A Pragmatic Cluster-Randomized Real-World Study of Biologic Therapy in Inflammatory Bowel Disease in a US Community Gastroenterology Network

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Objectives

Randomized controlled trials often lack external validity, limiting their applicability to routine clinical care. The persistent absence of prospective, randomized real-world evidence (RWE) constrains clinical, payer, and policy decision-making. This study describes a pragmatic trial embedded within a US community gastroenterology network designed to generate robust, decision-relevant evidence.

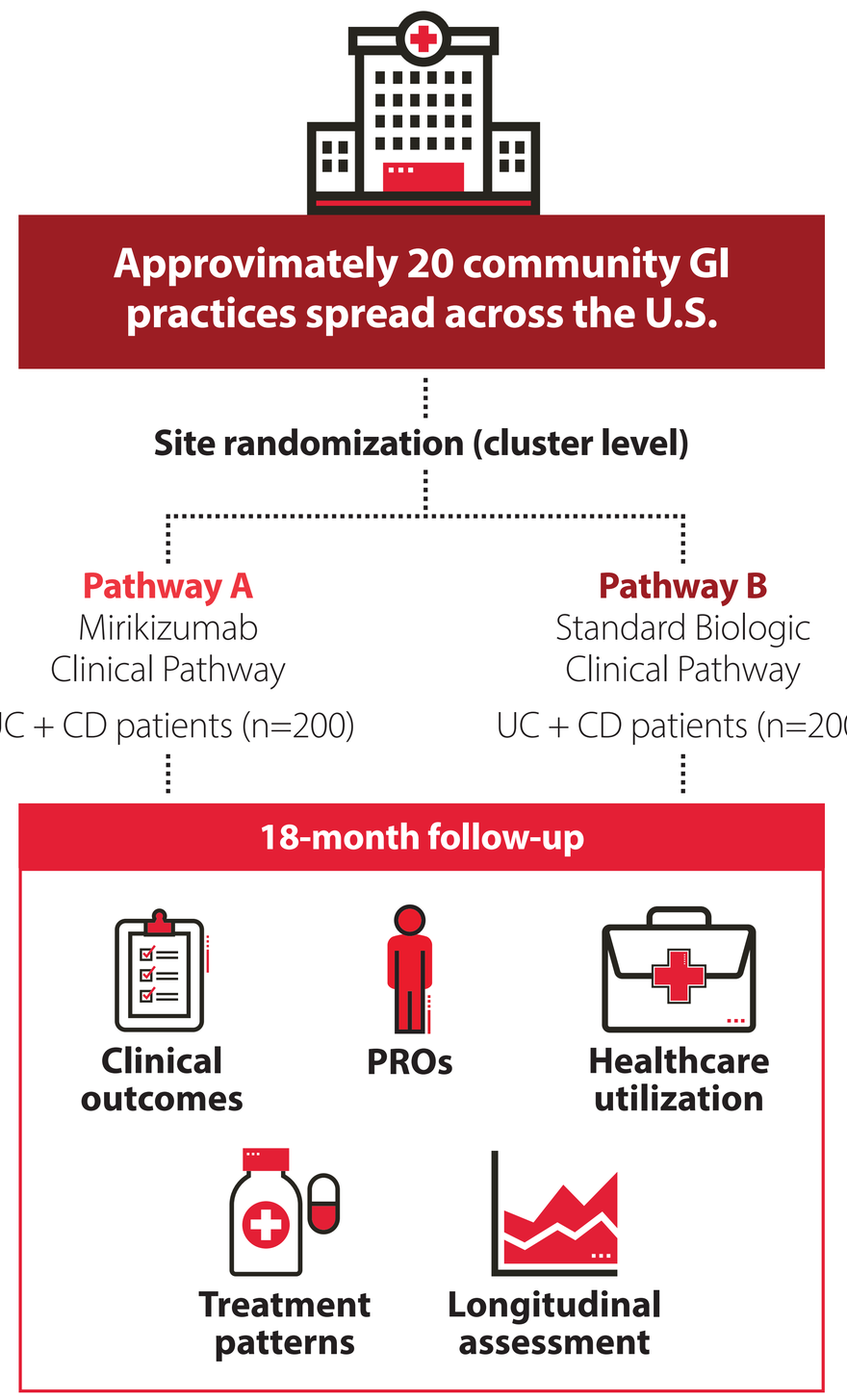
Methods

INSIGHT-IBD is a prospective, multicenter, cluster-randomized pragmatic study that is being conducted across 20 US community practices using a standardized clinical care pathway. Sites are being randomized to mirikizumab or other inflammatory bowel disease (IBD) indicated biologic therapy, preserving naturalistic prescribing and minimizing contamination. Approximately 400 adults with ulcerative colitis or Crohn's disease initiating biologic therapy will be enrolled and followed for 18 months.

To reflect routine care, post-initiation treatment decisions remain at the physicians' discretion. The primary end point is a composite measure of disease management escalation (e.g., treatment switching, dose escalation, IBD-related emergency visits or hospitalizations), capturing clinically meaningful outcomes and healthcare burden. Secondary outcomes include clinical remission, treatment persistence, concomitant medications, and patient-reported outcomes (PROs). Data are integrated from electronic health records (SoNaR-GI), claims, electronic case report forms, and PROs. Analyses will employ multilevel regression models to address clustering and confounding.

Figure 1. IBD Study Design

Prospective, multicenter, open-label, cluster-randomized pragmatic study embedded in routine care. Total target enrollment: 400 patients (Ulcerative Colitis [n=200] | Crohn's Disease [n=200])



Study Population

Diverse real-world patients initiating biologic therapy in community gastroenterology practices

Key Inclusion Criteria

- Adults ≥21 years
- Confirmed ulcerative colitis or Crohn's disease
- Candidate for biologic therapy
- No prior mirikizumab exposure
- Able to provide informed consent

Key Exclusion Criteria

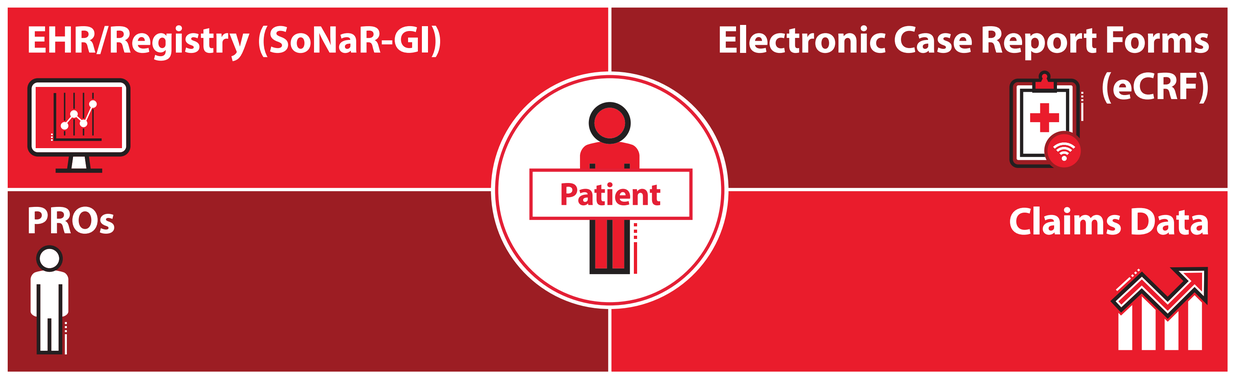
- Prior exposure to IL23p19, JAK inhibitors, or S1P modulators for IBD
- Participation in an interventional clinical trial within 90 days
- Significant prior bowel resection
- Investigator-determined safety or other concerns

Results

This study is expected to generate novel prospective, randomized RWE datasets evaluating biologic therapy within routine practice, enabling direct treatment strategy comparisons and quantification of real-world disease management burden. The study will produce actionable evidence on treatment effectiveness, care pathways, and variability across community settings to inform clinical, payer, and health technology assessment decision-making.

Figure 2. Integrated Real-World Evidence Platform

Multiple data sources are integrated to create a comprehensive longitudinal view of the patient journey across 18 months



Conclusions

By embedding randomization within routine care, INSIGHT-IBD represents a necessary evolution in evidence generation, establishing a scalable, high-validity model that bridges the gap between clinical trials and real-world practice. Broader adoption of pragmatic, community-based study designs will be essential to inform guideline development, optimize care pathways, and accelerate value-based care.

Study Follow-up

Longitudinal assessment of patients from biologic initiation through 18 months.

Expected Impact

- INSIGHT-IBD will generate prospective randomized real-world evidence on biologic treatment strategies in routine community gastroenterology practice.
- The study evaluates clinical outcomes, treatment durabiity, healthcare utilization, pathway adherence, and patient-reported outcomes in UC and CD.
- Findings may inform clinical pathways, payer and Health Technology Assessment decision-making, and guideline development.
- INSIGHT-IBD represents a scalable model for embedding randomization into routine care to produce high-quality, decision-relevant real-world evidence.

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