

OmniScience

A New Era of Clinical Development Reasoning

Agentic AI's Transformative Role in Clinical Trial Operations



SUMMARY

OmniScience has developed the industry's first AI system capable of clinical development reasoning, transforming the way biotech and pharma organizations interact with clinical trial data to shorten timelines, reduce cost, and increase probability of success.

Their platform, Vivo, employs the latest advances in agentic AI systems to bring on-demand insights to clinical development teams to increase acuity and accelerate informed decision-making. Vivo's novel cognitive framework employs the latest foundational large language models (LLMs) with a specialized retrieval-augmented generation (RAG) approach to unify trial data, extract actionable insights, and answer complex clinical trial questions. These capabilities are bolstered by autonomous multi-agent systems that streamline reasoning processes and ensure explainability, allowing users to trace decision pathways back to source data with confidence. Robust data validation pipelines further enhance the system's reliability, ensuring data consistency and compliance.

This whitepaper focuses on the high-level approaches that make Vivo an indispensable partner to clinical development teams, driving efficiency and innovation to get more treatments to patients faster.



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The Art of the Possible in Clinical Development

Recent advances in agentic AI enable computers to reason like humans to solve challenges that once seemed insurmountable. Over the next few years, agentic AI is poised to revolutionize clinical development by not only enhancing efficiencies but also addressing the fundamental pain points that have long hindered the industry.

While groundbreaking large language models (LLMs) have transformed the landscape of natural language processing and content generation, they were not built with the complexities of clinical trial data in mind. OmniScience has taken the transformative power of agentic AI one step further - tailoring it to meet the specific demands of clinical development, paving the way for innovations that truly make the “impossible” possible.

The pharma and biotech sectors stand on the cusp of a AI revolution, with opportunities that extend far beyond document generation.

Agentic AI has the potential to solve critical challenges in clinical trials, such as unifying fragmented datasets, improving data quality, and delivering actionable insights in real time.

These advances empower teams to move beyond manual, error-prone, and reactive processes and unlock new possibilities to accelerate study timelines, ensure safety, and optimize trial outcomes.

However, bringing these technologies into clinical development requires more than just cutting-edge AI models. It demands a deep understanding of the clinical trial domain, life sciences expertise, and a focus on building systems that address regulatory and operational complexities.

OmniScience has worked across hundreds of clinical trials, bringing deep expertise in clinical data science. With deep experience in data integration, predictive analytics, and AI-driven solutions, OmniScience's work has supported diverse applications, including: precision diagnostics, biomarker analytics, clinical trial analytics, pharma market intelligence, digital therapeutics, and clinical decision support. This combination uniquely positions OmniScience to help today's study teams redefine what is achievable in clinical development.

While some teams remain cautious to embrace AI due to concerns about risks such as data security, compliance, and accuracy, OmniScience ensures that these barriers are addressed with rigor. Vivo, the industry's first AI-powered clinical trial control tower, is designed specifically for clinical trial data, providing robust safeguards, transparency, and domain-specific capabilities that traditional AI tools lack.

By combining state-of-the-art technology with domain expertise, Vivo transforms clinical trial data into actionable knowledge, enabling teams to navigate complexity with confidence and precision.

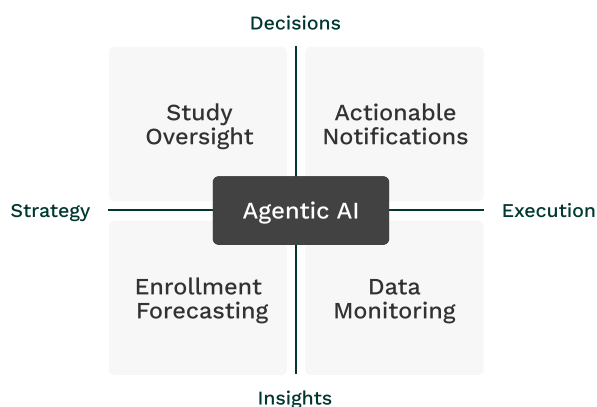
This whitepaper explores the transformative potential of AI in clinical development, how agentic AI is overcoming long-standing challenges, and why OmniScience's Vivo platform is uniquely suited to lead this revolution. The future of clinical trials lies in harnessing the power of AI to make former impossibilities – such as automated clinical trial data unification and insight generation – realities for today's clinical trial teams.

Vivo: Your AI-Powered Colleague

Vivo - the first Agentic AI Control Tower for clinical trials - redefines how biotech and pharma organizations manage clinical trial data by unifying complex, multi-modal datasets into a single, intuitive platform.

This integration provides sponsors and study teams with a real-time, comprehensive view of their clinical trial landscape, breaking down the silos that traditionally hinder decision-making.

What is a clinical trial control tower?



As an AI clinical trial control tower, Vivo goes beyond data aggregation and visualization to deliver actionable insights, forecast enrollment patterns, and issue role-relevant notifications, ensuring trials stay on track. The Ask Vivo tool harnesses cutting-edge AI to answer nuanced operational, safety, and clinical questions.

By centralizing trial data, Vivo eliminates inefficiencies and enables entirely new operational capabilities. Teams can detect discrepancies instantly, access insights in seconds, and respond proactively to emerging challenges, driving smarter, faster decision-making. These advancements translate into optimized workflows and a streamlined approach to clinical trial management.

Unify Clinical Trial Data

DATA CAPTURE: Vivo relies on a dynamic data ingest and integration layer. This component serves as the gateway for data from multiple sources - such as electronic data capture (EDC), clinical trial management systems (CTMS), clinical outcome assessments (COAs) and patient-reported outcomes (PROs), and lab systems. Vivo's data pipelines centralize and harmonize data from disparate sources, enabling a single, cohesive view of trial data with support for complex and diverse clinical datasets.

DATA UNIFICATION: One of the largest challenges in modern clinical trials is the inability to combine data from all sources, all vendors, all data types into a single location. Teams are spending 1000's of programming hours combining data into spreadsheets to monitor trial status. The mapping process is a critical step in ensuring seamless data integration.

Vivo leverages agentic AI tools and its ability to understand trial protocols and case report forms (CRFs) to automate the mapping of source data into the unified Vivo system via configurable data integration pipelines supporting both APIs and flat files. This automated approach reduces manual effort and improves the speed and accuracy of data onboarding.

Vivo's data integration pipelines are rigorously tested via automated means and human review to confirm source data has been accurately mapped and loaded into Vivo's data model, thereby ensuring that data is trustworthy and readily accessible within Vivo's architecture.

Vivo: Your AI-Powered Colleague

DATA MODEL: Clinical trial data is highly heterogeneous, reflecting the diverse needs of every study and the priorities sponsors and their stakeholders. Bringing this data together is a long standing challenge faced by pharma organizations, slowing trial- and portfolio-level insights.

OmniScience has developed a trial-agnostic data model to unify and standardize currently siloed datasets. This creates a robust foundation for Vivo and its AI capabilities, ensuring more accurate insights and streamlined decision-making within and across trials.

The Vivo data model draws inspiration from established industry standards such as the Clinical Data Interchange Standards Consortium (CDISC) models and the Observational Medical Outcomes Partnership (OMOP).

By incorporating relevant ontologies and vocabularies, the data model accommodates each organization's unique data setup and facilitates a more holistic view of all trial data within a portfolio whether completed, in progress, or planned.

DATA DISCREPANCIES: Traditionally, data management teams are tasked with reviewing trial data for inconsistencies. The growing volume and complexity of trial data is making this process increasingly difficult, posing risks to study closeout timelines and budgets.

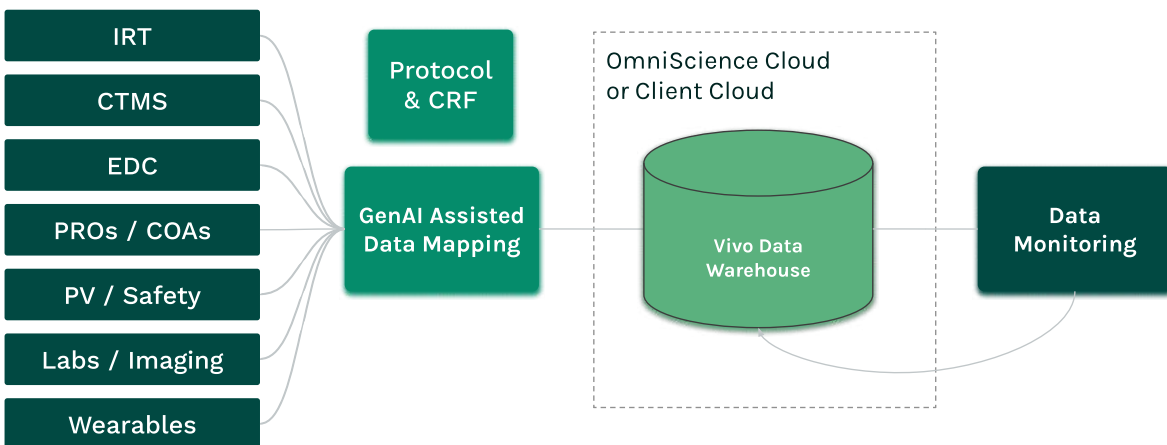
Vivo automatically identifies data discrepancies by cross-referencing datasets from different sources as data is collected. Its intelligent validation pipelines flag mismatches, inconsistencies, and anomalies in real time, enabling teams to better maintain data quality throughout the trial lifecycle.

Enable Clinical Development Reasoning with AI Agents

Clinical development teams spend a significant amount of time fielding questions from a large number of internal and external stakeholders. Due to the complexity and distributed nature of trial data today, considerable time and often multiple people are required to synthesize accurate answers.

Vivo's AI Agents democratize insights, enabling each stakeholder to ask questions directly of the data themselves. By empowering clinical development teams with the ability to ask trial questions via Ask Vivo, Vivo helps teams focus increasingly on the factors necessary for trial success.

AI Assisted Data Onboarding Process



Vivo: Your AI-Powered Colleague

AGENTIC AI: To deliver actionable, on-demand insights, Vivo securely employs state-of-the-art foundational LLMs. This component, which we call Ask Vivo, interprets questions about clinical trial data, from the simplest to incredibly complex, using advanced reasoning techniques to generate meaningful answers.

This is achieved through a finely tuned understanding of clinical trial context and terminology, guided by a sophisticated multi-agent framework that translates user queries into actionable database searches. The resulting data is synthesized and summarized into cogent, natural-language answers to users' questions.

EXPLAINABLE AI: Ask Vivo's cognitive architecture ensures explainability and transparency in its insights. Each generated insight is supported by a traceable rationale that links back to the underlying data and clinical context. This approach guarantees that users can understand not just the answer, but also how the system arrived at the answer.

Deliver Intelligent Insights with Agentic AI

The current paradigm in clinical trials is a reactive one: teams identify concerns based on past experiences and then search for answers. For example, teams might ask, "Is Site 3 recruiting at the rate I expected?" or "Does Subgroup C show any increased safety concerns?" This approach means teams only find what they are actively looking for - and often only discover issues late in the process.

Vivo revolutionizes this paradigm, going beyond visualizations and dashboards to enable proactive monitoring and insight generation. Instead of waiting for humans to ask the right questions, Vivo continuously analyzes trial data, automatically identifying trends or anomalies of concern. By acting as an ever-vigilant colleague, Vivo empowers clinical development teams to address emerging risks or opportunities before they escalate.

The deployment of AI systems requires a proactive and intentional approach to mitigate risks and ensure the reliability of outputs. Without proper safeguards, these systems risk generating misleading information and compromising sensitive data. This section outlines how Vivo delivers trustworthy AI outcomes.

BLOG

Revolutionize Trial Oversight with Vivo: On-Demand Insights to Improve Clinical Trial Success

The Agentic AI Clinical Trial Revolution: How AI amplifies clinical development teams to manage the data explosion, enabling faster and safer delivery of treatments to patients.



Mitigate Risk & Ensure Quality

Grounded and Reliable Responses

Vivo is grounded in unified, accurate, well described clinical trial data. For organizations with centralized trial data repositories, Vivo enhances insights by seamlessly layering onto their existing data warehouse. For teams lacking a unified data structure, Vivo offers an end-to-end solution for data integration, harmonization, and AI-driven analysis.

This adaptability ensures that biotech and pharma teams - regardless of their data infrastructure - can leverage Vivo to address data gaps, streamline operations, and extract actionable insights from complex datasets. By grounding responses in accurate, up-to-date data, Vivo empowers organizations to make informed decisions with confidence.

Data Security, Privacy, & Built-in Guardrails

Vivo is designed with industry-leading cybersecurity practices and compliance with data security and privacy regulations, including HIPAA. Our platform employs zero retention agreements with LLM providers, ensuring sensitive information remains secure.

To further mitigate risks, OmniScience restricts the data accessible to each AI agent within Ask Vivo. This ensures that AI agents cannot disclose information they are not authorized to access, such as blinded study data.

Ask Vivo employs robust guardrails to prevent it from generating responses when insufficient data or confidence levels exist. These measures build user trust by ensuring every response is grounded in validated data and sound reasoning.

Accuracy and Reproducibility

Vivo's AI capabilities are engineered to meet the stringent compliance requirements of clinical trials. Its cognitive RAG architecture incorporates a comprehensive validation strategy to ensure accuracy, consistency, and transparency. This strategy validates both the final AI-generated responses and the underlying database queries used to retrieve information. By ensuring that Ask Vivo accurately interprets user queries and retrieves the correct data, we deliver verifiable responses.

Our validation framework includes:

- **Data Validation:** Automated checks and manual reviews ensure data consistency and accuracy during ingest. Logical discrepancies across source systems are flagged for resolution to maintain the integrity of insights generated by Vivo.
- **Response Validation:** Benchmark testing with verified questions and answers ensures Ask Vivo interprets queries correctly and generates accurate responses. Human reviewers further evaluate the system's performance to identify areas for improvement.
- **Feedback Loops:** Continuous feedback from users, both internal and external, informs ongoing enhancements to Vivo. This iterative process identifies and resolves challenges in AI performance, ensuring the system remains reliable and aligned with user needs.
- **Transparency:** Generated insights are provided with reasoning steps and corresponding SQL code to enable human validation.

CONCLUSION

The complexity and volume of clinical trial data continue to grow, posing challenges that many biotech and pharma organizations struggle to overcome. Siloed systems, fragmented datasets, and time-intensive manual processes slow progress and hinder clinical development teams from realizing the full potential of their data.

~20% of the total costs of a study (which can translate to between \$16M-\$24M) is allocated to duplicating and verifying data

- *Applied Clinical Trials: Innovations in Data Capture Transforming Trial Delivery*

OmniScience is working toward a future in which clinical trial data is automatically unified to enable real-time, on-demand insights and empower clinical trial decision-making.

Vivo represents a breakthrough in clinical trial oversight, empowering sponsors to turn fragmented data into actionable knowledge in real time. By centralizing trial data into a single portal and providing intuitive, AI-driven experiences, Vivo reduces trial timelines and costs while driving faster, more effective outcomes.

We invite you to explore how OmniScience can help you unlock the full potential of your clinical trial data.

CONNECT WITH US

OmniScience is the first and only company in the world to enable AI as a personal data analyst for on-demand insights into clinical trial data. Our team of clinical data science experts is revolutionizing the way pharma employs AI to streamline clinical trials and bring novel treatments to patients faster.

We created Vivo to unify clinical trial data and deliver real-time insights, empowering teams to reduce costs, shorten timelines, and improve oversight. Vivo transforms data into actionable knowledge, enabling smarter decisions and seamless navigation of modern trial complexities.

If you're ready to explore how AI can transform your clinical trials, contact us at hello@omniscience.bio or connect with us on LinkedIn. Join us in building a future where clinical data is not just managed but transformed into immediate, actionable knowledge - accelerating innovation and improving patient lives.

omniscience.bio

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