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Accelerating enrollment in phase 2 and 3 inflammatory bowel disease trials through an innovative site network

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OBJECTIVE

Assess enrollment rates in IBD RCTs acoss a centralized site network.

CONCLUSION

This site network represents a scalable solution to the longstanding recruitment crisis in IBD RCTs.

This model represents an operational and cultural shift in trial execution and could meaningfully accelerate develelopment of novel therapies.

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Introduction

- Recruitment for randomized controlled trials (RCTs) in inflammatory bowel disease (IBD) is challenging, with the average number of patients randomized per site per month declining significantly between 1998 and 2020 from 0.32 to 0.12 in ulcerative colitis (UC) and from 0.65 to 0.08 in Crohn's disease (CD) (1).
- Trial execution is hindered by substantial operational burdens at investigative sites, including study-specific training, administrative tasks (contracting, budget negotiations, regulatory documentation), and time-consuming and inconsistent pre-screening workflows.
- These inefficiencies contribute to delayed site activation and slow patient enrollment, driving underperformance across multicenter trials. Site networks present a potential solution.

Methods

Trial Inclusion Criteria

- All Phase 2 and 3 IBD RCTs supported by the network beginning April 2024 through October 2025.
- Studies were included only if the network had been formally engaged before the trial's official start date.

Global Site Network Overview

Participating sites are part of Iterative Health's global research network of more than 80 clinical research sites. This model supports sustainable research operations at the site level through:

- **Operational Backbone:** Sites are supported through standardized clinical and business operations, including study start-up and activation, regulatory and compliance management, trial-specific training, financial operations, Sponsor coordination, and staff hiring and development.
- **Artificial Intelligence (AI)-Enabled Pre-Screening:** AI technology reviews electronic health records and endoscopic videos to identify potentially eligible patients and reduce the manual burden of chart reviews.

Statistical Analysis

- Per study randomization rates measured the patients randomized per site per month and were summarized using:
  - Weighted average reflecting overall network-level performance, calculated by dividing the total number of patients randomized by the total number of active site-days, then multiplying by 30.44 to normalize to a monthly rate.
  - Median, reflecting study-level performance, calculated as the median of study-level randomization rates.
- Additional site performance metrics were summarized using medians of study-level rates and include:
  - Time from site selection to activation, defined as the number of days between site selection for study participation and the date it receives all necessary approvals to begin enrolling patients, and includes contracting and budget agreement, regulatory and ethics approval, and site initiation activities.
  - Time from site activation to first patient screened and first patient randomized, defined as the number of days between site approval for enrollment and first patient consented for formal screening, and first patient to pass screening to be randomized, respectively.
- Results were compared to published benchmarks.

Results

Characteristics of Included Studies and Sites

- 6 RCTs (two Phase 2 and four Phase 3) were included, three UC and three CD, conducted in 27 sites with network support (21 U.S., 6 Europe).

Figure 1. Per study randomization rates at sites with network support are 3.4-fold higher than benchmarks of 0.10 patients per site per month. Network performance rates (purple) summarize all RCTs.

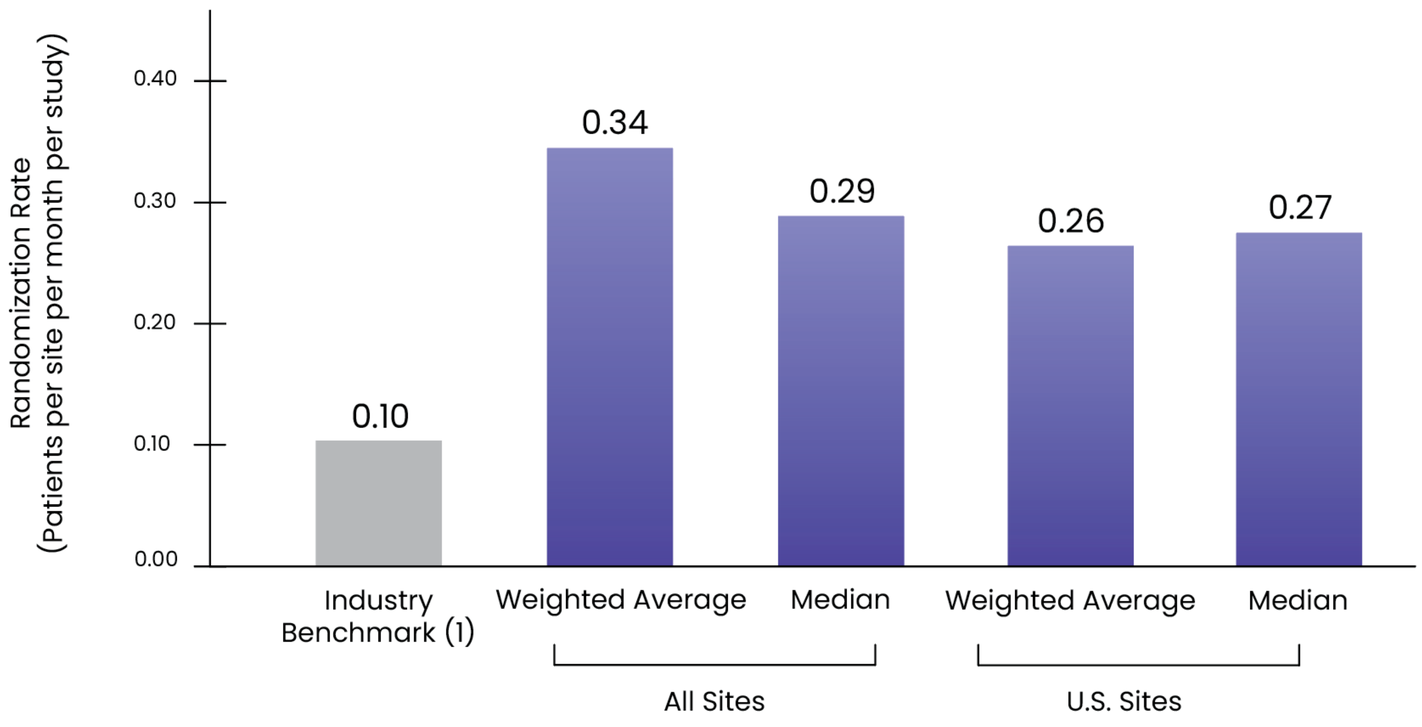

Table 1. Increased per study randomization rates at sites with network support is consistent across trial phase and IBD indication.

Category	All Sites		U.S. Sites		Industry Benchmark
	Weighted Average	Median	Weighted Average	Median	
Phase 2	0.29	0.29	0.29	0.29	N/A
Phase 3	0.39	0.28	0.25	0.17	N/A
UC	0.31	0.32	0.22	0.27	0.12 (1)
CD	0.39	0.21	0.32	0.26	0.08 (1)

References are provided in parentheses for industry benchmarks where available. Abbreviations: N/A, Not Available; U.S., United States; UC, ulcerative colitis; CD, Crohn's disease.

Table 2. Network sites reduce time to site activation, initiation of screening, and time to first patient randomized.

Performance Metric	All Sites	U.S. Sites	Industry Benchmark	Delta vs Benchmark (All Sites)	Delta vs Benchmark (US Sites)
Median time from site selection to site activation (days)	74.4	69.8	122 - 171 (2-4)	47.6 - 96.6	52.2 - 101.2
Median time from site activation to first patient screened (days)	45.4	50.2	N/A	N/A	N/A
Median time from site activation to first patient randomized (days)	82.7	69.6	140 (4)	57.3	70.4

References are provided in parentheses for industry benchmarks where available. Abbreviations: N/A, Not Available.

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