STRATEGY SHIFT SPEEDS ENROLLMENT RATE AND TIMELINE

IQVIA™ Biotech increased the enrollment rate and beat projected timelines by five weeks

STUDY OVERVIEW

IQVIA Biotech was asked to manage a Phase II efficacy and safety study on common warts (verruca vulgaris). The multicenter trial required skin assessments and measurements of the warts to determine efficacy and a swab of the skin cells to determine the type of virus.

CHALLENGES

A 12-week study startup goal had been established by the sponsor, so sites were activated on a rolling basis to meet the First Patient In (FPI) milestone.

SOLUTIONS AND OUTCOMES

Working closely with the site teams and principal investigators, IQVIA Biotech adopted an aggressive strategy to increase the rate of enrollment. All healthy patients presenting with the correct criteria were given the opportunity to participate in the trial, and while all received an active drug mixture, one arm utilized the investigational product (also an active drug) as the additive, while the other arm received a placebo in combination. Giving both arms an active drug significantly helped in recruiting eligible subjects.

The enrollment period, which had been scheduled for 13 weeks, was completed in seven and a half weeks; the enrollment rate, which had been planned for 3.8 subjects/week, was actually 6.9 subjects/week. Sixty-one subjects were screened to complete randomization. The screen fail rate, which was estimated at 25 percent, performed better than planned at 15 percent.

To maintain consistent training and communication across sites, webinars were scheduled for investigators; for any investigators who were unable to attend the webinar, the project manager performed protocol training on a one-to-one basis.

SCOPE

- U.S.
- 12 sites
- 13-week enrollment period; 13-week treatment period

TYPE

Multicenter, randomized, double-blind, parallel-group, active-controlled

POPULATION

- Patients displaying at least one wart, ≥1mm in diameter
- Included only back of hands, palms of hands and tops of feet, including tops of toes
- Adults between 18 and 50 years old

> *"I am extremely pleased with [your project manager's] performance on the study. I find her to not only be professional, proactive and detail-oriented, but she is a pleasure to work with. It is this reason that I have recently requested that we reach out to IQVIA Biotech for additional proposals."*
>
> *— Director, Clinical Operations*

KEY ELEMENTS OF SUCCESS

EFFICIENT PRE-SCREENING PROCESS

Through consistent and frequent communication with the sites and study staff, the study remained top-of-mind with all the key players. Protocol training was given a top priority, and the project manager followed up with one-to-one training for investigators who failed to attend scheduled training events. Providing all eligible subjects with an active drug helped accelerate enrollment overall. Additionally, because no lab work was required of patients before entering the study, subjects could be randomized the same day they were screened.

CROSS-FUNCTIONAL COMMUNICATION

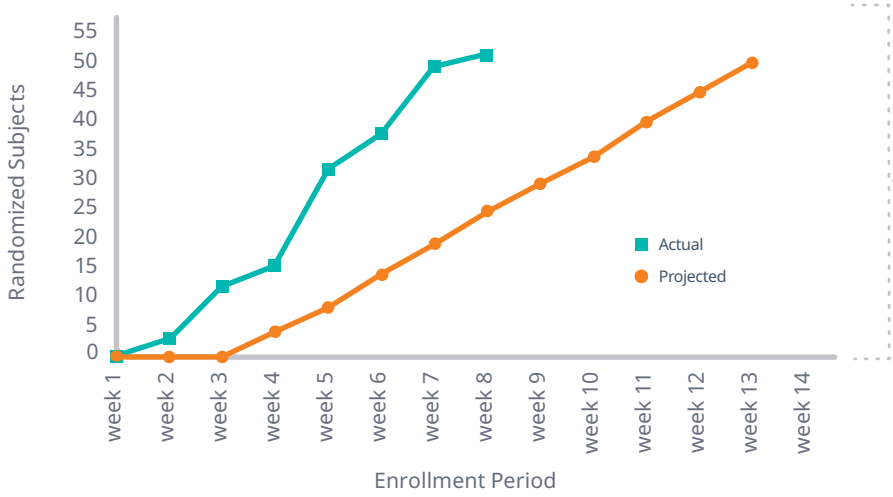
IQVIA Biotech coordinated regular meetings with core sponsor, investigator and external teams to establish close communication and build an environment of team trust and mutual respect. Site teleconferences were held to discuss enrollment challenges and share suggested strategies, and sites were encouraged to continue the push to enroll subjects on their own.

MANAGEMENT FOCUS

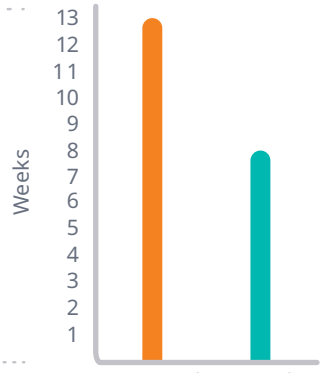
IQVIA Biotech consulted with the core management team on enrollment metrics and planned site activity and coordinated sponsor approval of site-requested advertising.

	PLANNED	ACTUAL
TOTAL # OF RANDOMIZED SUBJECTS NEEDED FOR STUDY	50 total	52 total
STUDY ENROLLMENT RATE	3.8 subjects/ week	6.9 subjects/ week
SCREEN FAIL RATE	25%	15%

Success Metrics: Projected vs. Actual



Enrollment Period



5 weeks fewer than projected

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iqviabiotech.com