

Accelerate Clinical Trial Timelines

Tap Into AI-Powered Intelligence for
Streamlined Trial Design and Operations

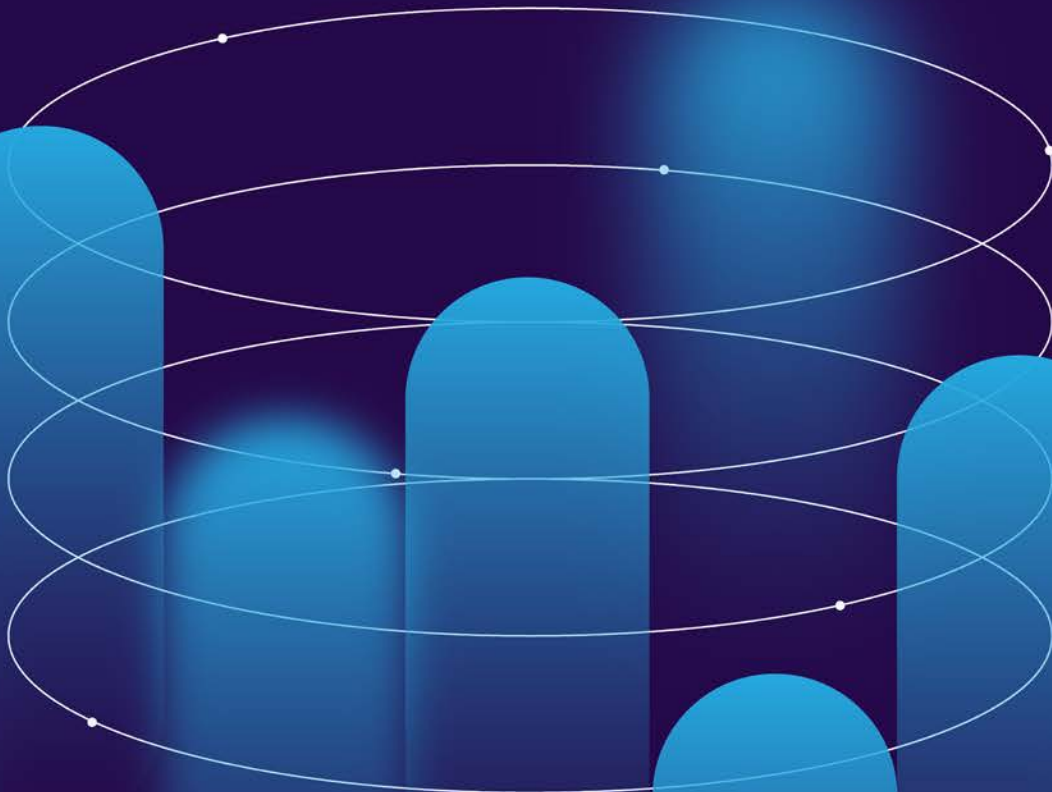


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Executive Summary

Clinical trials often take too long, cost too much and delay patient access to life-saving therapies.

Rising protocol complexity, fragmented systems and manual processes introduce avoidable risks and inefficiency across the clinical development lifecycle.¹ As the pharmaceutical industry grapples with the rising cost of innovation, a traditional sequential model — where protocol design, feasibility, site selection and recruitment planning occur in disconnected phases and potentially by separate teams — is no longer sustainable.

Accelerated Clinical Trials™ (ACT) is an enterprise AI platform that automates and optimizes the end-to-end clinical trial lifecycle across therapeutic areas to address these issues. By integrating real-world data (RWD), proprietary customer data and operational systems together with a robust agentic AI architecture and data capabilities, ACT transforms trial planning and execution from reactive to predictive.

Outcomes

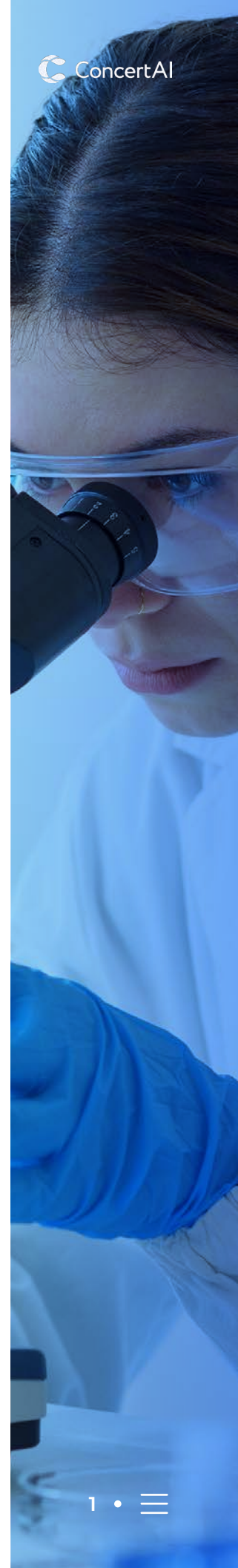
- Clinical timelines accelerated by 6–19 months.
- Portfolio-level efficiency gains of 6–9 months per study.
- Earlier commercial launches can generate tens of millions of dollars per month in potential revenue acceleration.

Primary audience

- Clinical Development Teams.
- Clinical Operations Teams.
- Trial Portfolio and Program Leaders.

Proof points

- Fewer protocol amendments.
- Higher-performing sites.
- Better-aligned eligibility criteria.
- Stronger enrollment forecasting.
- Predictive planning replaces reactive feasibility.



Artificial intelligence addresses systemic bottlenecks to deliver life-changing medicines faster. By shifting from reactive trial management to a predictive, data-driven framework, sponsors can significantly de-risk study designs, optimize site performance and ultimately accelerate the delivery of life-changing oncology therapies to patients.

This white paper explores how the integration of agentic AI and a variety of data sources and enterprise systems, including high-depth RWD, transforms operational bottlenecks into competitive advantages.

CHALLENGES IN TRADITIONAL CLINICAL TRIALS

The Inherent Barriers That Cause Delays

Despite significant investment in digital health and decentralized trial technologies in recent years, the core mechanics of clinical trial design and execution remain as heavily manual, siloed and organizationally disconnected as they have for decades.

The major challenges within Clinical Research and Trials cover four areas:

1. Study Design Challenges

Protocols rely heavily on historical assumptions and personal experience rather than RWD on patient populations and emerging trends in treatment and healthcare during their design and refinement.² When designers lack access to high-fidelity data, they often create overly restrictive eligibility criteria that exclude large portions of viable patients or are misaligned with where patient treatment will be during study execution. Consequently, protocol design cycles take months and frequently require costly amendments once the trial meets the reality of patient care and availability at participating sites.

Furthermore, standards of care evolve faster than traditional protocol development workflows, leaving many studies outdated before practitioners even screen the first patient.

2. Site Selection Challenges

Sites are selected based on previous relationships or sparse, incomplete or outdated historical performance data. This “usual suspect” approach ignores the fact that past enrollment success alone doesn’t reflect current staffing capacity or competitive trial load — or ability to successfully execute unique aspects of certain study designs.³ Underperforming or non-performing sites introduce delays and inflate per-patient costs, forcing sponsors into costly amendments or expansion of the number of participating sites to simply complete the trial, even with an extended timeline.

3. Recruitment Challenges

Recruitment difficulties arise from many places. Incidence and biomarker prevalence vary widely by geography and practice type; standard of care varies across geography and over time; and site resources, bandwidth and capabilities can change almost overnight. Without granular visibility into these variations, enrollment forecasts routinely overestimate available patient populations and the potential to enroll these patients into a clinical trial.⁴

On top of these difficulties, patient screening itself remains highly manual and resource-intensive. This places a heavy burden on site staff, leading to both high screen-fail rates and patients either going unidentified — or identified too late — despite being perfect candidates for a clinical trial.

4. Operational Inefficiencies

Disjointed, siloed or decentralized operational, data, vendor and related data systems make unified visibility across the trial lifecycle difficult, if not impossible. Manual processes dominate document generation and workflow monitoring, leading to human error and siloing of data both during a study and after. This hampers the ability to effectively manage an ongoing study and utilize study data for improved execution and insights for future studies. In addition to operational inefficiencies, protocol amendments introduce major timeline delays and budget overruns that could be avoided with better upfront modeling and integrated study risk management.

The Current Reality of Clinical Development and Execution

As the landscape of clinical research shifts toward precision medicine, which inherently increases the difficulty of finding the right patients at the right time, unprecedented complexity increases are occurring across therapeutic areas, particularly in oncology:

- Protocols are growing more stringent and restrictive.⁵
- Real-world practice evolves rapidly, with new therapies and approaches launching regularly.
- On average, the U.S. Food and Drug Administration approved approximately 47 to 50 new novel drugs per year between 2015 and 2024.⁶
- Traditional approaches fail to account for the pace of scientific advancement.

Manual review cycles, siloed operational systems and static spreadsheets continue to slow decision-making and increase risk. In a world where data is generated in real-time, relying on retrospective snapshots for design making and planning is a strategic liability.



47- 50

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A New Opportunity Emerges

AI, automation and near-real-time data now make it possible to fundamentally redesign trial planning and execution. Accelerated Clinical Trials™ (ACT) is ConcertAI's enterprise AI platform built to transform clinical development and operations across therapeutic areas — unifying data, intelligence and operational workflows within a single environment.

ACT enables this shift by combining:

- A robust, best-in-class agentic and generative AI architecture and platform (Cara™).
- AI-enabled data integration and alignment capabilities to integrate real-world, operational and proprietary data sets (in minutes vs. days/weeks).
- Flexible, end-to-end workflow automation and customization leveraging both ConcertAI and 3rd party agents, models and systems.

ACT is built on Cara, an engine with the depth and detail of ConcertAI's integrated oncology data. This enables users to get support from AI agents such as the Study Design Assistant, which helps optimize for key study design points aligned with identified evidence, critical criteria and more.

How ACT Transforms Trial Design and Execution Across Therapeutic Areas

The ACT platform serves as the central intelligence layer for clinical development, unifying data, AI and operational workflows within a single enterprise environment.

Precision Trials is a pre-configured, oncology-focused SaaS deployment of the ACT platform. Where ACT can be implemented and customized across therapeutic areas, broader enterprise workflows, and bi-directionally integrated into various trial and enterprise solutions, Precision Trials packages ACT's core capabilities into a ready-to-deploy SaaS solution purpose-built for oncology clinical trial optimization and site selection. Sponsors and CROs get the same AI-driven study design optimization, competitive landscape analysis, enrollment forecasting, and patient-to-trial matching that powers ACT - provided as a ready-to-use offering powered by ConcertAI's best-in-class oncology data, AI-powered agentic workflows, and comprehensive US-site details available immediately. This makes Precision Trials the fastest path to value for oncology teams who need to design and optimize a clinical trial and select the best sites for success within the US.



At its foundation, ACT integrates high-depth RWD, such as ConcertAI's Precision360® data, with client first-party clinical operations systems such as CTMS and eTMF platforms, as well as external scientific sources like PubMed and ClinicalTrials.gov. This unified data architecture eliminates silos between clinical, operational and regulatory functions, giving sponsors a comprehensive, portfolio-wide view of performance and risk.

Built on this integrated foundation, ACT embeds generative and agentic AI directly into the clinical development lifecycle. Study design, feasibility assessment, protocol drafting, compliance workflows and study monitoring are streamlined through intelligent automation, reducing manual handoffs and minimizing error. AI agents continuously monitor evolving standards of care, enrollment dynamics and operational signals, identifying emerging risks and triggering proactive interventions before delays compound.

ACT also strengthens site strategy and execution. By analyzing patient availability, site capacity, competitive trial activity and historical performance in real time, the platform supports more precise feasibility modeling and site selection. Ongoing monitoring of enrollment velocity and performance trends ensures that small, timely adjustments replace costly downstream corrections — keeping trials on track, within budget and aligned with portfolio objectives.

50% ↓ Using an AI-driven platform can reduce protocol amendments by up to 50%

25% ↓ Nonproductive sites are reduced by approximately 25%

10% ↓ Per-patient trial costs are reduced by more than 10%

QUANTIFYING THE IMPACT

Measurable Business and Patient-First Outcomes

The transition to an AI-powered platform is not merely a technical upgrade; it's a financial and ethical imperative.

Trial Phase	Traditional Approach	Act-Enabled Approach	Savings/Gains
Protocol Design	3–6 months	1–2 months	50%–70% reduction
Site Activation	6–9 months	4–6 months	2–3 months saved
Enrollment Duration	24–36 months	15–20 months	6–19 months saved
Protocol Amendments	2–3 per study	0–1 per study	50% reduction

The Financial Implications Explained

Earlier regulatory approval enables faster commercialization. For high-value therapies, the potential revenue acceleration can exceed \$30M per month. By reducing the time to market, biopharma companies can maximize the value of their patent life.⁷

Where Operational Improvements Are Best Evidenced

Using an AI-driven platform can reduce protocol amendments by up to 50%, saving millions in administrative costs and site re-training. Nonproductive sites are reduced by approximately 25%, allowing operations teams to focus their energy on high-performing locations. Per-patient trial costs are reduced by more than 10%, while study startup and activation timelines are shortened by 1–2 months.

The Impact for Patients

The most significant outcome is faster access to innovative therapies. AI-driven design also leads to improved representation and diversity by identifying underserved populations. Finally, there is a better alignment between clinical care and trial design, making it easier for patients to participate in research without disrupting their lives.

Use Case Highlights

ACT is purpose-built for oncology trials, but it also enables users to structure and compare “what-if” scenarios.

Below are some of the top use cases:

- ✓ **Digitizing criteria to define cohorts:**
Ensure specific criteria can automatically inform every scenario you create, accounting for oncology clinical trial nuances. Apply these criteria to patient pools to determine eligibility.
- ✓ **Get automated recommendations:**
Agents like the Study Design Assistant can run autonomously, providing recommendations to optimize scenarios based on RWD on standards of care, competitive trial design and more. Supporting evidence for these recommendations is always available in the Competitive Landscape tab.
- ✓ **Make informed decisions:**
View all your considerations in one place, including real-world standards of care and impact quantifications. Compare automated projected timelines to reach enrollment targets and get specific site insights including data on geography, diversity, site type and more.

Broader Implications for the Clinical Research Ecosystem

The shift toward AI-integrated clinical development creates a ripple effect across the entire healthcare landscape:



For Biopharma

Sponsors experience portfolio-wide efficiency gains and extended effective patent windows. By reducing the cost and time of failure, companies can improve capital allocation across their entire pipelines, funding more “successful shots on goal” for rare and neglected diseases.



For Clinical Teams and CROs

AI reduces the operational burden on clinical teams, moving them away from data entry and toward high-value strategic work. It facilitates improved collaboration across functions and provides more reliable enrollment forecasting, which builds trust with executive leadership and investors.



For Healthcare Systems

For the broader healthcare ecosystem, this technology means faster access to therapies and more realistic eligibility criteria that reflect the patients seen in daily practice. This results in improved outcomes through aligned trial design.

Build Faster, Smarter Clinical Trials With ACT

ACT addresses the core challenges limiting clinical trial performance: protocol misalignment, feasibility delays, site underperformance, operational inefficiency and costly amendments.

AI assistants extend this foundation to oncology, enabling faster, more predictable cancer study planning.



Key Points To Remember

The future of clinical development isn't a question of if AI will be used, but how effectively it will be integrated into modern workflows.

By moving from a reactive to a predictive posture, sponsors can ensure that their clinical programs are as innovative as the medicines they develop, leading to:

- ✓ Faster timelines.
- ✓ Fewer amendments.
- ✓ Stronger site performance.
- ✓ Earlier patient benefit.
- ✓ Greater operational confidence.



Request a demo today to transform your
clinical development strategy.

Learn more

Request a demo



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