TARGETED RECRUITMENT CAMPAIGN FULFILLS ENROLLMENT TARGETS

After a delayed Last Patient In (LPI) date, IQVIA™ Biotech reviewed the tactics and helped devise and execute a campaign that helped sites complete enrollment

STUDY OVERVIEW

The project began with an open label study conducted with six healthy volunteers, followed by a Phase IIa study requiring more than 100 subjects with acne vulgaris. The study assessed the safety, tolerability and preliminary efficacy of a test topical gel in subjects with acne on the face.

CHALLENGES

Although acne vulgaris affects a widespread population, subjects with acne are often difficult to recruit, especially with the enrollment criteria outlined for this study. The widespread availability of over-the-counter therapies curbs many potential subjects from seeking out novel treatment options or participating in studies for new medicines. Acne is also more prevalent in younger subjects (who often already have received or are receiving treatment) than in adult populations. Moreover, acne therapies are increasingly covered by insurance. As a result, the clinical research community is facing a growing scarcity of subjects with acne, and sites are often reluctant to participate in recruitment efforts.

Beyond the challenges the study population posed, the extended enrollment end date ran into a holiday season (offices were closed, staff were on vacation, subjects were less likely to enter a study due to time commitments, and media is often more difficult or expensive to place). The study also necessitated accelerated startup activities – the first patient, first visit occurred just seven weeks following the date of the final protocol.

SOLUTIONS AND OUTCOMES

The original timeline called for Last Patient In (LPI) at 13.5 weeks after the first patient, first visit, and sites were asked to tap their subject databases and place advertisements if necessary. However, as enrollment numbers continued to fall short of necessary projections, the LPI date was pushed back more than two months.

SCOPE

- Canada
- 12 sites
- Four-week screening period, 12-week treatment period, scheduled 12-week enrollment period extended to 23 weeks

TYPE

- Phase I open label study
- Phase IIa randomized, vehicle-controlled; parallel group study

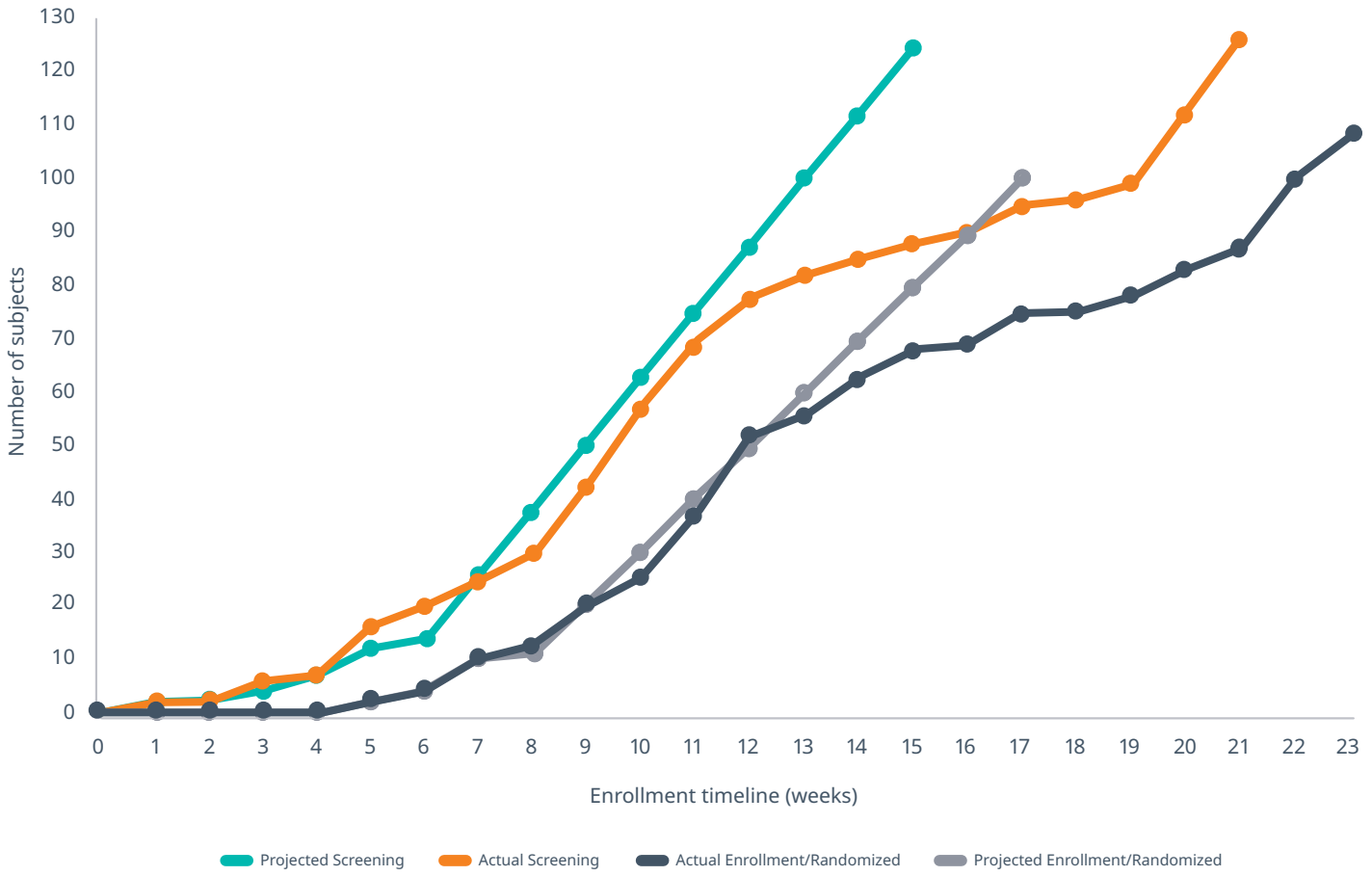
POPULATION

- Phase I: Six healthy volunteers with ≥20 inflammatory lesions
- Phase IIa: 100+ subjects with moderate to severe acne vulgaris with ≥20 inflammatory lesions and ≥20 non-inflammatory lesions, investigator's global assessment score of severity of ≥3
- All subjects age ≥18

Sixteen weeks into the enrollment timeline, IQVIA Biotech was asked to initiate a recruitment program to help the sites complete enrollment objectives by the new LPI date. IQVIA Biotech identified radio as the ideal advertising medium. Radio could be used immediately while Canadian timelines for television advertisement approval were too lengthy. The recruitment campaign launched to support eight of the 12 participating sites, with a budget for one round of advertising. This campaign ran during week 17 for seven sites, and three weeks later for the eighth site. The targeted campaign resulted in ten subjects screened and eight subjects randomized.

IQVIA Biotech initially recommended additional recruitment management practices, though they were declined by the sponsor. Slightly more than half of the subjects were enrolled by the original target date through the sites' own efforts. According to IQVIA Biotech's analysis, had a proactive recruitment program been implemented at the onset of the trial, the initial target date could have been met. Based on the response rates of the actual advertising that was placed, four rounds of media advertising, starting shortly after first patient, first visit, should have fulfilled recruitment targets. Had this occurred, sites may have had sufficient responses to screen and could have randomized all subjects before the initial LPI date.

Acne Vulgaris: Target for Enrollment, Final



KEYS TO SUCCESS

STRONG SITE SELECTION

Strong site selection can make a tremendous difference in the rate of enrollment. Additionally, setting a realistic structure and expectation of enrollment metrics (e.g., number of sites, subjects per site, timespan of enrollment) is a critical step to selecting the right sites. A robust recruitment management strategy developed and executed, in conjunction with the structure and expectations, before study startup can also help build rapid momentum to fulfill enrollment numbers.

CONTINUOUS COMMUNICATION WITH SITES

Although IQVIA Biotech helped bring in the few final subjects needed to complete enrollment, sites were still encouraged to continue the push to enroll subjects on their own. IQVIA Biotech hosted site teleconferences to discuss enrollment challenges and share suggested strategies and adjustments.

SPONSORING WEEKLY MEETINGS

IQVIA Biotech's core management team discussed enrollment metrics and planned site activities. This provided a realistic look at the target enrollment end date, which led to revisions and more realistic expectations of how to reach completion. By requiring the sponsor to review and approve site-requested advertising, the sponsor also realized the value of leveraging each site's media buys.

CONCLUSION

Delays in recruitment affect much more than timelines – the costs can be staggering when the expenses of last-minute advertising, labor and excess administrative duties come into play. Although recruitment delays occurred in this instance, IQVIA Biotech was able to step in to improve communication, create effective media purchasing plans and help sites complete enrollment.

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