OmniScience

Transforming Trial Economics: How Agentic AI Unlocks Cost Savings and Improves Probability of Success

How Vivo achieves ROI and improves outcomes in clinical trials

SUMMARY

Despite generating thousands of new drug candidates each year, pharma cannot test all of them in clinical trials due to cost, timelines, and competing interests.

Vivo changes that. It's the first agentic AI system purpose-built for clinical development - far beyond dashboards or analytics tools. Vivo doesn't just summarize trial data; it works alongside study teams to anticipate delays, detect risks, and recommend next-best actions in real time.

Vivo unlocks 20% bottom line savings, shortens study timelines, and improves the probability of success. These gains aren't hypothetical - they're grounded in real efficiencies observed across enrollment, data reconciliation, vendor oversight, and decision-making.

Moreover, the impact of Vivo goes beyond a single trial, extending across portfolios, helping sponsors optimize resource allocation, identify cross-study risks, and scale learnings over time. This creates strategic optionality: with more capacity, teams can pursue more indications, test more candidates, or accelerate go-to-market plans.

In an industry where time, precision, and data-driven agility define success, Vivo is not just an efficiency play - it's a strategic enabler.

CONTENTS

Summary 1

Pharma's Throughput Problem 3

- Inefficiencies are hiding in plain sight

Agentic AI: A Strategic Enabler 4

- Agentic AI enables unprecedented efficiencies

The Business Case for Vivo 5

- Reduce cost by automating manual tasks and optimizing resources
- Shorten timelines through proactive trial management
- Improve probability of success by reducing operational risk

Unlocking Optionality: Vivo's Greatest Return on Investment 10

Pharma's Throughput Problem

Inefficiencies are Hiding in Plain Sight

The $1.2 trillion[1] prescription drug market hinges on clinical trials. Every new therapy - whether a groundbreaking oncology treatment or a next-generation rare disease drug - must navigate a complex, costly, and inherently risky clinical development process to obtain regulatory approval, recognizing that the majority of drugs in this pipeline fail along the way.

The ability to bring treatments to market is dictated not only by safety and efficacy, but also by trial timelines and costs, which have steadily increased over the years. The average time from trial initiation to regulatory approval now exceeds a decade, with pivotal late-stage trials often taking three to seven years. Development costs have soared into the billions per drug, and recent reports estimate that for every day a trial is delayed, sponsors lose $40,000 in direct costs and $500,000[2] in unrealized sales.

While biopharma companies invest heavily in accelerating drug discovery, identifying tens of thousands of promising treatments in the process, biopharma organizations lack the throughput needed to test these candidates in clinical trials. This directly impacts company valuations, competitive positioning, and patient access.

Despite these stakes, trial operations remain riddled with inefficiencies. As development complexity grows - with adaptive designs, decentralized components and novel endpoints, and an evolving regulatory landscape the cost of these inefficiencies continues to climb.

Clinical trials are mired in outdated, labor-intensive processes that result in wasted time, avoidable costs, and unnecessary risks that threaten study timelines, outcomes, and safety.

Here are a few examples:

→ Manual Data Monitoring and Reconciliation
Trial data flows in from multiple sources: electronic data capture (EDC), clinical trial management systems (CTMS), lab systems, safety databases, wearables, patient-reported outcomes (PROs), and more. Integrating and verifying this data remains a largely manual process, introducing delays, discrepancies, and compliance risks.

→ Spreadsheet-Driven Process Tracking
Despite billions spent on clinical trial analytics, many study teams still rely on static spreadsheets, email chains, and ad hoc reports to track enrollment progress, site performance, and operational risks. These methods are time-consuming, prone to errors, and lack the agility required for real-time decision-making.

→ Lack of Real-Time Visibility Increases Risk of Overruns and Failures
With trial data housed in disparate systems, teams often lack a unified, up-to-date view of study progress. This blind spot leads to reactive decision-making, recruitment shortfalls, and costly protocol amendments, all of which contribute to trial delays and, in some cases, outright failures.

These inefficiencies are more than an operational burden. They are an existential threat to speed, cost, and trial success.

1 https://www.databridgemarketresearch.com/reports/global-prescription-drugs-market

2 https://pubmed.ncbi.nlm.nih.gov/38773058/

Agentic AI: A Strategic Enabler

Agentic AI Enables Unprecedented Efficiencies

Pharma spends $5 billion[3] annually on clinical trial analytics, but the tools and workflows used to manage trials have remained largely unchanged for over a decade. Clinical trial teams continue to operate in siloed systems, via manual processes, using retrospective approaches, which is ill-suited for the complexity and urgency of modern drug development.

OmniScience has created Vivo, an AI-enabled control tower to revolutionize clinical trials by going beyond dashboard analytics and enabling automated workflow orchestration. Instead of gathering evidence first and determining potential actions later, teams can now identify and act on critical insights in real time, with supporting evidence surfaced instantly. This fundamental shift enables faster, more efficient decision-making at every stage of a trial.

At the core of Vivo is the first and only agentic AI system capable of clinical development reasoning. Ask Vivo is an AI-powered interface built around Vivo's agentic AI that allows teams to interact with their trial data as they would with a colleague - asking questions, making requests, and receiving real-time feedback. This drastically reduces the need for custom reports, dashboards, and trackers, and corresponding manual effort.

The Business Case for Vivo

Embedding agentic AI into clinical development delivers important efficiencies, including:

→ Reduce costs
Automate redundant tasks, streamline operations, and optimize resource allocation - saving millions per trial.

→ Shorten timelines
Reduce costly delays through real-time monitoring and proactive trial management.

→ Improve probability of success
Identify risks early, optimize site performance, and dynamically adapt trial execution to improve outcomes.

These benefits apply not only within individual trials but can extend across portfolios.

Our Methodology: In the next sections, we outline each opportunity and describe their bottom-line savings and top-line benefits. Each is modeled based on a *3.5 year phase 2 study with a budget of $20M*, of which ~$13M is assumed to be allocated to cover the costs of services and pass through expenses from a full-service CRO. Finally, we apply efficiencies we have observed by percentage to these costs to yield the final estimated savings for this illustrative trial.

3 https://www.grandviewresearch.com/industry-analysis/clinical-data-analytics-solutions-market-report

The Business Case for Vivo

Reduce Cost by Automating Manual Tasks and Optimizing Resources

Manual processes, redundant work, and fragmented systems create significant operational burdens that translate into millions in unnecessary expenses. Vivo eliminates these inefficiencies through AI-driven automation, freeing teams from routine tasks and enabling smarter resource allocation. By automating key trial processes, Vivo unlocks human effort and cost savings across multiple areas.

Vivo Delivers Significant Bottom Line Cost Savings: Vivo's AI-driven automation directly reduces manual effort, redundant processes, and inefficiencies across clinical trials, resulting in significant cost savings. Vivo unlocks operational efficiencies of up to 60-70%, translating into ~$4M in savings in an illustrative $20M 3.5 year phase 2 trial.

Automate Data Unification and Export

The Current State: Trial teams spend hundreds of hours manually extracting, transforming, and formatting data from fragmented sources (EDC, CTMS, labs, eCOA, safety systems). Data inconsistencies require repeated reconciliation, slowing down analysis and decision-making.

The Vivo Advantage: Vivo reduces manual effort and costs linked to data management, biostatistics, project management, and pass through line items by up to 70%.

It accomplishes this by:

- Seamlessly integrating and structuring trial data across systems in real time
- Eliminating redundant data handling and manual spreadsheet work

Estimated Savings for a $20M 3.5 year phase 2 trial: **~$1.3M per trial**

Streamline Data Monitoring & Reconciliation

The Current State: Sponsors and CROs spend millions on manual data validation, discrepancy tracking, and query resolution. Teams manually cross-check data across multiple data sources. Data cleaning and reconciliation delays database lock, which increases costs.

The Vivo Advantage: Vivo reduces human effort and costs linked to tedious, manual tasks by 25-40% across budget line items for data management, statistics, quality control, sponsor/CRO communications, and pass through.

It accomplishes this by:

- Automatically detecting discrepancies, duplicates, anomalies, and missing values across all trial data sources.
- Reducing manual query management and quality control overhead.
- Accelerating issue resolution and database lock timelines.

Estimated Savings for a $20M 3.5 year phase 2 trial: **~$1.5M per trial**

The Business Case for Vivo

Reduce Cost by Automating Manual Tasks and Optimizing Resources

Reduce Effort on Custom Dashboards

The Current State: Study teams rely on business intelligence (BI) tools (e.g., Tableau, Spotfire, Power BI) to manually build and maintain dashboards. Custom BI development requires specialized analysts and ongoing engineering support. Maintaining and updating dashboards is time-consuming and costly.

The Vivo Advantage: Vivo eliminates the need for custom dashboarding solutions and the manual effort required for their upkeep, amounting to a 15-25% human effort and cost savings across data management, statistics, project management, quality, and pass through budget line items.

It accomplishes this by:

- Enabling real-time trial performance tracking based on plain language user requests rather than code.
- Reducing reliance on specialized analytics and programming

Estimated Savings for a $20M 3.5 year phase 2 trial: **~$800k per trial**

Automatically Generate Patient Profiles

The Current State: Teams and their service providers must integrate and analyze large volumes of patient data to track protocol adherence and safety. Patient data is scattered across EDC, lab systems, safety databases, and more, offering limited real-time visibility into adverse events and other risk factors.

The Vivo Advantage: Vivo automatically aggregates data in real time to construct patient profiles to reduce manual tracking effort, improve risk identification, and enhance protocol adherence. This lowers human effort and costs across site and safety management line items by 10-20%.

Estimated Savings for a $20M 3.5 year phase 2 trial: **~$400K per trial**

Opportunity	Human Efficiency Gain	Estimated Savings
Automate Data Unification & Export	Up to 70%	$1.3M
Streamline Data Monitoring & Reconciliation	Up to 40%	$1.5M
Reduce Effort on Custom Dashboards	Significant	$800K
Automatically Generate Patient Profiles	Significant	$400K
Total Savings Potential	**60-70%**	**$4M**

Summary of savings opportunities for an illustrative 3.5 year phase 2 study with $20M budget.

The Business Case for Vivo

Shorten Timelines Through Proactive Trial Management

The current state

Delays are a primary driver of cost overruns, often leading to change orders, extended timelines, and increased operational burden. Such common occurrences heavily influence the ~22% of phase 3 studies that fail for commercial reasons (e.g. due to a lack of funding to continue the trial)[4].

- **Enrollment Issues Surface Too Late**
  Site underperformance and recruitment problems are often caught after delays accumulate, leading to costly interventions like site expansions or protocol changes.
- **Data Discrepancies are Flagged Too Late**
  Retrospective reviews mean missing or inconsistent data isn't identified until database lock, requiring time-intensive manual cleanup.
- **Slow Decisions Increase Study Risk**
  Without real-time insights or scenario modeling, teams react late to challenges, driving up costs and compounding delays.

The Vivo Advantage

Vivo enables study teams to intervene before issues escalate into costly delays. By embedding AI-driven monitoring and real-time insights into trial operations, Vivo turns passive tracking into active management, allowing teams to course-correct in real time.

- **Early Identification of Bottlenecks**
  Vivo continuously monitors site and patient enrollment data, flagging underperforming sites early and suggesting corrective actions (e.g., site expansion, recruitment strategy shifts) before delays accumulate.
- **Dynamic Enrollment Forecasting**
  Vivo predicts future enrollment performance trends, allowing teams to intervene early if recruitment is falling behind.
- **Faster, Data-Driven Decision-Making**
  Ask Vivo enables real-time question answering based on available clinical trial data.

Potential Impact: The impact of Vivo's proactive forecasting and ability to surface data issues as they arise is significant. Reduced enrollment delays, faster database lock timelines, and improved real time, evidence-guided decisions present incredible top-line opportunities.

Challenge	Current State (Reactive)	Vivo Impact (Proactive)
Enrollment Delays	Bottlenecks detected too late, requiring costly interventions (e.g., site additions, protocol changes).	Early identification allows proactive adjustments, minimizing disruptions.
Data Discrepancies	Issues surface late in reconciliation, delaying database lock.	Real-time anomaly detection prompts early resolution, streamlining reconciliation and database lock.
Decision-making	Slow, manual analysis of risks and trade-offs.	AI-driven scenario models enables fast, evidence-based decisions.
Risk of Budget Overruns	Increased costs due to unanticipated delays and change orders.	Avoids expensive amendments and reduces the need for mid-study adjustments.

4 https://pmc.ncbi.nlm.nih.gov/articles/PMC6092479

The Business Case for Vivo

Improve Probability of Success by Reducing Operational Risk

A lack of efficacy and safety concerns are well known causes of clinical trial failures; however, a shocking 22% of studies fail because they run out of funds[4]. Budget overruns are often driven by factors such as under-enrollment, participant dropouts, protocol adherence challenges, etc. Such operational risks often go undetected until they have already disrupted study timelines, jeopardized data integrity, or triggered costly remediation efforts.

The Current State:

- **Missed Visits and Activities Go Unnoticed Until Protocol Deviations Accumulate**
  Patient visits, assessments, and procedures are tracked manually across disparate systems, leading to gaps that may compromise study endpoints.
- **Protocol Adherence Issues are Handled Individually Without Tracking Trends**
  Teams rely on case level monitoring rather than addressing root causes.
- **Data Quality and Completeness is Assessed Too Late**
  Missing or inconsistent data is often discovered at database lock, forcing time-consuming queries, re-contacts, and potential data loss.
- **Safety Signals Emerge Too Late**
  Adverse event patterns and emerging safety trends are typically identified through periodic review cycles rather than real-time detection, delaying necessary interventions.
- **Feasibility-Based Enrollment Projections are Unreliable**
  Without real-time monitoring and dynamic forecasts, sponsors lack insight into whether enrollment is trending in the right direction, leading to last-minute recruitment crises.

CUSTOMER CASE STUDY

Enabling Real Time Enrollment Decisions

During a screening visit, a potential study participant had a biomarker value that made eligibility ambiguous, and the site was unsure whether to proceed with enrollment. The site contacted the Director of Clinical Operations, who asked Vivo to compare the patient's biomarker profile to those of already-enrolled subjects.

Within seconds, Vivo confirmed that the subject's biomarker values were within range, and the site was able to enroll the subject. Without Vivo, hours would have been spent synthesizing and analyzing subject data, and the patient would not have been enrolled. Instead, Vivo was able to preserve recruitment momentum while reinforcing a responsive, site-friendly approach that minimized risks to the study timeline.

The Business Case for Vivo

Improve Probability of Success by Reducing Operational Risk

The Vivo Impact

Vivo embeds real-time intelligence and AI-driven monitoring into trial oversight, continuously monitoring study data from operational, safety, and clinical perspectives to avoid preventable operational failures.

- **Continuous Data Monitoring**
  Instead of waiting until just prior to database lock to perform data reconciliation, Vivo flags missing or incomplete data in real time, enabling proactive resolution and reducing the risk of missing endpoints.
- **Next-Best Action**
  Vivo continuously evaluates trial data for early warning signals (e.g., high screen failure and dropout rates, screening issues, data inconsistencies, etc.) and recommends corrective actions before issues escalate.
- **Automated data issue identification**
  Instead of waiting for periodic data reports, Vivo detects issues in real time, enabling rapid resolution and reducing database lock timelines.
- **Improved Site Performance**
  Identifying trends in safety, enrollment, endpoint data acquisition, and protocol deviations allows for targeted corrective actions, ensuring study integrity and reducing the need for extensive amendments.
- **Optimized Data Consistency**
  Continuous data monitoring facilitates immediate resolution of discrepancies, preserving data integrity and reducing the likelihood of costly errors.

CUSTOMER CASE STUDY

Detecting an Overlooked Safety Data Discrepancy

Vivo detected a serious adverse event that had been recorded in the pharma-covigilance (PV) database but was missing from the EDC for the same subject - an oversight that had gone unnoticed for months despite manual reviews. Vivo's real-time cross-system monitoring automatically flagged the discrepancy, prompting immediate action. Once alerted, the EDC was quickly updated, ensuring data consistency and compliance. This highlighted the value of continuous, automated oversight in preventing data gaps that could compromise trial integrity or delay safety reporting.

CUSTOMER CASE STUDY

Recognizing when Vendors and CROs are Missing Critical Data

Vivo detected a data discrepancy between the sponsor's lab portal and the EDC. The root cause was traced to a missing detail in the data transfer agreement between the lab vendor and the CRO. The sponsor was able to identify the issue early, notify both third parties, and coordinate a revision to the data transfer agreement, avoiding potential downstream data integrity issues and saving significant future time and manual effort.

Unlocking Optionality: Vivo's Greatest Return on Investment

Vivo is reshaping clinical trial oversight with on-demand intelligence, delivering 60-70% human efficiency gains and unlocking significant savings and strategic flexibility across development programs.

While the immediate impact is clear at the trial level, Vivo's value extends further - unifying data across studies to drive deeper portfolio insights and smarter investment decisions.

The industry is entering a new era of agentic AI and automation, reducing costs, shortening timelines, and increasing the probability of success.

If you could unlock 20% of your trial budget, how would you use it?

- Reduce operating costs?
- Explore more indications?
- Test more treatments?
- Empower your core team to be more strategic?

Running trials faster and with greater certainty keeping clinical teams in control of timelines, budgets, and long-term pipeline strategy.

Join OmniScience to build the future of clinical development with Vivo.

CONNECT WITH US

OmniScience is the first and only company in the world to enable agentic 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 Vivo can transform your clinical trials, contact us at hello@omniscience.bio. 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 **hello@omniscience.bio**