MEDIDATA

AI REPORT 2026

The State of AI in Clinical Trials

From Pilot to Practice: Insights into AI Adoption, Impact, and Expectations

AI FOR IMPACT

Key Findings

01
The Adoption Wave Has Crested – But Enterprise Scale Remains Elusive

1/3
of organizations have moved AI into actual implementation or deployment. The majority remain in exploration or limited pilots, a reflection of how recently this adoption wave began.

82%
have been using AI in clinical trial operations for 18 months or less.

02
Investment Is Accelerating Even As Value Delivery Lags

92%
of respondents expect AI spend to increase over the next 12–24 months.

29%
say AI currently meets or exceeds their expectations, pointing to a trust gap between what AI is being asked to do and what it's delivering today.

03
AI Is Proving Itself In High-frequency, Rules-based Workflows

46.5%
report above-expectation improvements in task automation, data cleaning, and query resolution.

Harder outcomes like trial timeline reduction and protocol deviation rates remain largely unchanged for most organizations.

04
Early Adopters Are Pulling Ahead

Organizations with more than
18 Months
of AI experience report materially stronger results across nearly every KPI.

2-3 Years
suggested timeframe for the industry to stratify between AI-enabled leaders and followers due to the compounding advantage of early adoption.

05
Agentic AI Is On The Horizon, But The Industry Isn't Ready

90%
of respondents are aware of agentic AI.

Only
10.5%
have hands-on experience. The move from analytics-led AI to autonomous, decision-driving AI is the industry's next frontier.

06
Simulated Outcomes and Digital Twins Will Change How Trials Are Designed

The next tangible step-change will be in the world of simulation and next-best action decisioning.
31%
of respondents believe AI will simulate protocol choices/outcomes.

26.5%
believe digital twins will model patient, site, and trial-level outcomes in the next **2-3 years.**

AI FOR IMPACT

The clinical trial industry is not deciding whether to use AI. That question has been answered. The question it's grappling with now is how to scale AI responsibly, equitably, and in a way that delivers durable value that goes beyond efficiency metrics to impact the speed and quality of the medicine that reaches patients.

Introduction

One year ago, we asked a simple question: how is the clinical trial industry actually using AI? The answer, captured in our first annual State of AI in Clinical Trials report, painted a picture of an industry at an inflection point — aware of AI's potential, beginning to experiment, and cautiously optimistic about what lay ahead.

This year's report tells the next chapter of that story. Conducted by Everest Group, our second annual industry survey gathered responses from 200 senior clinical operations leaders across large and mid-size pharmaceutical companies, biotechs, and CROs in North America and Europe. The results offer a clear window into where the industry stands, and how far it still has to go.

What's changed in a year? Quite a lot, and less than many expected. Budgets are rising sharply. Awareness has broadened. Governance frameworks are being established. And a cohort of early adopters is beginning to pull measurably ahead of their peers. At the same time, enterprise-wide deployment remains the exception rather than the rule: organizations need a clear path to ROI and evidence of returns to meaningfully scale AI, and the hardest operational outcomes like faster trials and fewer protocol deviations, are proving stubbornly difficult to move.

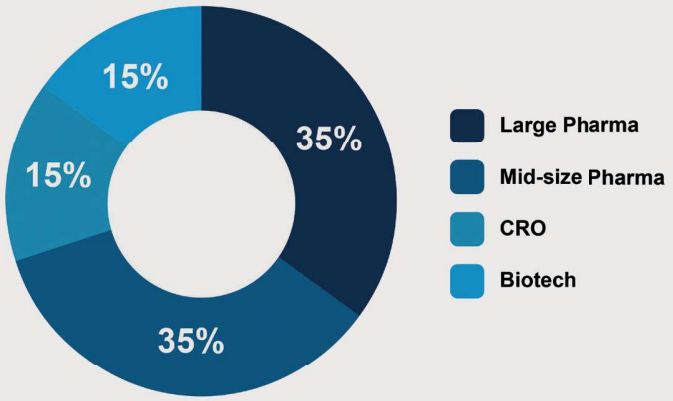
The central theme of this year's report is transition: from exploration to execution, from pilot projects to programmatic investment, from AI as a tool for a handful of teams to AI as infrastructure for the whole enterprise. That transition is underway, but not yet complete, and the path forward demands more than technology. It demands data readiness, change management, and a clear-eyed view of what AI can and cannot do today.

Survey Methodology

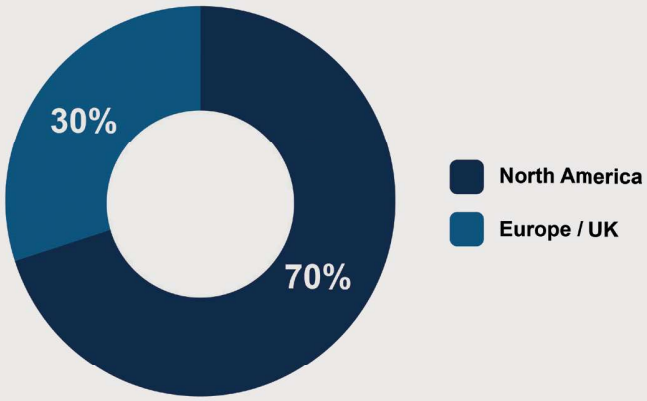
This report is based on a primary survey of 200 senior decision-makers at pharmaceutical, biotechnology, and CRO organizations, conducted by Everest Group in early 2026. Respondents spanned North America (70%) and Europe/UK (30%) and held titles ranging from Director to C-suite.

All respondents had responsibilities in clinical operations, R&D management, clinical technology, data management, or related functions. Organizations ranged in size from emerging biotechs to global enterprises with revenues exceeding $50 billion.

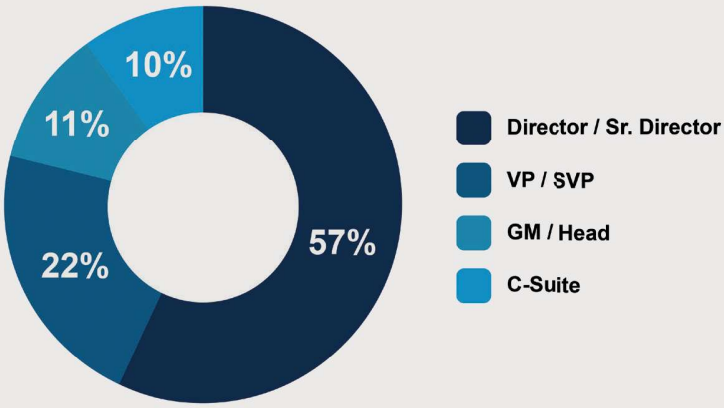
Org Type



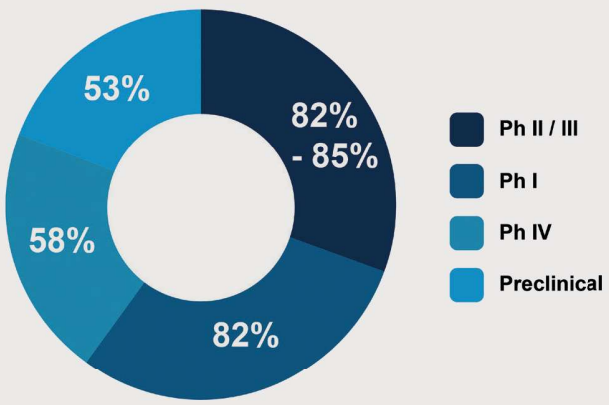
Geography



Seniority



Dev Phases



The State Of AI Adoption: Where The Industry Stands

Taken together, our two annual surveys now span the most consequential period in the history of AI adoption in clinical research. The picture they paint is of an industry that moved fast to experiment and is now working hard to make those experiments stick.

Year-Over-Year: A Rapidly Maturing Conversation

Our 2025 survey found broad awareness of AI's potential and a growing base of users deploying AI tools across the clinical trial lifecycle. By 2026, the narrative has shifted from 'should we use AI?' to 'how do we scale it?'

The industry's view of AI is maturing — from proof-of-concept to deployment, from experimentation to ROI accountability, from awareness to governance.

TABLE 1

Dimension	2025 Survey Findings	2026 Survey Findings	Direction
Primary AI focus	Data capture & quality oversight	Data interpretation & analytics	From managing data to extracting value from it
Top benefit realized	Improved data accuracy	Manual task / Workflow automation	From knowing to doing
Investment outlook	Growing, with expected expansion across lifecycle	Vast majority expect spend to increase in next 12–24 months	Near universal acceleration
Main challenge	Complexity & integration with existing systems	Integrations, model accuracy, fragmented data	Foundational challenges remain
Hardest outcomes to move	Patient retention, site selection, reduced costs	Protocol deviations or timeline reduction	Progress in many areas yet expectations still exceed realities
Regulatory/ governance	Emerging as critical consideration	Most have legal / compliance risk reviews and use human-in-the-loop	Processes being formalized

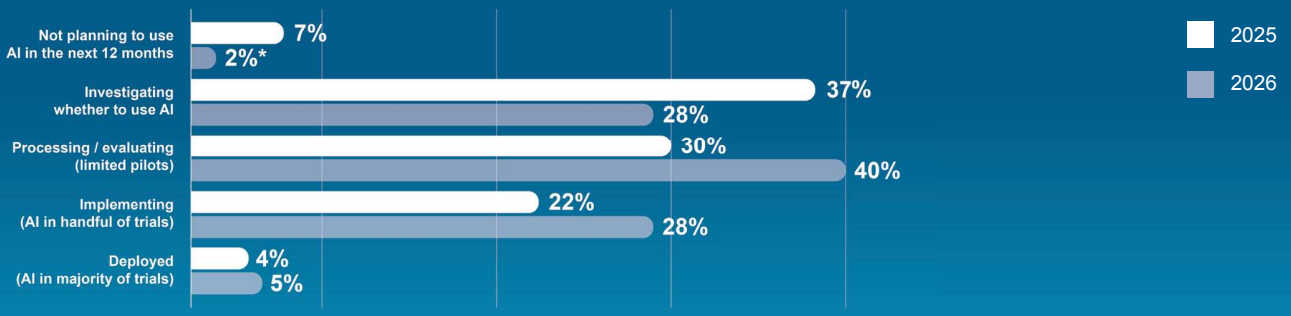
Where Organizations Stand Today

The 2026 survey asked respondents to characterize their organization's current stage of AI adoption.

The results reveal an industry still heavily weighted toward the early phases of the adoption curve:

FIGURE 1

Current Stage of AI Adoption in Clinical Trials (n=200)



**Numbers add to greater than 100% due to termination of respondents not planning to use AI from the remainder of the survey*

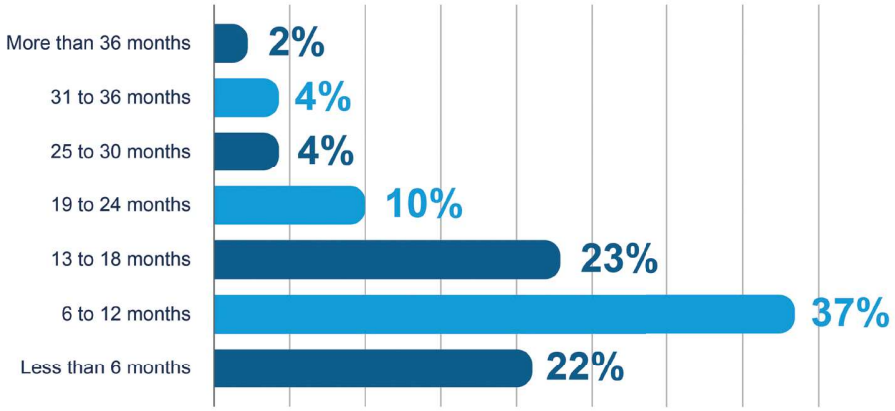
Q: How would you describe your company's use of AI in your clinical trials?

Sources:
Medidata / Everest Group 2026 Survey
Medidata / ISR 2025 Survey

Only 33% of organizations have reached actual implementation or deployment. The remaining two-thirds are still in exploration or controlled pilots. This is not surprising when you account for how recently this adoption wave began: 59% of respondents have been using AI in clinical trial operations for 12 months or less, and 82% for 18 months or less.

FIGURE 2

Respondents by AI Usage Maturity (n=200)



Q: For how long has your organization been using AI in any clinical trial operations workflows?

Source:
Medidata / Everest Group 2026 Survey

These are not organizations that are late to AI. In most cases, they are organizations that are one to two budget cycles into a journey that will likely take four to six years to complete at enterprise scale. The pipeline is full; the question is conversion speed.

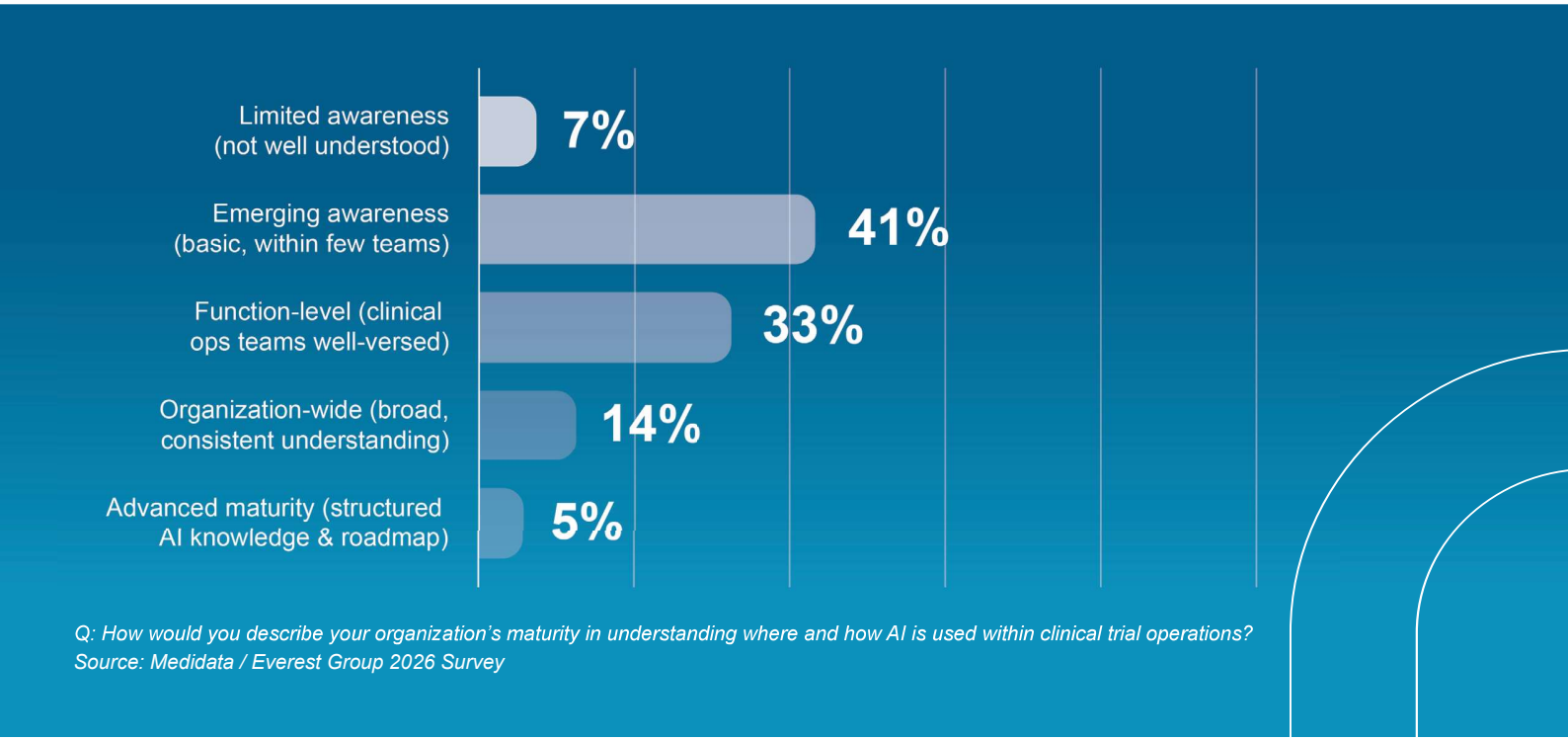
Organizational Awareness: Depth Matters

Beyond adoption stage, the survey assessed AI maturity at the organizational level. Specifically, how broadly and deeply AI knowledge is distributed across the enterprise. The results underscore a critical limitation: for most organizations, AI understanding remains concentrated in a few teams rather than embedded across functions.

74% of respondents sit in the 'emerging' or 'function-level' awareness bands, meaning AI insight is present but not yet pervasive. **Only 19% report organization-wide or advanced maturity.** This concentration of AI literacy within a few teams is itself a scaling barrier: when AI understanding is not shared across clinical operations, regulatory affairs, data management, and IT simultaneously, implementation bottlenecks are inevitable.

FIGURE 3

Organizational AI Awareness Maturity (n=200)



Q: How would you describe your organization's maturity in understanding where and how AI is used within clinical trial operations?
Source: Medidata / Everest Group 2026 Survey

AI Adoption In Context: The Technology Adoption Lifecycle

The numbers in this year's survey — one-third in implementation, 82% with less than 18 months of experience, 74% with basic to function-level awareness — might read as disappointingly slow. In the context of how complex technologies actually diffuse through large regulated enterprises, however, they tell a very different story.

The technology adoption lifecycle, first articulated by Everett Rogers and later adapted by Geoffrey Moore into the famous 'crossing the chasm' model, describes a predictable arc: Innovators (roughly 3%) experiment first; Early Adopters (14%) build on initial proof-of-concepts; the Early Majority (34%) arrives once patterns are established and risk is reduced; the Late Majority (34%) follows when adoption becomes the norm; and Laggards (15%) join last, often under competitive or regulatory pressure.

TABLE 2

Adopter Group	% of Market	Clinical AI Characteristic	Survey Signal
Innovators	~3%	Custom AI builds, bespoke models, tolerance for failure	The 5% deploying AI in a majority of their trials
Early Adopters	~14%	Strategic pilots with clear ROI targets, governance emerging	The 28% using AI in a handful of their trials
Early Majority	~34%	Proven use cases, vendor-led, workflow integration focus	The 40% in the process of implementing AI in trials
Late Majority	~34%	Risk-averse, awaiting regulatory clarity and peer proof	The 28% still investigating the use of AI in trials
Laggards	~15%	Compliance-driven adoption, often externally mandated	The 2% of respondents not using/planning to use AI in the next 12 months (excluded from broader survey data)

By this mapping, **the clinical AI landscape sits at the cusp of crossing the chasm and transitioning from Early Adopters to the Early Majority.** This is the most turbulent and consequential phase of the adoption lifecycle: it's where many technologies stall, where vendor consolidation accelerates, and where the gap between leading and lagging organizations begins to widen in ways that are difficult to reverse.

Several features of this year's survey data are characteristic of this crossing-the-chasm moment. The concentration of AI's applications in data-heavy, rules-based workflows (automation, data cleaning, query resolution) reflects the Early Majority's preference for proven, lower-risk use cases.

The emphasis on integration ease, compliance, and ROI measurability in vendor selection criteria reflects a maturing buyer rather than an experimenter.

And the sharp divergence between early adopters (>18 months of experience) and the broader market in realized outcomes reflects the compounding advantage that builds once an organization has completed its first full AI implementation cycle.

> *The industry is not behind. By the standards of regulated enterprise technology adoption it's exactly where it should be, and it is accelerating. The organizations that crossed the chasm earliest will be the ones setting the standard for everyone else within the next 24 months.*

Where AI Is Delivering – And Where It Isn't

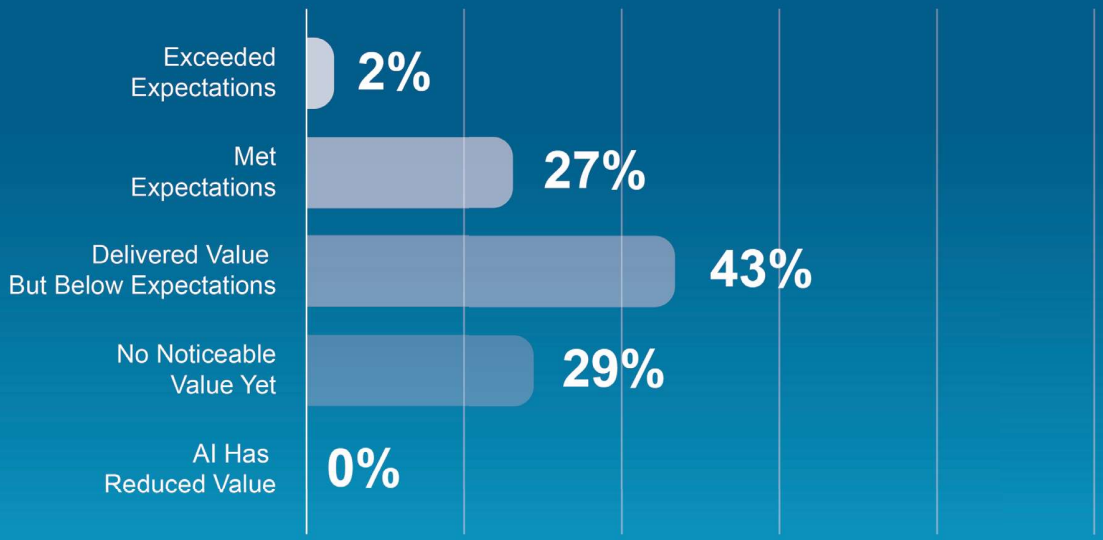
Measuring AI's impact in clinical trials is harder than measuring it in, say, customer service or supply chains. Trials are long, outcomes are multifactorial, and the most meaningful metrics — site activation speed, reduction in protocol deviations, cost savings/avoidance — often reflect dozens of variables beyond AI. With that caveat firmly in mind, this year's data offers the clearest picture yet of where AI is genuinely moving the needle.

The Value Signal Is Real But Selective

Overall, **72% of respondents report that AI has delivered at least some value. However, only 29% say that value has met or exceeded their expectations.** This gap reflects both the ambition of early AI roadmaps and the time required for complex, multi-system AI deployments to mature.

FIGURE 4

Overall AI Value Realization vs. Expectations (n=200)



Q: To date, how would you describe the overall value (defined as ROI through timeline reduction, efficiency gains, and/or cost impact) created by AI in your clinical trial operations?

Source: Medidata / Everest Group 2026 Survey

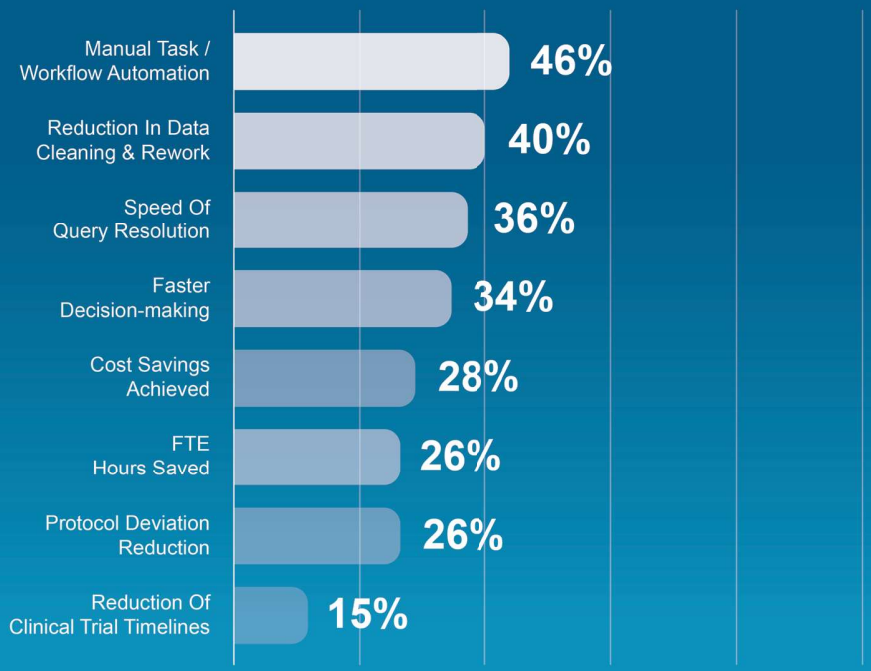
Where AI Wins: Automation and Data-Heavy Workflows

The most consistent above-expectation results are concentrated in high-frequency, rules-based workflows, precisely the category where AI is most mature and where the input-output relationship is clearest.

These results echo a consistent theme from both years of the survey: Data cleaning, query resolution, and workflow automation are natural early wins as they are measurable, defensible to stakeholders, and capable of being deployed incrementally without disrupting ongoing trials.

FIGURE 5

Workflows Where AI Exceeded Expectations (% 'Above Expectations', n=200)



Q: For each KPI, rate the amount of improvement your organization has seen after adopting AI.
Source: Medidata / Everest Group 2026 Survey

Where AI Struggles: Timeline and Quality Outcomes

The harder operational outcomes remain out of reach for most. Nearly half of respondents report no improvement in protocol deviation rates or overall trial timeline reduction, two key metrics that influence the success of a study. This is not a technology failure; it is a reflection of how much more than AI is required to move these metrics. Protocol deviations are driven by site training, patient behavior, and protocol complexity.

Trial timelines are driven by regulatory processes, site selection, patient recruitment, and supply chain logistics. AI can influence all of these, but only within a fully integrated, data-ready operational environment that most organizations have not yet built.

The Early Adopter Advantage

The most important forward-looking signal in this year's data is the performance gap between organizations that have been using AI in clinical trial operations for more than 18 months and everyone else. With n=37 early adopters in this survey, the sample is small but directionally striking: across every KPI measured, early adopters report materially stronger above-expectation results, and the gap is largest precisely where the rest of the industry is struggling most.

TABLE 3

KPI Performance — Early Adopters vs. Broad Population (% 'Above Expectations')

KPI	Broad Population	Early Adopters (>18 mo.)	Δ
Manual Task / Workflow Automation	46.5%	62.2%	+15.7 pts
Speed of Query Resolution	36.5%	45.9%	+9.4 pts
Data Cleaning / Rework Reduction	40.5%	48.6%	+8.1 pts
Faster Decision-making	30%	37.8%	+7.8 pts
Protocol Deviation Reduction	26.5%	40.5%	+14 pts
Clinical Trial Timeline Reduction	15%	29.7%	+14.7 pts
FTE Hours Saved	26%	32.4%	+6.4 pts
Cost Savings Achieved	15.5%	27%	+11.5 pts

Early Adopters defined as >18 months of AI use in clinical operations (n=37).
Source: Medidata / Everest Group 2026 Survey.

The Compounding Advantage of Time

The data tells a consistent story: the gains that matter most do not arrive quickly. Early adopters are reporting above expectation performance at a higher frequency than the general population in the two metrics that have proven hardest to move: protocol deviation reduction and trial timeline reduction. These are not metrics that respond to a single AI deployment. They require AI to be embedded across multiple interconnected workflows like protocol design, site selection, data monitoring, and query management so improvements compound rather than cancel each other out.

The implication is that AI's value function in clinical trials is non-linear. Organizations that have completed a first full implementation cycle are beginning to experience the second-order effects: AI-trained data models that improve with accumulating data, established governance processes that accelerate new deployment approvals, and teams with the literacy and confidence to push AI into progressively more complex workflows. Each completed cycle shortens the next one. Organizations starting today will reach this compounding stage, but the longer they wait to start, the further behind they will be when they get there.

What Separates Early Adopters From The Rest

The survey data, combined with what we know about the organizational composition of early adopters, points to four distinguishing factors characterizing the organizations that have moved from AI experimentation to AI execution:

Integrated Data Foundations First

Early adopters invested in unified clinical data environments that are standardized, connected, and governed before deploying AI tools. AI is only as reliable as the data it runs on. Organizations that skipped this step are the ones reporting the model accuracy and fragmentation issues that now constrain their scaling.

Governance As An Enabler, Not Just A Constraint

Early adopters established AI usage guidelines, human-in-the-loop protocols, and validation frameworks early. These weren't viewed as compliance obligations, but as the mechanism that builds the internal trust required for clinical teams to actually use AI in their workflows. Governance is what converts a technically successful pilot into an operationally adopted tool.

Use Case Selection Discipline

The organizations reporting the strongest early results chose their initial AI use cases deliberately: high-volume, rules-governed workflows with clear success metrics and limited dependency on data that was not yet ready. Automation, query resolution, and data monitoring are not the most glamorous AI applications, but they are the ones that build organizational confidence and generate the operational returns needed to fund the next phase.

Organization-wide Literacy Investment

19% of all survey respondents report organization-wide or advanced AI maturity. Among early adopters, that proportion is materially higher. The organizations that scaled fastest are those that treated AI literacy as a shared organizational capability by training clinical operations, data management, regulatory, and IT teams in parallel rather than sequentially.

The Cost Of Waiting

Perhaps the starkest implication of the early adopter data is what it suggests about the organizations that have not yet crossed the implementation threshold. After just 18 months, a larger percentage of early adopters are reporting above expectation performance than the broader population on the hardest metrics (protocol deviations and trial timelines).

As early adopters continue to compound their advantage, and as the gap between their trial execution performance and the industry average widens, the cost of delayed AI adoption will begin to show up not just in efficiency metrics but in competitive positioning: faster portfolio progression, lower development costs, and stronger regulatory relationships built on a track record of data quality and trial reliability.

The organizations currently in the active pilot phase have a narrow window to close this gap before it becomes structural. **92% expect to increase AI spend in the next 12–24 months.** The question is whether that spend will be directed at adding AI tools or at building the organizational and data infrastructure that makes AI tools work. The early adopter data suggests the answer matters enormously.

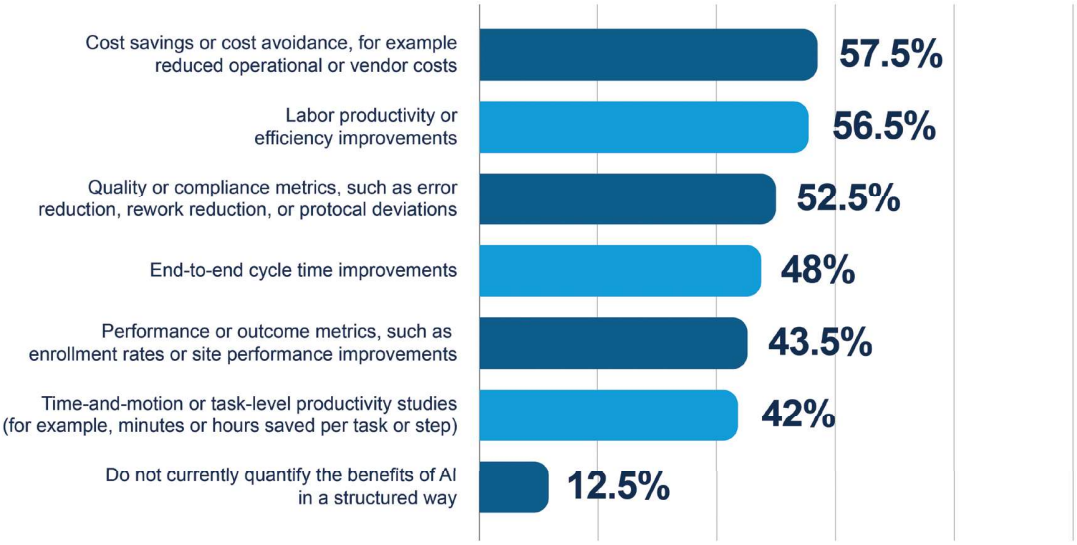
ROI Expectations and Timelines

The survey asked organizations to quantify their AI ROI expectations. 82% are expecting 2x or 3x returns, a sign of strong belief in AI's value potential. The timeline expectations are realistic rather than aspirational: 63% expect payback within 13–24 months, and only 13.5% expect ROI within 12 months.

This measured outlook is healthy, suggesting organizations are beginning to treat AI as a multi-year strategic investment rather than a quick win.

FIGURE 6

Respondents By AI Benefits In Clinical Trials (%) (n=200)



Q: How does your organization currently measure or quantify the benefits of AI in Clinical Trials operations?
Source: Medidata / Everest Group 2026 Survey

How an organization measures AI's value is a reliable indicator of how deeply AI is incorporated into its operations. The survey shows that cost savings (57.5%) and labor productivity (56.5%) are the most widely used measurement frameworks.

These metrics are natural starting points: they are well-understood, straightforward to attribute to a specific tool or workflow, and familiar to the finance and leadership stakeholders who approve AI budgets. They are also the metrics most accessible when AI is deployed in discrete, bounded tasks such as query automation or data cleaning, where the before-and-after comparison is relatively clean.

As AI becomes more deeply woven into trial execution, measurement naturally evolves toward harder, more systemic outcomes.

52.5% of organizations are already tracking quality and compliance metrics such as error reduction and protocol adherence, and 48% are measuring end-to-end cycle time improvements. These are the metrics that reflect AI operating not as a point solution within a single workflow, but as a connected capability across multiple stages of the trial.

The fact that 12.5% of respondents have no structured measurement approach at all is consistent with the broader adoption picture: for organizations still in early pilots, the priority is proving that AI works before building the measurement infrastructure to quantify by how much. The measurement hierarchy, in other words, is not a gap to be criticized but a roadmap. As adoption deepens, measurement will follow.

AI Across The Clinical Trial Lifecycle: What's Possible Today

AI is no longer confined to a single stage of the clinical trial process. As the survey data shows, use cases now span the entire lifecycle — from the earliest decisions about study design to the final steps of regulatory submission. The maturity, however, varies significantly by stage.

What follows is a stage-by-stage review of what AI can do today, grounded in both survey data and current evidence from the field.

Stage 1: Study Design & Planning

Study design sits at the intersection of scientific strategy and operational reality. It is one of the areas where AI is generating significant early momentum. The survey shows that protocol design and optimization, enrollment forecasting, budget forecasting, and feasibility assessment are all active AI deployment areas, with roughly 54-60% of respondents in active pilot or implementation phases for these use cases.

Protocol Design and Optimization

Poorly designed protocols are one of the most common, but preventable, sources of trial failure. AI is being used to reduce this risk in several ways: by analyzing historical protocol performance data to flag design elements associated with high amendment rates; by using natural language processing to compare draft protocols against regulatory guidance and approved labeling; and by modeling patient eligibility criteria against real-world data to predict enrollment feasibility before a single site is activated.

Survey data from both 2025 and 2026 consistently identifies protocol design and optimization as a top-five area of AI deployment. In 2025, 80% of AI users reported using AI in this way. **In 2026, approximately 90% of respondents are using or plan to use AI in protocol design and optimization activities *(Fig7)*.**

Study Feasibility and Site Selection

Selecting the right sites for the right trials is among the most consequential and data-intensive decisions a clinical operations team makes. AI platforms can now analyze millions of data points across historical site performance, patient population characteristics, competitive trial landscape, and regulatory environments. With this higher quality data it can generate ranked site recommendations with quantified confidence intervals.

The result is a shift from relationship-based site selection (relying on the experiences of investigator/key opinion leaders and institutional reputation) to evidence-based selection (grounded in granular, current performance data). **Survey data *(Fig7)* suggests approximately 54% of organizations are in active pilots or implementation for AI-assisted feasibility and site selection.**

Digital Twins and Simulation

Among the most forward-looking applications in study design are digital twins. Digital twins are computational models of disease progression, treatment response, and trial behavior that can be used to simulate study outcomes before execution begins. These models, which integrate real-world data, omics data, and historical trial data, allow sponsors to stress-test protocols, optimize design parameters, and identify high-risk scenarios without conducting costly real-world experiments. Current deployment is limited but growing: **approximately 22.5% of respondents *(Fig7)* use digital twins to model patient, site, and trial-level dynamics.**

Stage 2: Study Build & Startup

Study build and startup is where many trials lose weeks and months before a single patient is enrolled. Industry benchmarks place average study build timelines at approximately 73 days (Tufts CSDD, 2019). Site activation timelines, from contract to first patient visit, often extend 6–9 months or longer. AI is beginning to compress both.

EDC Configuration and Study Build

Configuring an electronic data capture system for a complex Phase II or III trial is a technically demanding, error-prone process. AI-assisted study build tools use natural language processing to interpret protocol requirements and translate them into system configurations, reducing the manual effort involved and the errors that typically require rework. Automated validation checks can run continuously during build, catching issues that would previously surface weeks later during user acceptance testing. **Survey data *(Fig7)* shows approximately 79% of respondents are using or planning to use AI to assist EDC configuration and study build.**

Country and Site Activation

Country and site activation — managing the cascade of regulatory submissions, contracts, and approvals required to activate a site — is one of the most administratively burdensome phases of any trial. AI is being applied to contract review and redlining (flagging non-standard clauses and suggesting alternatives), regulatory submission tracking, and site readiness scoring. AI implementation in this area has held steady with 41% using AI in 2025 and 41.5% in 2026. However, an additional 31% are planning to use AI for country and site activation indicating an appetite to expand AI's use in this area *(Fig7)*.

Enrollment Forecasting and Patient Identification

Getting enrollment forecasting right at startup can be the difference between a trial that completes on schedule and one that extends by 12–18 months. AI models trained on historical enrollment data, site performance benchmarks, and real-world patient population data can generate probabilistic enrollment projections that allow teams to make resource and timeline decisions with more precision than traditional spreadsheet-based forecasting allows.

Patient identification tools, including models that analyze electronic health records to identify potentially eligible patients, are also maturing rapidly. Meaningful productivity gains in this area are particularly impactful as site staff time is a critical constraint.

Stage 3: Study Execution & Monitoring

Study execution, the longest phase of any trial, is where AI has both its deepest roots and its most significant unresolved challenges. Data-centric execution workflows (data capture/integration, quality oversight, anomaly detection, query resolution) are the furthest along in adoption: roughly 52%–69.5% *(Fig7)* of respondents are in active implementation or pilot for these use cases, making them the most mature category in the survey.

Data Capture, Integration, and Quality Oversight

Modern clinical trials generate data at a scale that is simply unmanageable through traditional manual review. AI-powered data quality tools continuously monitor incoming data for anomalies, missing values, protocol deviations, and cross-form inconsistencies to enable near-real-time identification of issues that would previously surface only during periodic data reviews. Year over year, these data-centric workflows are the most active category of use cases for AI.

Risk-Based Monitoring and Safety Surveillance

Remote and risk-based quality monitoring (RBQM), accelerated by the pandemic and codified in regulatory guidance, is a natural home for AI. Machine learning models can score sites by risk level, directing limited monitoring resources toward the sites and data domains that most need attention. Concurrently, AI is being used for continuous safety signal detection: monitoring adverse event data as it accumulates to identify emerging safety patterns earlier than periodic manual safety reviews would allow. **At present 50% of respondents are leveraging AI in RBQM processes *(Fig7)*.**

Query Resolution and Data Cleaning

Query resolution, the back-and-forth between data management and sites to resolve data discrepancies, is one of the most labor-intensive activities in clinical data management. AI is reducing this burden in two ways: by generating automated, context-aware queries that require less site clarification, and by pre-populating query responses based on patterns in resolved query history. **The 2026 survey *(Table3)* shows query resolution as one of the top three metrics where AI is exceeding expectations (36.5% above expectations).**

Patient Engagement and Retention

Patient dropout is one of the most costly execution-phase risks in clinical research. AI-powered engagement tools, including predictive models that identify patients at high risk of dropout, intelligent reminder systems, and AI-assisted eCOA tools, are beginning to be explored to address this. Adoption is still relatively early: patient-facing workflows like consenting (35% not planning or unable to use AI) and eCOA deployment (24%) lag behind data management workflows in adoption maturity *(Fig7)*.

Stage 4: Submission & Closeout

Regulatory submission and study closeout represent the final, high-stakes phase of the clinical trial lifecycle and a growing area of AI investment. The combination of data volume, regulatory precision requirements, and time pressure makes submission one of the highest-value targets for AI-assisted productivity.

Data Integration and CDISC Standardization

Converting trial datasets to CDISC SDTM and ADaM formats required for regulatory submission has traditionally been a manual, time-consuming process, particularly for complex trials with diverse data sources.

AI-powered CDISC mapping tools can automate a significant portion of this work, using natural language understanding to map source data variables to CDISC standards and flagging exceptions for human review. This reduces both the time and cost of the standardization process while improving consistency. **With 69.5% of respondents using AI for data integration/ standardization, it represents the most common use of AI in the industry today *(Fig7)*.**

Database Lock and Regulatory Package Preparation

Reducing time-to-database-lock is a critical efficiency goal for most data management teams. AI-driven data reconciliation tools can significantly accelerate the final data review cycle by automating cross-dataset consistency checks and identifying outstanding queries at scale.

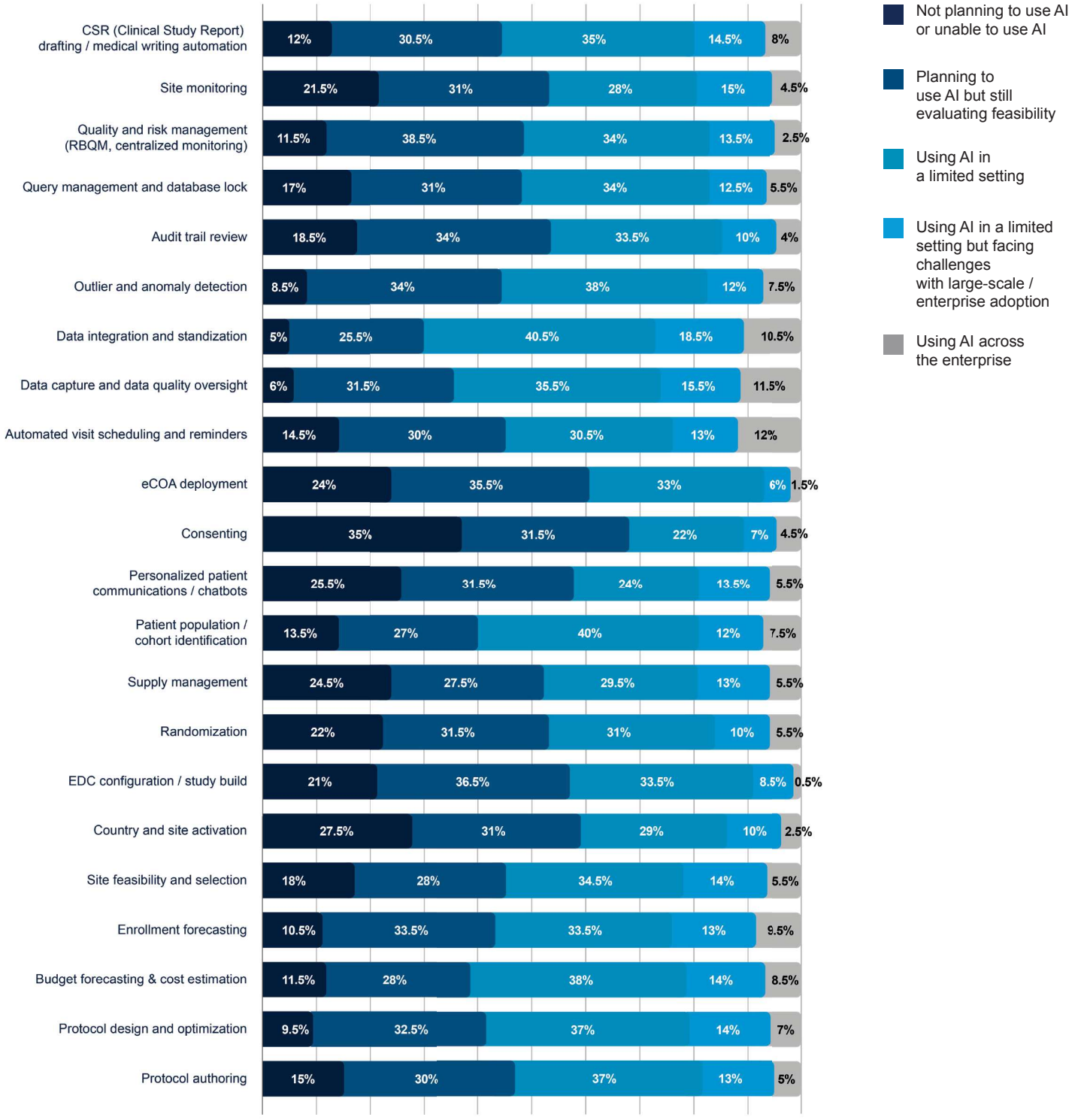
52% of respondents are leveraging AI for query management and database lock. In preparation of the regulatory submission package itself, AI tools are being used to assist with clinical study report drafting (57.5%) *(Fig7)*, automated table and listing generation, and cross-document consistency review.

Regulatory Intelligence

Regulatory intelligence — understanding evolving FDA, EMA, and other agency guidance in real time — is an emerging AI use case with significant implications for submission strategy. Natural language processing tools can continuously monitor agency guidance documents, advisory committee proceedings, and approval decisions, surfacing relevant regulatory intelligence to clinical and regulatory teams.

FIGURE 7

Respondents By Current Stage Of AI Adoption (%) (n=200)



Q: For each clinical trial operations workflow listed below, please indicate your organization's current stage of AI use.
Source: Medidata / Everest Group 2026 Survey.

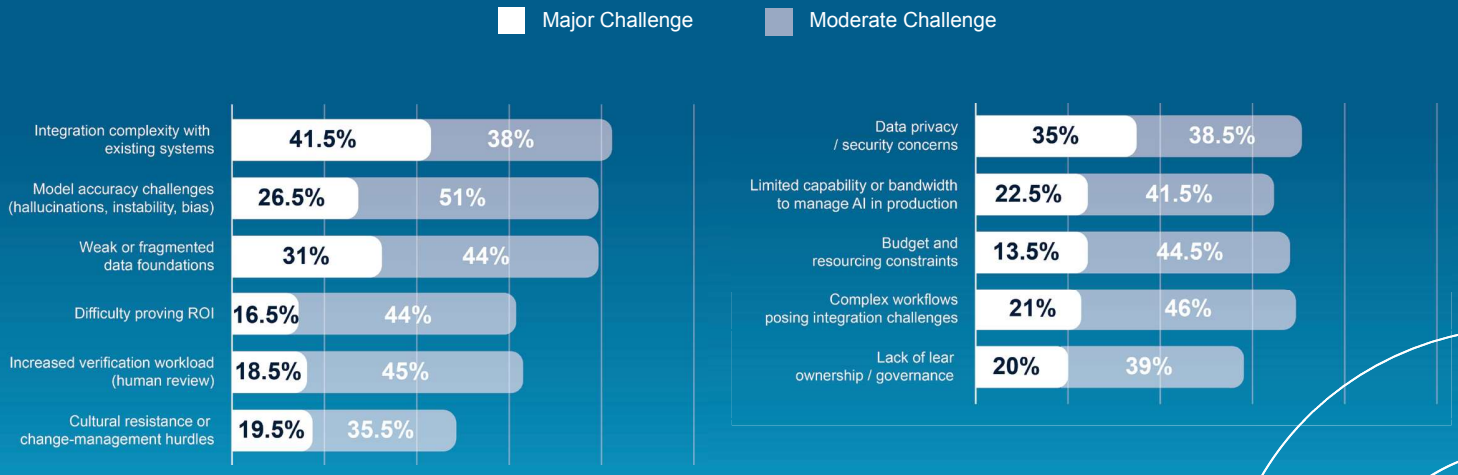
Scaling AI: What's Holding The Industry Back

The survey asked respondents to identify the greatest challenges they face in scaling AI across their organizations.

The results paint a coherent picture of an industry not struggling with AI technology per se, but with the organizational and technical infrastructure required to deploy it reliably at scale.

FIGURE 8

Barriers to Scaling AI in Clinical Trial Operations (% Major/Moderate Challenge, n=200)



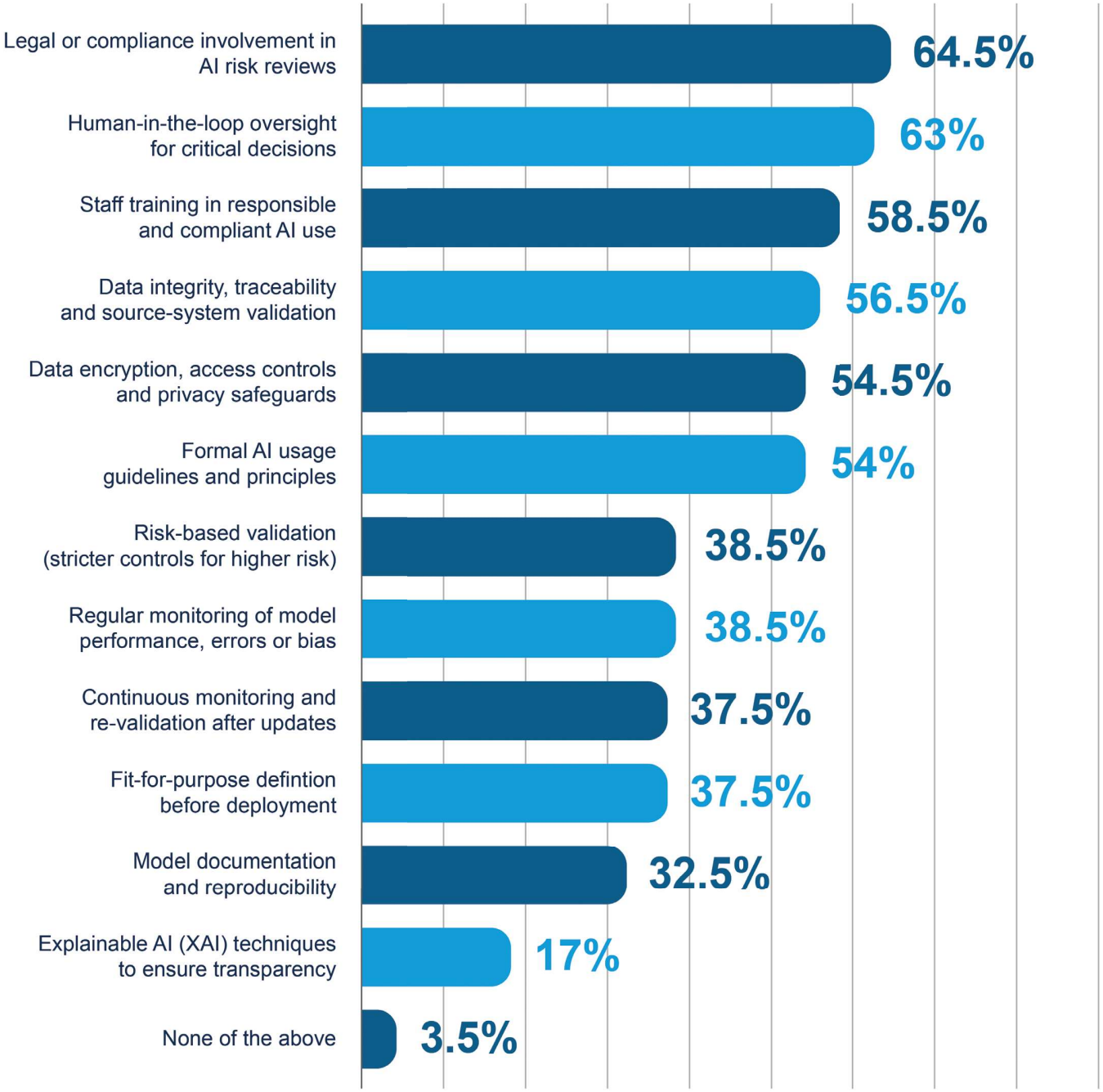
Q: How significant are the following challenges when attempting to scale AI beyond pilots?
Source: Medidata / Everest Group 2026 Survey

The top three barriers — integration complexity (79.5%), model accuracy (77.5%), and fragmented data foundations (75%) — form a self-reinforcing constraint. AI models require clean, consistent, well-integrated data to perform accurately. Fragmented data foundations produce unreliable model outputs. Unreliable outputs increase the verification workload, consuming the efficiency gains AI was supposed to generate. Breaking this cycle requires investment not just in AI tools, but in the underlying data infrastructure that makes AI trustworthy.

The emphasis on human-in-the-loop oversight (63% cite it as a governance requirement) and legal/compliance risk reviews (64.5%) reflects the industry's thoughtful approach to AI governance, and its awareness that in a regulated environment, auditability and explainability are not optional features. Data governance controls currently in place include data integrity/traceability (56.5%), formal AI usage guidelines (54%), and data encryption and access controls (54.5%). Model lifecycle governance — including risk-based validation (38.5%), regular monitoring of model performance (38.5%), and explainability (17%) — is notably less mature, suggesting an area where the industry will need to invest over the next 1–2 years *(Fig9)*.

FIGURE 9

Respondents by Governance Measures for AI in Clinical Trials (%); (n=200)



Q: What governance measures does your organization currently have in place for the use of AI in clinical trial operations?
Source: Medidata / Everest Group 2026 Survey

Where The Industry Is Headed: Five Predictions For 2026 – 2030

The trajectory of AI adoption in clinical trials is now clear enough to make confident predictions about where the industry is headed. Based on the survey data, the early adopter signals, and the broader technology adoption curve, we offer five predictions for the next two to five years.

Prediction 1: The Early Majority Will Close The Gap, Quickly

The largest concentration of organizations in this year's survey sits in the active pilot phase — the 40% who are evaluating and experimenting with AI across a handful of use cases. Within 18–24 months, the most motivated of these organizations will have completed their first full implementation cycle and begin to replicate early adopter results. Expect the proportion of organizations in active implementation to double by 2028, driven by the combination of rising budgets (92% plan to increase spend), maturing vendor capabilities, and competitive pressure from peers who have already made the journey.

Implication:

The window for organizations to establish a first-mover advantage is narrowing. Those still in exploration in 2027 will face a significantly more crowded and competitive implementation landscape.

Prediction 2: Data Infrastructure Will Emerge As The Decisive Competitive Variable

The survey is unambiguous: fragmented, inconsistent data foundations are one of the root causes of most AI scaling failures. The organizations that will extract the most value from AI over the next five years are not necessarily the ones with the most sophisticated AI models, they're the ones with the cleanest, most integrated, most comprehensive data estates. Investment in unified clinical data platforms, real-world data integration, and CDISC-ready data architectures will increasingly be understood not as infrastructure spending but as AI enablement spending.

Implication:

Competitive advantage in clinical AI will increasingly correlate with historical investment in data quality and integration, not with the most recent AI tool acquisition.

Prediction 3: Protocol Design And Optimization Will Become AI's Breakout Use Case

Protocol design was identified in both years of the survey as a high-value, high-interest use case, but one where AI has not yet fully delivered on its potential. That is about to change. The combination of increasingly capable language models, growing training datasets of protocol performance history, and regulatory agency engagement with AI-assisted development tools will make AI-assisted protocol design one of the most impactful clinical AI applications by 2027–2028. Earlier, better-designed protocols will reduce amendment rates, improve enrollment efficiency, and ultimately compress total development timelines in ways that cascade across the entire trial.

Implication:

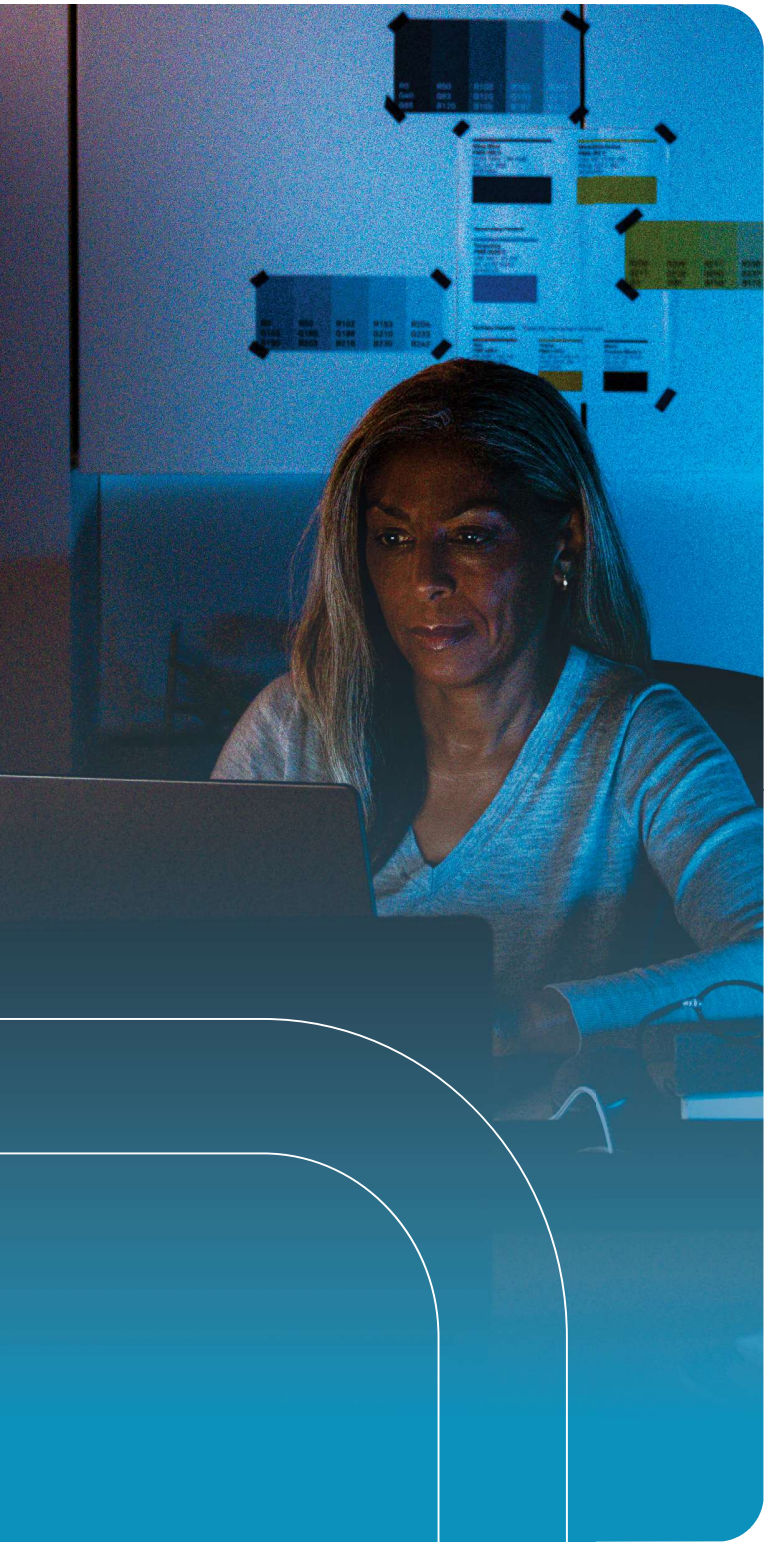
Organizations that invest now in the data infrastructure to support AI-assisted protocol design — specifically, structured repositories of protocol performance data and amendment histories — will be positioned to realize stronger returns when AI design tools mature.

Prediction 4: Agentic AI Will Move From Buzzword To Operational Reality, In Narrow Domains First

90% of survey respondents are aware of agentic AI; only 10.5% have hands-on experience with it. Over the next two to three years, this will change, but not in the way that the most bullish predictions suggest. Agentic AI (AI systems that autonomously plan and execute multi-step tasks) will not replace clinical operations teams, but will begin to autonomously handle well-defined, rules-governed sub-workflows: query generation and resolution cycles, regulatory submission tracking, automated visit scheduling, and risk-score-triggered monitoring actions. The 23.5% of respondents who expect AI to have autonomous capabilities for selected workflows within the next 2-3 years are pointing at exactly this trajectory.

Implication:

Organizations should begin designing their clinical operations workflows now with agentic AI in mind — identifying the bounded, rule-rich workflows where autonomous AI action can be deployed safely and where human oversight can be structured rather than eliminated.



Prediction 5: Governance Will Become A Source Of Competitive Advantage, Not Just Compliance

Today, AI governance in clinical research is primarily defensive — focused on managing risk, ensuring regulatory compliance, and protecting against liability. Over the next 2–5 years, governance maturity will begin to function as a competitive differentiator. Organizations with robust AI governance frameworks (validated model performance monitoring, explainability documentation, and clear audit trails) will be better positioned to engage with regulatory agencies on AI-assisted submissions, attract institutional investor confidence, and accelerate the pace at which new AI capabilities can be deployed. The ROI expectation of 2–3x held by 82% of respondents will prove accurate only for organizations that can move from experimentation to trusted deployment. Governance is the mechanism that makes that trust possible.

Implication:

Treat AI governance investment not as overhead, but as the infrastructure that enables AI's strategic value to be fully realized and sustained.

Conclusion

Two years into this annual survey series, the broad arc of AI adoption in clinical trials is becoming clear. AI is no longer a curiosity or a peripheral experiment. It is becoming the infrastructure and operational foundation on which the clinical trials of the next decade will be built.

The journey from curiosity to infrastructure is not a linear one. It runs through the hard, unglamorous work of data architecture and governance; through the organizational change required to build AI literacy across functions, not just within them; through the patient accumulation of evidence that turns promising pilots into trusted, validated workflows. This year's survey shows an industry that is fully engaged in that work, and while not yet at the finish line, is running hard toward it.

The early adopter data is the most important signal in this year's report. The organizations that crossed the adoption threshold earliest are now reporting outsized results not only in efficiency, but in the harder clinical outcomes that ultimately matter to patients and regulators. That divergence will deepen over the next 2–3 years. The companies that invest now in data infrastructure, governance frameworks, and AI literacy across their organizations will be positioned to lead. Those that wait for the technology to mature further before committing to programmatic investment risk falling behind in ways that compound over time.

At every stage of the clinical trial lifecycle, from the first sketch of a protocol to the final regulatory submission, AI is creating new possibilities for speed, quality, and insight. The question for every organization in this industry is not whether to harness those possibilities, but how quickly, how carefully, and how strategically it chooses to do so.

> *The patients waiting for new therapies cannot afford for this industry to be cautious about AI's potential. They can afford for the industry to be thoughtful, rigorous, and deliberate about how that potential is realized. Those are not the same thing.*

About This Report

The State of AI in Clinical Trials is Medidata's annual industry survey series, tracking AI adoption, impact, and expectations across the clinical trial lifecycle. This second edition is based on a survey of 200 senior clinical operations leaders conducted by Everest Group in early 2026. The first edition was based on a survey of clinical operations professionals conducted by ISR Market Research in 2025. All data referenced as 'survey findings' or 'this year's survey' refers to the 2026 Everest Group survey unless otherwise indicated.