ENROLLMENT TIMELINE REDUCED BY 43%

Unique predictive enrollment model reduced projected enrollment period from 52 to 30 weeks

SPONSOR

A leading pharmaceutical company with a focus on men and women's health selected IQVIA™ Biotech's dermatology team to provide patient recruitment services for a Phase III external genital warts study. The sponsor selected IQVIA Biotech because of its reputation as a provider of patient recruitment strategies that drive enrollment and accelerate timelines. With its proven patient recruitment process and a record of successfully enrolled clinical studies, IQVIA Biotech was poised to save the sponsor time and budget.

CHALLENGE

- Enroll 900 young adults, ages 18-30, a study population more transient, less reliable, and less responsive to clinical trial advertising, and thus difficult to recruit for clinical trials
- Ensure even distribution of males and females

SOLUTION

This patient recruitment process utilizes IQVIA Biotech's unique predictive enrollment model, which is based on a clear understanding of the disease condition and identifying the most appropriate target demographic. IQVIA Biotech's model uses a performance-based approach that analyzes and "cascades" the steps from initial response to advertising through the various "loss points" all the way to randomization. Loss points include telephone, medical and exclusion-criteria screening, and pre-randomization dropouts. This gives IQVIA Biotech the ability to identify the enrollment dynamics for each site as well as for the study as a whole.

An essential part of IQVIA Biotech's process included contemporary messages that were tailored specifically to each of the study's demographic target audiences: one strategy for males and a different strategy for females, ages 18-30. IQVIA Biotech then designed spot market patient recruitment advertisements that not only met the needs of each of the investigative sites, but also included a specific media strategy designed to recruit young adult males and a different strategy for young adult females. Daily tracking and analysis of the media schedule as well as screening and enrollment metrics, enabled IQVIA Biotech to optimize site-specific recruitment plans on a real-time, as-needed basis.

RESULTS

IQVIA Biotech designed a patient recruitment program that reduced the sponsor's projected enrollment period from 52 weeks to only 30 weeks:

- Full enrollment of 900 randomized young adult patients
- 22 weeks ahead of the sponsor's projected timeline
- 43% reduction in the sponsor's original projected timeline
- Achieved a nearly even ratio of males to females, 46% to 54%

STUDY DESIGN
Phase III, multicenter, randomized, double-blind, placebo-controlled, concurrent, two-arm study

STUDY DRUG
Once daily, topical formulation for treatment of external genital warts

STUDY POPULATION
Healthy adults, ages 18+ with clinically confirmed external genital warts

STUDY PARAMETERS
- **Patients randomized:** 900, 50% male, 50% female
- **Sites:** 85
- **Disease profile:** external genital or perianal warts with at least two and no more than 30 warts
- **Treatment regimen:** once daily, up to 16 weeks

STUDY OBJECTIVES
To determine the safety and efficacy of a once daily topical treatment for external genital warts in a young adult population

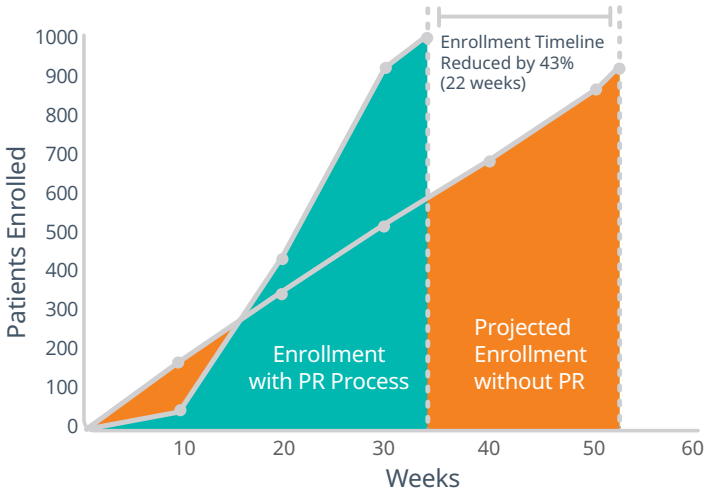
The actual per-response advertising cost was lower than anticipated. Therefore, the advertising campaign was highly cost-effective, reached the right "eligible" subjects and motivated them to go to the study sites. The bottom line was that fewer subjects and advertising responses were required, enabling IQVIA Biotech and the sponsor to keep the overall media investment below projection.

IQVIA Biotech's efficient patient recruitment management process helped ensure the most effective use of the advertising campaign budget and resulted in significant reductions in study timelines.

CONCLUSION

IQVIA Biotech's intelligent use of advertising accelerated the patient recruitment process and provided a dramatic reduction in the enrollment timeline.

Patients Enrolled Through Patient Recruitment (PR) Process, Actual vs Projected



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