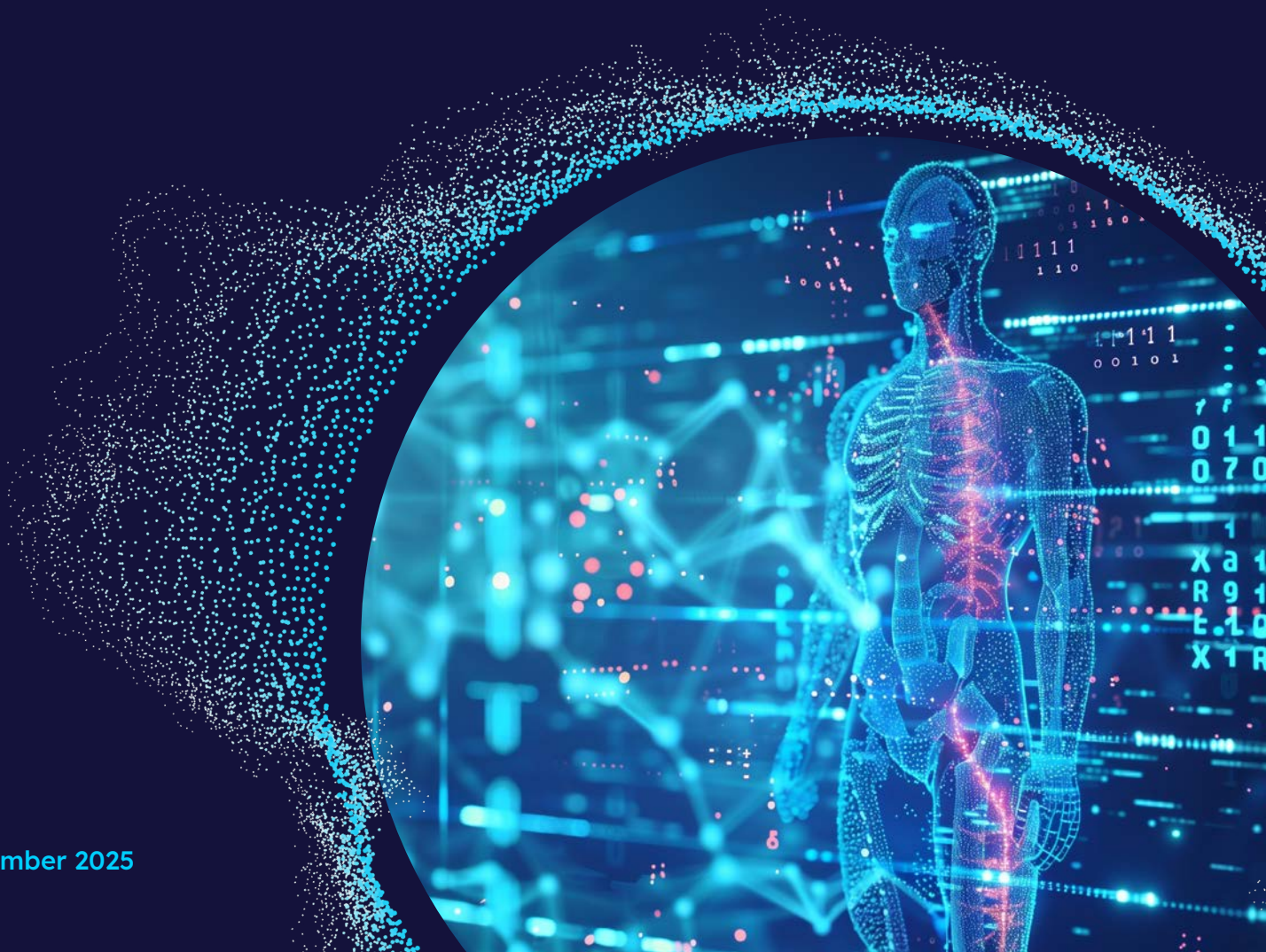


Strategic Playbook

The New Standard:

How AI Is Reshaping Trial Design, Execution, and Disclosure



September 2025

Executive summary

AI is no longer experimental in clinical trials; it's already transforming the way work is performed. But the change hasn't come from moonshot technologies or radical automation. Instead, AI has quietly embedded itself into the operational heart of clinical development where it is accelerating decisions, reducing manual burden, and improving outcomes.

This strategic playbook explores how artificial intelligence is reshaping clinical workflows — not just in trial design or regulatory compliance, but across the full trial lifecycle. It offers a blueprint for how leading teams are adopting AI in practical, measurable ways, from protocol feasibility and cohort modeling to clinical trial disclosure and transparency.

Featuring real-world examples from Citeline's **SmartSolutions** suite and **TrialScope Disclose**, this playbook highlights what the new AI-enabled standard looks like and how clinical teams can start benefiting from it today.



A quiet revolution

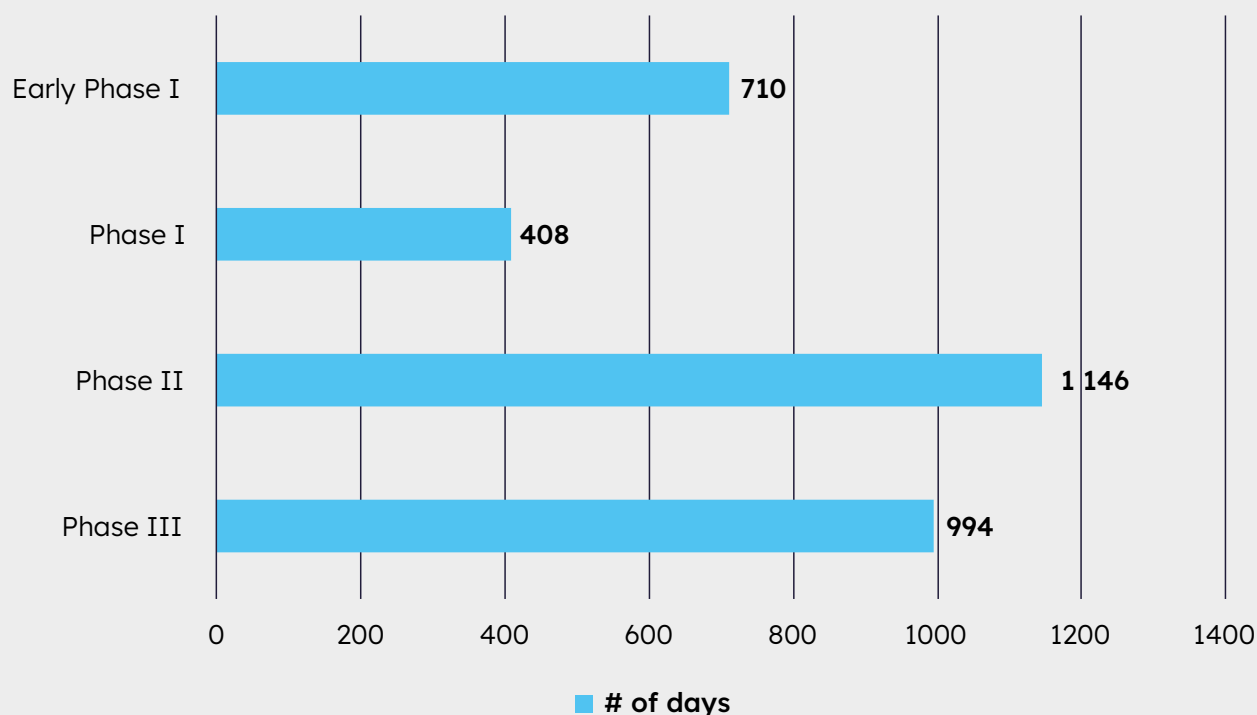
For years, AI has been positioned as a promise — a future breakthrough that might eventually change clinical research. But the revolution is already under way, and it's far more practical than many expected.

AI is not replacing clinicians, scientists, or regulatory teams. It's augmenting them: automating what's manual, streamlining what's complex, and surfacing insights where there used to be noise.

In today's environment, trial teams face growing pressure to:

- **Shorten timelines without increasing risk**

According to ClinicalTrials.gov, the median length of completed clinical trials by phase in 2024 was as follows:¹



Source: Our World in Data (using ClinicalTrials.gov data)

This adds up to nearly nine years for the active clinical trial process. Adding preclinical activities and the time it takes to secure approval, sponsors are looking at over a decade to bring one drug to market.

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- **Design more inclusive and realistic protocols**

As protocols become more complex, the average number of protocol amendments has soared. According to results of a 2022 study by the Tufts Center for the Study of Drug Development (Tufts CSDD), 76% of protocols in Phases I-IV require at least one amendment, up from 57% in 2015. The mean number of amendments increased 60% to 3.3 per protocol, up from 2.1 per protocol.²

- **Improve enrollment performance and trial diversity**

Patient enrollment remains a thorny problem for clinical trials, with an estimated 37% of sites under-enrolling patients and 11% of sites failing to enroll a single participant.³ And once patients are enrolled, it can be a challenge to keep them, with patient dropout rates ranging from 10% to 30% across clinical trials depending on disease type and trial complexity.⁴

- **Deliver regulatory reporting with greater speed and transparency**

According to a 2024 survey of biopharma executives, complicated regulatory requirements are one of the top challenges increasing clinical trial complexity and one of the factors driving the rise in clinical trial costs.⁵



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On a daily basis, AI in tools and workflows is already helping meet those demands across protocol planning, patient feasibility, site selection, and compliance.

For example, AI can be used during the clinical trial design process to simulate data that can predict participant outcomes. One report notes that machine learning (ML) prediction models allowed reduction of cancer mortality by 15% to 25% across several clinical trials.⁶

In a 2019 study, the Cincinnati Children's Hospital Medical Center found that employing its Automated Clinical Trial Eligibility Screener (ACTES), a real-time natural language processing (NLP) and ML-based system, cut patient screening time by 34%. The time saved was applied by the clinical research coordinators (CRCs) to activities like study-related administrative tasks and related conversations that streamlined teamwork. ACTES also improved the numbers of patients screened by 14.7%, the number of patients approached by 11.1%, and the number of participants enrolled by 11.1%.⁷

AI can be integrated in the site selection process to predict site enrollment rates and forecast site performance, as well as plan for any contingencies that could arise during the trial.⁸ And it can streamline regulatory compliance by automating documentation, assessing risk, and monitoring processes to ensure compliance.⁹

From these examples, it's clear the question is no longer "Will AI change clinical trials?" but "Are your teams already working differently because of it?"



Where AI delivers real operational value

Today's most effective clinical teams aren't chasing innovation for its own sake. They're using AI to solve real bottlenecks that have held trials back for years.

Here are areas where AI is already delivering impact:

PROTOCOL FEASIBILITY

The challenge:

When study teams create protocols, assumptions are often made about the patient population that don't always fit with actual patient demographics, particularly when it comes to underserved groups. This can lead to amendments, delays, and recruitment failures.

AI's role:

- Automatically generate inclusion/exclusion (I/E) criteria based on past trials and validate against real-world data (RWD)
- Spot risks and false assumptions before the protocol is finalized

DECISION SUPPORT

The challenge:

Cross-functional teams can spend hours searching siloed systems for answers to their clinical planning questions.

AI's role:

- Surface structured responses from complex datasets instantly through conversational interfaces, improving speed and confidence in planning

SITE AND INVESTIGATOR SELECTION

The challenge:

It can take weeks to build a list of potential sites for a clinical trial — and that list often doesn't take into account any potential misalignments or shortages in patient recruitment pools.

AI's role:

- Match trial needs to investigators with relevant experience, based on historical trial performance and patient access data

REGULATORY DISCLOSURE

The challenge:

Disclosure teams often must manually extract and structure data from unstandardized trial documents — a process that can take days or even weeks.

AI's role:

- Automatically ingest, extract, and classify key fields from protocols, statistical analysis plans (SAPs), and other documentation for trial registration and results reporting

These aren't hypotheticals. These are working, proven use cases already being implemented across sponsors, contract research organizations (CROs), and regulatory teams.

A modern, AI-enabled clinical workflow

AI isn't a standalone tool — it's a capability built into the infrastructure clinical teams already use. Let's explore how Citeline's solutions help put this theoretical AI-powered workflow into practice.

SMARTER PROTOCOL DESIGN AND FEASIBILITY

Tools: Protocol SmartDesign + Cohort SmartBuilder

It can take weeks to develop a clinical trial protocol. **Protocol SmartDesign**, part of Citeline's **SmartSolutions** suite, shrinks that time frame by using AI to instantly generate primary endpoints and I/E criteria based on real-world benchmarks. Its advanced AI models mine 60,000 data sources, including Citeline's gold-standard **Sitetrove** and **Trialtrove** data, to produce endpoints and I/E criteria specific to your trial.

The next step is to determine the protocol's feasibility, which is where **Cohort SmartBuilder** comes into play. Cohort SmartBuilder provides more intelligent design through real-world cohort validation. It translates I/E criteria into protocol-specific patient counts using open claims and EMR data powered by NorstellLinQ RWD assets, allowing the visualization of demographic and geographic cohort impact in real time.

Cohort SmartBuilder seamlessly integrates with Protocol SmartDesign to form a dynamic duo that provides more realistic protocols, fewer amendments, and higher enrollment confidence.

OPTIMIZED SITE AND INVESTIGATOR MATCHING

Tool: Investigator SmartSelect

Through the power of AI, **Investigator SmartSelect** slashes the timeline for clinical trial investigator selection from weeks to minutes. Investigator SmartSelect, part of Citeline's SmartSolutions suite, leverages AI-enabled technology built on Citeline's industry-leading Sitetrove data to identify high-performing sites and investigators based on therapeutic area, geography, and trial success rate. The solution employs a proprietary algorithm to sift through more than 530,000 investigators from over 190,000 global sites alongside proprietary performance data to generate a list of investigators matching your trial's specifications.

Investigator SmartSelect offers better-aligned site selection, quicker start-up, less risk, and enables the coordination of recruitment strategies with real patient availability.

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FASTER CROSS-TEAM ANSWERS

Tool: Ella, AI assistant

Getting answers to clinical trial planning questions can require hours of digging through multiple systems and their data. With **Ella**, Citeline's AI chat assistant included in its SmartSolutions, you get those answers instantly.

Ella's natural language interface allows teams to ask clinical, pipeline, or feasibility questions and receive structured, data-driven answers seconds after hitting the enter key — all in one place. This allows for quicker decisions, less friction among functions, and more time for strategy.

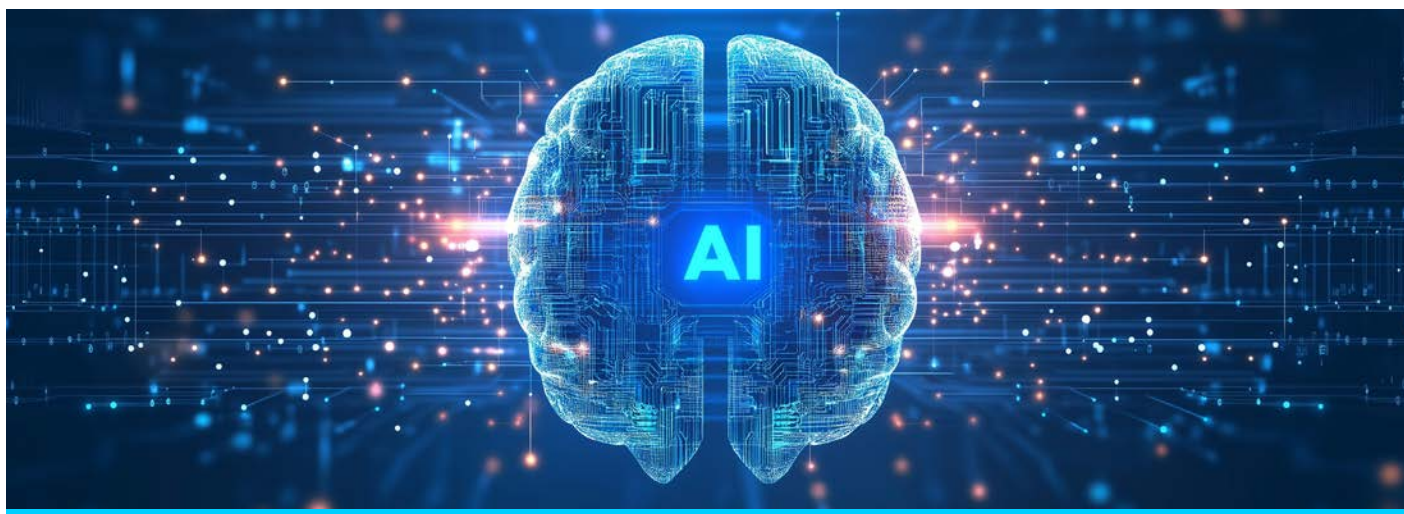
AUTOMATED TRIAL DISCLOSURE

Tools: TrialScope Disclose with AI Importer

TrialScope Disclose is the industry's most trusted end-to-end disclosure solution. And the addition of **AI Importer**, a unified global disclosure form, further optimizes the disclosure process.

AI Importer reads trial documents and extracts structured data for registries. It classifies and tags fields automatically for faster disclosure preparation, cutting the number of manual hours required to enter that information.

TrialScope Disclose with AI Importer streamlines review and lowers compliance risk, allowing you to monitor and benchmark compliance with confidence and control.



What an AI-ready clinical organization looks like

Adopting AI in clinical development doesn't require a digital overhaul. It demands smart adjustments to existing tools, workflows, and team mindsets.

Here is what distinguishes AI-ready teams:



Integrated tools

Planning, recruitment, and compliance systems that talk to one another



Auditability

Built-in transparency and traceability, especially in regulatory processes



No-code intelligence

AI that helps clinicians, feasibility leads, and regulatory staff without needing technical intervention



Cultural trust

An understanding of what AI does (and doesn't do) and support to use it well



Human oversight

Workflows designed for people and AI to work together, not apart

Conclusion

AI in clinical development has moved beyond the theoretical. It's working today, in unobtrusive but powerful ways.

From smarter protocol design and feasibility to faster disclosure and compliance, AI is streamlining processes, reducing risk, and accelerating timelines. The most forward-thinking teams aren't just experimenting with AI, they're using it to better operationalize.

With Citeline's **SmartSolutions** and **TrialScope Disclose**, AI is no longer a future concept — it's your everyday advantage.

[Book a call to speak to a Clinical Planning or Regulatory Disclosure expert.](#)

CLINICAL PLANNING

REGULATORY DISCLOSURE

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About Citeline

Citeline, a [Norstella](#) company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory related decisions and create real-world opportunities for growth.

Citeline's global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted health science partners, visit [Citeline](#) and follow on [LinkedIn](#) and [X](#).