INCORPORATING THE PATIENT VOICE TO IMPROVE ULCERATIVE COLITIS RECRUITMENT

Case Study

The exact cause of ulcerative colitis (UC) is still unknown, but approximately 700,000 people in the United States suffer from this chronic, life-long disease that causes inflammation in the large intestine. A wide range of treatment options are available, but drug development sponsors are seeking additional ways to control inflammation, achieve remission and address relapses.

While there is an urgent need to continue to study this disease and develop effective treatments, nearly 90% of UC patients have never enrolled in a clinical trial. This creates a shortage of qualified patients for researchers to study, a problem exacerbated by a shortage of qualified and available investigators due to so many competing studies.

Dr. Joan Meyer, Covance Executive Director of Strategy & Planning for Inflammation, Infectious Diseases and General Medicine, recently discussed her team's efforts to better understand patients' opinions about inflammatory bowel disease trials and develop patient-centered clinical strategies to improve study recruitment.

Incorporating the Voice of the Patient

As a potentially debilitating disease, patients with UC need to maintain ongoing communication with their doctors to manage their condition. While patients can be very involved with their medical providers, what is holding them back from joining a clinical trial? Dr. Meyer's team conducted insightful research to understand the patient perspective.

In an online questionnaire that collected data from 320 respondents across the US, UK, Brazil and Mexico, patients with inflammatory bowel disease were asked a range of questions about their willingness to participate in a trial as well as concerns with the process.

"A top concern from the respondents was the potential side effects of a treatment," said Meyer. "This finding stressed that the informed consent process needs to be very clear. Sponsors and CROs should ensure that their clinics are trained to address these valid concerns."

The Covance team also found that patients would be more willing to take part in a study if they knew they had continued, free access to the study drug after the trial concluded. "Based on this observation, it could really help patient retention if sponsors included an open label extension study," said Meyer.

This has the added benefit of contributing to the long-term safety data for the compound.

COVANCE CAN HELP
FIND THE OTHER 90%
OF UC PATIENTS

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Bridging Gaps and Creating Awareness

The survey results also revealed that if patients were to participate in a study, they would appreciate the opportunity to provide feedback about their clinical trial experience. "Some sponsors are nervous about exit interviews because they are worried about potential adverse events or other issues with collecting and handling the data," explained Meyer. "But I believe that with the right techniques, sponsors can gain new insights from patients to bridge current gaps and inform future studies."

Survey respondents also expressed their preference for receiving information from patient advocacy groups. "As we've heard before, it is important for sponsors to create connections with these patient advocacy groups and ensure they share their study's objectives. Working together, we can help create awareness about the study among their members," said Meyer.

Expanding a Competitive Landscape

The other half of the patient recruitment challenge for studying inflammatory bowel diseases like UC involves working within the confines of the overwhelmed study site network. "Many drug development sponsors are currently evaluating compounds, but there is a finite number of UC investigators," explained Meyer. "Some of these investigators are already running four to five studies, decreasing their ability to recruit patients into a new study, or they are only recruiting one or two patients into each study, which means you need more sites, and that gets expensive."

Meyer's team ran an analysis of known UC investigators to determine how many active studies they were supporting and their average number of patients. "Not surprisingly, the investigator's rate of patient accrual per study drops as they take on more studies," she said. "This leads to diminishing return at these in-demand sites."

Within oversaturated sites unavailable to new studies, the Covance team evaluated sites' levels of patient participation to pinpoint hundreds of sites for targeted outreach. The team also included data from its patient survey to see how far patients were willing to travel to a clinical site. By compiling locations of sites and physicians within the desirable ranges of clusters of UC patients, Covance generated valuable lists of untapped clinical sites to target for these studies.

Meyer hopes that these efforts to recruit potential investigators – combined with a better understanding of patients' concerns surrounding clinical trial participation, will ease the pressure that sponsors face in recruitment – and ultimately lead to improved treatment options for UC patients.

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