

Engaging Sites and Patients in the Highly Competitive IBD Landscape

Fostering friendly-competition among sites to improve enrollment

Sponsor Challenges

Due to the size of the trial, and the fierce competition for IBD patients, the sponsor needed a CRO that had the global reach to identify the right sites, and that could keep enrollment on track throughout the duration of the study after the initial excitement from sites died down. Other challenges such as the COVID-19 pandemic introduced a whole new set of challenges, that slowed down enrollment, leading the sponsor to PSI to re-energize the study team and keep enrollment on track.

At a glance

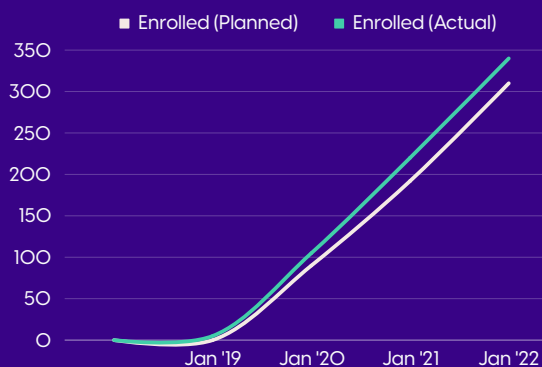
After a large pharmaceutical company delivered enrollment 60 days ahead of schedule for a Phase 2 inflammatory bowel disease (IBD) study with PSI CRO, the sponsor faced a new challenge: one of the largest-ever IBD programs in the same indication. Competition for IBD patients is fierce, and we knew success depended on not only identifying the right sites but also keeping them engaged throughout the duration.

Key Metrics

800
Planned Patients

400
Trial Sites

40
Countries



3 Steps to Empower Your Sites

- ### 1 Create a compelling campaign to motivate sites

PSI divided the study teams to stand for their respective countries and introduced a scoring system modeled after the 2020 Summer Olympics:

 - Gold medal: Awarded for every subject randomization
 - Silver medal: Awarded for every subject screening
 - Bronze medal: Awarded for every subject rescreening

PSI developed creative materials and branding to engage the teams during the campaign, and we made sure that countries of all sizes stayed visible within the competition thanks to an averaged rating system.
- ### 2 Invest time in close relationships with site teams

The team prioritized a unique approach to improve site support processes, working closely with the site staff to prevent and fix any signs of screening and enrollment delays. PSI worked with each investigator to increase the percentage of patients entering the study by providing training and resources so that site teams understood the ideal time to screen potential patients for the study, and to reassess patients who had previously failed screening.

Additionally, the team offered personal protective equipment to patients and site teams, implemented procedures for direct shipment to patients' homes, and identified local labs to minimize patient trips during the pandemic and prioritize patient comfort during travel.
- ### 3 Build on long-standing partnerships

With the same program leadership team in place since 2015, including the same Global PM and Co-Manager from the Phase 2 Study, the PSI teams drew on their experience from previous studies for the sponsor throughout the program. PSI Country Managers and Clinical Operations colleagues also helped the project teams come together to meet a common goal: meet or beat patient enrollment while building patient and site relationships.