Nasal Influenza Vaccine

CASE STUDY

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Study Description
Randomized, multicenter, double-blind, Phase III trial of an intranasal trivalent influenza vaccine

Study Objective
To assess the efficacy and safety of 1 dose versus 2 doses of an intranasal trivalent influenza vaccine in healthy children

Study Compound
Live attenuated influenza vaccine

Patient Population
Children 6 to 36 months of age

Treatment Period
2 years (2 influenza seasons)

Primary Efficacy Parameter
The first episode in the first season in a study child of a culture-confirmed influenzal illness caused by community-acquired subtypes antigenically similar to those in the vaccine

Participating Countries
3 - Argentina, Brazil, South Africa

Study Specifics
- Number of active sites: 35
- Patients recruited: 3200
- Recruitment period: 3 weeks
- Recruitment date: April 2001

Quintiles Services
Clinical Monitoring, Project Management, Data Management, Regulatory

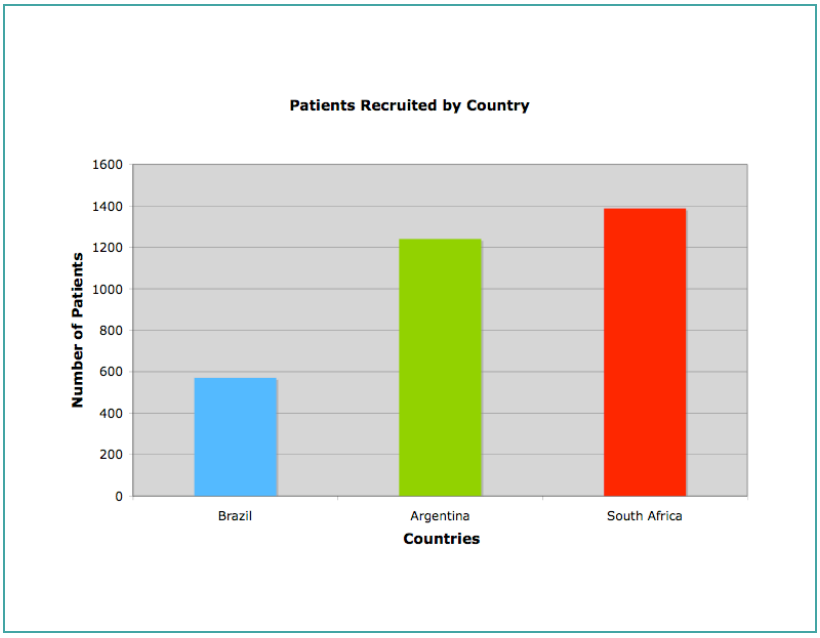
Key Challenges
This study posed multiple challenges with respect to enrolling patients. First, it involved a large number of infants and young children—a target population that can be difficult to recruit and enroll quickly. Second, the enrollment period for this study was restricted to the few weeks just before the start of the autumn/winter influenza season, which spans May to September in the southern hemisphere. Failure to enroll sufficiently during this period would have meant delaying the study by a year.

Enrollment was further complicated by requests from the local health authorities in Brazil and Argentina that the study adhere to national vaccination calendars that were sometimes inconsistent with study protocol requirements. By the time these local health authorities approved the protocol, only 14 days of enrollment time remained in South America.

How Were These Challenges Met?
Quintiles pre-screened study sites in order to ensure that sufficient numbers of patients meeting eligibility criteria were available to meet enrollment requirements. In fact, a contingency plan was implemented because of the anticipated challenges for enrollment. The number of CRAs dedicated to the program was doubled in order to cover the upsurge in monitoring inspections that coincided with approval of the protocol in Brazil and Argentina. This strategy proved to be necessary and useful as some sites enrolled as many as 500 patients.

Quintiles' experts used their knowledge of the local regulatory environment to facilitate resolution of challenges arising from the regulatory requirement to adhere to national vaccination calendars in South America. To ensure local regulatory authorities' comfort with the protocol, Quintiles supplied them with national vaccination calendars, signed and dated by the investigators confirming site compliance with regulatory requirements.

Outcome
Enrollment targets were met in an extremely tight timeframe and in compliance with local regulatory requirements. In 3 weeks, 3200 patients were recruited—1812 of them over a period of 14 days in South America.



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