PREMIER INSIGHT 270

A Rosacea Trial Failed Many Enrollment Hurdles. We Cleared the Path to Success.

Two large, parallel trials with 107 sites spread across the United States. Heavy competition for patients because of multiple competing treatments already on the market. And an advertising strategy that needed to attract more than 1,400 subjects fast enough to meet the sponsor's aggressive schedule.

Those were just some of the challenges we faced when studying a topical drug to treat rosacea. And as with most complex problems, the strategy required a broad set of solutions and experience-based insights.

The sponsor initially planned to enroll fewer patients, and when it added to that requirement it did not increase its target number of sites. More sites were added later but, by then, recruiting was behind schedule. Based on the original enrollment plans, the sponsor also opted against a central advertising campaign instead relying on the sites' own individual campaigns.

Coming to terms with the deficit, the sponsor implemented our recommended central ad campaign with heavy emphasis on television. While TV is the most expensive medium, it's by far the most effective – and daytime air offered good outreach to our target population at significant value versus prime time.

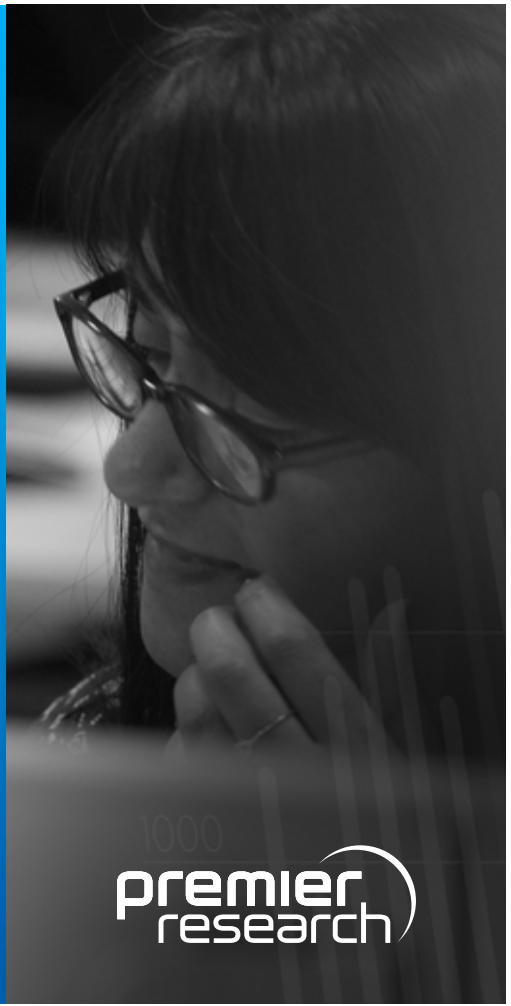
Managing site performance

Our experience underscored a critical truism in clinical drug research: that past performance does not necessarily predict future results. Indeed, one site we added – a high enroller in another recent dermatology trial – fell far short of its targets. While feasibility questionnaires and other traditional tools are useful in predicting how a site will perform, you need to dig deeper to determine whether they can really meet the needs of a particular trial under particular circumstances. Having seen this in other studies, we made prompt adjustments to offset the underperforming site.

We also implemented an incentive system that rewarded sites for prescreening and enrollment performance with bonus payments. And to coordinate monitoring strategy and streamline data cleaning, our senior line managers met with project staffers once or even twice weekly.

The strategy succeeded. The twin studies were both completed and the results are pending review by the FDA.

DERMATOLOGY



107 Sites, 1,400 Patients – The Challenge Was Just Getting Started

Study Description:
Phase III study of a topical treatment for rosacea

Therapeutic Area:
Dermatology

Geographic Scope:
107 sites in the United States

Patient Population:
More than 1,400 patients

Length of Enrollment Period:
Twelve months

Outcome:
Phase III trial completed and results are pending submission to FDA

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