Health Decisions CRO+

CASE STUDY

HPV Diagnostic Study Wins Race to Market by 2.5 Years, Saves $30M

Key Challenges

Winning the race to market against a competitor with deep pockets

Enrolling the study rapidly but intelligently—rather than taking a brute-force approach that would enroll ≈ 50,000 subjects to find the required 4,000+

Maintaining the highest data quality to prevent delays in regulatory filing

Containing monitoring costs without compromising quality

The sponsor was eyeball to eyeball with a large multinational competitor initiating a similar study in the same timeframe. The sponsor had to reach market first by a substantial margin to overcome the multinational's marketing heft. The biggest challenge was finding the most efficient way to identify and enroll the requisite 4,000+ patients with the distribution of abnormal serotypes required to demonstrate sensitivity and specificity. The traditional way to find the 4,000 patients would be to enroll and Pap-test 50,000 subjects, which would drive study costs above $50M and timelines beyond five years—a terrifying prospect for the sponsor and its investors.

Health Decisions Approach

Design for Efficiency

Health Decisions and the sponsor agreed that the most important design question was whether abnormal Pap results could be identified before a patient was enrolled. The next most important question was whether it would be possible to stop enrollment individually for each of the several required abnormal Pap serotypes immediately upon reaching the FDA-specified number of subjects with each abnormality. The conventional approach to the study, and the approach actually taken by the competitor, was to enroll women first and then assess Pap smears. On this approach, enrollment continues until the study identifies among the many thousands of enrolled women the Pap results required for each abnormality. Costs soar and timelines stretch far into the future.

The Ability to Execute the Design

Health Decisions advised the sponsor that its systems and processes could gather and report information quickly enough so that women could undergo Pap tests as Standard of Care and then the study could enroll only the target number of women with each abnormality, along with an adequate sample of normal patients to follow forward in time to measure potential false negatives.

Study at a Glance

Type of Study:

Registration

Sponsor:

Innovative, venture-funded

Competition:

Similar product from multinational

Product:

Molecular Diagnostic Test for HPV High-Risk and HPV 16/18, linked to cervical cancer

Active Sites: 1, U.S.

The critical enablers for this strategy were Health Decisions' SmartPen, a digital pen EDC system, and Health Decisions' HD360° Clinical Management System. These tools provided the study team with continuous access to data on Pap results and current enrollment status for each abnormality within 24 hours of the availability of such information in the field.

The competitor, hampered by delays characteristic of typical data handling capabilities, had no choice but to enroll subjects first and then perform Pap tests.

"We got this diagnostic to market years ahead of competitors because our technology and processes gave us key information like Pap results, enrollment by serotype and screen fails daily," said Dan Cormican, Health Decisions project manager. "With most trial management systems, the study team spends days trying to gather that kind of information. All we have to do is look at the data that is automatically updated every few hours in HD360°."

Full Transparency and Data Immediacy

Like the study team, the sponsor had full transparency on the study and immediate access to information. The sponsor's Vice President said, "We literally knew daily how many women were screen fails and how many were enrolled with each test result, which was a huge win for us." There was initial concern going into the study about the ability to cope with unforeseen developments while staying within budget. The sponsor's Vice President said, "No matter how well you plan clinical trials, unexpected things happen and you have to be able to adapt quickly to be successful." The HD360° platform provided that capability. "When something happened in the field, it was on my desktop in minutes or hours. We would literally react within 24 hours of receiving certain information and make changes either to things we did at specific sites or updates to the protocol."

The Bottom Line

"Partnering with Health Decisions allowed us to change and change quickly," said a sponsor VP. "We knew that the opportunity in the marketplace required speed. Our competitors were trying to get into this product line as quickly as possible, but we beat them to it. We beat multi-billion dollar corporations with the speed and accuracy of our trial."

Adaptive Monitoring Based on Real-Time Data

The sponsor's project manager valued the ability to adapt monitoring intensity in response to streaming performance metrics. "Getting the data back quickly and having access to the data not only as the sponsor but also for monitors allowed us to jump in front of issues instead of dealing with issues that occurred six months ago. We could work more closely with the sites, which allowed tighter control and produced higher quality data."

Health Decisions CRO+

Health Decisions' Project Manager Dan Cormican said, "We allocated monitoring visits based on the number of unmonitored fields at each site. In between visits, access to real-time data allows us to monitor remotely. Besides saving a lot of money on monitor travel, we know what's going on at the sites between visits and so does the sponsor. We can identify and fix problems fast."

Data Management and Database Lock

Health Decisions performed continuous data checks and progressive data lock during the study to ensure high data quality and minimize the time required for database lock and submission. Following FDA approval, the sponsor's Vice President said, "We locked down the database, produced all the tables, analyzed all the data, and submitted it to the agency within two months of completing all clinical procedures. From an industry perspective, that is incredibly fast. The agency then cleared our products within eleven months. The fact that we got approval for both products in 11 months tells us that not only were we able to generate the data quickly, it was high quality data."

Key Enablers

- A thoughtful study design that enrolled women after Pap results.
- The ability to execute the design based on timely data and streaming enrollment metrics.
- Transparency on the study and timely data access that allowed rapid response to the unforeseen.
- Adaptive monitoring, with a blend of remote monitoring and dynamically scheduled site visits.
- Progressive data locks during the study, ensuring high data quality and minimizing time for regulatory submission.

Results

- Rapidly completed development of the first DNA test approved by the FDA in more than 10 years and the first test approved by the FDA for genotyping the HPV 16/18 types
- Exceeded every target endpoint for quality and timeliness
- Reached market 2.5 years ahead of competitor, generating extra ~$500M in sales
- Paved the way for acquisition of the sponsor for almost $600M

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+