



TCG DIGITAL

Unlocking Clinical Trial Potential with AI-Driven Transformation



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Introduction

The modern clinical trials ecosystem faces pressing challenges - from lengthy timelines to spiraling costs and lagging productivity. Yet within these challenges lies immense potential for optimization through digitization and adoption of advanced technical tools like artificial intelligence (AI) and machine learning.

Clinical trials remain a foundational pillar to translate scientific discoveries into life-changing therapies for patients in need. But to unlock the ecosystem's full potential, a digital transformation is imperative. Integration of predictive analytics, AI, machine learning and smart management systems can catalyze this transformation.

This whitepaper explores the critical pain points and roadblocks facing clinical trials today. Discover how adopting AI-powered digital solutions purpose-built for the clinical trials space can help address these gaps through an integrated, modular approach engineered to target inefficiencies across the trial lifecycle. From feasibility and site selection to patient recruitment, trial execution, and completion, these smart tools enhance control and provide end-to-end visibility so sponsors can achieve peak performance.

By embracing digital transformation and leveraging data-driven AI solutions, we can accelerate medical research to unlock the full potential of clinical trials - bringing new hope and innovative therapies to patients worldwide.



Key Industry Challenges

Delays in Patient Recruitment - For clinical trials, timely patient enrollment is essential. Recruitment delays substantially prolong trial completion. To encourage rapid accrual that keeps trials on schedule, it is important to leverage digital tools like advanced analytics, coordinated outreach strategies, study coordinators, and removal of obstacles to participation.

Some Key Metrics as per industry data-

- 37% of sites do not meet enrollment targets.
- 11% of sites do not enroll a single patient.
- 80% of the trials do not meet enrollment timelines.

Low Patient Retention Rate - For effective data collection and trial success, it is essential to keep patients involved throughout the whole study process. Low patient retention rate is a severe problem within the industry.

Some Key Metrics as per industry data

- 85% of trials experience inadequate patient retention until completion.
- On average, the dropout rate across all trials stands at 30%
- There has been a 70 Percentage Point increase in trial lengths over the last few years.

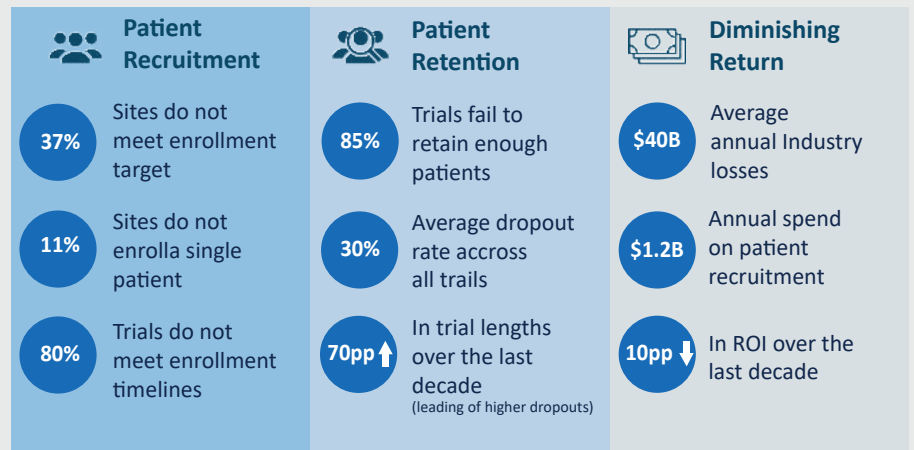


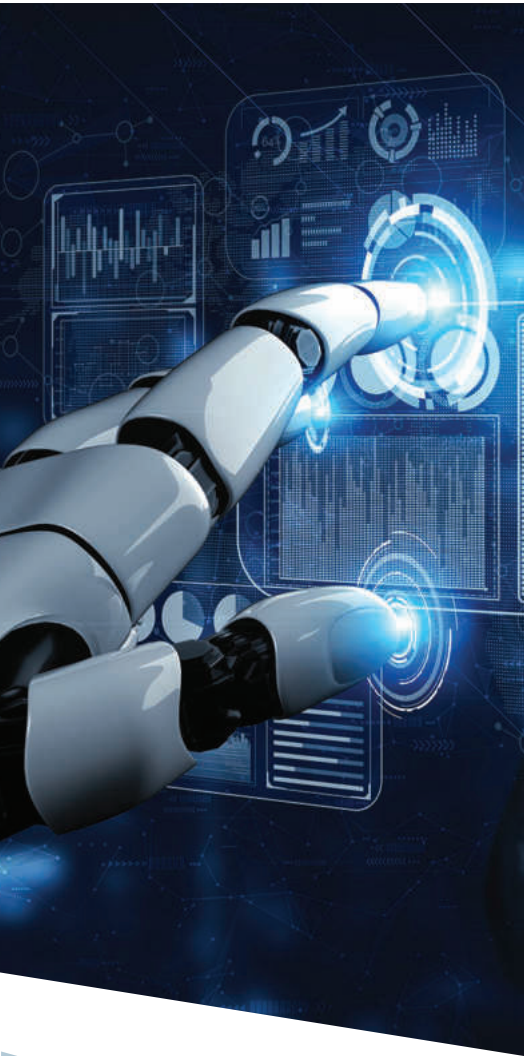
Diminishing Return on Investments - Pharmaceutical companies have experienced a substantial decline in return on investment for clinical trials over the past decade. The cost of running these trials has significantly increased while success rates for new drug approvals have stagnated.

Some Key Metrics as per industry data

- The Average industry losses while running clinical trials rose to as much as \$40 Billion.
- The spend was \$1.2 Billion annually on patient recruitment for clinical trials.
- There has been a 10 Percentage point decrease in Return-on-investment from clinical trials over the decade.

Clinical Trials - Industry Challenges...





How AI can help overcome the challenges

Clinical trials face multiple obstacles that impede successful and timely completion. Adopting AI-based digital solutions provides a holistic approach to tackle these challenges using data-driven strategies.

AI empowers organizations to:

Accelerate Patient Recruitment - AI tools analyzing big data on recruitment patterns identify high-yield sites. AI also enables targeted outreach to perfectly matched patients. Research shows AI-based trial matching improved enrollment rates by 12-15%. Another study found AI-driven patient identification decreased recruitment timelines by 8-12%.

Boost Patient Retention - Granular patient data analyzed by AI identifies individuals prone to dropout. Custom engagement initiatives can then retain them. Studies indicate AI-enabled personalized patient engagement increased retention by 15-20%. AI also facilitates protocol optimization to enhance trial experience. Research found AI-optimized protocols reduced dropouts by 10%.

Optimize Operational Efficiency - Predictive analytics forecast resource needs ahead of time for strategic planning and cost control. Data platforms integrated with AI lowered resource planning costs by 10-30% according to industry reports.

Gain Real-Time Visibility - Consolidated AI dashboards surface unified performance metrics for rapid data-driven decisions. Analysis shows real-time analytics increased data-driven choices by 70% in one study.

Proactively Mitigate Risks - AI and predictive analytics identify potential compliance gaps and risks early. Preventive measures can then be deployed to avoid violations and improve adherence. Studies found predictive systems decreased regulatory violations by 29%.



Driving Digital Transformation with AI-Powered Clinical Trials

There are many obstacles that clinical trials must overcome to be completed successfully and on schedule. Embracing digitization and advanced technical tools provides a comprehensive approach to address the challenges faced by clinical trials.

The key components of this approach include:

Consolidate Data into a Unified Model - Integrating data from disparate systems into a unified model provides complete visibility into trial performance. This enables optimization of operations. Studies show most sponsors use disconnected systems currently.

Enable Dynamic Analysis Through Data Model Flexibility - A flexible, unified data model facilitates multi-dimensional analysis across trial sites, studies, and programs. Consolidated data produces insights to guide strategic decisions at each stage.

Create a Single Source of Truth via Centralized Platforms - Centralized platforms integrate data sources into a single source of truth. This unified view allows optimized oversight through comprehensive analytics and reporting. Research shows centralized data reduces costs significantly.

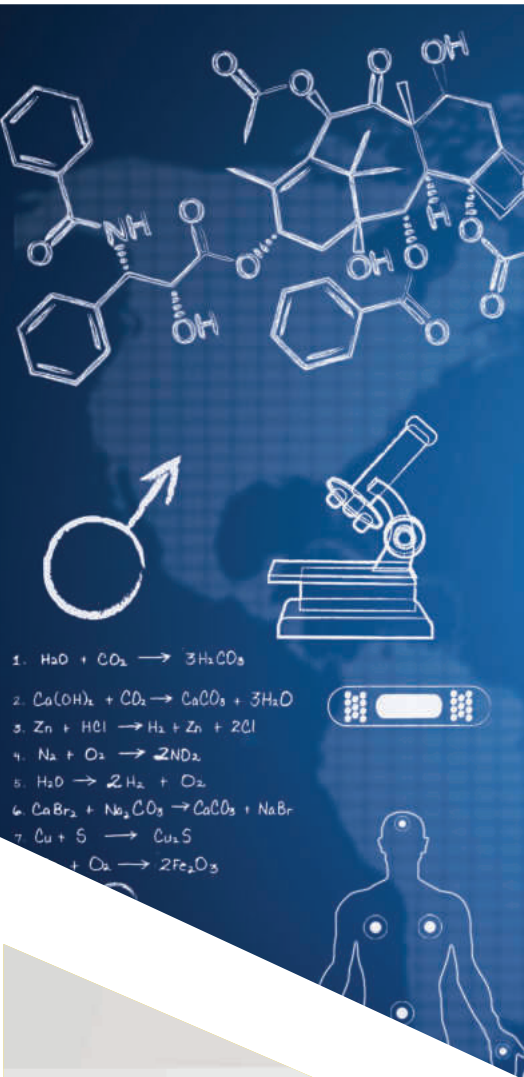
Generate Rapid Insights for Proactive Management - Libraries of pre-built metrics quickly generate insights to trigger alerts and enable data-driven management across the trial lifecycle.

Employ Custom Benchmarks for Objective Assessment - Custom benchmarks compare trial progress to prevailing standards for objective assessment and course correction. Data shows benchmarks enhance planning and cut cycle times.

Enable Customized Deployment for Maximum Relevance - Extensive configurability allows customized deployment tailored to each trial's unique needs and user roles for maximum relevance.

Drive Proactive Decisions via Advanced Analytics - Advanced analytics and AI deliver actionable forecasts, modeling, and recommendations to optimize proactively. Predictive tools identify trends and at-risk patients early to drive successful trial management.

In summary, AI and analytics are key enablers of the digital transformation required to address clinical trial challenges. By consolidating data, generating insights, powering oversight, enabling customization, and driving proactive decisions, these technologies unlock the full potential of clinical trials.



The AI-Powered Future of Clinical Trials

By providing a suite of advanced analytics, AI, and digitization tools, these smart solutions empower organizations to harness technology to revolutionize trial management. Robust analytics and real-time visibility into integrated trial data facilitate proactive, data-driven decision making to optimize trial design, execution, resource allocation, and planning.

With end-to-end visibility into performance metrics across operations, teams can rapidly identify issues, trends, and opportunities. AI-enabled predictive modeling evaluates choices to determine the optimal path forward.

By embracing AI and digital solutions, forward-thinking organizations can maximize the potential of clinical trials through technology-enabled, analytics-driven decision making. This will achieve new heights of efficiency, quality, and productivity to accelerate research and patient impact.

TCG Digital's AI Solution, TrialVision enables data-driven optimization of outcomes, timelines, and costs.

References

1. <https://www.appliedclinicaltrials.com/view/enrollment-performance-how-are-sites-doing-at-patient-recruitment>
2. <https://www.nature.com/articles/nrdp201771>
3. <https://www.ama-assn.org/practice-management/sustainability/patient-recruitment-secrets-how-design-faster-clinical-trials>
4. <https://www.appliedclinicaltrials.com/view/why-patients-quit-trials-and-how-understand-prevent-or-manage-early-withdrawal>
5. <https://www.sciencedirect.com/science/article/abs/pii/S2452302X16300036>
6. <https://www.policymed.com/2011/07/nejm-the-cost-of-drug-development-2-6-billion-over-a-decade-of-research.html>
7. <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rethinking-rd-productivity>
8. https://www.researchgate.net/publication/277816643_Protocol_Design_and_Regulatory_Considerations_for_Phase_I_II_Trials_in_Patients_With_Multiple_Myeloma
9. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4944272/>
10. <https://www.ibm.com/downloads/cas/OJDVQGRY>
11. <https://www.oracle.com/a/ocom/docs/industries/life-sciences/ebook-data-driven-transformation-clinical-trials.pdf>
12. <https://www.sciencedirect.com/science/article/pii/S1532046420300540>
13. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7289413/>
14. <https://www.mckinsey.com/industries/life-sciences/our-insights/how-predictive-analytics-can-improve-clinical-trials>
15. <https://www.appliedclinicaltrials.com/view/application-metrics-benchmarks-and-analytics-improve-clinical-trial-performance>
16. <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-clinical-development-platform.pdf>
17. <https://www.sciencedirect.com/science/article/pii/S1532046417302317>

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