CASE STUDY

Health Decisions

Diagnostics Health

Dual 510(k)/CLIA Waiver Study of Point-of-Care Influenza Diagnostic

Test Product: A single-use, multiplexed, molecular, point-of-care (POC) test for the qualitative detection and discrimination of influenza A and B viral RNA in nasal swabs from patients with signs and symptoms of respiratory infection.

Comparator product for substantial equivalence determination: An FDA-cleared nucleic acid amplification test (NAAT).

Patient Population: Patients of any age presenting at a study site with influenza-like illness. Having a fever within the last 72 hours and at least one additional symptom including feeling feverish/chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, or fatigue. Patients taking an antiviral medication for influenza were excluded from participating.

Challenges Faced:

- Intricate study design to encompass both 510(k) and CLIA Waiver specifications.
- Collecting an adequate number of samples rapidly during flu season despite starting late in the year with limited supplies.
- Ensuring sample integrity through proper sample collection and shipment.
- Ensuring quality results through daily oversight of quality control results and patient results.

Study at a Glance

Type of Study:

Dual 510(k)/CLIA Waiver

Objective:

Obtain data to support dual 510(k)/CLIA Waiver submission

Active Sites:

13 CLIA-certified throughout the U.S

Subjects Enrolled:

573

Evaluable Samples:

567

Risk Management and Mitigation:

Intricate study design to encompass both 510(k) and CLIA Waiver specifications – Health Decisions worked with the sponsor to ensure that all specifications to support both 510(k) clearance and CLIA waiver could be achieved within one clinical trial. Health Decisions ensured that all sites participating in the trial had staff that would be considered "naïve" per FDA definition and could perform the point-of-care (POC) testing on site. Health Decisions helped develop the self-guided training materials for the sites and also developed a familiarization experiment to be able to ensure the naïve staff could adequately perform testing on the POC device before patients were enrolled. Study results were monitored weekly to track the number of positive samples for each naïve user and the number of results overall so that the CLIA criteria of 5 positives per user and 360 samples tested overall were met.

Collecting an adequate number of samples rapidly during flu season despite starting late in the year with limited supplies – The sponsor had a slight delay in finalizing the study protocol and manufacturing study devices. Therefore, sites were unable to begin enrolling subjects until late in the flu season. With this in mind, Health Decisions had recommended use of regulatory-ready back-up sites which could be up and running within a week's time if needed. Because of the delay in manufacturing investigational devices, Health Decisions had to allocate devices with care based on the level of flu activity at the location of each site to ensure that enrollment remained on schedule.

Ensuring Sample Integrity – Sample-collection requirements for the study were complex and in some respects unusual for site personnel. The study required site personnel to use two different types of swabs. The comparator device required a sample collected with a nasopharyngeal swab (NPS) but the investigational device required a sample collected with a midturbinate swab. Furthermore, if a subject had any type of swab taken for standard of care, then the research staff had to collect the research swabs from the opposite nostril. Study requirements also included testing the midturbinate swab within 2 hours of collection and storing the NPS swab at 2-8°C until shipment. All NPS swabs were to be shipped day of collection due to 72-hr stability. Health Decisions created a CRF to hold tracking information for all NPS being shipped daily to ensure they were shipped and delivered to the reference laboratory.

Ensuring Quality Results – The results from the investigational device were uploaded via iPhone pictures immediately after testing. This enabled the study team to monitor the quality of results in real time. Health Decisions utilized this method to monitor not only patients results but also the daily running of quality controls. Any trends among naïve users or device lots were immediately reported to the sponsor to allow prompt troubleshooting.

The Leading Full-Service Women's Health CRO from Pre-IND or -IDE to Regulatory Approval and Beyond

Health Decisions is a full-service CRO offering therapeutic, operational and regulatory excellence for clinical development of drugs, diagnostics, medical devices and combination drug/devices in all areas of women's health. Our experience, expertise, site network and KOL and investigator relationships enable us to address the challenges of developing products in areas including general gynecology indications, contraception, sexual health, infertility, obstetrics, menopause and osteoporosis and other indications that affect women disproportionately and profoundly, including autoimmune disorders and male-factor infertility. If it matters to women's health, it matters to Health Decisions. Health Decisions is headquartered in Durham, NC and operates on five continents.

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