Act (delayed)	AI Observatory reports; DARWIN EU; EHDS 2027–31	Castor, Viedoc, CluePoints, Clinerion, Koda; sponsor in-house tools
United Kingdom	None specific; HRA AI plan; NICE evidence statement	AI Airlock; 2030 strategy incl. protocol checker	DigiTrials, Akrivia/Arcturis, Lifebit, uMotif, Qureight
China	None; CDE e-systems guideline Sep 2026	NMPA AI opinions Apr 2026 (2030/2035 targets); rebuilt GCP	Taimei, Yidu Tech, Tigermed YIYa, XtalPi
Japan	None; basic approach due Mar 2027	PMDA AI action plan; GenAI device consultation	Shionogi, Astellas, Chugai in-house; CMIC–Bluenote; MICIN; Ubie
South Korea	Draft Jun 2024; final due Dec 2026	₩22.3bn AI review system; GenAI device guideline	Evidnet FeederNet-AI; C&R Research
Singapore	In development; MHRA corridor covers AI	15-day Phase III approvals (lower risk)	Oncoshot, Holmusk
India	None; ICMR AI ethics 2023; CDSCO AI panel Sep 2026	SUGAM replacement; DDRS; IndiaAI hackathon	Clinion, Freyr, TCS/TechM/Wipro PV agents; diagnostics start-ups
Canada, Australia	None; CDA AI-RWE guidance (CA); TGA evaluation aids (AU)	Modernised trial regulations; One Stop Shop	pMATCH; Evrima, HealthMatch, Oncoshot
Gulf, Israel	None (device-level only); Israel AI sandbox	EDE agentic agenda; SFDA AI lab; SFDA reliance pathway	M42/Med42; Sheba–Paradigm; CytoReason; Ibex
Latin America	None	Brazil statutory clocks; COFEPRIS 90→45 days; INVIMA 60-day target	Hapvida EHR pre-screening; Fiocruz Rebec@
Africa	None; SAHPRA AI device rules	AMA operational; AVAREF; SAHPRA e-CTA	Penda–OpenAI copilot; OpenClinica/REDCap backbone

Three implications follow for anyone selling or buying AI-enabled trial services across borders. First, the FDA and EMA frameworks are, in practice, the global standard: no other regulator has written a

sponsor-facing rule, and Korea's forthcoming document and Japan's 2027 approach are both being drafted with those texts in view. Second, the Asian platform vendors are real competitors in their home markets and increasingly in cross-border trials; a sponsor running a China–Japan or Korea–India programme will meet Taimei, Yidu or Evidnet as readily as Medidata. Third, in the Gulf, Latin America and Africa the near-term efficiency lever is regulatory digitisation and reliance, and the AI opportunity is in the data infrastructure being built around genomic programmes and health-information exchanges rather than in trial-operations software, which these markets will largely import.

SECTION 18

18 Market size, adoption and the evidence gap

Market estimates for AI in clinical trials differ by a factor of two on the base year and more on the forecast, which is itself a finding. MarketsandMarkets sizes the market at US$1.35 billion in 2024 growing to US$2.74 billion by 2030 (12.4% CAGR);[311] BCC Research puts 2024 at US$2.0 billion rising to US$6.5 billion by 2030 (a stated 22.6% CAGR from a 2025 base; the rounded 2024–2030 endpoints imply about 21.7%);[312] and Precedence Research estimates US$3.3 billion in 2026 reaching US$25.5 billion by 2035 (25.7%), with Asia-Pacific the fastest-growing region.[313] McKinsey's 2024 estimate of generative AI's potential value to pharma and medtech is US$60–110 billion a year, of which US$13–25 billion sits in clinical development; its 2025 agentic-AI analysis projects 35–45% productivity gains in clinical development and 45–50% time savings in biostatistics and data management, figures that are explicitly projections.[314,315]

Adoption surveys tell a more sober story. WCG CenterWatch's 2025 benchmarking of more than 400 sponsors, providers and sites found enthusiasm concentrated in protocol design, start-up, data management and participant engagement, with training, infrastructure and data-security guidance as the stated needs; companion data put fully implemented AI at 11% of companies, partial at 22% and exploratory at roughly two-thirds.[316,317] Florence Healthcare's 2025 survey found half of sponsors and CROs but only 15–17% of sites using AI regularly, with budget and integration each cited by 58% as barriers.[318] eClinical Solutions found 72% of clinical-data professionals had integrated or were considering AI, and 98% of adopters reporting compliance or privacy challenges.[319] Deloitte's 2026 executive outlook records 22% of life-science leaders having scaled AI and 9% reporting significant return.[9]

The evidence gap, then, has a shape. Where a task is narrow, measurable and has an expert gold standard (coding a verbatim, matching a patient to criteria, scoring a biopsy, extracting a progression event), peer-reviewed and regulator-recognised evidence exists and is generally favourable. Where a task is broad, generative and judged by downstream outcomes (drafting a protocol, writing a CSR, programming an analysis), the evidence is vendor-reported, single-site or explicitly cautionary. In our reading, the market forecasts only reach their upper ranges if the second category matures at the pace of the first; the adoption data suggest it has not yet.

SECTION 19

19 The services landscape: CROs, IT services and India

AI reaches most sponsors not as software they license but as capability embedded in the services they buy. Three groups of providers package it differently.

Global CROs

The large CROs have moved from point tools to branded platforms within eighteen months. IQVIA launched its first agents in June 2025 and now markets IQVIA.ai; ICON published a portfolio of named tools in January 2025 (One Search, ICONex, Cassandra, iSubmit, site-contract drafting) and in 2026 built Orbis with Microsoft and Anthropic; Parexel launched ParexelAI on Palantir in May 2026; Fortrea unveiled Fortrea Intelligent Technology in April 2026 across full-service, functional-service and SaaS models; Syneos announced its ecosystem in August 2026; and Thermo Fisher's PPD is embedding OpenAI models.[186,71,49,50,112,51,188] The common pattern is "human-led AI services": the CRO's staff use the platform, and the sponsor buys the outcome. The buyer's due-diligence question has therefore shifted from "which model?" to "what is validated, what is logged, and what do I inherit at inspection?".

Indian IT services and biometrics specialists

India's IT-services firms have long run clinical data, programming and safety operations for global sponsors, and the 2025–2026 cycle has seen them productise. TCS's ADD AgentHub (August 2026) offers role-based agents for adverse-event intake and coding, protocol digitisation, data review, SDTM transformation and medical monitoring, with claimed gains of up to 40% in data-management efficiency, 30% in study build and 30% in safety case-processing cost (vendor-reported).[98] Indegene's NEXT medical-writing platform (July 2025) runs on its Cortex orchestration engine.[160] LTIMindtree markets decentralised-trial tooling, a digital command centre with AI anomaly detection and pharmacovigilance copilots;[320] Tata Elxsi's AI centre of excellence addresses patient selection, protocol-adherence monitoring and dropout prediction;[321] Axtria has published on agentic site intelligence;[322] and Ephicacy appointed its first head of AI in August 2026 to build USDM-grounded, auditable data workflows.[323] Saama, whose Pfizer relationship was expanded in 2024 to a biometrics research and analysis network covering statistical programming, is headquartered in California with substantial Indian operations.[324] Cytel, with a large Pune presence, remains the reference for design and simulation software.

Indian CROs and start-ups

Beyond the IT majors, India has a layer of home-grown eClinical and safety software. Clinion (Hyderabad) is the clearest case of a specific, published feature set: an agentic assistant inside its EDC, AI medical coding and CDASH mapping, ICH M11 protocol drafting and CSR auto-population, with SCDM 2024 and ACDM 2025 innovation awards and vendor-reported cost and time claims of 35% and 30%.[325] Octalsoft (Ahmedabad), Cloudbyz and CliniOps describe AI-enabled suites in general terms in their public materials, with Cloudbyz's ClinicalWave.ai naming redaction and extraction modules.[326,327,328] In pharmacovigilance, Vitrana (Noida), whose platform automates intake, extraction and narratives with a vendor-reported 60% cut in case-processing time, was acquired by Parexel in April 2026;[137] Tech Mahindra's agentic PV solution on NVIDIA NeMo reports 40% faster turnaround (vendor-reported), Wipro's TaloSafe applies GenAI to literature adverse-event identification, and HCLTech markets AI case intake with autocoding;[138,329,330] Navitas, Sarjen's PvEdge, Techsol and Soterius describe AI in qualitative terms in the materials reviewed.[331,332,333] In regulatory writing, Freyr's freya fusion (Hyderabad) ships fine-tuned regulatory language models deployable on-premise, and Zifo (Chennai) launched an explainable regulatory-authoring tool in 2026;[165,334] Hexaware was named a sample vendor for GenAI clinical intelligence in Gartner's 2026 life-science R&D hype cycle, with vendor-reported figures whose basis is not published;[335] and Coforge's work with Espero Health on ML-driven protocol design won a 2025 MedTech Breakthrough award.[336] Cognizant's Shared Investigator Platform, with more than 400,000 users, does not name a specific AI feature on its public page.[337]

Among CROs, Lambda adopted Medidata's Rave suite in 2023 without an AI claim of its own,[338] Syngene's AI work (SynAI, SynSight) is discovery-stage,[339] Auriga Research describes AI EHR screening and adverse-event anomaly detection in pilot,[340] and Karkinos Healthcare's oncology network offers trial services on an EHR-integrated insights platform with NLP on clinical notes.[341] The strongest independently published evidence from Indian start-ups is in diagnostics and monitoring rather than trial software: Dozee's contactless monitoring (97% of deteriorating patients identified about 19 hours early, *JMIR*), 5C Network's chest-X-ray model (855,482 images in a live multi-site evaluation, preprint), Artelus' diabetic-retinopathy screening (5,029 participants, 92% sensitivity, preprint), SigTuple's FDA-cleared microscopy, DeepTek's cleared chest-X-ray platform, Niramai's thermal breast screening and Wysa's FDA Breakthrough-designated conversational agent, each a potential source of screening or digital-endpoint capability for trials run in India, subject to the separate validation that any clearance for a diagnostic use does not supply.[342,343,344,345,346,347,348] Elucidata (Delhi/US) applies LLM-based EHR mapping and multimodal data harmonisation to IND-stage programmes.[349]

The regulator is also a demand signal. CDSCO moved clinical-trial site addition and investigator changes online in 2025, plans to replace the SUGAM portal with an open-architecture platform, and in March 2026 ran a hackathon with IndiaAI whose problem statement explicitly asked for AI-driven de-identification under the DPDP Act, summarisation of SUGAM applications and SAE narratives, and completeness and duplicate checks.[350,351,352]

Veeda Lifesciences invested in Mango Sciences' generative-AI patient-identification platform and adopted an AI platform across its trial network in 2025; its group CEO's view, in March 2026, is that no Indian CRO will grow or survive within five years without AI.[353,354] Among start-ups, Qure.ai (Mumbai) holds FDA clearances for chest-imaging and tuberculosis algorithms and took Merck Global Health Innovation Fund investment in 2024, a signal of the kind of domestic AI that can feed trial imaging and screening.[355] Published evidence of AI use by other mid-size Indian CROs (Cliantha, JSS, Siro Clinpharm, Clininvent among them) remains thin, and several providers' public materials do not yet describe specific AI features.

> **What this means for a mid-size Indian sponsor or CRO**
>
> The platforms are global, the models are American, and the data-protection and ethical frameworks are now Indian. A mid-size organisation is unlikely to build its own models; its competitive position will depend on how well it validates, governs and operates tools built elsewhere, and on whether its data and workflows are structured enough (CDISC, USDM, FHIR) for those tools to work. That is a process and skills problem before it is a technology one.

SECTION 20

20 Specialist and smaller providers: the long tail

The platform vendors and large CROs dominate announcements, but most of the lifecycle is served by a long tail of mid-market eClinical companies, venture-backed AI-native start-ups and regional specialists. This review audited roughly 160 of them. Three findings shape how the long tail should be read.

First, the mid-market eClinical vendors converged on the same two products in 2025–2026: study-build automation and a conversational assistant over study data. OpenClinica's AI Foundry offers a free protocol-to-CRF-and-edit-check build with a new subscription, with logged, reviewable AI decisions;[86] ClinCapture's Captivate AI converts protocol specifications into EDC elements and generates edit checks from plain-language prompts;[87] CRIO's AI eSource Builder drafts site eSource

from the protocol with a vendor-reported four hours saved per build;[77] Anju markets Luminee as an engine that "builds validated EDC databases in days";[88] and Crucial Data Solutions' TrialKit AI adds synthetic-participant simulation and natural-language reporting.[89] Medrio's AI-Enabled Reporting and its planned MCP connectors follow the assistant pattern.[356] In randomisation and supply, Suvoda's agentic RTSM assigns an agent to each build phase (vendor-reported up to 80% timeline reduction in preliminary testing) and its Sofia assistant maps intent to pre-validated "skills" rather than open prompting, with Daiichi Sankyo as a named customer;[73,357] Signant Health reports AI-assisted RTSM builds up to 45% faster and has released four supply-planning agents;[74,358] endpoint Clinical describes a nine-role "elo" agent architecture;[75] and 4G Clinical's NLP-driven Prancer, which generates an RTSM from written specifications, dates from 2017.[76] The common design features are human sign-off gates, audit trails and, where vendors state it publicly (CRIO and Suvoda among them), commitments not to train on customer data; individual contract terms were not reviewed.

Second, the sharpest independent evidence in the long tail sits in data extraction and endpoint measurement, not in generative drafting. Castor's Catalyst extracts eCRF values from scanned, PDF or FHIR-retrieved records with confidence scores and local redaction, and is the only mid-market vendor in this sample found citing comparative-study data: chart review from about 39 to 6 minutes and a post-QC error rate of 0.7% against 6.6% manual across twelve of its own studies (vendor-reported).[90] In eCOA, Medable has shipped four agents since 2025 (a no-code Agent Studio, a CRA monitoring agent, a TMF agent and a principal-investigator oversight agent)[78,359,360] and YPrime reports 74% fewer localisation errors from AI-assisted migration (vendor-reported).[361] In imaging and pathology, Onc.AI's Serial CT Response Score holds FDA Breakthrough Device Designation and outperformed RECIST 1.1 for survival prediction in its own analyses;[121] Qynapse's QyPredict screened out 73.7% of predicted-stable participants in a modelled Alzheimer's placebo arm, doubling observed decline over 24 months;[122] Nucleai's spatial-AI biomarker is the first used prospectively for trial enrolment tied to a drug programme (vendor-reported);[123] Quibim, Proscia and Qureight each raised US$20–50 million in 2025–2026 for imaging and pathology foundation models;[124,362,363] and Lunit's SCOPE is now embedded in CellCarta's trial workflows.[364] In speech and cognition, Aural Analytics holds a Breakthrough designation for ALS speech analytics and Cambridge Cognition acquired Winterlight Labs for speech-based cognitive endpoints.[365,366]

Third, the recruitment and protocol-design start-up layer is consolidating fast. Deep Lens was absorbed by Paradigm (2023), Paige by Tempus (2025), Grove AI's "Grace" screening agent by Hippocratic AI (January 2026), Trilogy Writing by Indegene (2024), scite by Research Solutions (2023) and Topography Health's site business by FOMAT (May 2026); Science 37 sold to eMed for US$38 million after revenue fell, and both CVS and Walgreens have exited or stalled their retail trial businesses.[367,368,369,370,371,372,373,374] Among those still independent, Massive Bio (oncology matching, recognised by the White House Cancer Moonshot), Triomics (oncology LLMs matching GPT-4 at roughly 35 times lower cost in a Medical College of Wisconsin test), BEKhealth and Leal Health are the better-evidenced matching companies;[375,376,377,378] Risklick's Protocol AI and Nurocor's USDM-native platform (used by Roche, Regeneron, Pfizer, GSK, BMS and Amgen per the vendor) are the protocol-side specialists;[379,380] Reify Health's StudyTeam, valued at US$4.8 billion in 2022, remains the largest enrolment-analytics independent;[381] and AstraZeneca's spin-out Evinova signed study-design AI agreements with Astellas and BMS in February 2026.[382] Lindus Health, the "anti-CRO" with US$55 million raised, and Ryght AI, backed by Accenture Ventures for agentic site activation, are the start-ups most explicitly built around AI operations.[383,384]

On the regulatory-writing side, Weave Bio (US$36 million raised; Takeda deploying across 14 programmes), Celegence's CAPTIS Copilot (Kenvue pilot: 80–95% alignment with approved

submissions, vendor-reported), Freyr's freya fusion, Vivpro's REGAIN (presented with Pfizer at DIA 2026) and RegASK's regulatory-change monitoring form the specialist layer beneath Certara, Yseop and Veeva.[163,164,165,166,167] In pharmacovigilance, biologit and DrugCards automate literature monitoring, and Qinecsa's Halo and Reportum products bring AI into intake with human oversight.[139,140] In real-world data, Truveta (US$320 million Series C; a Truveta Language Model normalising 120 million records), OM1 (PhenOM foundation model trained on more than a billion patient-years, vendor-reported), Verana Health, PicnicHealth and MDClone's synthetic-data platform sit alongside the larger Flatiron, Aetion and TriNetX.[385,386,387,388,389] Literature AI used across the lifecycle includes Causaly's knowledge graph (12 of the top 20 pharma) and Consensus.[390,391]

> **What the audit could not find**
>
> Of the 55 mid-market eClinical vendors whose public materials were reviewed, roughly a third describe AI capability in general terms without a specific feature, technique or metric being published, and a further group make no AI claim at all. Within this sample, one vendor was found citing comparative-study data for its AI; every other metric located is vendor-reported. The absence of a published feature does not mean a capability does not exist, but for a buyer it is a prompt to ask.

The open-source statistical layer

The least visible and perhaps most consequential "provider" in biostatistics is not a company. The pharmaverse, now a PHUSE working group, maintains the R packages (admiral, sdtm.oak, metacore, xportr, teal, rtables and others) that have carried FDA submissions from Roche, Novo Nordisk, GSK and Johnson & Johnson since 2020,[392] and Posit's validated R stack reports customer metrics such as Roche's 50% faster SDTM creation and GSK's migration of half its clinical code from SAS (vendor-reported).[393] Appsilon, a pharmaverse council member, has built an agentic workflow platform in which an agent scores package health with human council approval.[394] Commercial design software (nQuery, PASS, JMP Clinical) makes no AI claim.[395] This is the layer that the generative tools in Section 12 generate code against, and its maturity is why R-based submissions with AI-assisted programming are now within reach of a mid-size function.

SECTION 21

21 What the evidence says: six patterns

1. Maturity follows measurability. The tools with regulator qualification for a defined context of use (PROCOVA, AIM-MASH, SV95C), the peer-reviewed algorithms (Koda, TrialGPT, RECTIFIER, Flatiron's extraction) and the commercial products are three different kinds of evidence, but they share one feature: all solve narrow problems with an expert reference standard. Tools that generate open-ended artefacts lack that anchor and are judged on vendor time-savings claims.

2. Vendor metrics are not outcomes. "80% faster review", "50% faster site selection" and "CSR in five minutes" describe the speed of a task, not the effect on database lock, enrolment completion or approval. It helps to keep four levels apart: task efficiency (minutes per query, drafting hours), process efficiency (query-resolution time, review-cycle duration, rework), study outcomes (database lock, enrolment completion, submission readiness) and regulatory and patient outcomes (inspection findings, accepted evidence, safety). Evidence at one level does not carry to the next, and marketing claims, observational operational data and controlled comparisons are not the same kind of evidence. Only a handful of sources reach beyond task efficiency: the 2025 *JAMA* recruitment comparison is a controlled study-level result; Merck's CSR programme and Pfizer's vaccine-trial cleaning are operational case outcomes at the process level, and neither demonstrates an overall study-timeline improvement.

3. Human oversight is the regulatory default, applied in proportion to risk. The FDA's draft guidance rates autonomous determinations as higher risk, CIOMS XIV centres on augmentation, the EMA locked the AIM-NASH model and kept the pathologist responsible for the final read, and the draft Annex 22 excludes generative AI from critical GMP use. None of these requires a person to approve every automated step; what they require is that the nature and extent of oversight match the system's intended use, the consequence of error and its demonstrated reliability, with the closest review where outputs touch patient safety, data integrity or a regulatory decision. Product design is converging on the same point: the 2026 agent announcements from Veeva, TRI, CluePoints and IQVIA describe accept-or-reject workflows with audit logs.

4. Structured data is where reliability comes from. Language models can and do extract useful information from unstructured protocols and specifications; several products in this review start exactly there. But repeatable, validated automation (protocol-to-build, protocol-to-risk, SAP-to-ADaM) benefits from standardised inputs, validated transformations and traceable metadata. ICH M11, USDM and Dataset-JSON therefore matter as much to dependable AI adoption as any model release; organisations working from Word protocols and spreadsheet specifications can begin, but will find the results harder to validate, reproduce and inspect.

5. The failure modes are documented and specific. Fabricated references, silent code errors that produce plausible but wrong cohorts, prompt sensitivity in screening, moderate specificity in literature triage, vendor documents that disagree on their own baselines, and, less visibly, model drift after updates, automation bias in reviewers, weaker performance in under-represented subgroups and dependence on proprietary foundation models that can change or be withdrawn. None of these is an argument against adoption; all of them are arguments for independent QC that the tool's vendor does not supply.

6. Scale changes which benefit matters. The documented throughput wins (Pfizer's 40,000-participant trial, Merck's late-phase pipeline, Tempus's 1.3 million screened patients, ArisGlobal's 350,000-case client) are at volumes where even modest per-unit gains are large. Smaller sponsors can still realise material value, but it comes from avoided rework, caught errors and milestones met rather than from volume; their business case rests on quality and inspection readiness more than on throughput.

SECTION 22

22 White space: where AI has not yet reached, and where efficiency remains

Mapping ~160 providers against twelve lifecycle stages shows where the money has gone: study build, query generation, patient matching, case intake, imaging reads and report drafting. It also shows, by omission, where it has not. This section sets out the gaps that the evidence in Sections 2–21 makes visible. They are of three kinds: tasks for which this review did not identify a documented, independently evaluated solution; tasks addressed only for the largest sponsors and trial types; and the organisational work that sits between buying a tool and getting value from it. Three statements are kept distinct throughout: that no product was found in the sample reviewed, that products exist but do not serve a particular kind of user well, and that a capability does not exist at all. Only the first two are claimed here; the gaps are offered as hypotheses for market validation rather than as settled findings, and each is a place where a sponsor or CRO can still take cost out.

Gaps in the lifecycle itself

1. The amendment cascade. Tufts counts 3.4 substantial amendments per Phase III protocol, three-quarters of protocols amended and roughly US$1 million and three months per amendment;[8] IQVIA, Phesi and Faro all sell tools to prevent amendments. Within the solutions reviewed, we did not identify a clearly documented, independently evaluated end-to-end capability for what happens after one: tracing an amended protocol line-by-line into the statistical analysis plan, data management plan, edit-check specification, reconciliation plans and eCRF, assigning accountable reviewers and retaining a unified audit trail. Document-management, requirements-management and clinical-development platforms may address parts of this workflow, and the vendors building on USDM will reach more of it as protocols are structured; integration and traceability across the document set remain the open questions. For sponsors still working from documents, which is most, the cascade is handled by e-mail and memory. It suits a deterministic-first approach (document diff and structured impact mapping) supplemented by semantic analysis and qualified reviewer assessment, and it is small enough per trial to be delivered without a platform.

2. Reconciliation, as distinct from query generation. The data-management AI market (Section 8) is concentrated on detecting discrepancies in captured data. The reconciliations that consume data-management time in the final months of a trial - serious adverse events against the safety database, laboratory values against adverse-event grading, dosing against exposure, and imaging responses against the recorded overall response - are governed by published standards (RECIST 1.1, CTCAE) in which rules do a large part of the work and an AI component is needed for the semantic residue, such as linking a laboratory finding to the right adverse-event term. They are not simple: they span separate systems, timing differences, medical judgement and exception handling, and the hard part is integrating reliable source data and resolving exceptions safely. They are under-served because they do not fit the query-generation product shape rather than because they lack value.

3. Medical monitoring and medical review. CluePoints' Medical & Safety Review, launched in 2024 and generally available in 2026, was the product in this review most clearly built for the medical monitor's review of patient-level data;[96] TRI's RiskIQ reaches the risk-assessment step, and medical-monitoring functions appear inside several broader platforms. What is scarce is an independently evaluated, comprehensive medical-review workflow rather than any single vendor. The medical monitor's working day - reviewing patient profiles, adjudicating eligibility deviations, answering site medical questions, reviewing SAE narratives for consistency - remains largely manual, and the clinical-data-review literature itself notes that a third of queries are still raised by hand at roughly €150 each.[106]

4. Statistical design transparency for small sponsors. Commercial sample-size software makes no AI claim (Section 20), LLM-generated statistics carry documented silent errors (Section 12), and the consultancies that bridge the two price for Phase III. For an investigator-initiated study, a Phase I or bioequivalence trial, or a mid-size sponsor's first adaptive design, what is missing is not a more powerful engine but a transparent one: a tool that shows the formula with the numbers in it, emits the protocol-ready assumptions table and a sensitivity grid, and reproduces published reference values so that a statistician can review it in minutes. The failure mode in sample size is a wrong assumption, not wrong arithmetic, and none of the products surveyed is designed around that fact.

5. The operational decision layer. The platforms instrument the data; almost none of them instrument the running of the study. Status synthesis across trackers, RAID (risks, assumptions, issues, dependencies) management, vendor-build oversight for eCOA, IRT and central labs, and the weekly question "what should this study team decide next" are handled in spreadsheets and slide decks. The CRO agents announced in 2026 (ICON Orbis, Fortrea Foresight, Medable's CRA agent)

point at this layer from the vendor side, which means the sponsor sees it only through the vendor's lens. CTMS, portfolio-management and enterprise AI products overlap with parts of this; what this review did not find is an affordable, sponsor-controlled, auditable assistant that reads the trackers a study team already keeps, integrates vendor milestones and governance decisions, and runs inside the sponsor's own environment.

6. Oversight of the overseers. Sponsor responsibility for work done by service providers predates E6(R3); what E6(R3) adds is specificity about data governance and technology-supported processes, which now plainly includes the service provider's AI.[4] As CROs embed agents into monitoring, data review and medical writing, the sponsor's oversight obligation extends to those agents, yet no tool or service surveyed helps a sponsor assess a CRO's AI (its validation, its logging, its error rates) in the way sponsors have long audited a CRO's SOPs. This is a service gap before it is a software gap, and it will be most acute for mid-size sponsors who outsource most of their trials.

7. Early-phase and bioequivalence trials. Almost every efficiency claim in this review is a Phase III claim. Phase I units and bioequivalence trials, which dominate the Indian trial economy and a large share of generic-drug development worldwide, have different data flows (pharmacokinetic sampling schedules, bioanalytical run reconciliation, dense safety monitoring over days) and are served by legacy or in-house systems. The market has not priced these studies as worth an AI product, which leaves them to be served by configurable tools and services rather than platforms.

8. Low-volume and institutional research. Hospital and academic investigator-initiated trials, registries and post-marketing studies in India and other emerging markets run on paper, spreadsheets or free tools because subscription eClinical pricing assumes commercial trial volumes, and because institutional policies, sponsor contracts and sector rules often favour data staying on the premises (the DPDP Act itself regulates consent and transfer rather than mandating localisation; Section 16).[199] OpenClinica's free AI build is a signal that vendors see this segment, but a validated, installable EDC with a guided qualification kit remains rare. Self-hosted or offline-capable systems can offer advantages in data control, deployment flexibility and licence cost, but they are not automatically compliant or cheaper over their life: validation, cybersecurity, patching, backup and recovery, user support and change control remain ongoing obligations, and the comparison has to be made on total cost of ownership. The same logic applies to every tool in this paper: a deterministic-first design, with AI used only where language understanding is needed, is the form factor this segment can validate and afford.

9. Language and locality. YPrime's localisation AI (Section 20) is the only product in the audit aimed squarely at multilingual trial content, and it serves eCOA. Consent forms, site training, patient-facing materials and investigator correspondence in India's scheduled languages, or in Portuguese, Arabic and Bahasa, are produced by translation vendors in weeks. LLM-based simplification has peer-reviewed evidence in English (Section 7); its extension to regional languages with ethics-committee acceptance is open.

Gaps between the tool and the value

10. Credibility assessment as a service. The FDA's seven-step framework and the EMA–FDA principles (Section 16) are non-binding, but together they provide the framework by which a sponsor is expected to define context of use, assess model risk and document credibility for AI outputs that support a regulatory decision. Vendors supply validation packages for their own software; none of them will write the sponsor's credibility assessment, and the large consultancies price this work for top-twenty clients. Independent credibility assessment, GAMP 5 Appendix D11 qualification and CSA-

style assurance of AI components, sized for mid-size sponsors and CROs, is an unfilled professional-services market.

11. Process redesign and QC sampling. The (preprint) scoping review of statistical-programming automation found value only where generated outputs entered an unchanged review process;[5] the Merck CSR programme's gains came with a redesigned authoring workflow.[155] The SOP changes, risk-based QC sampling plans, role definitions and training that make AI-assisted review inspectable are not sold by tool vendors and are what the adoption surveys name as the binding constraint: training and integration cited by half or more of respondents.[318,316] SCDM's own competency work points the same way.[105]

12. Standards readiness. Protocol-to-build, protocol-to-risk and SAP-to-ADaM automation benefit from structured, standardised and traceable inputs (USDM, CDISC and increasingly Dataset-JSON; Section 12). Tools can start from unstructured documents, as Section 21 notes, but mid-size organisations that cannot yet produce structured inputs will find the results harder to validate, reproduce and inspect, and will realise less of the benefit. The work of structuring protocols, specifications and metadata is unglamorous, reusable across every tool, and largely unaddressed by the AI vendors themselves.

13. Inspection-readiness evidence. E6(R3)'s data-governance section expects validated systems, audit trails and metadata to be available and explicable at inspection; AI adds model versions, prompts, confidence thresholds and human-override logs to that list. No product surveyed produces the inspection evidence pack for an AI-assisted process, and most organisations have not yet decided what it should contain.

Gap	Why it persists	What a solution needs	Likely form
Amendment cascade and cross-document traceability	Unstructured source documents; partial coverage in document platforms	Line-level diff and impact mapping across protocol, SAP, DMP, edit checks, recon plans; reviewer routing; audit trail	Tool + service
Reconciliation (SAE, lab–AE, imaging response)	Does not fit query-generation products; cross-system exceptions	Standard-based engine (RECIST, CTCAE) with narrow AI for semantic matching and safe exception handling	Tool
Medical monitoring workbench	Few dedicated, independently evaluated products	Patient-profile review, deviation adjudication, narrative consistency	Tool
Transparent statistical design	Engines without explanation; LLM errors	Formula-with-numbers readout, assumptions table, sensitivity grid, reference-value validation	Tool + review service
Sponsor/site study PMO layer	Vendor agents serve vendors; CTMS overlaps partially	Affordable, sponsor-controlled, auditable assistant for status, RAID and vendor-build oversight	Tool + PMO service
Oversight of service-provider AI	Sponsor oversight of CROs is long-standing; E6(R3) adds specificity on data governance and technology-supported processes	Assessment framework for CRO AI validation, logging and error rates	Service
Phase I / BE data flows	Market prices for Phase III	PK scheduling, bioanalytical reconciliation, dense safety review	Configurable tool + service
Institutional and low-volume research	SaaS pricing; institutional data-control policies	Installable, validated systems with qualification kits, judged on total cost of ownership	Product

Gap	Why it persists	What a solution needs	Likely form
Regional-language content	Only eCOA localisation served	LLM simplification and translation with ethics-committee-acceptable QC	Service
AI credibility and validation	Vendors validate their own software only	Context-of-use definition, model-risk assessment, GAMP 5 D11 qualification with risk-based assurance	Service
Process redesign, QC sampling, skills	Not a vendor deliverable	SOPs, sampling plans, role definitions, training for AI-assisted review	Consulting + training
Standards readiness	Prerequisite, not product	USDM, CDISC, Dataset-JSON structuring of protocols and specs	Service
Inspection evidence for AI processes	Expectations still forming	Evidence-pack definition: model versions, prompts, overrides, audit trails	Service

The efficiency still on the table

The baseline figures in Section 2 bound the opportunity. Roughly a third of a Phase III protocol's 5.9 million data points fall outside the primary and key secondary endpoints (some of it still serving safety, exploratory or compliance needs);[7] a third of queries are still manual;[106] 11% of activated sites enrol no one;[16] every Phase III carries about three amendments;[8] and a CSR that took 180 human hours can be reviewed in 80 when the workflow is redesigned around the draft.[155] The products reviewed here attack the second and fifth of those; the first, third and fourth are design, governance and process problems, and the gaps above are where they will be solved.

> **A sequencing for mid-size organisations and the firms that serve them**
>
> The gaps cluster into work that a boutique can do and a platform cannot: structuring the inputs, validating and governing the tools, redesigning the process, and building narrow deterministic-first tools for the tasks the platforms skipped. Praveg's own practice areas - biometrics process set-up, PMO, and AI domain intelligence with the validation and training around it - and the small toolkit described in Section 24 were shaped by this map rather than the other way round. The gaps are hypotheses: readers can judge for themselves from the evidence cited for each, and Praveg's interest in several of them is disclosed in Section 24. Organisations wanting this map applied to their own portfolio, vendor set or geography can contact Praveg at info@pravegcs.com.

SECTION 23

23 A decision checklist for sponsors and CROs

The following questions, drawn from the evidence above and the regulatory frameworks in Section 16, are intended for a sponsor or CRO evaluating a specific AI tool or service for a specific stage.

Dimension	Questions to put to the vendor, and to yourself
Context of use	What decision does the output inform, and would that decision reach a regulator? If so, where does the model sit on the FDA's influence × consequence risk matrix, and who owns the credibility assessment plan?
Evidence	Which claimed metrics are vendor-reported, peer-reviewed or regulator-recognised? Is there a published comparison against the current process on your kind of study? What is the measured error rate, and against what reference standard?
Technique and determinism	Is the component statistical/ML, rule-based NLP, an LLM or an agent? Does it produce the same output for the same input? If not, how is reproducibility documented for an audit trail?

Dimension	Questions to put to the vendor, and to yourself
Validation and change control	How is the tool qualified under GAMP 5 (including Appendix D11), or under a risk-based assurance approach adapted from the FDA's CSA guidance (which is itself scoped to device production and QMS software)? What happens when the vendor updates the model? Is the model version recorded with each output?
Human oversight	Where in the workflow does a qualified person accept, reject or correct the output? Is that action logged? Can the tool act on a live system (post queries, change configuration) without that step?
Data governance	Where does the data go, under whose jurisdiction, and is it used to train vendor models? Does the arrangement comply with the DPDP Rules, GDPR and E6(R3) data-governance expectations? Is a no-data-leaves-the-premises deployment available where that matters?
Inputs and standards	Does the tool require structured inputs (USDM, CDISC, FHIR) that your organisation does not yet produce? What is the cost of getting there, and is that cost a one-off investment that benefits other tools?
Skills and process	Who reviews the output, with what training? Does the process change (SOPs, roles, QC sampling) when the tool is introduced, and have those changes been documented before go-live?
Economics	At your study volume, does the gain come from throughput or from quality and inspection readiness? What is the exit cost if the tool is withdrawn or the vendor is acquired?

A reasonable sequencing for a mid-size organisation is: first, the structured-data foundation (protocol and specification standards, data governance, SOPs for AI-assisted review); second, tools with regulator-recognised or peer-reviewed evidence in high-volume, well-bounded tasks (coding, safety intake, eligibility pre-screening, central monitoring); third, generative drafting tools with an unchanged review process; and only then agentic systems, once the organisation has the validation and logging practices to supervise them.

DISCLOSURE

24 A note on Praveg's own work

In the interests of disclosure: Praveg Consultancy Services LLP, the publisher of this review, advises sponsors and CROs on biometrics set-up and AI adoption and is developing a small family of offline, deterministic-first practitioner tools for data management and biostatistics tasks (RECIST 1.1 response reconciliation, sample-size and power estimation, protocol-amendment impact tracing), built on the no-data-leaves-the-premises and human-review principles argued for in Sections 16 and 21. None of these tools is cited as evidence in this paper, and the review's conclusions do not depend on them; the market gaps in Section 22 that correspond to them (amendment tracing, reconciliation, transparent statistical design, sponsor-side PMO support, installable systems) should be read with that interest in mind and treated as hypotheses for further validation. Readers evaluating any vendor, including Praveg, should apply the checklist in Section 23.

APPENDIX A

A Provider catalogue by lifecycle stage

Status describes availability as announced; Evidence describes the quality of support for claimed performance. The two are independent: a product can be in use with only vendor-reported evidence, or emerging with peer-reviewed evidence. Status key: `IN USE` commercially available; `EMERGING` announced, early-adopter or research-stage in 2025–26; `GENERAL` AI marketed but no verifiable feature found; **No AI claim** and **Acquired/exited** as stated. Evidence: VR = vendor-reported; PR = peer-reviewed journal; Conf =

conference abstract or proceedings; Preprint = not yet peer-reviewed; RR = regulator-recognised for a defined context of use. Sources are cited in the body sections and reference list; entries without a body citation carry one here. All classifications reflect public materials accessed in November 2026 and may not reflect unpublished capabilities.

A1. Protocol design, simulation, feasibility and site selection

Provider	Base	AI capability	Status	Evidence
Unlearn.AI	US	PROCOVA ML prognostic covariate adjustment (qualified for continuous endpoints in linear ANCOVA); digital twins	IN USE	RR (EMA 2022)
Medidata	US	Protocol Optimization; Synthetic Control Arm; AI Simulants; Intelligent Trials	IN USE	RR (SCA); VR
IQVIA	US	Protocol complexity analytics; Connected Intelligence site ID; start-up agents	IN USE	VR
Citeline (Norstella)	US/UK	Protocol SmartDesign; Investigator SmartSelect; Ella assistant	IN USE	VR
Phesi	US	Trial Accelerator digital patient profiles; digital-twin PoC	IN USE	VR; PoC published
Faro Health	US	USDM-aligned digital protocols; burden and amendment flags	IN USE	CDISC award; BMS
Nurocor	US	USDM study definitions; AI design checks; "Dan" assistant	IN USE	VR
Risklick	CH	Protocol AI drafting from historical trials	EMERGING	VR; Debiopharm pilot
Evinova (AstraZeneca)	UK	Study-design optimisation platform	EMERGING	Astellas, BMS deals
Intelligencia AI	US/GR	Probability of technical and regulatory success	IN USE	VR[396]
Opyl	AU	TrialKey simulation; TrialGen protocol design	EMERGING	VR (unverified)
Trial Pathfinder	US acad.	Eligibility-criteria optimisation	IN USE	PR (Nature 2021)
TriNetX	US	RWD feasibility; conversational AI (2026)	IN USE	VR
H1	US	GenosAI over Trial Landscape	IN USE	VR
Lokavant	US	Spectrum causal-AI feasibility	IN USE	VR
Inato	FR/US	Site marketplace matching	IN USE	VR
Ryght AI	US	AI site twins; agentic site activation	EMERGING	Accenture Ventures
Reify Health (StudyTeam)	US	Enrolment analytics	IN USE	No AI technique stated
Lindus Health	UK/US	AI protocol generation; automated central monitoring	EMERGING	VR
Coforge–Espero	IN/US	ML design recommendations; GenAI SAP/ICF drafts; rules engine to eCRF	IN USE	VR[336]
Clinion	IN	eProtocol agentic authoring (ICH M11)	IN USE	VR; ACDM 2025 award

Provider	Base	AI capability	Status	Evidence
Cytel; Berry Consultants	US	Simulation software (deterministic); East Horizon adds an AI R-code assistant, FACTS makes no AI claim	IN USE	Established software
nQuery; PASS; JMP Clinical	US/IE	Sample-size and design software	No AI claim	-

A2. Recruitment, screening and patient matching

Provider	Base	AI capability	Status	Evidence
TrialGPT (NIH/NLM)	US	LLM criterion-level matching	EMERGING	PR (Nat Commun 2024)
RECTIFIER (MGB)	US	RAG + GPT-4 screening	EMERGING	PR (NEJM AI; JAMA randomised comparison)
Tempus (Deep 6 AI)	US	TIME network matching; GPT-4o scoring	IN USE	Conf (ASCO 2025)
Mendel AI	US	Neuro-symbolic Hypercube	IN USE	Conf/press (benchmark study)
Paradigm Health	US	Matching and feasibility (ex-Flatiron research, Deep Lens)	IN USE	VR
Massive Bio	US	Genomic + RWD oncology matching	IN USE	VR; Cancer Moonshot
Triomics	US	OncoLLM family; chart review	EMERGING	VR (MCW test)
BEKhealth	US	AI chart abstraction and matching	IN USE	VR
Leal Health (ex-TrialJectory)	US	Patient pre-screening	IN USE	VR
Acclinate	US	ML participation-probability index for diverse enrolment	IN USE	Merck, Roche partners[397]
Carebox; Antidote; Power; HealthMatch; SubjectWell; Trialbee	US/AU/SE	Patient-facing matching and marketplaces	IN USE	VR; AI claims vary
Trially AI	US	LLM screening; voice/text outreach	EMERGING	VR[398]
Ancora.ai	CH	AI trial search	EMERGING	VR
Grove AI	US	"Grace" screening agent	Acquired (Hippocratic AI, Jan 2026)	VR
Deep Lens	US	Community oncology identification	Acquired (Paradigm, 2023)	-
Sanofi–OpenAI–Formation Bio Muse	FR/US	Multi-model recruitment tool	EMERGING	VR
Mayo Clinic / IBM Watson	US	Historical matching deployment	Historical	ASCO 2018

A3. Start-up, consent, TMF, RTSM and site technology

Provider	Base	AI capability	Status	Evidence
Veeva	US	TMF Bot; Falcon TMF intake; Study Builder Agent	IN USE / EMERGING	VR
Florence Healthcare	US	Agentic eISF/eTMF; MCP server	EMERGING	VR
Medable	US	TMF, CRA, PI-oversight agents; Agent Studio	IN USE	VR
Suvoda (Greenphire)	US	Agentic RTSM; Sofia assistant	IN USE	VR; Daiichi Sankyo
Signant Health	US	AI-assisted RTSM builds; supply-planning agents	IN USE	VR
4G Clinical	US	Prancer NLP RTSM generation	IN USE	VR
endpoint Clinical	US	elo agent assistant (nine roles)	EMERGING	No metrics
Almac	UK	Trial Coordinator platform	No AI claim	-
ICON; IQVIA	IE/US	Site-contract drafting; iSubmit; GrantPlan budget ingestion	IN USE	VR
CRIO	US	AI eSource Builder	IN USE	VR
Advarra	US	Braid data & AI engine; AI council	GENERAL	- [399]
WCG	US	Copilot-assisted consent summaries; IRB+ workflow	IN USE	VR[400]
Trial Interactive (TransPerfect)	US	ML TMF classification	IN USE	No metrics[401]
Egnyte–Espero	US	Content classification; AI protocol platform	IN USE	No metrics[402]
Sitero (StudyOS)	US	SiteroAI oversight and risk	EMERGING	VR[403]
Montrium; Teckro; Slope; Greenphire (pre-merger)	CA/IE/US	TMF, site performance, kit management, payments	No AI claim	- [404]
Consent LLM studies	US acad.	GPT-4 / Mistral consent simplification	EMERGING	PR (npj 2024; JMIR 2025)

A4. Data capture, eCOA/DCT and clinical data management

Provider	Base	AI capability	Status	Evidence
Medidata	US	AI Study Build; Clinical Data Studio; Rave Coder+; Medidata Plus	IN USE	VR
Veeva	US	Study Builder Agent; Clinical Data agents (Dec 2026); Coder (rule-based)	EMERGING	VR
Oracle	US	Life Sciences AI Data Platform; Clinical One	EMERGING	No metrics
Saama	US/IN	Smart Data Quality; ADaM Navigator	IN USE	VR; Pfizer
CluePoints	BE	IQD; MSR; Intelligent Medical Coding	IN USE	VR; SCDM award
eClinical Solutions	US	elluminate agents (mapping, review, RBQM)	EMERGING	Announced
IQVIA	US	CDAS Clinical Data Review; NVIDIA agents	IN USE	VR

Provider	Base	AI capability	Status	Evidence
WHODrug Koda (UMC)	SE	AI drug coding	IN USE	PR (Drug Saf 2022)
Castor	NL	Catalyst extraction and coding	IN USE	VR comparative studies
OpenClinica	US	AI Foundry Study Build; Unite eSource	IN USE	VR
Viedoc	SE	Vantage; Koda coding; MCP preview	EMERGING	No metrics[405]
Medrio	US	AI-Enabled Reporting; MCP connectors	IN USE	Early adopters
Crucial Data Solutions	US	TrialKit AI (Floyd) simulation, reporting	IN USE	VR
ClinCapture	US	Captivate AI build and Rule Builder	EMERGING	No metrics
Anju Software	US	Luminee EDC build engine	EMERGING	No metrics
Zelta (Merative)	US	"AI and supervised ML" described; 24-hour build vision	GENERAL	- [406]
Datatrak / Fountayn	US	TAILRD Heart AI collaboration	No native AI	- [407]
Clinical ink	US	TrialLens operations dashboard; SPUR retention	EMERGING	No metrics[408]
YPrime	US	AI localisation; calculation engine	IN USE	VR
Clario	US	50+ AI/ML algorithms across eCOA, imaging, cardiac, respiratory	IN USE	VR
THREAD; ObvioHealth; Curebase	US	DCT platforms describing AI capability	GENERAL	VR[409,410]
Huma (Alcedis)	UK	Trial data platform; AI is care-side	GENERAL	- [411]
Kayentis; Datacubed; Lightship	FR/US	eCOA and DCT platforms	No AI claim	-
Science 37	US	DCT platform	Acquired (eMed, 2024)	-
Clinion	IN	Agentic CDM assistant; AI coding; CDASH mapping; CSR	IN USE	VR; SCDM/ACDM awards
Octalsoft; Cloudbyz; CliniOps	IN/US	eClinical suites describing AI capability	GENERAL	- [326,327,328]
TCS ADD AgentHub	IN	Review, SDTM, safety, monitoring agents	EMERGING	VR
IgniteData Archer	UK	EHR-to-EDC transfer (AI planned)	IN USE	No AI today[412]
Certara Pinnacle 21	US	Specification workspace; CORE support	IN USE	No AI claim

A5. Monitoring, RBQM and central statistical monitoring

Provider	Base	AI capability	Status	Evidence
CluePoints	BE	CSM; SPOT deep-learning site oversight	IN USE	VR; 1,600+ studies
Medidata Detect	US	CSM in Clinical Data Studio	IN USE	VR
TRI OPRA	UK	RBQM; RiskIQ protocol-to-risk agent	IN USE / EMERGING	VR; 450+ trials

Provider	Base	AI capability	Status	Evidence
Fortrea	US	Xcellerate; Foresight predictive signals	IN USE	VR
Cyntegrity MyRBQM	DE	RBQM; AI discussed in general terms	GENERAL	-
Remarque Systems	US	ML for RBQM (webinar material)	GENERAL	-
ICON Orbis; eClinical RBQM agent; Lindus	IE/US/UK	Agentic or automated central monitoring	EMERGING	Roadmaps

A6. Imaging, pathology and digital endpoints

Provider	Base	AI capability	Status	Evidence
PathAI	US	AIM-MASH AI Assist (qualified for MASH trial histology, pathologist retains final read); algorithm library	IN USE	RR (EMA 2025; FDA 2025)
Sysnav SV95C	FR	Wearable stride-velocity endpoint (algorithmic digital endpoint; qualified for ambulant DMD only)	IN USE	RR (EMA 2023)
Perceptive; Clario; Median; IAG	US/FR/UK	Imaging CRO AI pipelines; ArtiQ spirometry	IN USE	VR
Onc.AI	US	Serial CT Response Score	EMERGING	RR (FDA Breakthrough)
Altis Labs	CA	IPRO survival prediction	EMERGING	Conf (WCLC 2026), retrospective
Qynapse	FR	QyScore (cleared); QyPredict enrichment	IN USE / EMERGING	Conf (AAIC 2025)
Quibim; Proscia; Qureight; Aiforia; Nucleai; Lunit; Brainomix; Perspectum	ES/US/UK /FI/IL/KR	Imaging and pathology AI, foundation models, biomarkers	IN USE / EMERGING	Mixed; some cleared[413]
Paige	US	Pathology foundation models	Acquired (Tempus, 2025)	FDA-cleared product
Friends of Cancer Research ai.RECIST	US	Inter-tool agreement project	EMERGING	Multi-stakeholder
ActiGraph; Koneksa; Empatica; Aural Analytics; Cambridge Cognition (Winterlight)	US/UK	Wearable, speech and cognitive digital endpoints	IN USE	RR (Breakthrough designations)
DiMe Library of Digital Endpoints	US	636 endpoints, 105 sponsors	Reference	-

A7. Safety and pharmacovigilance

Provider	Base	AI capability	Status	Evidence
ArisGlobal	US/IN	LifeSphere NavaX intake, signals, literature agents	IN USE	VR[414]
Oracle	US	Safety One Intake; Argus	IN USE	No metrics

Provider	Base	AI capability	Status	Evidence
IQVIA	US	Vigilance Detect (GenAI)	IN USE	VR
Veeva	US	Safety narrative agent; Falcon Safety	IN USE / EMERGING	No metrics
Genpact PVAI; Accenture INTIENT	US	End-to-end automated case processing	IN USE	No metrics
Vitrana	IN	AI intake, extraction, narratives, reconciliation	Acquired (Parexel, Apr 2026)	VR (−60% case time)[137]
Tech Mahindra	IN	Agentic PV on NVIDIA NeMo	IN USE	VR[138]
Wipro TaloSafe	IN	GenAI literature AE identification	IN USE	VR[329]
HCLTech	IN	AI case intake, MedDRA/WHO-DD autocoding	IN USE	No metrics[330]
Quantiphi baioniq; WNS	IN	GenAI AE detection; PV BPO	GENERAL	– [415,416]
Navitas; Sarjen PvEdge; Techsol; Soterius	IN	PV services and databases describing AI capability	GENERAL	– [331,332,333]
Qinecsa (Reportum)	UK	AI/ML intake with oversight	IN USE	No metrics
biologit; DrugCards	IE/UA	AI literature monitoring	IN USE	Published benchmark (biologit)
LLM research (FDA; UCSF; Evidence Prime)	US/PL	Literature screening; EHR ADE extraction	EMERGING	PR

A8. Biostatistics, programming, writing, submissions and RWE

Provider	Base	AI capability	Status	Evidence
SAS	US	Viya Copilot; Clinical Data Discovery Copilot; MCP server	IN USE	No metrics
R Consortium; pharmaverse; Posit; Appsilon; Atorus	US/PL	Validated R and FDA submission pilots (enabling layer, not AI); AI-assisted programming and agentic package governance are the AI element	IN USE	Submissions accepted; VR
Saama ADaM Navigator	US/IN	SAP-to-ADaM specs and code	EMERGING	VR
CDISC CORE; Certara P21; Dataset-JSON	US	Conformance and format layer (enabling standards, not AI)	IN USE	FDA collaboration
Merck–McKinsey; Yseop; Certara CoAuthor; Narrativa; QInscribe	US/FR/ES	CSR, narrative and summary generation	IN USE	VR; one assurance test
Weave Bio; Celegence; Freyr; Vivpro; RegASK; Zifo; DDi	US/IN/SG	Regulatory authoring, RIM, change monitoring	IN USE / EMERGING	VR[334]

Provider	Base	AI capability	Status	Evidence
Indegene (Trilogy); Hexaware; Clarivate Cortellis	IN/US/UK	Medical-writing automation; GenAI clinical intelligence; regulatory assistant	IN USE	VR[335]
TrialAssure	US	GenAI plain-language summaries	IN USE	VR[417]
Anthropic; OpenAI	US	Claude for Life Sciences; GPT-Rosalind	IN USE	Benchmarks; customer metrics
Flatiron; Aetion/Datavant; TriNetX; Komodo; ConcertAI; Tempus	US	LLM abstraction; RCT emulation; conversational RWD	IN USE	PR (VALID; RCT-DUPLICATE)
Truveta; OM1; Verana; PicnicHealth; MDClone; Prognos	US/IL	RWD networks, foundation models, synthetic data	IN USE	VR; PR (MDClone)
Causaly; Consensus; scite (Research Solutions)	UK/US	Literature and evidence AI	IN USE	VR
Elucidata; Innoplexus	IN/DE	Biomedical data harmonisation; ontology search	IN USE	VR[349]
EMA DARWIN EU; FDA Sentinel NLP	EU/US	Regulator RWE networks and NLP	Reference	-

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Praveg is a boutique consulting and training firm working across three practice areas: AI domain intelligence for life sciences, biometrics process excellence for clinical research, and PMO consulting anchored by the Praveg OPTIC Maturity Model™. The firm helps sponsors, CROs and service providers set up and run biometrics functions, build PMOs that produce decisions rather than reports, and adopt AI in GxP environments with the validation, governance and skills to make it stick. Praveg also develops a small family of offline, deterministic-first practitioner tools for clinical data management and biostatistics.

FOUNDER

Sagar Kalantre

Praveg was founded by Sagar Kalantre, PMP®, PMO-CP, CSM, LSSBB, who serves as Founder Director & CEO. He has more than twenty years of experience across pharmaceutical, CRO and IT-services environments, has set up biometrics functions for CROs, is a qualified independent director, serves as a PMI PMO Global Awards judge, is a recognised LinkedIn Top Project Management Voice, and is the author of *Primer to Project Management*. He speaks regularly at national and international forums on project management, clinical data management and AI.

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