



# Capabilities in Gastroenterology Studies

Health Decisions has extensive experience in GI clinical trials. We understand the needs and concerns of the patient populations, the competitive landscape and the operational challenges of GI studies, including limiting interrater variability in assessment of endoscopy recordings, enrolling placebo-controlled studies and enrolling studies that involve repeated intrusive procedures such as endoscopy. In addition, Health Decisions appreciates the importance of emerging outcome measures such as mucosal healing in addition to traditional measures of clinical remission in Inflammatory Bowel Disease (Crohn's disease and ulcerative colitis).

## Site, Investigator and KOL Relationships

The Health Decisions GI team has strong relationships with sites and investigators, including KOLs, and is proficient in the use of Health Decisions' advanced systems and processes to keep sponsors in control and ensure that studies meet their goals. Health Decisions' study management tools enable our proactive study teams to manage sites effectively, keep enrollment on track and work closely with sites to maximize subject retention.

Health Decisions' database of GI sites includes hundreds of sites in the US, Europe, South America, Australia and New Zealand and we have experience working with 361 GI sites and thousands of GI patients. The database includes 320 US and Canadian sites with GI research experience. Sites include a mix of institutions, including large GI private practices, university/research hospitals, independent clinical research centers and VA hospitals.

## Data-Driven Insight and Expertise

Whether advising on overall development strategy, program planning and study design, or planning individual trials and ensuring optimal trial management and execution, Health Decisions' senior professionals use their extensive development expertise, experience, and advanced data-driven analytics to provide insights that improve planning and execution of every Health Decisions study. Health Decisions' systems and processes provide streaming data and role-specific information that enable earlier, better decisions at all levels of trial management and execution throughout the life-cycle of each study.

## Health Decisions' GI Experience:

Health Decisions' GI experience includes studies in the following indications:

- Ulcerative colitis
- Crohn's disease
- Gastro-Esophageal Reflux Disease (GERD)
- Irritable Bowel Syndrome
- Stomach and duodenal ulcer
- Gastritis
- Gastroparesis
- Diarrhea
- Chronic idiopathic constipation
- Diverticulitis

## Case Study 1: Ulcerative Colitis Clinical Trial

### *Phase 2 Study of Monoclonal Antibody X for Induction of Remission in Patients with Moderate to Severe Ulcerative Colitis*

**Phase:** 2

**Active Sites:** 47 (North America, EU)

**Patients Enrolled:** 331

**Treatment Duration:** 8 weeks

**Patient Population:** Adults age 18 years and over with moderate to severe ulcerative colitis not responsive to conventional therapies

**Study Design:** A Phase 2 Multicenter, Randomized, Placebo-controlled, Doubleblind Study to Evaluate the Safety and Efficacy of mAb X for Induction Therapy in Subjects Aged 18 – 75 with Moderate to Severe Ulcerative Colitis

#### **Challenges Faced:**

- Enroll placebo-controlled study involving repeated endoscopies to assess mucosal healing
- Limit interrater variability in assessment of endoscopy recordings
- Minimize variability in quality-of-life outcome measures

**Risk Management and Mitigation:** Health Decisions worked closely with the sponsor and investigators to ensure that the informed consent process clearly presented information not only on randomization to placebo and the need for multiple endoscopies but also on the importance of mucosal healing and assessment of mucosal healing during the trial and eligibility for a follow-on 52-week maintenance study. In addition, the study utilized a tiered enrollment strategy providing for rapid activation of a second tier of sites if necessary. The study activated three second-tier sites and enrolled on time. In addition, use of a central endoscopy reader ensured consistency in endoscopy interpretation.

## Case Study 2: Colorectal Cancer Diagnostic Clinical Trial

### *Multi-Target Colorectal Cancer Screening Test for the Detection of Colorectal Advanced Adenomatous Polyps and Cancer*

**Active Sites:** 90 (US and Canada)

**Patients Enrolled:** 12,777

**Treatment Duration:** 13 months

**Patient Population:** Adults of average risk of colorectal cancer between the ages of 50 and 84 undergoing a colonoscopy for screening

**Study Design:** Subjects at average risk of colorectal cancer provided a fecal sample, which was compared to their colonoscopic results and a commercially available fecal immunogenicity test

#### **Challenges Faced:**

- Tracking thousands of sample collection kits
- Monitoring and managing the cancer prevalence rate
- Ensuring proper training and consistent colonoscopy
- Confirmation of diagnosis and outcome data for CRC+ subjects

**Risk Management and Mitigation:** Health Decisions' proprietary sample tracking system managed each collection kit from site to subject home to storage to laboratory for testing. LiveData™ enabled tracking enrollment rates and cancer prevalence rates and managing to timeline. Health Decisions worked with the sponsor to create unique training tools to ensure all colonoscopies met standards for bowel prep and cecal withdrawal time. Finally, Health Decisions developed tracking tools for CRC+ subjects that allowed central pathologists to review and request additional medical records or information from the sites.

### The Leading Full-Service Women's Health CRO from Pre-IND or -IDE to Regulatory Approval and Beyond

Health Decisions is a full-service CRO specializing in clinical development of drugs, diagnostics, medical devices and combination drug/devices in all areas of women's health as well development of diagnostics for all therapeutic areas. Our experience, expertise, site network and KOL and investigator relationships enable us to address the challenges of developing women's health products in areas including general gynecology indications, contraception, sexual health, infertility, obstetrics, menopause and osteoporosis and other indications that affect women disproportionately and profoundly, including autoimmune disorders and male-factor infertility. Health Decisions is headquartered in Durham, NC.



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