PRECISION for medicine

CASE STUDY

Targeted strategies secure enrollment for a phase 2 trial for eosinophilic esophagitis 2 months ahead of schedule

Study synopsis

Precision for Medicine was asked to manage enrollment for a double-blind, placebo-controlled phase 2 trial. The study sought to enroll 100 adult patients with biopsy-confirmed eosinophilic esophagitis at 40 centers across the United States.

Challenges

Precision faced 3 key hurdles to patient enrollment:

- The initial trial design included both pediatric and adult patients; following FDA feedback, the protocol was redesigned as an adult-only trial. This further limited the potential patient pool of this rare disease trial
- Site feedback identified an enrollment criterion that represented a potentially significant barrier to patient recruitment
- The sponsor requested the anticipated 12-month enrollment time frame to be accelerated in an effort to get topline results earlier

The anticipated 12-month enrollment time frame was accelerated by 2 full months, allowing the sponsor access to topline results ahead of the original schedule.

Solutions

- The study team quickly identified an enrollment criterion impacting enlistment that could be amended without impacting the validity of the study. Within 2 months of FPI, an amendment was drafted and submitted for site rollout. Additionally, the sponsor drafted and authorized protocol waivers, allowing for unnecessarily excluded patients to be enrolled
- The study team developed targeted patient screening campaigns to allow sites to be reimbursed for each patient screened for a 30-day period. This allowed sites to scan their databases for potential patients for enrollment. The first campaign was so successful that 2 additional screening campaigns were conducted during the study enrollment period
- Site feedback indicated that communication and workflow were the main reasons that they focused on recruiting patients for this study. This was evident in study newsletters, CRA team and central pathology communication, as well as study team and medical monitor responsiveness to queries and concerns. Overall, sites reported choosing to screen for this study over others, as our team worked to ensure the study ran smoothly and with minimal site effort

Results

Despite the hurdle of limiting enrollment to adult patients, Precision met the enrollment goals 2 months ahead of schedule. Sites reported that securing enrollment for this trial versus others was attributable to effective communications and the resultant ease of conducting the study.

Precision was able to meet enrollment goals 2 months early.

For more information about our clinical trial solutions, please contact us at info@precisionformedicine.com or visit precisionformedicine.com.

PRECISION for medicine
shift the curve