Case Study:

CHRONIC LOWER BACK PAIN

Though lower back pain is a relatively common medical disorder, enrolling subjects for a study proved to be challenging after several inclusion/exclusion criteria in the original protocol potentially threatened to hinder successful recruitment activities. By clarifying and communicating expectations, TKL Research was able to help the study complete enrollment more than two weeks early.

STUDY OVERVIEW

TKL Research was asked to manage a study to determine the safety and efficacy of a topical patch following daily administration for two weeks in patients with chronic lower back pain. The study also involved assessing the perception of study medication effectiveness and skin irritation where patches were applied.

Scope
- U.S.
- Nine sites
- Three-week screening period (included in 16-week enrollment), two-week treatment period

Type
- Phase 2, double-blind, placebo-controlled, randomized, parallel-group study

Population
- Phase 2a: 145 subjects with chronic lower back pain
- Lower back pain (lower than the twelfth thoracic vertebra) for more than three months before screening
- All patients age ≥18 to ≤80
CHALLENGES
Because lower back pain is so prevalent, the study was not expected to be difficult to enroll. However, before participating in the trial, subjects were required to discontinue the use of all of their own medications for pain — something that some potential subjects were unwilling to do.

Other inclusion/exclusion criteria included:
- Subject may not have any specific pathology for the back pain
- Subject may not have had surgery for lower back pain in the last six months
- Lower back pain could not be related to a motor vehicle accident
- Lower back pain could not radiate to below the knee

Some potential subjects also contended with depression, possibly due to pain, and were excluded for that reason. Other subjects had to be disqualified from the study after they came off their existing medication(s) because their pain did not increase sufficiently. The trial also necessitated rapid startup: The final protocol was dated March 12, 2015, and first patient, first visit occurred on April 22, 2015.

Altogether, the seemingly untroublesome recruitment schedule posed unexpected challenges.

SOLUTIONS AND OUTCOMES
The need for a protocol amendment was brought to the sponsor’s attention as soon as it became clear that some of the inclusion/exclusion criteria were unnecessarily affecting enrollment because the exclusion was too stringent.

The original target date was set for August 7, 2015. While enrollment efforts proved to be effective at the onset, actual enrollment fell behind projected numbers just over halfway through the original recruitment schedule. After amending the protocol and working with sites to intensify recruitment activities, 275 patients were screened and 145 were randomized. Last patient occurred 17 days before the original target date. Overall, the enrollment period ended up being just less than 14 weeks.
KEYS TO SUCCESS

Interaction With Sites
To reinforce recruitment efforts, TKL stayed in constant contact with sites and clarified expectations necessary to full enrollment.
• Sites were expected to continue the push to enroll subjects on their own
• Site teleconferences were held to discuss enrollment challenges and share suggested strategies
• Site relationships had been developed and may have been useful in pushing sites to enroll; sites were receptive to suggestions to fulfill enrollment targets

Interaction With Sponsors
TKL coordinated weekly meetings with core sponsor management teams. In these meetings, both parties focused on enrollment metrics and addressed specific issues particular sites were having with enrollment. This realistic look at the issues established honest, ongoing communication with the sponsor on what needed to be amended in the protocol to enhance enrollment without jeopardizing the integrity of the study.

Review of Site-Requested Advertising
TKL maintained oversight of recruitment advertising activities and provided recommendations throughout promotional campaigns to better allocate advertising spend. Internally, TKL performs a number of analyses to optimize ongoing recruitment. These analyses are reviewed by TKL’s management team and shared with the sponsor when requested or when important to fulfilling enrollment numbers.
• Report on data trends to monitoring/management team
• Query responses/resolutions to ensure appropriate corrections
• Time between subject visit and data entry
• Number of outstanding queries
• Query aging
• Queries per page
• Common pages/modules being queried
• Common issues being reported to help desk
About TKL
TKL Research is an international clinical research organization (CRO) serving pharmaceutical, biotechnology, generic drug, OTC/consumer health care and medical device companies. We offer comprehensive services for Phase 1–4 clinical trials in a wide range of therapeutic areas.

CRO Headquarters
North America
365 W. Passaic St., Suite 550
Rochelle Park, NJ 07662

Europe
Wienburgstr 207
D-48155 Münster, Germany