CASE STUDY

Health Decisions

# Pivotal Study of a Promising Alzheimer's Drug

## Time and cost projections threatened the future of a product at a major pharma company. Health Decisions stepped in with a faster, less costly way to complete phase III testing.

Based on promising results from previous studies, executives at a global pharmaceutical company projected substantial revenues for their new Alzheimer's treatment. However, the executives faced a difficult decision: commit to funding a large phase III study to seek regulatory approval or out-license the product, sacrificing future revenues to reduce present costs.

Conducting the phase III study would involve substantial cost and risk. The study drug, which impedes a brain enzyme suspected of playing a role in Alzheimer's, required administration for 52 weeks. Recruitment of the study population would involve six countries and more than 100 sites.

The company had experienced problems with site management and enrollment in previous global studies. Even if the drug worked, operational issues could delay or compromise study results. With competing products on the horizon and estimates of study costs and timelines at $110 M and five years, executives saw the market opportunity slipping away.

The alternative to conducting the expensive and risky phase III study was out-licensing the drug. Out-licensing could reduce risk and ensure an earlier revenue stream through milestone payments, but would also substantially reduce the sponsor's revenue following approval. After detailed examination of financial models, the executives decided to complete the trial—provided the program director could reduce the five-year timeline.

## Challenge

A global pharmaceutical company needed to complete a phase III pivotal Alzheimer's study faster and more efficiently than initial estimates of 5 years and $10M.

## Solution

Health Decisions incorporated adaptive enrollment, adaptive monitoring and advanced technology for data-driven site management to maximize speed and efficiency.

## Results

Health Decisions completed the trial in 3.5 years and saved the sponsor $32 M in development costs.

## A CRO Meets the Sponsor's Challenge

When an internal team debated the realization of shortening timelines, the program director decided to bid the project out. The RFP explicitly challenged CROs, including some of the world's largest, to recommend an approach that would trim timelines substantially.

Health Decisions, a CRO focused on adaptive clinical trials, was confident in its ability both to shorten timelines and reduce costs. Because enrollment accounted for a majority of the original five-year timeline and monitoring represented a substantial portion of costs, Health Decisions focused on those areas.

Accelerating enrollment in the multinational study required the ability to oversee recruitment efforts around the world from a centralized location. Health Decisions' technology and processes provided continuous real-time tracking and analysis of enrollment metrics for tight management of all sites—the key to meeting aggressive enrollment milestones. To reduce monitoring timelines and costs, Health Decisions proposed an adaptive monitoring program. A combination of remote monitoring with needs-based allocation of site visits would reduce overall travel costs while focusing increased attention on problem sites—such as sites that had too many unresolved queries or late query resolutions.

In awarding the contract to Health Decisions, the sponsor confided that other CROs had proposed meeting aggressive timelines by initiating far more sites and increasing recruitment and monitoring costs proportionally. Only Health Decisions proposed achieving the sponsor's goals through more efficient approaches to enrollment, site management and monitoring.

### Risk Mitigation Spotlight

Because CNS studies involve subjective assessments, variability of data can be a major issue. If assessments are not administered consistently at all sites, variability can increase to a degree that prevents the study from achieving statistically significant results. Close site management based on continuously updated information from around the world enabled Health Decisions to ensure uniform administration of subjective assessments of cognitive function across 100 sites in six countries to accurately demonstrate treatment effect.

## Data-Driven Site Management Keeps Enrollment on Track

Through Health Decisions' adaptive operational approach, advanced electronic data capture and HD360 Clinical Management System, the study team had continuous access to real-time performance metrics and same-day access to data from patient visits. Health Decisions boosted enrollment by analyzing metrics to identify critical factors such as reasons for screen failures, the effects of specific inclusion/exclusion criteria and the returns on different recruitment strategies. Benefits were immediate and substantial. The team found some sites were recruiting subjects that failed to meet the study's minimum requirements. Intervention fixed the problem within hours. Shifting recruitment resources to the most productive strategies accelerated enrollment while controlling costs.

## Study at a Glance

### Study Compound:

Molecule to slow Alzheimer's Disease

### Phase: III

### Active Sites:

107, U.S., Canada, UK, France, South Africa, Australia

### Patients Enrolled:

1,500

### Treatment Duration:

1 year

### Patient Population:

Patients with probable Alzheimer's

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## Adaptive Monitoring: Focus on Prevention

Adaptive monitoring allowed Health Decisions to bring poorly performing sites quickly up to standard and increase data quality for each site and the study as a whole. The goal was to identify what was causing problems and fix those causes at the source, reducing the number of problems for monitors to address. Time and cost savings were substantial because fixing site problems up front reduced the number of queries and the amount of monitoring work required to ensure accurate data. Health Decisions also streamlined other major operational components such as query resolution. If site personnel made a data entry mistake, Health Decisions' platform would generate a query automatically and allow sites to resolve queries without involving clinical or data management teams. Because queries and outstanding issues with sites were resolved promptly during the study, there were few issues to complicate site closeout and the study database was locked in two weeks.

## Industry-Leading Speed and Efficiency

Health Decisions carried out the Alzheimer's study with one-third of the staff needed for data entry compared to the initial study plan while making data available within hours instead of days or weeks. Far exceeding the sponsor's expectations, Health Decisions reduced study timelines by almost one-third and saved $32 M in development costs—all while preserving the sponsor's full share of future product revenues.

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