Gastroenterology

Expertise in IBD clinical trial delivery

Partnering to deliver IBD study success

The clinical trial environment is very competitive with new inflammatory bowel disease (IBD) products in development and many trials already running or currently being set up. This surge in clinical trial work creates challenges with site saturation and recruitment because of the decreasing availability of sites and existing IBD patients. In addition, evolving regulatory expectations, increasing endpoint complexity and the growth of precision targeted therapies require both scientific leadership and operational excellence. In the last few years recent drug approvals for new advanced therapies addressing specific targets have also provided an expansion of clinical treatment options for IBD patients. Also, there is an increase in IBD trials using combinations of therapies to explore improved therapeutic efficacy of treatments for patients.

The PPD™ clinical research business of Thermo Fisher Scientific has experienced ulcerative colitis (UC) and Crohn's disease (CD) trial teams who understand how to help overcome these patient recruitment challenges. We combine deep therapeutic expertise, regulatory insight and advanced analytics to support programs from early development through post-marketing and real-world evidence generation. We can identify and engage the right sites from our extensive global databases and utilize our established working relationships with the best sites across many countries to deliver your study. In addition, we incorporate a digital/AI approach in our recruitment plans for speed and maximum outreach to patients.

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IBD Phase I-IV studies in the past 5 years recruiting **8,000+ patients**

5,500
IBD global sites in our global database with associated metrics

1,465
IBD-experienced operations staff, including in-house gastroenterologists, clinical and project leads, oversight directors and CRAs

Leader in digital solutions aiding patient centricity and flexibility in trial conduct

Experience in site identification, engagement and performance

- Our established relationship with many sites provides a detailed understanding of their capabilities and ability to recruit patients
- Our sites have extensive referral networks to maximize recruitment
- Rapid start-up through defined point of contacts and streamlined processes
- Our IBD patient enrollment rate outperforms the industry average
- Advanced feasibility analytics and predictive enrollment modeling to mitigate recruitment risk
- Expertise in complex IBD endpoints including endoscopic, histologic and composite outcome measures
- Offer a range of decentralized, digital and AI solutions to make trial participation easier and more inclusive for IBD patients, enhancing patient recruitment and retention
- Strong experience with central endoscopy services ensuring efficiencies and timeliness of readout data
- Excellence in study management and vendors ensuring study efficiencies
- Integration of biomarkers, translational science and precision medicine
- Support for innovative and adaptive trial designs

Deep expertise in ulcerative colitis and Crohn's disease across early development, clinical development, global regulatory submission, post-marketing and real-world evidence programs.

Navigating IBD enrollment

Customized approach: experienced with BioPharma and BioTech

Surpassed industry average recruitment times in last 3 years

Expanding site footprint in the APAC region

Patient centric approach to support inclusion, diversity and enrollment

Learn more at **ppd.com**

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