

CASE STUDY

Proactive Engagement

Quintiles Expertise Vital to Pediatric H1N1 Study

Study Description

Randomized, multicenter, double-blind, placebo-controlled, Phase IV trial of an H1N1 vaccine in pediatric patients

Study Objectives

To evaluate the safety of an H1N1 vaccine in children 2 to 17 years old

Study Compound

H1N1 vaccine

Patient Population

Healthy children 2 to 17 years old

Treatment Period

2 vaccinations with 180 days of follow-up after the second vaccination

Primary Endpoint

Fever (axillary temperature 101°F) after Dose 1 (Days 1-8)

Participating Country

United States

Study Specifics

- > Number of active sites: 16
- > Patients recruited: 326
- > Recruitment period: 3 days

Quintiles Services

Site Startup, Clinical Monitoring, Project Management, Data Management, Public Health and Government Services, Regulatory

Disease Overview

The U.S. Centers for Disease Control (CDC) estimates that, from April through mid-October 2009, the H1N1 influenza virus infected 22 million people and was responsible for 3900 deaths and 98,000 hospitalizations in the United States. Young people appear to be disproportionately affected by H1N1 unlike the seasonal flu, which disproportionately affects the elderly.

Key Challenge

The short study timelines and complex study requirements were major challenges in conducting this government-funded pediatric study on the H1N1 vaccine. The study start-up and enrollment timeline was compressed to 12 weeks to meet the United States government requirement that all data be available before the 2009 influenza season. Data management was complicated by the need for four clean interim database locks scheduled every one to two weeks starting 8 days after last subject in.

How Were These Challenges Met?

Early Involvement

Given the need to make study data available quickly, the Public Health and Government Services Group at Quintiles was engaged early to assist with the specific requirements for government-funded studies and to facilitate development of contracting language and clinical trial agreements. Quintiles worked with the customer's legal team to develop and incorporate Federal Acquisition Regulations (FAR) flow-down language into investigator and vendor contracts and clinical trial agreements as appropriate.

To address the challenges in study startup and enrollment, Quintiles mobilized its network of experienced Partner Sites, which accounted for 14 of 16 sites that participated in the study, and used a central institutional review board (IRB).

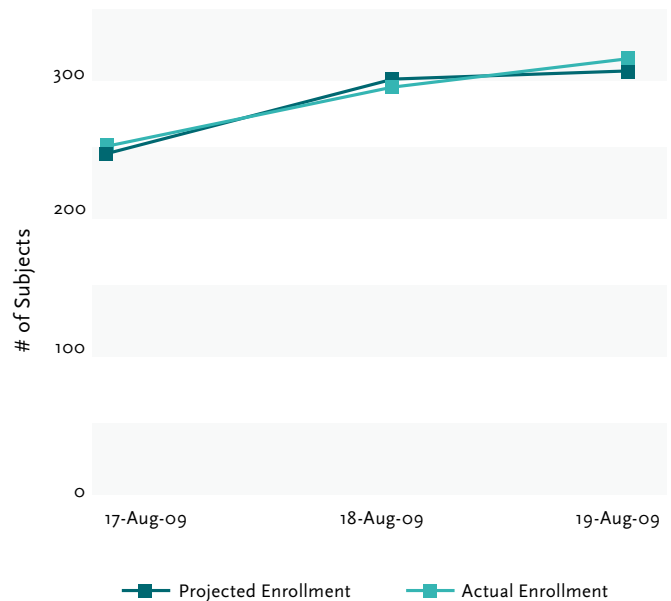
Enlisting Partners

To address the challenges in study startup and enrollment, Quintiles mobilized its network of experienced Partner Sites, which accounted for 14 of 16 sites that participated in the study, and used a central institutional review board (IRB). During the intense data monitoring period, Quintiles assigned dedicated lead clinical research associates (CRAs) and utilized a flexible pool of co-monitors to assist with the rigorous visit schedule. Furthermore, additional clinical and data management personnel were mobilized to perform daily data report reviews and to follow up with the team as necessary to ensure prompt resolution of issues and queries.

Outcome

All key study milestones have been met or exceeded to date. With the facilitation of Quintiles Public Health and Government Services Group, the contracting language was finalized and the clinical trial agreements were completed within three weeks. Through the mobilization of Quintiles Partner Sites, enrollment was completed in three days. The target dates for all four interim database locks were met. As a result, the interim data reviews provided useful information about the vaccine in pediatric subjects in time for use of the H1N1 vaccine during the 2009 influenza season.

Projected vs Actual Enrollment



Contact Us:

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