Postgraduate Medicine - April 2023

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TKL Research

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Accelerated Enrollment

Recruitment Management Plan Reduces Recruitment Timeline by 35% in Onychomycosis Study

Study Design
Phase 2, multicenter, double-blind, randomized, parallel-group, dose-response, vehicle-controlled, 5-arm study for distal subungual onychomycosis (DSO) of the toenail.

Study Drug
Topical emulsion formulation

Study Population
Adults, 18 to 65 years old, with clinically diagnosed mild-to-moderate DSO involving 25 to 67 percent of at least one of the great toenails.

Study Parameters
Number of subjects randomized: 440-460
Number of sites: 25 in U.S. and Canada
Treatment regimen: Once daily for up to 24 weeks

Study Objectives
To evaluate the efficacy and safety of three different dosing regimens in the treatment of DSO.

Background
Onychomycosis (tinea unguium) is a fungal infection of the nail bed, matrix or plate, and may account for one-third of fungal infections and half of all nail disease. Tight, unventilated footwear, crowded locker rooms and the distribution of different strains of fungus worldwide have contributed to the increased incidence of onychomycosis.

Sponsor
A leading pharmaceutical company specializing in dermatology approached TKL Research to conduct a large Phase 2 onychomycosis study involving approximately 440 to 460 patients across 25 U.S. and Canadian sites. TKL was selected because of its reputation as a provider of quality clinical trial management services in addition to its proven patient recruitment process with a record of rapid enrollment for specialty treatment populations.

Challenge
Failure of sites to achieve full enrollment on time is a major cause of delays and cost overruns in clinical development programs. Based on the sponsor’s historical data and prior experience with onychomycosis, the sponsor estimated that full enrollment of 460 subjects should take approximately 52 weeks. TKL’s analysis indicated that with a robust Recruitment Management Plan (RMP), enrollment of the minimum number of subjects could be completed in as little as 33 weeks, saving substantial time and money.

Process
To meet the revised enrollment target, TKL’s recruitment management team developed a comprehensive recruitment strategy to yield the maximum number of randomized patients at each site with the least amount of waste.

A robust U.S.-Canadian marketing campaign was launched, aimed to reach the study’s target population: adults, especially men between 45 and 54 years old. This campaign included news and talk radio advertising to reach males and network/cable daytime television advertising for females. As a result:

- 78 percent of the randomized subjects were male and 22 percent were female
- 83 percent of the total randomized subjects were 40 to 60 years old

Due to the ongoing analysis of the screening, potassium hydroxide (KOH) and culture rates for this study, TKL had greater predictability of the enrollment timeline. These actual metrics were used to re-calculate the necessary remaining number of required subjects needed for screening, KOH/culture phases in order to accurately titrate to the randomization target.

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Solution
TKL’s patient recruitment process provides real-time insights into enrollment metrics, enabling TKL to dynamically adjust patient recruitment advertising plans for each site to maximize effectiveness. Through ongoing analysis of media and randomization performance, TKL maintained an efficient recruitment campaign and provided accurate enrollment forecasting.

Results
TKL met the revised timeline, recruiting 443 randomized subjects in 33 weeks. TKL’s process more than satisfied the sponsor’s expectations. TKL was charged with delivering only 60 percent of the total number of subjects, with the investigative sites responsible for recruiting the other 40 percent. However, TKL exceeded expectations and contributed 83 percent of all subjects while sites contributed only 17 percent. This resulted in a 35 percent reduction in the timeline based on the sponsor’s original goal.

The campaign also exceeded client expectations in a number of other areas, including the number of advertising responses and the cost per response. In addition, less than two-thirds of the allocated advertising budget was actually used.

Conclusion
TKL’s patient recruitment method of concentrated, targeted marketing with ongoing analysis and adjustment based on media and randomization performance can significantly reduce the recruitment timeline and overall study costs.