ENROLLMENT OF 700 PATIENTS COMPLETED AHEAD OF SCHEDULE

Strategic patient recruitment process reduced enrollment timelines for two Phase II psoriasis studies

SPONSOR

A leading global pharmaceutical company with a focus on dermatology selected IQVIA™ Biotech to conduct two large, Phase II psoriasis studies involving a combined 700 patients at 40 sites. IQVIA Biotech's dermatology team was selected because of its reputation as a provider of quality clinical trial management services and its outstanding patient recruitment enrollment record that could save the sponsor valuable time and budget.

CHALLENGE

Failure of sites to enroll on time is a major reason for delays in clinical development programs. IQVIA Biotech was challenged to achieve the sponsor's goal of randomizing 300 scalp/body psoriasis and 400 body-only psoriasis patients in an 18-week period, from early May through the end of August, a difficult time of year for enrollment of this condition.

SOLUTION

To help ensure the enrollment goal was met, IQVIA Biotech developed an "overlap" recruitment strategy, which would efficiently yield the maximum number of patients randomized at each site with the least amount of waste. This included:

- Individual sites became "overlap" sites, participating in both studies and thus randomizing both scalp/body and body-only patients
- The recruitment campaign was designed to attract both scalp/body and body-only patients, with the strategy of enrolling patients into the more difficult scalp/body study first

Based on experience and because the warming weather could have potentially depleted the availability of the study population, IQVIA Biotech recommended an advertising campaign that was robust and heavily frontloaded from May through June to attract as many patients into the studies as quickly as possible.

IQVIA Biotech's patient recruitment process includes predictive enrollment, which offers valuable insights into managing, tracking, and reviewing enrollment metrics. Through regular analysis, IQVIA Biotech was able to efficiently adjust patient recruitment advertising plans as needed for each site. The results exceeded customer expectations.

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STUDY DESIGN

Scalp/body study: Phase II, multicenter, randomized, double-blind, three-arm, parallel group body-only study: Phase II, multicenter, randomized, investigator blinded, four-arm, parallel group

STUDY DRUG

Both studies: once daily, topical formulation for psoriasis vulgaris

STUDY POPULATION

Healthy adults, with clinically confirmed psoriasis vulgaris on scalp/body or body-only

STUDY PARAMETERS

Subjects randomized:

- Scalp/body study: 300
- Body-only study: 400

Sites:

- Scalp/body study: 33
- Body-only study: 40

Treatment regimen:

- Both studies: once daily, up to four weeks

INCLUSION CRITERIA

Scalp/body study: Psoriasis vulgaris on 2%+ trunk and/or limbs (excluding psoriasis on the genitals and skin folds); 10%+ scalp; and a total psoriatic involvement not exceeding 30% body surface area (BSA)
Body-only study: Psoriasis vulgaris on trunk and/or limbs (excluding psoriasis on the genitals and skin folds) involving 2-30% of the BSA

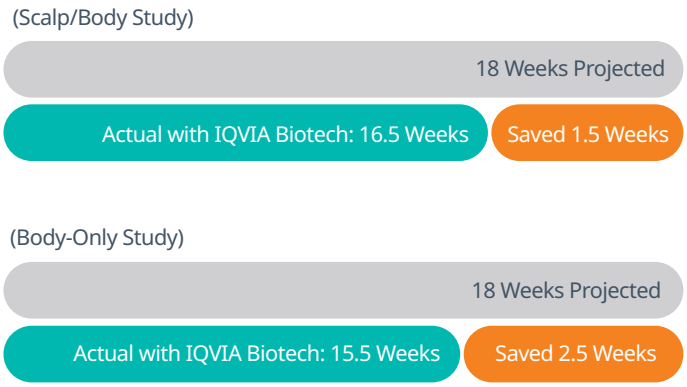
STUDY OBJECTIVES

To determine the safety and efficacy of a once-daily topical treatment for scalp/body or body-only psoriasis vulgaris in adults

RESULTS

Randomization of the scalp/body study was completed in 16.5 weeks and randomization of the body-only study was completed in 15.5 weeks, both ahead of the originally planned 18-week timeline. IQVIA Biotech's efficient management ensured the most effective use of the advertising campaign budget with daily monitoring of the advertising responses and screening productivity of each site.

Weeks to Randomization: Actual vs Projected



Having spent just over 50% of the advertising budget, IQVIA Biotech achieved enrollment targets in less time than expected.

CONCLUSION

IQVIA Biotech's patient recruitment process and predictive enrollment expertise can act as insurance by dramatically improving enrollment.

IQVIA™ BIOTECH

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