

GASTROINTESTINAL EXPERTISE (IBS, OIC, GERD, IBD)



There are three main forms of **irritable bowel syndrome (IBS)** – IBS with diarrhea (IBS-D), IBS with constipation (IBS-C), and IBS with both diarrhea and constipation (IBS-mixed). As much as 15% of the U.S. adult population has symptoms of IBS.

Opioid-induced constipation (OIC) is a common side effect that affects 41% of patients taking opioid medication for pain. In the GI tract, opioids slow the process of digestion by increasing intestinal contractions that fail to move stools along the system, while decreasing those that do so.

Gastroesophageal reflux disease (GERD) is a chronic reflux of acid into the esophagus. GERD has a high prevalence in Western countries, where approximately 10-20% of the adult population suffers at least weekly from the cardinal GERD symptoms: heartburn and regurgitation.

Inflammatory bowel diseases (IBD) is a category that encompasses any conditions occurring in the colon or small intestine. There are two main types: ulcerative colitis (UC) and Crohn’s disease. An estimated 1.7 million Americans are affected. UC and Crohn’s are distinguished by the parts of the digestive track they affect.

AES EXPERIENCE

Therapeutic area: **Gastrointestinal**

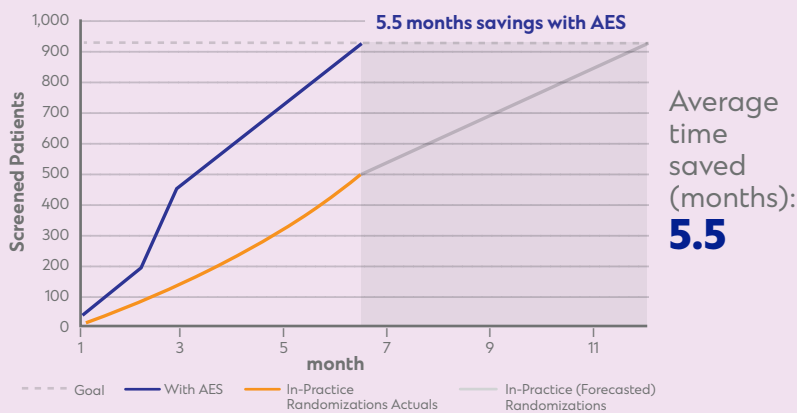
Number of protocols: **352**

Number of potential patients in database: **21.7 million**

Number of sites supported: **3,006**

Number of patients randomized: **11,218**

Average number of recruitment months: **7**



INSIGHTS

In AES patient surveys, people repeatedly say that being seen by a specialist in their disease (e.g., for an upper endoscopy) is a motivating factor to join a clinical trial.

Many people aren’t aware they have IBS. Even if patients have sufficient symptoms to meet diagnostic criteria, they may not have discussed it with their doctors or even be aware that their symptoms are severe enough to constitute a diagnosable condition. Often, these patients may just treat symptoms with over-the-counter medications.

OIC trials are difficult to recruit for because OIC symptoms may come and go, causing patients to lose interest in trial participation; and patients may opt to stop taking their prescription rather than enrolling in a trial. Additionally, OIC patients are dealing with chronic pain and other conditions that may make it difficult for them to keep up with their study visit schedule.

Patients suffering from UC, Crohn’s, and IBS can also have inconsistent or intermittent symptoms and may not think much about their condition between flares.