CASE STUDY · GASTROENTEROLOGY

# Phase IIb Inflammatory Bowel Disease Trial

Crohn's disease and ulcerative colitis · Endoscopy video, MR enterography · SES-CD and Mayo Endoscopic Score

## Challenge

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. Endoscopic and cross-sectional assessment of inflammatory bowel disease activity is inherently interpretive. When scoring is performed at individual sites, that subjectivity translates directly into variability: the same endoscopic finding may be scored differently by different investigators, and eligibility decisions diverge accordingly. The sponsor needed to remove this inconsistency from both the screening process and the SES-CD and Mayo Endoscopic Score assessments anchoring the trial's efficacy evaluation across all participating sites.

Endoscopic video brought its own practical difficulties. Recordings varied in completeness, quality and format, and many contained identifying information requiring removal before central review; bowel preparation, segment coverage and clarity all determined whether a recording could be scored reliably. MR enterography studies arrived under differing protocols and had to be evaluated consistently alongside the endoscopic findings. Consistent eligibility assessment was especially important, since variation in screening interpretation would alter the enrolled population in ways that later central review could not correct, however rigorous. Endoscopic appearance and cross-sectional bowel findings describe related but distinct features of inflammatory activity. Maintaining their individual scoring definitions preserves that distinction, while consistent screening interpretation addresses the composition of the enrolled population rather than retrospectively correcting eligibility through later endpoint review.

## Intrinsic Imaging’s Solution

Intrinsic Imaging provided sites with guidance for recording complete endoscopic procedures and acquiring MR enterography under a common protocol. Each submission was checked for completeness, technical adequacy and de-identification before reaching readers, and sites received prompt feedback when additional information or repeat submission was required.

A blinded dual-reader central review encompassed both endoscopic video and MR enterography. Recordings were anonymized and scored against standardized ulcer measurement conventions, while cross-sectional studies underwent quantitative review of bowel wall thickness and related parameters. Central readers were trained on the scoring definitions and calibrated against reference cases before reading began. Screening reads were prioritized so that eligibility decisions were returned within the timelines enrollment required, and efficacy timepoints followed the same charter, so that screening and endpoint assessments were governed by identical standards.

Discordant scores were resolved through structured adjudication, and adjudication outcomes and reader agreement were reviewed regularly to identify scoring features that generated recurring disagreement. Where needed, the charter was clarified and readers recalibrated, so that endoscopic and cross-sectional findings were scored consistently for the remainder of the trial. Reader agreement and adjudication rates were reported to the sponsor throughout, giving its clinical team a transparent view of scoring consistency as enrollment progressed.

## Intrinsic Imaging's Results

- 42% reduction in inter-reader scoring discordance for SES-CD and Mayo Endoscopic Score following central calibration of readers and introduction of structured adjudication
- Centralized eligibility review reduced inappropriate screening exclusions, bringing uniformity to enrollment decisions and to the composition of the randomized population across all sites
- Endoscopic video and MR enterography scored under a single charter from screening through efficacy timepoints, with every decision documented from submission to adjudication
- Scoring framework, ulcer measurement conventions and reader training materials retained by the sponsor for subsequent phases of its inflammatory bowel disease program

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Read the full study online: https://intrinsicimaging.com/case-studies/gastroenterology

### About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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