

## CASE STUDY

# Promoting Prevention

## Quintiles Wraps 4-Week Off-Season Recruitment in 4 Days

### Study Description

A randomized, double-blind, active-controlled Phase II study to evaluate the immunogenicity of a seasonal influenza vaccine in healthy adults enrolled off-season

### Study Objectives

To compare the immunogenicity of an investigational influenza vaccine with that of two commercially available formulations

### Study Compound

An investigational seasonal influenza vaccine

### Patient Population

Healthy adults, 18-49 years old

### Treatment Period

Single vaccination with 180 days of follow-up

### Primary Efficacy Parameter

Strain-specific serum antibody levels (geometric mean titers) 28 days post-vaccination

### Participating Country

United States

### Study Specifics

- > Number of active sites: 18
- > Patients recruited: 1800
- > Recruitment period: 4 days

### Quintiles Services

Site Startup, Project Management, Clinical Operations, Clinical Monitoring

### Disease Overview

Influenza viruses are omnipresent in the population during influenza season. Each year, up to 1 in 5 individuals are infected with influenza viruses, which cause an estimated 36,000 deaths and 200,000 hospitalizations each year in the United States. According to the Infectious Diseases Society of America, vaccination is the best method for preventing influenza.

### Key Challenge

In this study, subjects were recruited off-season and did not expect a benefit from the vaccine, which did not include the 2009 influenza strains. These factors were expected, based on previous experience, to slow recruitment efforts substantially. In this context, the study startup timelines and the relatively large number of subjects (1800) targeted for recruitment posed key challenges.

The study start date was to occur three months following Quintiles' first meeting with the customer, and four weeks were allotted for recruitment.

### How Were These Challenges Met?

#### Extensive Experience

To meet the challenges, Quintiles mobilized a group of individuals with extensive experience in planning and conducting vaccine clinical trials and dedicated this team solely to the study. This team met frequently and communicated continuously with the customer to ensure that study startup and recruitment initiatives were on target.

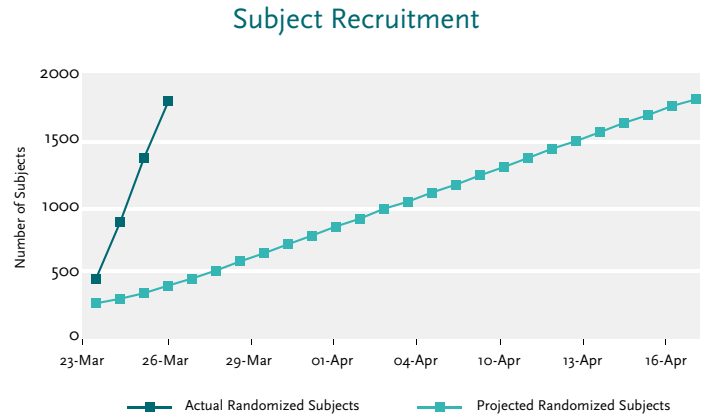
#### Proven Partners

Quintiles tapped its network of Partner Sites with proven track records in managing vaccine trials to address the challenges in subject recruitment. Sites were targeted based on Quintiles' previous experience with them in running vaccine trials. Eighteen (18) sites nationwide — 83% of them Quintiles Partner Sites — were identified as being capable of recruiting subjects quickly while maintaining excellent quality control with respect to subject care and study conduct.

Through the mobilization of Quintiles Partner Sites, enrollment was completed in only four days — a fraction of the four weeks that had originally been allotted by the biopharma sponsor. This achievement is outstanding in the context of an influenza vaccine trial run off-season.

### Outcome

Because of the efforts of Quintiles' expert vaccine trial team, study startup and enrollment activities were completed rapidly and efficiently. Through the mobilization of Quintiles Partner Sites, enrollment was completed in only four days — a fraction of the four weeks that had originally been allotted by the biopharma sponsor (Figure). This achievement is outstanding in the context of an influenza vaccine trial run off-season.



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