

CASE STUDY

New Frontiers

Searching for the Highest Efficacy at the Lowest Dose

Study Description

A multicenter, randomized, double-blind, comparator and vehicle controlled Phase III study in subjects with acne vulgaris

Study Objective

To assess the safety and efficacy of Duac low-dose gel versus clindamycin gel versus benzoyl peroxide gel versus vehicle gel

Study Compound

Duac low dose gel

Patient Population

Subjects age 12-45 with acne vulgaris

Treatment Period

12 weeks

Efficacy Parameter

Decreased total lesion count from baseline

Participating Countries

Belize, Canada, United States

Study Specifics

- > Number of active sites: 24
- > Patients recruited: 1320
- > Enrollment period: 11 months

Quintiles Services

Project Management, Clinical Monitoring, Site Startup, Regulatory

Acne vulgaris: an all too common condition

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous unit, characterized by papules, pustules, nodules, cysts, and scars, most often on the face, chest and back. The most common dermatological disorder, acne vulgaris affects nearly 85 percent of people over the course of their lives, generally between the ages of 12 and 24, though it can persist for many years.

Covering new ground

Using Belize as a site for clinical trials is a new, and relatively rare, phenomenon within the industry. As this was its first foray into Belize, Quintiles staff members had essentially no knowledge of the country's regulatory environment.

Further, Quintiles was a new partner for the sponsor. Assuming that Quintiles was too large to efficiently and cost effectively handle the trial, the sponsor nearly did not include the company in its vendor consideration set.

The final significant challenge had to do with the trial timelines. A high-dose version of the product, from a manufacturer of generics, was imminent and the sponsor was eager to submit an NDA for its low-dose proprietary product as soon as possible.

The key was flexibility

By utilizing a deliberately flexible monitoring schedule, Quintiles was able to accommodate fluxes in enrollment and substantial variations in enrollment from site to site. The monitoring process itself, however, was performed very carefully and conscientiously, to enable batch enrollment in Belize and to avoid costly over-enrollment figures.

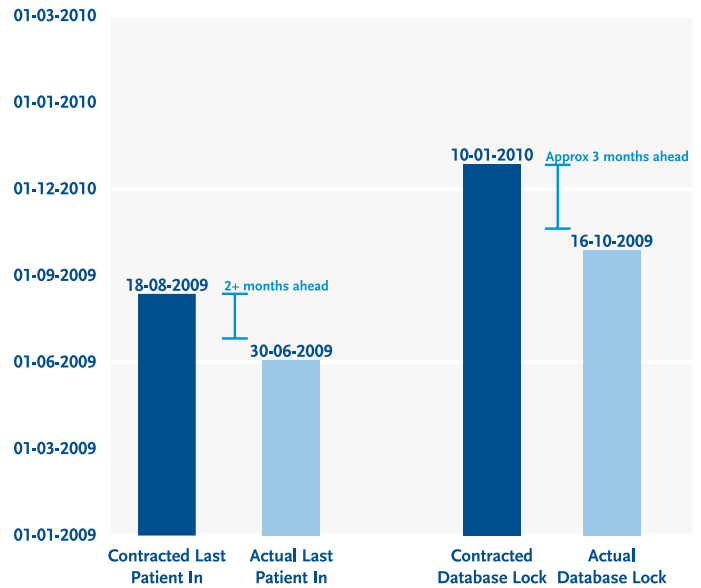
The Quintiles study group also maintained close communication with the company's regulatory and quality assurance experts, as well as with the sponsor, to ensure a smooth and successful trial.

Perhaps most important, the study sponsor's initial reservations about Quintiles were quickly dispelled. The acne vulgaris study, though not huge, got the attention it deserved.

Exceeding expectations

Enrollment for the acne vulgaris study was completed 49 days ahead of schedule and the number of patients enrolled met the recruitment target exactly – no money was spent recruiting individuals who were ultimately not needed for the trial. In addition, batch enrollment in Belize was accomplished in two weeks.

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