Health Decisions CRO+

CASE STUDY

Cure for the Common Vaccine Trial

Challenge

The sponsor of a Phase I influenza vaccine trial required immediate access to safety data, while accelerating timelines and conserving limited development funds.

Solution

Through its SmartPen EDC system and adaptive monitoring, Health Decisions provided access to safety data within minutes, eliminating 90% of source-document verification and cutting on-site monitoring visits by 80%.

Results

Health Decisions reduced the development budget by 30% and cut timelines by 20%, while conserving funds for continued development of the influenza vaccine and the other vaccines in the pipeline.

Immediate access to reactogenicity and safety data accelerates enrollment and cuts study costs

When a sponsor decided to begin human trials of a promising influenza vaccine, more than one product was hanging in the balance. The candidate was one of the first products in human trials from a decade-long program to develop a novel process for creating vaccines.

The Phase I study was a test of both the new influenza vaccine and the process that produced it. The sponsor had a broad range of other vaccines in the pipeline, created through this new technology. The results of this one study could put all the candidate vaccines on a fast track—or block the way.

As sponsor executives planned the Phase I trial, they wanted results as rapidly as possible but faced a tightening development budget. Maximizing return on investment required moving this vaccine through the development process as quickly as possible. Competition would only increase as the vaccine industry experienced explosive growth, expected to reach $20 billion by 2015.

The executives quickly concluded that conducting the study with traditional methods would take too long, cost too much and, based on past experience, tell the sponsor too little. The sponsor sent RFPs to a range of CROs, challenging them to reduce typical timelines and meet the sponsor's requirement for timely information.

Up to the Challenge

The sponsor chose to partner with Health Decisions, the industry leader in adaptive clinical research. The Health Decisions proposal illustrated a plan for maintaining high quality while reducing timelines and costs and providing the sponsor with real-time updates on study metrics. The key elements included innovative data capture, the use of electronic CRFs as source documents, and adaptive monitoring—a leading technique in Health Decisions' adaptive approach to study operations. Adaptive operations optimize a study continuously based on real-time data and performance metrics.

Study at a Glance

Overview:

Placebo-controlled, randomized, double-blind trial evaluated the safety and humoral and cellular immune responses of Influenza vaccine candidate

Phase: III

Active Sites: 1, U.S.

Patients Enrolled: 216

Treatment Duration:

One or two inoculations with eight-month follow-up to ensure continued safety and efficacy

Patient Population:

Healthy adults, 18 – 47 years old

Real-Time Data Access, Reduced Monitoring Costs

After evaluating electronic data capture (EDC) options, Health Decisions determined its SmartPen was the best choice for this study because rapid access to reactogenicity and immunogenicity data was a top priority. Integrated with Health Decisions' HD360° Clinical Management System, the SmartPen provided the sponsor with reactogenicity data within minutes of a patient visit. The SmartPen enabled data to be uploaded immediately, and HD360° provided a variety of timely reports that summarized key data on enrollment and safety.

Site coordinators fill out CRFs with the SmartPen.

Docking pen sends data to HD360° immediately.

Continuous study metrics enable fast decision-making.

Adaptive Monitoring techniques replaced rigid monitoring schedules with a combination of continuous remote monitoring and needs-based site visits. Study managers scheduled site visits based on metrics such as the number of unmonitored fields and unresolved queries. When site visits took place, monitors knew exactly where to focus their attention based on information shown on their dashboard or reports specific to their role.

The greatest single contribution to the outstanding speed and efficiency of the study was the use of SmartPen CRFs as source documents. Using CRFs as source eliminated 90% of source-document verification (SDV), helped reduce the number of on-site monitoring visits by 80%, and simplified database lock. The streamlined process reduced site costs by minimizing site coordinator hours through reduction of unnecessary transcription and paperwork.

Safety Reviews in Two Hours Instead of Two Weeks

Health Decisions also reduced timelines by tightly coordinating the timing of patient visits following safety reviews. Reactogenicity reviews were required after the first few patients were tested with each new route and dose. The Principal Investigator (PI), medical monitor and sponsor reviewed data before allowing the new dose to be administered to a wider sample of subjects. In one of the sponsor's previous trials, another CRO took two weeks to coordinate this review, schedule the visits and provide the necessary data.

With Health Decisions' SmartPen, safety and reactogenicity data was available for review within two hours of each subject visit. Health Decisions scheduled the reviews with the PI, medical monitor and sponsor the same day as dosing the first patients with each new route and dose.

Health Decisions CRO+

Assessment	Malaise	Fatigue	Myalgia	Nausea	Vomiting	Headache
30 Minutes After	None	None	None	None	None	None
Later Day Zero	None	None	None	None	None	Mild
Day 1	None	None	None	None	None	Mild
Day 2	Mild	None	None	Mild	None	Mild
Day 3	Mild	None	None	None	None	Mild
Day 4	None	None	Mild	None	None	Moderate
Day 5	None	None	None	None	None	Mild
Day 6	None	None	None	Mild	None	Mild

Reactogenicity reports provided the sponsor with real-time, actionable subject data to ensure safety for each new route and dose.

At the time of each review, the study team had already pre-screened patients for the next round of patient visits and ensured that site personnel scheduled the visits for the morning following the expedited safety review. If the PI, medical monitor and sponsor gave the go-ahead, the study would begin administering the new dose to a larger number of test subjects the very next day. This approach saved the sponsor two weeks for each new route and dose.

A Customized Subject Visit Model for Vaccine Development

To ensure fast patient processing and data collection at the site, Health Decisions developed a multi-station approach to enrollment and dosing. Each station included a SmartPen that enabled site personnel to capture patient data quickly and easily while eliminating later transcription of paper forms. This arrangement played a central role in providing early data availability for the sponsor.

Successful Study Moves on to the Next Phase

By minimizing monitoring visits and SDV, Health Decisions reduced the sponsor's development budget by 30% compared to a study that had to perform conventional SDV. Fast access to study data, expedited safety review and proactive scheduling of visits cut the overall study timeline by 20% compared to a similar trial conducted by a different CRO. The sponsor expressed great appreciation for the real-time data that gave them complete visibility into all key performance metrics.

The combination of HD360° and the SmartPen enabled the sponsor to complete the Phase I study on schedule without any major safety issues while conserving development funds. The results of the initial Phase I trial were promising, allowing the sponsor to advance development of the new influenza vaccine and the other vaccines in the pipeline.

Please visit www.HealthDec.com for more case studies about how Agile Clinical Development gives sponsors their greatest chance of success.

About Health Decisions

Health Decisions is an innovative CRO that for 25 years has enabled forward-looking biopharma and device companies to bring products to market successfully, earlier and with less risk. Notable successes in IVD studies include early completion of both a 4,000-subject study of a diagnostic for human papilloma virus and a 13,000-subject study of a diagnostic for colorectal cancer. These large IVD studies illustrate how Health Decisions' market-leading Agile Development methodology, powered by LiveData™ and advanced analytics, enables highly trained and experienced project teams to provide responsive, proactive trial management that consistently meets or exceeds development goals for sponsors worldwide.

Health Decisions 2510 Meridian Pkwy. Durham, NC 27713
Tel: +1.919.967.1111 Toll Free: +1.888.779.3771 Email: agile@healthdec.com
www.healthdec.com

Health Decisions CRO+