Health Decisions CRO+

CASE STUDY

Universal Flu Vaccine

Study at a Glance

Study Compound:
Universal Flu Vaccine

Phase: III

Active Sites: 2, U.S.

Patients Enrolled: 80

Enrollment Period:
3 weeks

Patient Population:
Healthy adults 19 – 49 years old

Numerous strains of influenza A circulate every given flu season, many of which thwart the predictions of epidemiologists. The successful development of this Universal Flu Vaccine would eliminate the need for annual flu shots and prevent the occurrence of public emergencies like the recent avian and swine flu pandemics.

What's more, this Universal Flu Vaccine is developed using a novel biologic process capable of producing billions of doses per month with relatively low manufacturing costs—far exceeding the speed and efficiency of the current egg- and cell-based vaccine production processes.

Key Challenges

- **Accelerated timeline**
  Enrollment and dose administration had to be completed before the expiration date of the comparator vaccine—only three weeks after the first site initiation and less than ten weeks after the partnership was contracted. Failure to reach this would invalidate results and delay the program until the following year's standard vaccine became available.
- **Access to reactogenicity data**
  With previous studies, the sponsor waited six to eight weeks for safety data—far longer than the current trial's timeline would allow. Data had to be captured, verified and made accessible to the sponsor immediately in order to closely monitor patients' reactogenicity levels and proceed toward the goal date with utmost accountability.

Solutions and Results

Health Decisions applied its Agile Clinical Development platform to the trial's complex challenges, continuously detecting and correcting emerging issues in both safety data and operational performance before they could threaten the trial's timeline, budget or validity.

- ### Speed at the point of patient contact

  To ensure enrollment and dosing deadlines were met, Health Decisions equipped investigational sites with the SmartPen advanced EDC system. Compact and portable, the system allowed investigators to effortlessly capture source data on the CRF and automatically transmit it to Health Decisions for validation and verification.
  The SmartPen also facilitated an efficient multi-station approach in which patients were quickly moved through a series of stations dedicated to enrollment and dosing tasks. By eliminating the need to manually enter data or transcribe between multiple sources, the system effectively reduced time and errors.

- ### Key metrics in near real-time

  As investigators enrolled new patients, the SmartPen system worked simultaneously to capture and track key metrics about site performance and enrollment status so that operations could be continuously refined. These metrics, along with patient data, were reported in near real-time to the Health Decisions project team, making it easy to manage sites and keep the deadline in check.

- ### Data to the sponsor in 24 hours

  Once transmitted from the investigator sites, patient data was cleaned on an immediate, continuous basis both automatically and by Health Decisions' data management team. Custom reports let the sponsor access clean data within 24 hours of the patient visit instead of having to wait weeks for interim database locks. This was key to making informed decisions about the trial's progress, ensuring meticulous adherence to protocol, and achieving the accelerated timeline with full accountability for patient safety data.

The Bottom Line

Health Decisions worked closely with the sponsor to establish performance metrics and implement a system that enabled near real-time tracking of data, successfully completing a critical study under aggressive timelines and exceeding sponsor expectations.

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.

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