

RECRUITMENT MANAGEMENT PLAN REDUCES TIMELINE BY 35%

Patient recruitment in onychomycosis study delivers accelerated enrollment

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.¹ Tight, unventilated footwear, crowded locker rooms and the distribution of different strains of fungus worldwide have contributed to the increased incidence of onychomycosis.²

SPONSOR

A leading pharmaceutical company specializing in dermatology approached IQVIA™ Biotech to conduct a large Phase II onychomycosis study involving approximately 440 to 460 patients across 25 U.S. and Canadian sites. IQVIA Biotech's dermatology team 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. IQVIA Biotech'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.

1. Scher RK, Coppa LM. Advances in the diagnosis and treatment of onychomycosis. *Hosp Med.* 1998;34:11-20.

2. Elewski BE. Onychomycosis: pathogenesis, diagnosis, and management. *Clin Microbiol Rev.* 1998;11:415-29.

PROCESS

To meet the revised enrollment target, IQVIA Biotech'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, IQVIA Biotech 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.

SOLUTION

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

RESULTS

IQVIA Biotech met the revised timeline, recruiting 443 randomized subjects in 33 weeks. IQVIA Biotech's process more than satisfied the sponsor's expectations. IQVIA Biotech 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, IQVIA Biotech 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 customer 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

IQVIA Biotech'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.

STUDY DESIGN

Phase II, 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

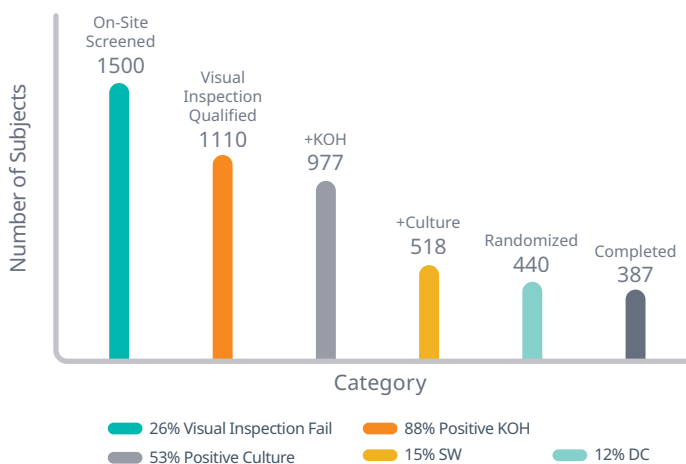
Treatment regimen: Once daily for up to 24 weeks

STUDY OBJECTIVES

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

Multicenter Phase II Onychomycosis Enrollment Metrics

Total Subjects – 400 Randomized Subjects



Multicenter Onychomycosis Study

Projected vs. Actual Enrollment

