



Endoscopy plays a key role in evaluating the efficacy and safety of new drugs for Inflammatory Bowel Disease (IBD) and determining patient eligibility for gastroenterology clinical trials. Sponsors designing clinical trials of experimental therapies to treat IBD face challenges including:

- Acquisition, management and analysis of video data from endoscopic evaluations
- Lack of standardized approaches for centralized assessments
- Varied study designs without consensus regarding optimal read paradigms

Bioclinica provides the scientific, regulatory and operational expertise to advance your GI clinical trial:

- Network of Key Opinion Leaders (KOL) specialized in gastroenterology
- Technology for endoscopic acquisition including video annotation and digital upload
- Site training and support for high quality video submission
- Dedicated Project Management Team — Applying best practices from years of GI clinical trial experience
- Expert centralized image review

INDICATIONS

Bioclinica has extensive experience applying imaging for Eligibility, Efficacy, and Safety components of clinical trials.

- Bowel Prep
- Crohn's Disease
- Fecal Incontinence
- Primary Sclerosing Cholangitis (PSC)
- Reflux Esophagitis
- Ulcerative Colitis (UC)

SCORING SYSTEMS

- Crohn's Disease Endoscopy Index of Severity (CDEIS)
- Magnetic Resonance Index of Activity (MaRIA)
- Mayo scoring (endoscopic subscore)
- Modified Baron's
- Simple Endoscopic Scoring in Crohn's Disease (SES-CD)
- Ulcerative Colitis Endoscopy Index of Severity (UCEIS)

MODALITIES

- Capsule Endoscopy
- CT Enterography (CTE)
- Endoscopy (Ileocolonoscopy and Sigmoidoscopy)
- Endoscopic Ultrasound (EUS)
- MR Enterography (MRE)
- Stool Photography
- Upper Endoscopy