

Driving ROI

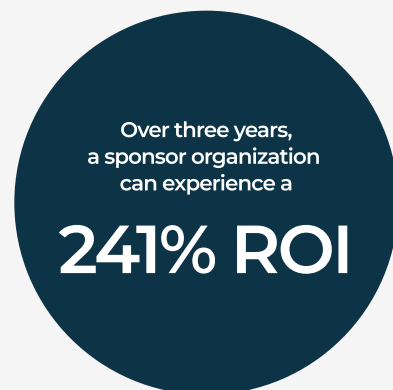
The Business Case for a Comprehensive
Clinical Data and Analytics Solution for Sponsors

Introduction

Advancements in clinical development have led to greater trial complexity and have intensified the challenges of managing an exponential amount of clinical trial data, being captured from diverse sources at an increasingly fast pace.¹ Just a decade ago, an average Phase III study collected around a million data points. Today, that same late phase trial involves approximately 3.5 million data points, and this volume is rising fast.² Trials are also incorporating an ever-increasing variety of data types and sources, collected outside of traditional electronic data capture (EDC) systems.³

This increase in data presents challenges for data management, medical monitoring, and trial operations teams. Without a unified, modern clinical data infrastructure, these teams must devote significant time to data aggregation, report generation for safety reviews, data review, and raising queries. This time-intensive work can lead to extended cycle times in areas such as getting from last patient last visit (LPLV) to database lock, which can also prolong trial timelines.

Hobson & Company, a research firm specializing in Return on Investment (ROI) studies, partnered with eClinical Solutions to investigate these challenges. In-depth interviews were conducted with eClinical Solutions clients to test and confirm the sources of value generated by eClinical's illuminate® platform and examine how it can deliver measurable results. This white paper highlights key examples of the operational and business benefits that can be achieved with a comprehensive, AI-powered clinical data and analytics solution.



A sample organization that has an average of 40 active studies/year and spends: 8 hours/study/week on data aggregation; 20 hours/ study/month on data review, queries, and issues; and 6 weeks getting from last patient last visit to database lock, could see an ROI of 241% and total value creation of \$17.2M over three years with eClinical Solutions.

1. <https://www.eclinicalsol.com/news/how-living-datasets-will-shape-the-future-of-precision-medicine/>

2. <https://www.eclinicalsol.com/blog/accelerating-cycle-times-with-external-data-management-best-practices/>

3. <https://www.eclinicalsol.com/news/complexities-in-data-management/>

Clinical Trial Data Challenges

Increasing data management efficiency

The growing number of external data sources in clinical research is significantly increasing the effort required to consolidate and standardize disparate datasets, and to pull data from multiple systems for review. This results in inefficient, time-consuming processes frequently handled by highly skilled (and costly) resources. An inability to reuse assets from previous trials can also result in a good deal of time being spent each trial to recreate and re-validate listings, and to create new reports, mapping logic, and data quality checks. This can increase the cycle time from database go-live to initial data review.

Reducing effort needed for data review and analysis

When study data is housed across multiple systems, listings, and spreadsheets, the data management, medical review, and trial operations teams often spend excessive time navigating siloed sources. This fragmentation leads to inefficient workflows—such as manually sharing spreadsheets and email chains—to review patient data, monitor trial progress, and resolve issues. Manual processes can also result in time being spent going back and forth with data intermediaries to obtain updated analyses in response to evolving trial conditions. As a result, there's a greater risk of working with outdated information. Additionally, outsourced work can be difficult to track, as CROs often only provide reports once a month. Further reducing these manual burdens with the addition of AI-enabled capabilities is only possible once this data fragmentation is addressed.

Decreasing cycle times and study delays

Study teams can be inundated with Excel trackers, clinical milestone trackers, enrollment trackers, and visit completion trackers, so that much of their time is spent downloading reports and data from various systems and pulling it all together to understand project status and troubleshoot risk. Additionally, when study data is managed across multiple spreadsheets, or across disparate systems, access to this data can be delayed, and there is often no single source of truth. This can limit a study team's ability to uncover issues and course-correct earlier, leading to longer cycle times and potentially costly study delays.

Customer research verified benefits of the eClinical Solutions illuminate® platform in three key areas:

 **Modernizing Data Infrastructure & Analytics**

 **Streamlining Clinical Operations**

 **Improving Speed & Quality of Clinical Trials**

Modernize Data Infrastructure & Analytics

Reduce existing effort for data aggregation from multiple disparate systems

illuminate provides a centralized environment, with APIs and bi-directional interoperability with Rave and other systems, allowing for faster integration of new data sources. Built-in standardization, AI and automation, and interoperability allow teams to get data on demand in real time, reducing time spent assembling data sources.

“With the **APIs and the integration with Rave**, there is now no manual data download required. This has saved essentially all of the time that programmers used to spend on this work.”

DIRECTOR, DATA ANALYTICS BIOTECH

90%

Reduction in time spent on data aggregation from multiple disparate systems

75%

Less time spent creating reports, listings, and data quality checks per new study

Reduce time to create new reports, listings, and data quality checks

Data Central, illuminate's data management and review workspace, enables reuse of forms and logic from prior trials and leverages the wider platform's single source of truth for data. Aggregated cross-trial data powers analytics to improve trial design, site strategy, data collection, patient safety, and CRO performance.

“Having a library of existing tools can **save 1-2 weeks in set-up time for new studies**. The library can also be a resource for lessons learned from one trial to the next and can be helpful when there is a loss of continuity between trials, as people leave and new people join.”

SVP, CLINICAL OPERATIONS PHARMA/BIOPHARMA

Reduce number of existing disparate systems and vendor contracts

illuminate centralizes self-service access to all trial data in one platform with advanced analytics and AI. Three integrated repositories eliminate silos to accelerate data intelligence and ensure data quality, transparency, and audit readiness.

“We were able to **reduce the number of systems being maintained by 65%**, saving IT support time, annual license costs, and annual maintenance costs for each system that was no longer needed.”

HEAD OF CLINICAL DATA AND ANALYTICS
TOP 30 PHARMA

80%

Reduction in number of internal systems and vendor/CRO support agreements needed

Streamline Clinical & Data Operations

Reduce time spent gathering data for monitoring trial progress and oversight

Clinical Trial Operational Analytics (CTOA) within elluminate centralizes data into a single source of truth, offering 20+ dashboards for trial management, real-time insights on enrollment, data quality, and visit timelines, plus self-service analysis, reporting, and integrated issue tracking for streamlined oversight.

“We can now import all data files sent from CROs, the operational data from internal studies, and all clinical data from EDCs, into one platform, **making it easier to monitor and report on studies and to keep trials moving forward.**”

AD, CLINICAL INNOVATION PHARMA/BIOPHARMA

30%

Less time spent gathering data for monitoring trial progress/ oversight

Reduce time spent by medical monitors on medical data review and issue management

elluminate provides a centralized clinical data platform with sophisticated visualizations and analytics dashboards, enabling the review of data across sources and trials in real time. Self-service data exploration tools eliminate delays associated with having to ask a statistician or programmer to write a program or generate output for review.

“We can now access global sets of data, across all patients, and can see safety data right away, **saving 50-65% of the time** that used to be spent on this effort. This allows us to make decisions faster, and we have more confidence in the data.”

CLINICAL TRIAL LEADER BIOTECH

25%

Reduction in time spent by medical monitors on medical data review and issue management

Reduce time spent by data managers on data review, queries, and issue management

Clinical Data Analytics (CDA) allows teams to: review, comment, and raise issues on any data or report; create customizable graphical patient profiles; quickly identify data changed since the last review by each role, and flag it for re-review; automate clinical review objectives to detect anomalous data; and raise/process EDC queries without having to access another system.

“**Data reviews are more efficient**, as we are no longer re-reviewing the same data. In elluminate we can now see when data is new, or has been updated, or if the data has already been reviewed. Time spent on issues was also reduced, as issues can be raised right in a given record in the system.”

SENIOR DIRECTOR, DATA MANAGEMENT
TOP 30 PHARMA

45%

Reduction in time spent by data managers on data review, queries, and issue management

Improve Speed & Quality of Clinical Trials

Reduce cycle time from last patient last visit (LPLV) to database lock

The illuminate platform brings all the data, from any data source, together in a single, integrated platform. Data managers and medical reviewers work collaboratively to quickly and effectively manage data, resolve queries and other data issues, and produce a high-quality database in near real time, positively impacting cycle time metrics such as LPLV to database lock.

"Saw a **40% reduction**, on average, in time needed from last patient last visit to database lock with illuminate, allowing us to get data to the next gate earlier."

DIRECTOR, DATA ANALYTICS BIOTECH

25%

Reduction in cycle time from LPLV to database lock

+1-3 weeks

Increase in number of weeks in market, per study, due to reduced cycle times/trial delays

Protect patent time in market with reduced cycle times/trial delays

illuminate provides a unified end-user experience with: integrated data review capabilities for faster decision-making; easy to use analytics and workflows; and issue management. It is a one-stop-shop for all of an organization's clinical data and analytics needs, from ingestion through to submission, increasing the speed and efficiency of clinical trials.

"illuminate can play a role in getting to market faster, as it helps reduce the time needed for key tasks, such as data review and issue resolution, as well as helping to get from last patient, last visit to database lock faster."

SVP, CLINICAL OPERATIONS PHARMA/BIOPHARMA



Key Findings ROI Research Results

The value of the illuminate Clinical Data Cloud is immediate and demonstrable. In the following example, a sample sponsor organization is migrating to the platform from a more manual process with the following pre-illuminate inputs:

40 active studies per year and 12 new study starts per year

8 hours per study, per week, spent on data aggregation

20 hours per study, per month, on average, spent gathering data for monitoring trial progress/oversight

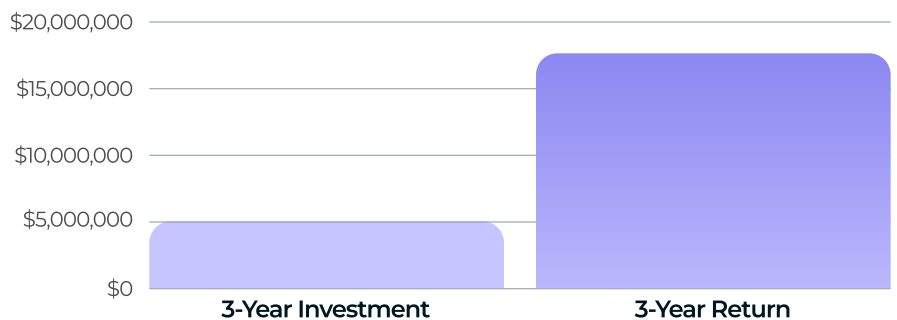
40 hours per study, per month, spent by medical monitors on medical data review and issue management

120 hours per study, per month, spent by data managers on data review, queries, and issue management

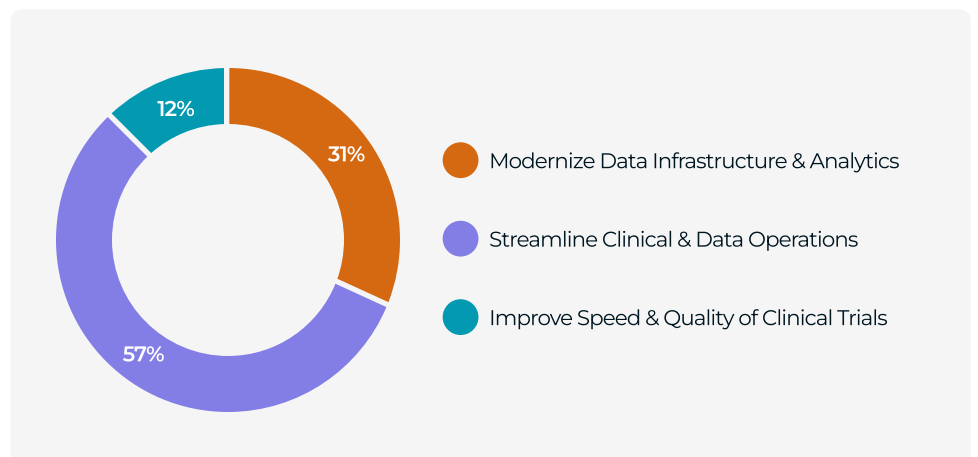
6 weeks needed from last patient last visit to database lock

Investment vs. Return

A total investment of \$5.0M over three years in the eClinical Solutions illuminate platform generates positive cash flow in 4.6 months. The 3-year total value created and return on investment are strong, at \$17.2M and 241%, respectively.



Percent of Total Value Delivered by Business Objective



Hobson & Company

About Hobson & Company

For over two decades, Hobson & Company has created ROI tools that help technology vendors and purchasers uncover, quantify, and validate the key sources of value driving the adoption of new and emerging technologies. Our focus on robust validation has helped many technology purchasers more objectively evaluate the underlying business case of a new technology, while better understanding which vendors best deliver against key value drivers. Our well-researched, yet easy-to-use ROI tools help technology companies better position and justify their unique value proposition. We have worked with early-stage start-ups all the way up to some of the largest technology vendors in the world. For additional information, please visit www.hobsonco.com.

Disclaimer

The return on investment (ROI) and other financial calculations expressed in this paper are based on data provided by eClinical Solutions clients, and various assumptions, and provide estimates only. The actual ROI realized may vary from the estimates provided. eClinical Solutions offers this paper to assist clients with evaluating their illuminate® platform; however, eClinical Solutions and Hobson & Company (the firm that created the ROI calculator) are not responsible for the accuracy of any estimates.

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eClinical Solutions' industry-leading clinical data intelligence platform, illuminate®, and biometrics services experts help biopharma researchers at large, mid-size, and emerging life sciences organizations develop tomorrow's breakthroughs with today's resources. Learn more at www.eclinicalsol.com and follow eClinical Solutions on [LinkedIn](#).



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