Development of a Novel Longitudinal Observational Cohort of Adult and Pediatric Patients with Inflammatory Bowel Disease: TARGET-IBD



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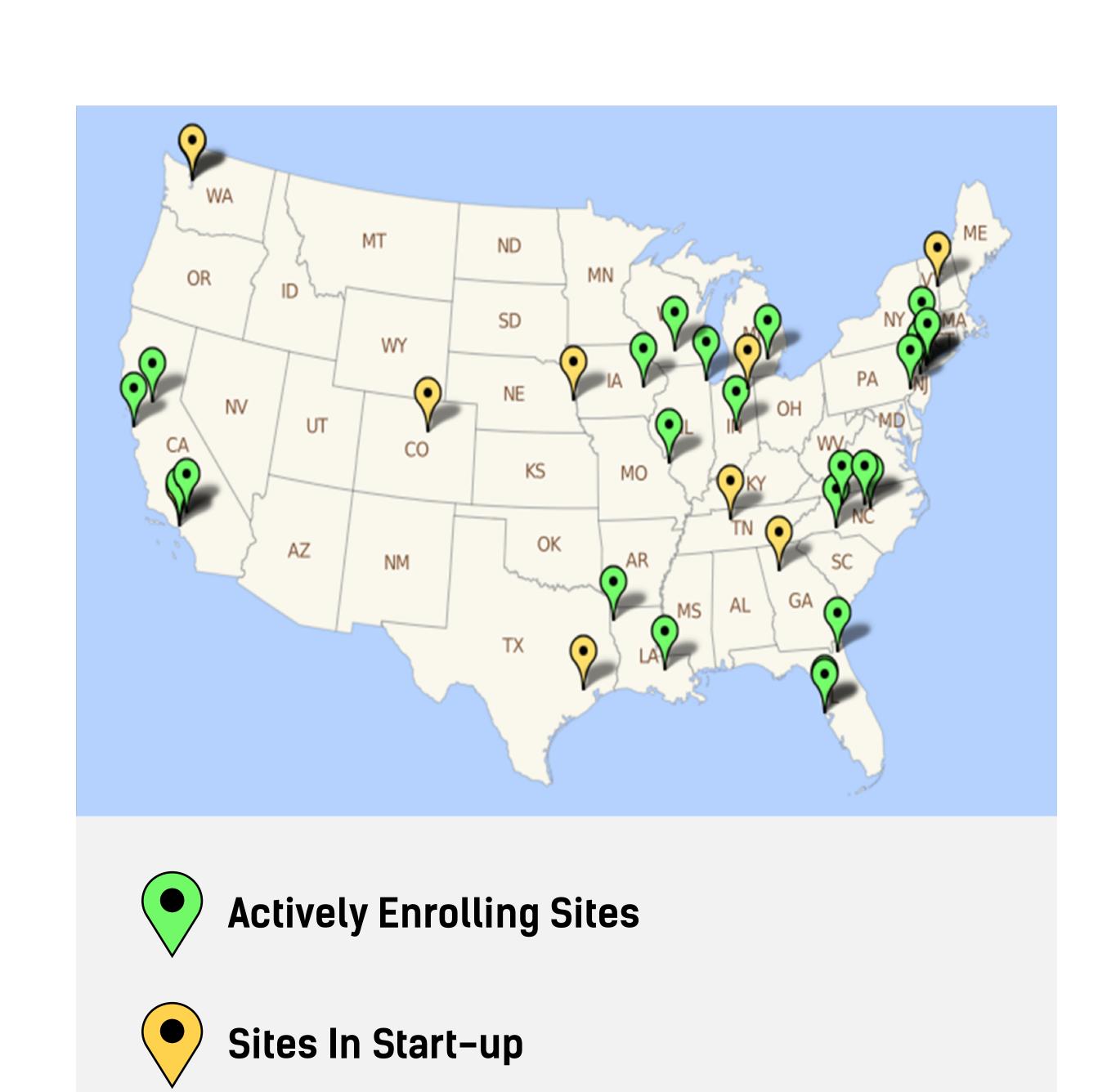
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INTRODUCTION

- Management of IBD is complex, commonly involving multidisciplinary care including chronic medications, surgery, and psychological support.
- The aim of this study is to characterize the natural history and management paradigms for IBD utilized in usual clinical practice.

METHODS

- TARGET-IBD is a longitudinal, observational study of pediatric and adult patients with IBD managed according to local standards at academic (n=22) and community (n=13) sites in the US. Up to 15,000 patients will be enrolled.
- In a combined retrospective/prospective design, the redacted medical record (structured and unstructured data) from consented patients, including narratives, laboratory, endoscopic, pathology, infusion records, and imaging data utilized for IBD diagnosis and treatment are abstracted into a unique centralized data core.
- Patient reported outcomes (PRO) are assessed prospectively on a quarterly basis.
- Interventions for IBD, adverse events, and disease progression are longitudinally assessed.
- A biospecimen repository for biomarker validation and translational studies is maintained.



RESULTS

Between 7/2017 and 8/2018, 997 participants were enrolled and entered into the database.

- 599 (60.1%) have Crohn's Disease (CD), 388 (38.9%) have Ulcerative Colitis (UC), and 10 (1.0%) have Indeterminate Colitis (IBDU).
- Median duration of disease is 10.0 years (0–62 range).
- 44.5% are male, with a racial distribution of White (85.3%), Black (8.8%), and Asian (1.3%). 1.8% are of Hispanic ethnicity.
- Distribution of disease involvement for those with CD was 19.8% colon, 58.3% ileocolon, and 21.9% ileum.
- Among those with UC, 48.9% have extensive colitis, 38.6% have left sided colitis, and 12.5% have disease limited to proctitis.
- 45.8% of participants are enrolled at community sites with 54.2% enrolled at academic sites.

Academic Sites (22) Community Sites (13) MW NE SE SW W MW NE SE SW W

Table 1. Demography and Medical History				
Summary	Participant Type			
	UC (N=388)	CD (N=599)	IBDU (N=10)	Total (N=997)
Demography				
Age at Entry (years) ¹ Median (n) Min – Max	47 (385) 9 - 91	44 (597) 8 - 87	37 (10) 24 - 72	45 (992) 8 - 91
Gender, n (%) n Female	388 203 (52.3%)	599 226 (55.1%)	10 3 (42.9%)	997 370 (55.5%)
Race, n (%) n White Black/African American	388 325 (83.8%) 26 (6.7%)	599 499 (83.3%) 59 (9.8%)	10 8 (80%) 1 (10%)	997 832 (83.5%) 86 (8.6%)
Age > 65 Years Age < 18 Years	66 (17.1%) 1 (0.3%)	84 (14.1%) 6 (1.0%)	1 (10.0%) 0 (0.0%)	151 (15.2%) 7 (0.7%)
Duration of Disease (years) ² Median (n) Min - Max	8.0 (342) 0 - 51	11.0 (525) 0 - 62	8.0 (10) 0 - 18	10.0 (877) 0 - 62
Medical History Occurring in >5% of Participants				
Blood & Lymphatic System Disorders Anemia Vascular Disorders Hypertension	95 (24.5%) 49 (12.6%) 100 (25.8%) 90 (23.2%)	166 (27.7%) 96 (16.0%) 146 (24.4%) 117 (19.5%)	1 (10.0%) 0 (0.0%) 2 (20.0%) 2 (20.0%)	262 (26.3%) 145 (14.5%) 248 (24.9%) 209 (21.0%)

 $^{^{1}}$ Age calculated based on year of consent minus birth year. 2 Years based year of diagnosis.



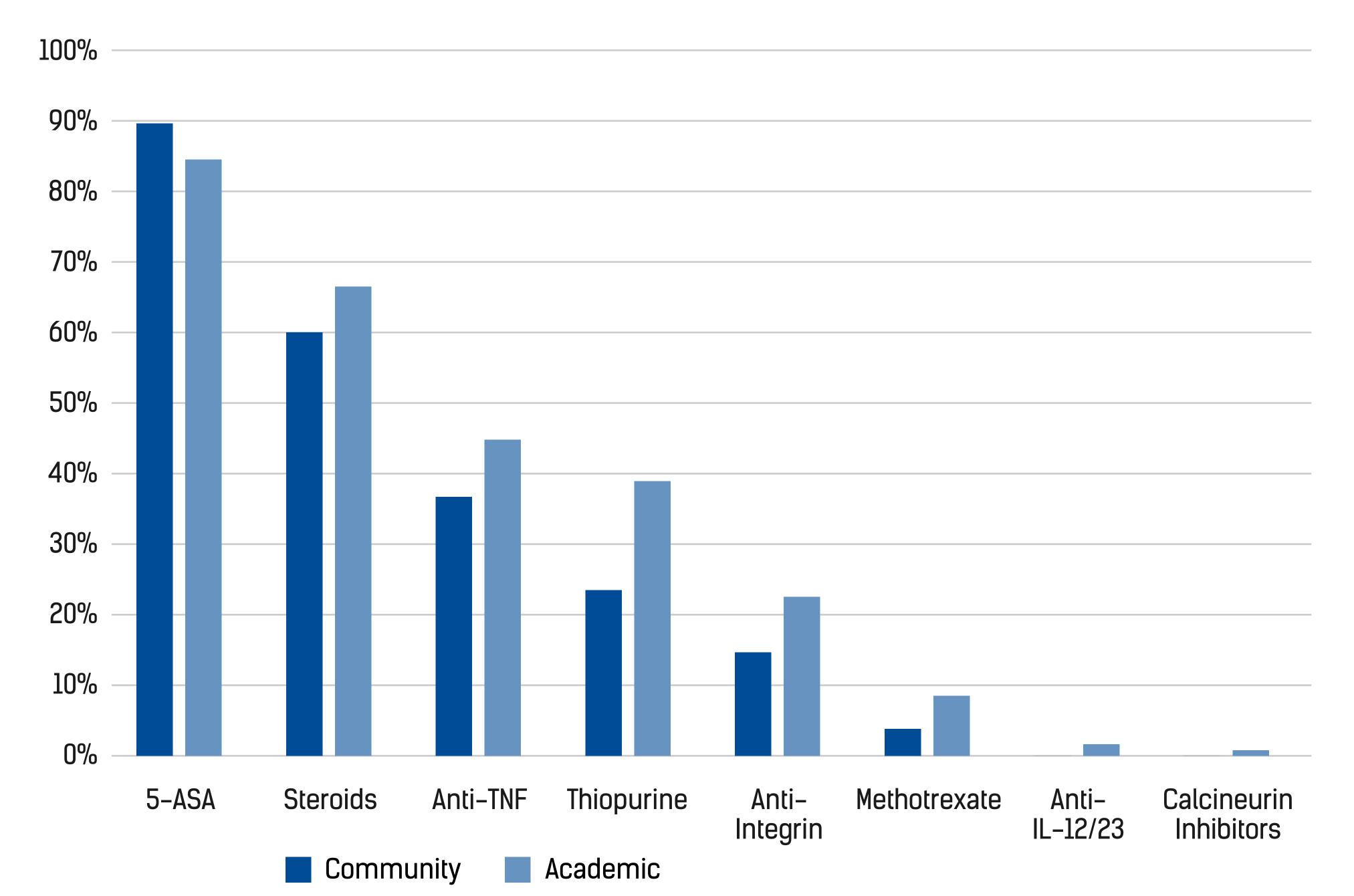


Figure 3. IBD Treatments at Enrollment; Crohn's Disease

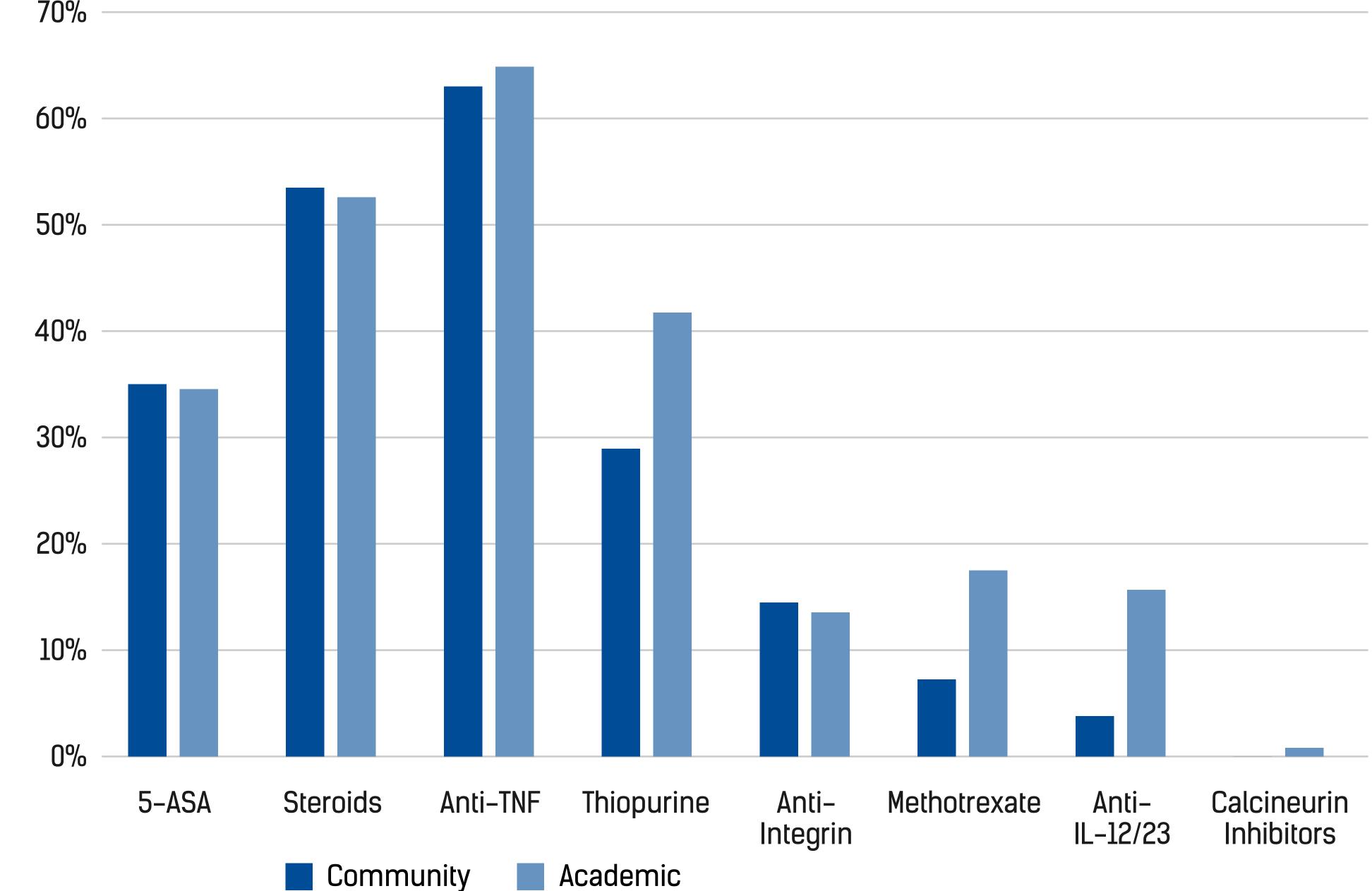


Table 2. Disease Characteristics [N=997]Crohn's Disease Location of Crohn's Disease, n (%) 114 (19.8%) 335 (58.3%) Ileocolon 126 (21.9%) lleum Not Available Type of Crohn's Disease, n (%) 238 (44.0%) Inflammatory (B1) 149 (27.5%) Stricturing (B2) 154 (28.5%) Penetrating/Fistulizing (B3) Not Available Patients with Upper Disease, n (%)¹ 95 (19.6%) Patients with Perianal Disease, n (%) 154 (30.6%) **Ulcerative Colitis** Location of Ulcerative Colitis, n (%) 45 (12.5%) Proctitis (E1) 139 (38.6%) Left-Sided (E2) 176 (48.9%) Extensive (E3) Not Available

¹ Upper disease = stomach, duodenum, jejunum, esophagus.

CONCLUSIONS

- TARGET-IBD, a novel prospective observational cohort of patients with IBD, is evaluating treatment patterns in both academic and community settings.
- Centralized abstraction of redacted medical records reduces the burden of site participation, contributing to strong enrollment rates across all site types.
- Ongoing recruitment and longitudinal follow up of this cohort will provide an important resource for comparative effectiveness and safety data.

TARGET-IBD is a study sponsored by Target PharmaSolutions (TPS). TPS is a real-world clinical data company based in Chapel Hill, NC. The authors would like to thank all the investigators, participants and research staff associated with TARGET-IBD. ClinicalTrials.gov Identifier: NCT03251118