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CLINICAL TRIAL INTELLIGENCE

Intelligence Report

A Study of Eltrekibart and Mirikizumab in Adult Patients With Moderately to Severely Active Ulcerative Colitis

LEAD SPONSOR
Eli Lilly and Company

NCT ID
NCT06598943

DATE GENERATED
2026-03-13

Index

Major sections start on new pages. Larger tables can continue across pages while preserving this section order.

Summary

Generated: 2026-03-13

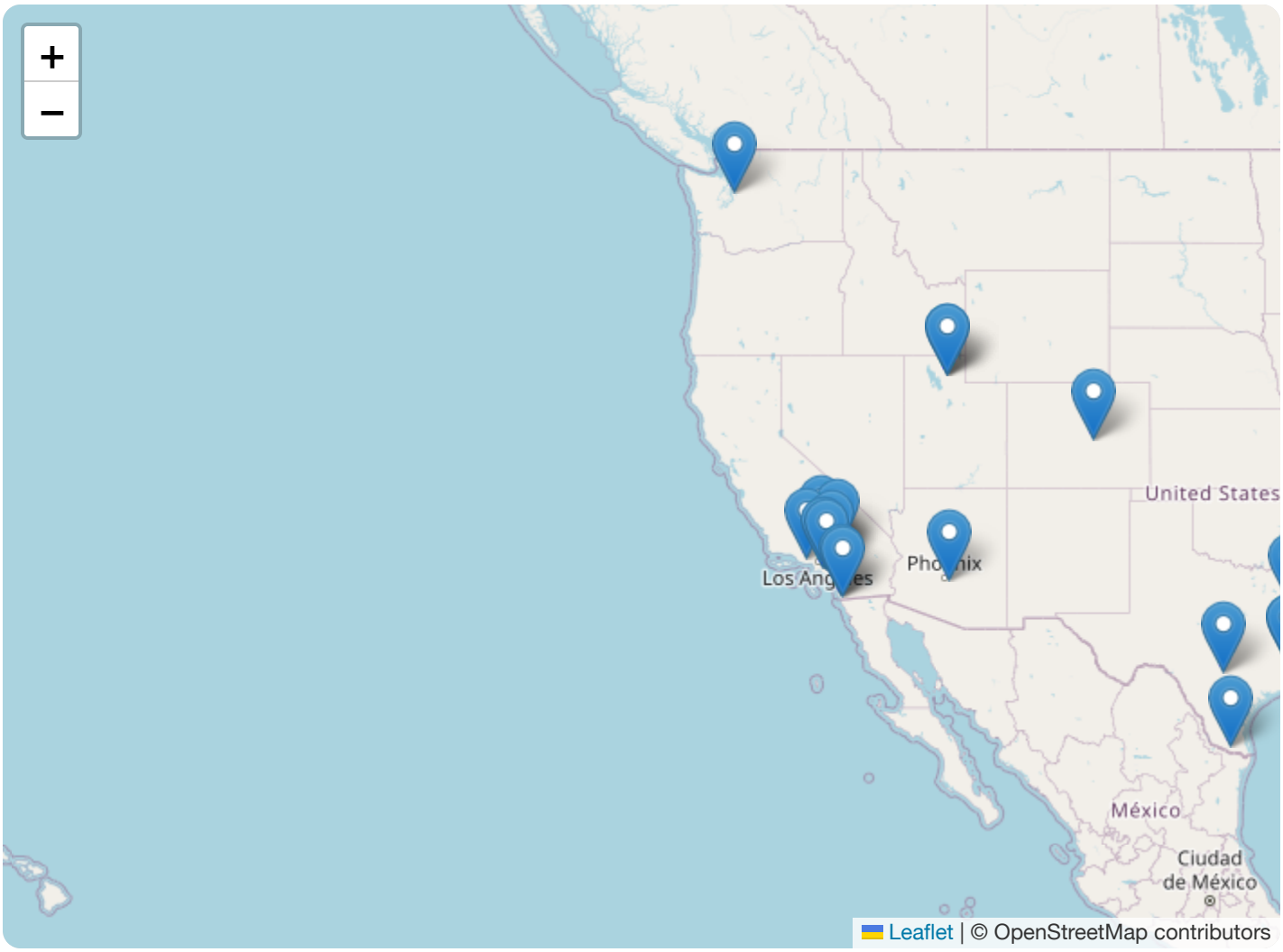
Summary	Details
Lead sponsor	Eli Lilly and Company
Condition	Ulcerative Colitis
Study type	INTERVENTIONAL
Phase	PHASE2
Enrollment	140.0
Inclusion points	5.0
Exclusion points	5.0
Locations	207.0
Patients per site per month	< 0.1

- With 207 locations and an enrollment of 140, your trial exhibits a highly decentralized model, resulting in a low recruitment density of 0.0145 patients per site per month.
- The trial's 46.8-month duration is significantly longer than the 12-month duration of direct competitors like Jina Pharmaceuticals (NCT06867042), suggesting a more extended clinical development timeline.
- While your trial maintains a balanced inclusion/exclusion profile (5 points each), other trials in the landscape show high variability, ranging from as few as 2 inclusion points to as many as 43 exclusion points, indicating diverse stringency in patient selection across the field.
- Compared to single-site trials that achieve up to 5.29 patients per site per month, your multi-site strategy will require rigorous site management to improve the current yield of 0.6763 patients per site.

✓ ClinicalTrials.gov extracted study record.

Diagnostics: Stored report loaded.

Map



- ✓ ClinicalTrials.gov extracted site records.
- ✓ OpenStreetMap basemap.

Similar trials

☐ Include only trials with at least 1 US site

Showing Phase PHASE2 interventional trials for ulcerative colitis, studying a drug, Recruiting or Not yet recruiting.

NCT ID	Lead sponsor	Enrollment	Sites	Duration	Patients per Site per Month	Map
NCT06213857	Tanta University	44.0	2.0	4.0	5.5	View
NCT06606808	University Medical Center Groningen	18.0	1.0	12.8	1.4	View
NCT06421818	The Second Hospital of Nanjing Medical University	144.0	1.0	32.0	4.5	View
NCT05466890	Palatin Technologies, Inc	16.0	14.0	30.5	< 0.1	View
NCT06764615	Takeda	183.0	16.0	55.1	0.2	View
NCT05177835	Abivax S.A.	203.0	46.0	52.0	< 0.1	View
NCT05731128	Sanofi	68.0	77.0	49.3	< 0.1	View
NCT06254950	Takeda	207.0	140.0	40.2	< 0.1	View
NCT05907330	Curacle Co., Ltd.	45.0	0.0	22.0	N/A	View
NCT05287126	Pfizer	36.0	47.0	103.7	< 0.1	View
NCT06619990	Xencor, Inc.	270.0	40.0	50.8	0.1	View
NCT05327790	University of Alberta	40.0	1.0	45.9	0.9	View
NCT07297069	Asian Institute of Gastroenterology, India	60.0	1.0	24.0	2.5	View
NCT06257875	AbbVie	156.0	191.0	41.3	< 0.1	View
NCT06867042	Jina Pharmaceuticals Inc.	150.0	0.0	12.0	N/A	View
NCT06850727	Odyssey Therapeutics	57.0	32.0	17.0	0.1	View
NCT06667934	The Second Affiliated Hospital of Anhui University of Traditional Chinese Medicine	60.0	0.0	6.1	N/A	View
NCT03869905	Muhammad N Aslam, MD	40.0	1.0	99.8	0.4	View
NCT07295834	Imperial College London	70.0	4.0	24.0	0.7	View
NCT07427017	Northwestern University	180.0	1.0	34.0	5.3	View
NCT07012395	Spyre Therapeutics, Inc.	645.0	126.0	33.2	0.2	View
NCT06636656	Boehringer Ingelheim	45.0	41.0	38.7	< 0.1	View
NCT03804931	Guangzhou First People's Hospital	120.0	1.0	143.4	0.8	View
NCT06420375	Brigham and Women's Hospital	20.0	1.0	26.2	0.8	View
NCT07186101	Eli Lilly and Company	252.0	147.0	39.7	< 0.1	View
NCT04925973	McMaster University	24.0	1.0	30.0	0.8	View
NCT06353828	CannaMore Biotechs	45.0	1.0	25.1	1.8	View
NCT06979336	Genentech, Inc.	224.0	51.0	37.1	0.1	View
NCT07335055	Haisco Pharmaceutical Group Co., Ltd.	150.0	1.0	36.0	4.2	View
NCT04373473	The University of Texas Health Science Center, Houston	58.0	1.0	87.6	0.7	View
NCT06117423	University Medical Center Groningen	21.0	1.0	15.1	1.4	View

NCT ID	Lead sponsor	Enrollment	Sites	Duration	Patients per Site per Month	Map
NCT07064707	Alexandria University	60.0	1.0	15.3	3.9	View
NCT07300553	Assistance Publique - Hôpitaux de Paris	45.0	1.0	19.0	2.4	View
NCT07222189	Sanofi	325.0	0.0	48.0	N/A	View
NCT06127043	AnaptysBio, Inc.	132.0	100.0	28.9	< 0.1	View

✓ ClinicalTrials.gov extracted study records.

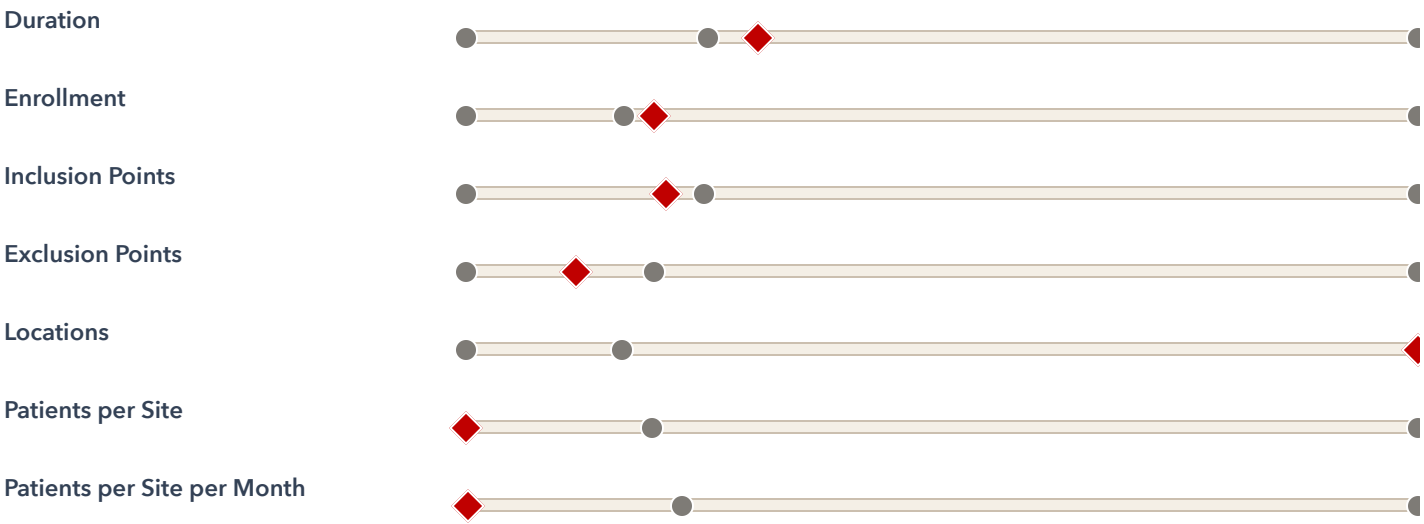
✓ Zlick-related-trial matching and saved comparison dataset.

Key metrics comparison

☐ Include only trials with at least 1 US site

Similar trials found: **35** ?

Metric	My Trial	Min	Average	Max
Duration	46.8	4.0	39.4	143.4
Enrollment	140.0	16.0	120.4	645.0
Inclusion Points	5.0	1.0	5.7	20.0
Exclusion Points	5.0	0.0	8.5	43.0
Locations	207.0	0.0	31.1	191.0
Patients per Site	0.7	0.8	35.7	180.0
Patients per Site per Month	< 0.1	< 0.1	1.3	5.5



Legend: green circle = average, red diamond = My Trial, end circles = min/max.

✓ ClinicalTrials.gov extracted study records.

✓ Zlick-derived benchmark calculations from matching trials.

Closest competitors

Showing competing trials with sites in the same city than my trial.

NCT ID	Lead sponsor	Site overlap ?	Map
NCT06257875	AbbVie	30.9%	Link
NCT06127043	AnaptysBio, Inc.	27.1%	Link
NCT06254950	Takeda	23.7%	Link
NCT07186101	Eli Lilly and Company	18.8%	Link
NCT07012395	Spyre Therapeutics, Inc.	16.9%	Link
NCT05177835	Abivax S.A.	13.5%	Link
NCT06619990	Xencor, Inc.	12.6%	Link
NCT06636656	Boehringer Ingelheim	12.1%	Link
NCT05287126	Pfizer	10.1%	Link

US sites only

In-site competition

Showing which of my sites are also running competing trials.

Facility	City	State	Other Running Trials	Example NCT IDs
Peak Gastroenterology Associates	Colorado Springs	Colorado	3	NCT06636656, NCT06979336, NCT07186101
Tyler Research Institute	Tyler	Texas	3	NCT06254950, NCT06764615, NCT07186101
Baylor College of Medicine	Houston	Texas	2	NCT06257875, NCT06636656
Intergrity Research	Houston	Texas	2	NCT06257875, NCT06636656
Florida Research Institute	Lakewood Rch	Florida	2	NCT06636656, NCT07186101
University of Washington School Medicine	Seattle	Washington	2	NCT06254950, NCT06636656
Northwestern University	Chicago	Illinois	1	NCT07427017
Om Research, LLC	Lancaster	California	1	NCT07186101
Advanced Research Institute - South Ogden	Ogden	Utah	1	NCT07186101
Care Access-Ogden	Ogden	Utah	1	NCT07186101
GCP Clinical Research, LLC	Tampa	Florida	1	NCT06257875
International Center for Research LLC	Tampa	Florida	1	NCT06257875
Nodal Medical Center	Tampa	Florida	1	NCT06257875
Research Bay,Inc.	Tampa	Florida	1	NCT06257875

Facility	City	State	Other Running Trials	Example NCT IDs
Digestive Disease Medicine of Central New York	Utica	New York	1	NCT07186101

- ✓ ClinicalTrials.gov extracted study records.
- ✓ Zlick-derived city-level overlap and facility matching across active related trials.

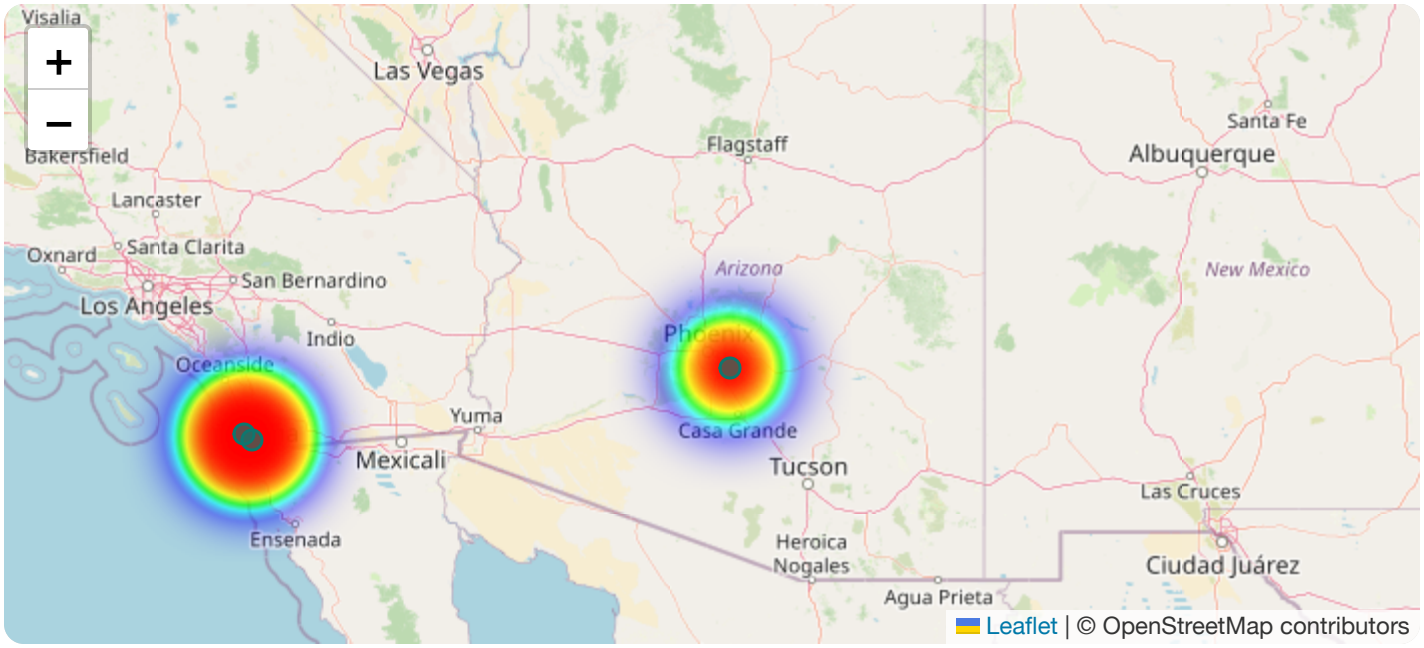
Ulcerative Colitis research nearby | Industry-sponsored

Showing PIs conducting relevant research near your sites. It also shows who they're working with and whether those sponsors have trials competing with yours.

Year: 2024 | Specialty lane: Gastroenterology

Closest site	Provider	Specialty	Distance	Total payments	Entities	Top payer	Competitor overlap
AZ Gastro Care - Chandler	JOSEPH DAVIS	Internal Medicine, Gastroenterology	On site	$1,404,266	26	ModernaTX, Inc.	AbbVie, Boehringer Ingelheim, Pfizer
	SANJAY AHLUWALIA	Internal Medicine, Gastroenterology	On site	$8,093	10	Eli Lilly and Company	AbbVie, Eli Lilly and Company, Pfizer
	LAYTH AL-JASHAAMI	Internal Medicine, Gastroenterology	17 mi	$2,399	19	AbbVie Inc.	AbbVie, Pfizer, Takeda
	JAMES BURGESS	Internal Medicine, Gastroenterology	On site	$1,994	23	AbbVie Inc.	AbbVie, Boehringer Ingelheim, Pfizer
	MATTHEW BALDUS	Internal Medicine, Gastroenterology	On site	$1,700	18	AbbVie Inc.	AbbVie, Takeda
Preferred Research Partners	JOHN BABER	Internal Medicine, Gastroenterology	On site	$173,636	17	Vanda Pharmaceuticals Inc.	AbbVie, Pfizer, Takeda
	ANGELO COPPOLA	Internal Medicine, Gastroenterology	On site	$68,269	18	Genentech, Inc.	AbbVie, Genentech, Inc., Pfizer
	DAVID BACKSTEDT	Internal Medicine, Gastroenterology	On site	$20,725	17	GastroGPO, LLC	AbbVie, Pfizer, Takeda
	TERENCE ANGTUACO	Internal Medicine, Gastroenterology	On site	$1,639	14	AbbVie Inc.	AbbVie, Pfizer, Takeda
	MEER ALI	Internal Medicine, Gastroenterology	On site	$1,280	3	Enterra Medical, Inc.	Takeda
Erick Alayo Medical Corp/Gastro SB Clinic	ERICK ALAYO	Internal Medicine, Gastroenterology	On site	$306,858	10	Genentech, Inc.	AbbVie, Genentech, Inc., Takeda
	IVAN CUBAS	Internal Medicine, Gastroenterology	On site	$350	8	AbbVie Inc.	AbbVie, Pfizer
	PATRICK SWEET	Internal Medicine, Gastroenterology	93 mi	$156	2	Madrigal Pharmaceuticals	AbbVie
	JOHN DUQUE	Internal Medicine, Gastroenterology	On site	$103	5	Evoke Pharma, Inc.	AbbVie
	GREGORY WIENER	Internal Medicine, Gastroenterology	On site	$256,149	8	Vanda Pharmaceuticals Inc.	None

Closest site	Provider	Specialty	Distance	Total payments	Entities	Top payer	Competitor overlap
Southern California GI and Liver Centers (SCLC)	TAREK HASSANEIN	Internal Medicine, Gastroenterology	On site	$652,087	21	Bausch Health US, LLC	AbbVie, Boehringer Ingelheim, Pfizer
	PREETI RESHAMWALA	Internal Medicine, Gastroenterology	On site	$24	1	FUJIFILM Healthcare Americas Corporation	None



- ✓ CMS Open Payments 2024 payments grouped by covered recipient and reporting entities
- ✓ CMS Open Payments 2024 payments grouped by covered recipient and nature of payments
- ✓ Condition-relevant provider search from CMS NPI Registry

Specialty lane: Gastroenterology | Candidate NPIs scanned: 47

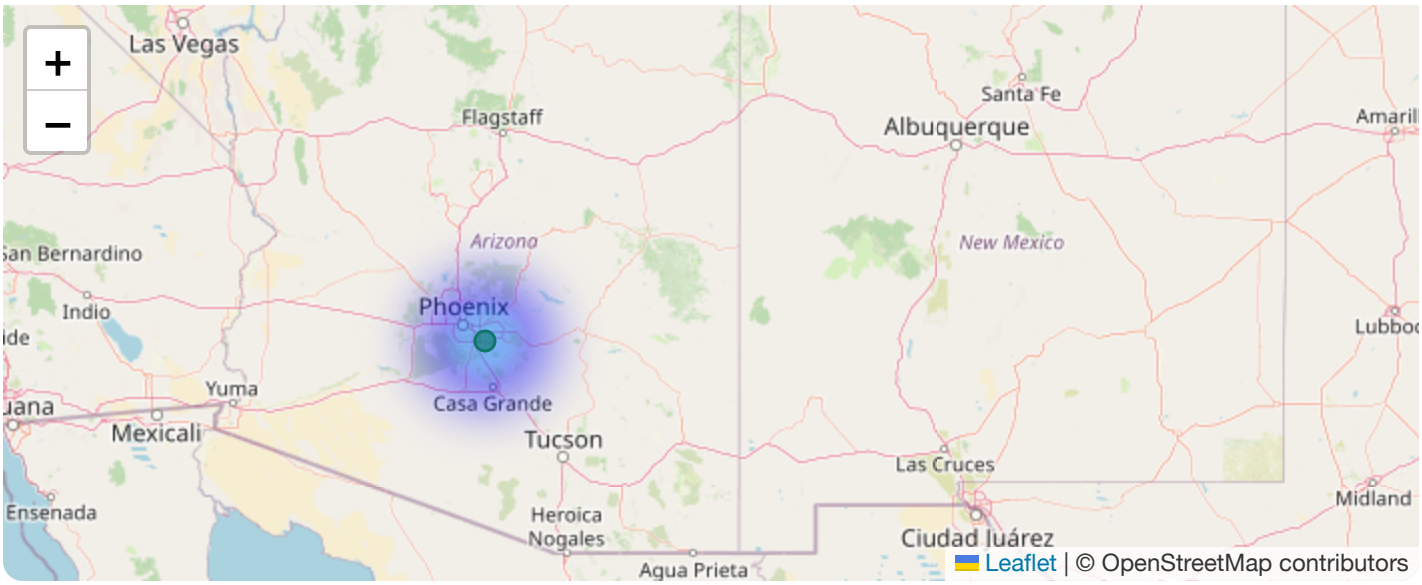
- ✓ CMS Open Payments 2024 payments grouped by covered recipient and reporting entities
- ✓ CMS Open Payments 2024 payments grouped by covered recipient and nature of payments
- ✓ Condition-relevant provider search from CMS NPI Registry

Ulcerative Colitis research nearby | NIH/public-funded

Showing research centers conducting relevant studies near your sites (funded by NIH).

Condition query: Ulcerative Colitis

Closest site	Institution	Lead PI	Recent grants	Total NIH funding	Latest FY	Example project
Erick Alayo Medical Corp/Gastro SB Clinic	CEDARS-SINAI MEDICAL CENTER	Gil Y Melmed	8	$4,621,716	2025	Targeting the Mycobiome in Genetically Defined Patients with Crohns Disease
	AVERTO MEDICAL INC	Kenton Dodyan Fong	3	$2,959,491	2025	Safety and Efficacy Trial of the ColoSeal ICD System for the Treatment of Rectal Cancer Patients
	STANFORD UNIVERSITY	CALVIN J KUO	7	$2,413,633	2025	Impaired cellular RNA editing as a cause of inflammation in inflammatory bowel disease
	UNIVERSITY OF CALIFORNIA, SAN DIEGO	John T Chang	4	$2,190,327	2025	Immune adaptations in acute pouchitis
	VIVREON BIOSCIENCES, LLC	Milton L Greenberg	2	$1,999,994	2025	Predevelopment of VV8220, a Gut-selective CRAC Channel Therapeutic for Ulcerative Colitis
Southern California GI and Liver Centers (SCLC)	CEDARS-SINAI MEDICAL CENTER	Gil Y Melmed	8	$4,621,716	2025	Targeting the Mycobiome in Genetically Defined Patients with Crohns Disease
	AVERTO MEDICAL INC	Kenton Dodyan Fong	3	$2,959,491	2025	Safety and Efficacy Trial of the ColoSeal ICD System for the Treatment of Rectal Cancer Patients
	STANFORD UNIVERSITY	CALVIN J KUO	7	$2,413,633	2025	Impaired cellular RNA editing as a cause of inflammation in inflammatory bowel disease
	UNIVERSITY OF CALIFORNIA, SAN DIEGO	John T Chang	4	$2,190,327	2025	Immune adaptations in acute pouchitis
	VIVREON BIOSCIENCES, LLC	Milton L Greenberg	2	$1,999,994	2025	Predevelopment of VV8220, a Gut-selective CRAC Channel Therapeutic for Ulcerative Colitis
Applied Research Center of Arkansas	UNIV OF ARKANSAS FOR MED SCIS	Teresa Jo Hudson	2	$859,991	2023	Population-Based Analyses of Healthcare Utilization and Outcomes in Users of Medical Marijuana
Preferred Research Partners	UNIV OF ARKANSAS FOR MED SCIS	Teresa Jo Hudson	2	$859,991	2023	Population-Based Analyses of Healthcare Utilization and Outcomes in Users of Medical Marijuana
AZ Gastro Care - Chandler	MAYO CLINIC ARIZONA	Elizabeth Carey	1	$499,996	2022	A Prospective, Randomized, Multi-centered, Placebo-controlled Clinical Trial of Oral Vancomycin in Adults with Primary Sclerosing Cholangitis



- ✓ NIH RePORTER API v2 projects search
- ✓ My Trial US site footprint from ClinicalTrials.gov extracted records

Condition query: Ulcerative Colitis | Institutions matched: 13

- ✓ NIH RePORTER API v2 projects search
- ✓ My Trial US site footprint from ClinicalTrials.gov extracted records

Competitive timeline

- ClinicalTrials.gov extracted study records.
- Zlick-derived timeline model from study start and completion dates.

Prevalence signal

County-level prevalence heatmap for Ulcerative Colitis, with optional overlay of My Trial US sites.

☐ Show My Trial US sites

Scoring prevalence signal, competitor density, referral support, CDC social vulnerability, HRSA shortage, and county-level Census access data.

Geography: state | Source: Secondary sources | Year: N/A

No state-level data for condition 'Ulcerative Colitis'. Checked other sources but no compatible direct location-level prevalence data was found. Attempts: CDC WONDER: No direct machine-query state prevalence endpoint configured for this automated workflow. | NHANES (NCHS): No state/county prevalence granularity for this automated map workflow.

✓ CDC PLACES prevalence data.

✓ ClinicalTrials.gov extracted My Trial US site records.

Protocol burden

Burden score: **91.3** (In line with similar trials). Score compares protocol complexity vs similar trials using duration and inclusion/exclusion criteria.

Factor	My Trial	Similar Trial Average	Difference
Study duration (months)	46.8	39.4	+18.7%
Inclusion criteria count	5.0	5.7	-12.9%
Exclusion criteria count	5.0	8.5	-40.9%

Scale: 100 = equal to similar-trial average burden; >100 = higher burden than peers; <100 = lower burden than peers.

- ✓ ClinicalTrials.gov extracted study record.
- ✓ Zlick-derived comparison against saved similar trials.

Predicted funnel

Eligibility-only US feasibility score (1 = very easy, 10 = very difficult).

Point-by-point criteria review

Quantifiable: 4 | Estimable: 4 | Not quantifiable: 2 | High bottleneck: 1

Type	Criterion	Category	US data signal / proxy	Why it may be a bottleneck	Bottleneck
Inclusion	Have moderately to severely active UC as assessed by the UC disease activity score.	Not quantifiable	Proxy using high-frequency medication changes or recent hospitalizations for UC flares.	UC disease activity scores (like Mayo or UCDAI) require clinical assessment and endoscopic findings not consistently captured in structured data.	High
Exclusion	Have a history of certain adenomas, dysplasia's, or malignancies.	Estimable	ICD-10 codes for neoplasm history.	Malignancy history is often available in structured data, but specific types of dysplasia may be buried in pathology reports.	Medium
Exclusion	Have had certain abdominal surgeries within the past 3 months or are likely to require surgery for UC during the study.	Estimable	CPT codes for abdominal surgery in the last 90 days.	Past surgeries are identifiable via CPT codes, but 'likelihood of future surgery' is clinical judgment.	Medium
Inclusion	Are on a stable dose of certain oral UC medications (including corticosteroids).	Estimable	Consistent dosage recorded in EHR over a 3-month period.	Stability can be inferred from prescription refill patterns and dosage consistency in EHR data.	Medium
Inclusion	Have an inadequate response to, loss of response to, or intolerance to at least one conventional medication (including corticosteroids) or one advanced therapy (including biologics, JAK inhibitors, or S1P immunomodulators).	Estimable	Pharmacy claims showing discontinuation of one therapy followed by initiation of another.	Requires identifying medication switches or additions, which can be inferred from pharmacy claims or EHR medication lists.	Medium

Type	Criterion	Category	US data signal / proxy	Why it may be a bottleneck	Bottleneck
Exclusion	Have a current diagnosis of Crohn's Disease or certain other inflammatory gastrointestinal diseases.	Quantifiable	Presence of ICD-10 K50.x codes.	Diagnosis codes for Crohn's (K50.x) are distinct from UC (K51.x).	Low
Exclusion	Have experienced a thrombotic event within 24 weeks before baseline.	Quantifiable	ICD-10 codes for DVT (I82.x) or PE (I26.x) within 6 months.	Thrombotic events (DVT/PE) are well-coded in medical claims.	Low
Exclusion	Have received anti-interleukin (IL)-23p19 or anti-IL-12p40 antibodies in the past.	Quantifiable	Claims for Ustekinumab, Risankizumab, Mirikizumab, etc.	Specific biologic therapies are identifiable via HCPCS/NDC codes in claims data.	Low
Inclusion	Have had an established diagnosis of UC of ≥3 months in duration before baseline.	Quantifiable	ICD-10 K51.x codes with date of first occurrence.	Diagnosis duration can be calculated from ICD-10 codes and initial diagnosis dates in EHR/claims data.	Low
Inclusion	Must meet contraception requirements.	Not quantifiable	None.	Contraception status is a behavioral/lifestyle factor not reliably documented in clinical databases.	Low

Predicted enrollment funnel is not available for this trial. Showing point-by-point criteria review instead.

Actual enrollment speed

Calculated using patients enrolled, number of sites, and start/end dates for similar trials reported as 'completed'.

Patients per site per month	Value
My Trial	**< 0.1**
Trials included	76.0
Mean	0.5
50th percentile	0.1
75th percentile	0.3
Minimum	0.0
Maximum	6.8

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The data reveals a significant disparity between the mean (0.4671) and the median (0.1022) patients-per-site-per-month, indicating a highly right-skewed distribution. With the maximum value of 6.8182 far exceeding the 75th percentile of 0.2832, the mean is heavily inflated by a small number of high-performing outlier sites. Consequently, the median provides a more accurate representation of typical site performance, as the majority of sites are enrolling patients at a rate significantly lower than the calculated average.

Given that 172 sites were excluded from this analysis, the current dataset likely represents only a subset of high-activity or specific-cohort locations. To improve future trial planning, stakeholders should prioritize the median performance metrics to establish realistic enrollment expectations rather than relying on the skewed mean. Further investigation into the operational characteristics of the top-performing outliers is recommended to determine if their recruitment strategies can be replicated across the broader, lower-performing site network.

In plain English: My Trial's estimate (0.01) is below the completed-trial average (0.47), so the target appears conservative versus historical enrollment speed.

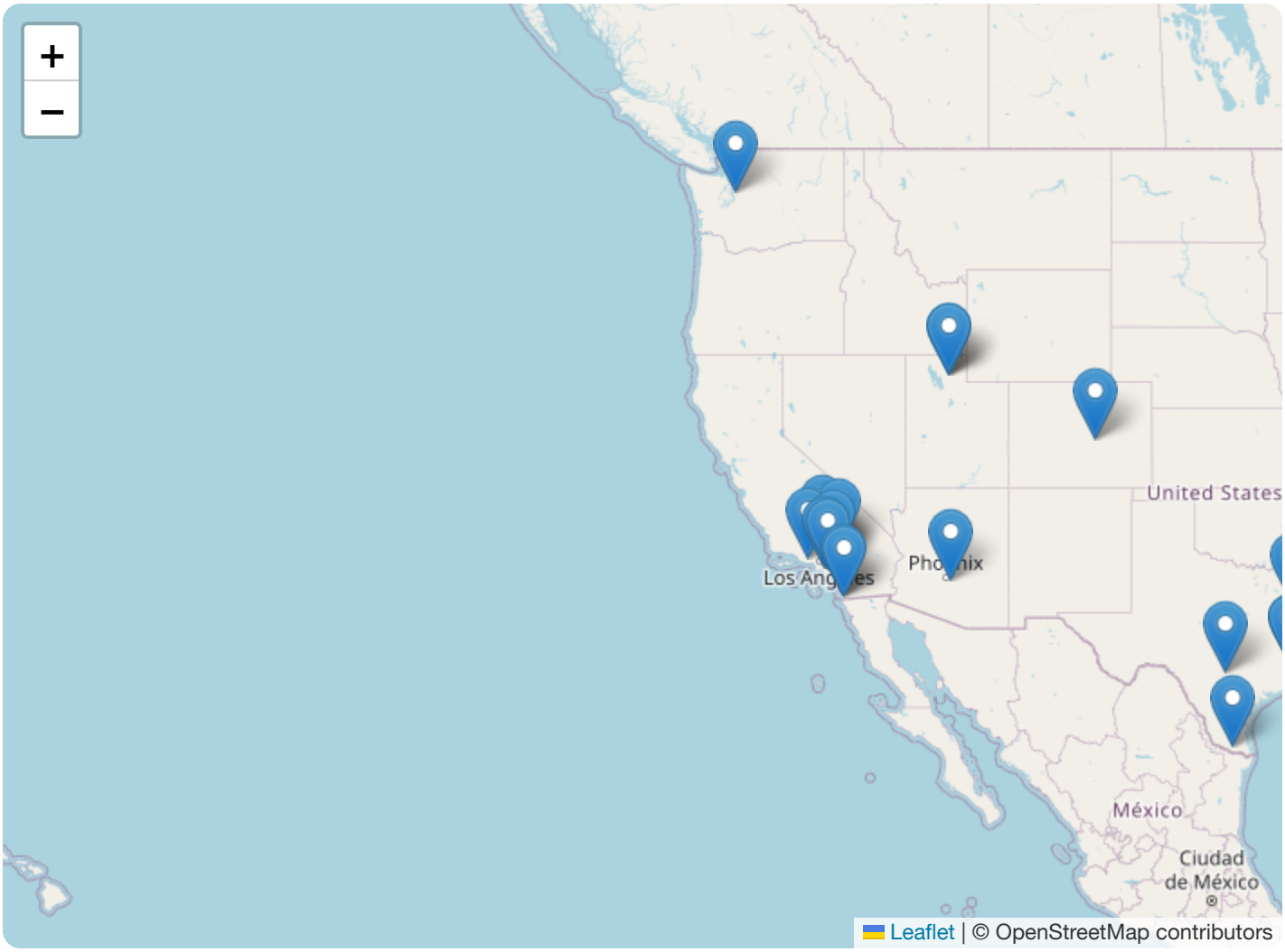
- ✓ ClinicalTrials.gov extracted study records for completed matching trials.
- ✓ Zlick-derived patients-per-site-per-month calculations.

Geographic hotspots

Showing areas with high prevalence of Ulcerative Colitis and low density of competing trials.

Map legend: blue = My Trial US sites, red circles = whitespace recommendations.

US sites: 46 | Geocoded My Trial sites: 45 | Whitespace areas: 0



This block loads automatically the first time you enter the Recruitment section.

- ✓ CDC PLACES (state) with county fallback, latest available year.
- ✓ ClinicalTrials.gov extracted study records for competitor density.

Find referring centers

Support enrollment in your sites with patient referrals from nearby specialists and treatment centers.

Selected site: Orlando Health Digestive Health Institute - Orlando, FL | ZIP: N/A

My site	Referrer	Type	Distance
Orlando Health Digestive Health Institute	DOCTORS OF CLINICAL SPECIALTIES LLC	Internal Medicine, Gastroenterology	4.2 mi
Orlando Health Digestive Health Institute	CFAGI, LLC	Internal Medicine, Gastroenterology	6.0 mi
Orlando Health Digestive Health Institute	STEVEN BRINT	Internal Medicine, Gastroenterology	10 mi
Orlando Health Digestive Health Institute	ABDUL BHUTTA	Internal Medicine, Gastroenterology	17 mi
Orlando Health Digestive Health Institute	ADVANCED MEDICAL GROUP OF CENTRAL FLORIDA, LLC	Internal Medicine, Gastroenterology	17 mi
Orlando Health Digestive Health Institute	MOHAMMAD ANWER	Internal Medicine, Gastroenterology	17 mi
Orlando Health Digestive Health Institute	SAEED ALI	Internal Medicine, Gastroenterology	24 mi
Orlando Health Digestive Health Institute	CURTIS ADOLPHSON	Internal Medicine, Gastroenterology	78 mi
Orlando Health Digestive Health Institute	PATRICK BRADY	Internal Medicine, Gastroenterology	78 mi
Orlando Health Digestive Health Institute	WOJCIECH BLONSKI	Internal Medicine, Gastroenterology	78 mi

Derived ZIP: N/A | Specialty lane: Gastroenterology | Specialty filter: Gastroenterology, Clinic/Center, Gastroenterology

- ✓ CMS NPI Registry.
- ✓ My Trial site location derived from ClinicalTrials.gov extracted site records.

Recommendations

Generate new

Action plan generated from the trial profile, benchmarks, competitive pressure, recruitment opportunity/risk, eligibility burden, and nearby research/referral evidence.

1. Consolidate the site footprint by closing or pausing the lowest-enrolling sites and concentrating resources on proven high-capacity locations.

High

The trial has 207 active locations versus a peer average of ~31, yet patients per site per month is <0.1 compared to a peer average of 1.3 — a 98.8% deficit — indicating extreme site dilution. Completed-actuals data (median 0.10 patients/site/month across 76 comparable trials) confirms that even well-run UC trials enroll slowly per site, so spreading across 207 sites without proportional enrollment is operationally inefficient. Reducing to a focused set of 40–60 top-performing sites would improve per-site economics and allow reallocation of monitoring and startup budgets toward patient-finding activities.

2. Leverage Southern California academic GI networks — particularly investigators connected to Cedars-Sinai and UC San Diego IBD programs — to accelerate referrals into nearby enrolled sites (Erick Alayo Medical Corp, Southern California GI and Liver Centers).

High

NIH research-network data shows Cedars-Sinai (PI Gil Y Melmed, 8 projects, $4.6M funding) and UCSD (PI John T Chang, 4 projects, $2.2M) as the highest-funded IBD research hubs proximate to two current trial sites in Southern California. These institutions have active UC-focused research pipelines (e.g., 'Impaired cellular RNA editing as a cause of inflammation in IBD') and established patient cohorts. Formalizing referral pathways from these academic centers to the nearby trial sites could tap a concentrated, trial-aware patient pool.

3. Mitigate patient competition at multi-trial sites (Peak Gastroenterology–Colorado Springs, Tyler Research Institute–Tyler TX, Baylor/Intergrity–Houston TX) by negotiating enrollment priority agreements or deploying dedicated recruitment support at those locations.

High

In-site competition data shows Peak Gastroenterology, Tyler Research Institute, and multiple Houston sites each running 2–3 competing UC trials (including Lilly's own NCT07186101 as well as AbbVie NCT06257875 and Takeda NCT06254950). With 35 related trials in the competitive landscape and the highest competitor overlap at 30.9% (AbbVie), these shared sites risk splitting an already narrow eligible population. Dedicated site-level coordinators or enhanced per-patient stipends at these contested sites can help secure referral priority for NCT06598943.

4. Differentiate the trial's value proposition to prospective participants by emphasizing the novel eltrekibart + mirikizumab combination mechanism and the relatively low protocol burden compared to competitors.

Medium

The protocol burden score of 91.3 ('in line with similar trials') with 40.9% fewer exclusion criteria than peers makes this trial comparatively accessible. Meanwhile, the eltrekibart + mirikizumab dual-mechanism design is unique in the UC landscape — web evidence from [clinicaltrials.eu](https://clinicaltrials.eu/trial/study-on-eltrekibart-and-mirikizumab-for-adults-with-moderate-to-severe-ulcerative-colitis/) and [allclinicaltrials.com](https://www.allclinicaltrials.com/study/NCT06598943) confirms this is the only active trial combining an anti-IL-13 (eltrekibart) with an anti-IL-23p19 (mirikizumab). Patient-facing recruitment materials should highlight the chance to receive two novel biologics and the streamlined eligibility, which may attract patients who have screened out of more restrictive competitor protocols.

5. Proactively plan for the endoscopy bottleneck by pre-scheduling central-read endoscopies and shortening the screening-to-randomization window at top sites.

Medium

The single high-bottleneck eligibility criterion — 'moderately to severely active UC as assessed by the UC disease activity score' — requires endoscopic confirmation that is not captured in structured data and adds scheduling complexity. Lilly's own parallel UC trial (NCT06937086 per [trial.medpath.com](https://trial.medpath.com/clinical-trial/aeee2d54bd1a297f/nct06936086-mirikizumab-tirzepatide-ulcerative-colitis-obesity)) uses the same modified Mayo/endoscopic subscore requirement, meaning endoscopy suites at shared sites face double demand. Pre-booking endoscopy slots and establishing rapid central-read turnaround agreements can reduce screen failures and the screening-to-enrollment lag that compounds the already low per-site enrollment rate.

Market analysis

Optional: Indicate a sponsor of focus

Enter company name here

Generate new

Currently marketed

The moderate-to-severe UC market is intensely competitive, with three distinct advanced therapy classes—IL-23 inhibitors, JAK inhibitors, and S1P modulators—now all established alongside the maturing anti-TNF and anti-integrin segments. The IL-23 class has become the fastest-moving battleground: risankizumab (Skyrizi, approved June 2024) is ramping aggressively on AbbVie's commercial infrastructure, guselkumab (Tremfya) entered UC in March 2025 as the newest IL-23 entrant, and mirikizumab (Omvoh)—the backbone of NCT06598943—is still in early launch ramp with $432 million in 2024 global sales across UC and Crohn's disease. Upadacitinib (Rinvoq) remains the fastest-growing oral advanced therapy in UC at $4.4 billion across indications, setting a high efficacy bar for any new entrant, while ustekinumab (Stelara) faces accelerating biosimilar erosion that is reshaping prior-line treatment patterns and, critically, disqualifying a growing pool of patients from NCT06598943 via its anti-IL-12p40 exclusion criterion. Vedolizumab (Entyvio) holds a durable position on gut-selective safety grounds, and the S1P agents ozanimod and etrasimod occupy a modest but growing oral niche; patients failing any of these agents represent the core eligible population for the Lilly combination trial.

Drug	Type	Manufacturer	~Annual sales
Stelara (ustekinumab)	Anti-IL-12/23p40 monoclonal antibody	Johnson & Johnson (Janssen)	**$10.4 billion (2024, all indications, global)** FY2024, all indications, global; UC-specific not broken out Biosimilar entry began in US in early 2025 following patent expiration; multiple biosimilars (Wezlana, Selarsdi, Otulfi, Pyzchiva) now launched or launching, creating significant pricing pressure. Still a major UC anchor therapy but revenue declining. Excluded from NCT06598943 (prior anti-IL-12p40 use is an exclusion criterion), making it a prior-line reference rather than direct competitor in the trial population.

Drug	Type	Manufacturer	~Annual sales
Entyvio (vedolizumab)	Anti-α4β7 integrin monoclonal antibody (gut-selective)	Takeda	**$2.5 billion (FY2024, global, all indications)** FY2024, all indications (UC + CD), global Subcutaneous formulation (Entyvio SC) approved and growing; IV formulation remains standard of care. Biosimilar competition emerging in Europe; US biosimilar entry expected mid-to-late 2020s. Gut-selective mechanism favored in patients with safety concerns around systemic immunosuppression. Directly competes in the biologic-experienced moderate-to-severe UC population targeted by NCT06598943.
Omvoh (mirikizumab)	Anti-IL-23p19 monoclonal antibody	Eli Lilly and Company	**$432 million (FY2024, global, all indications)** FY2024, all indications (UC + CD), global; UC approved Oct 2023 US, CD approved Feb 2025 US Approved for moderate-to-severe UC in US (Oct 2023) and EU (Sep 2023); Crohn's disease approval received Feb 2025 in US, expanding addressable market. Still in early launch ramp. Serves as the backbone drug in NCT06598943 (eltrekibart + mirikizumab combination), making it both a comparator and a platform asset for Lilly's combination strategy. Competing in the same IL-23 class as risankizumab and guselkumab.

Drug	Type	Manufacturer	~Annual sales
Skyrizi (risankizumab)	Anti-IL-23p19 monoclonal antibody	AbbVie	**$4.0 billion (FY2024, all indications, global)** FY2024, all indications (UC + CD + psoriasis + PsA), global; UC approved Jun 2024 US UC approval received June 2024 in US; rapidly ramping in IBD following strong Phase 3 data. Competes directly with mirikizumab in the IL-23 class for moderate-to-severe UC. AbbVie's commercial infrastructure and established IBD relationships (post-Humira) give it significant launch momentum. Key competitor in the same patient population as NCT06598943.
Xeljanz / Xeljanz XR (tofacitinib)	Pan-JAK inhibitor (JAK1/JAK3 preferential)	Pfizer	**$1.8 billion (FY2024, all indications, global)** FY2024, all indications (UC + RA + PsA + AS), global First oral advanced therapy approved for UC (2018). Black box warning for serious infections, malignancy, MACE, and thrombosis limits use, particularly in patients >50 or with cardiovascular risk factors. Declining in UC as newer, more selective JAK inhibitors (upadacitinib) and biologics gain share. Still used in moderate-to-severe UC refractory to biologics.
Rinvoq (upadacitinib)	Selective JAK1 inhibitor	AbbVie	**$4.4 billion (FY2024, all indications, global)** FY2024, all indications (UC + CD + RA + PsA + AS + AD), global; UC approved May 2022 US Fastest-growing advanced therapy in UC; strong Phase 3 data showing superiority over adalimumab in CD and robust UC remission rates. Black box warning (class effect for JAK inhibitors) but JAK1 selectivity profile considered more favorable than tofacitinib. Competes directly in the biologic-experienced moderate-to-severe UC population. Key commercial benchmark for any new UC entrant.

Drug	Type	Manufacturer	~Annual sales
Zeposia (ozanimod)	Sphingosine-1-phosphate (S1P) receptor 1/5 modulator	Bristol-Myers Squibb	**Not publicly broken out** UC-specific revenue not disclosed; included in BMS immunology segment Approved for moderate-to-severe UC in May 2021. Oral agent with cardiac monitoring requirements at initiation. Modest market penetration relative to JAK inhibitors; competes in the same oral advanced therapy space. Patients who fail ozanimod are eligible for NCT06598943.
Velsipity (etrasimod)	Sphingosine-1-phosphate (S1P) receptor 1/4/5 modulator	Pfizer (acquired from Arena Pharmaceuticals)	**Not publicly broken out** Recently launched; Pfizer does not break out UC-specific etrasimod revenue Approved for moderate-to-severe UC in October 2023 in US. Once-daily oral agent; differentiated from ozanimod by receptor selectivity profile. Competing in the S1P class alongside ozanimod. Patients who fail etrasimod are eligible for NCT06598943 (S1P failure is an inclusion criterion). Pediatric extension study ongoing (NCT05287126).
Tremfya (guselkumab)	Anti-IL-23p19 monoclonal antibody	Johnson & Johnson (Janssen)	**$3.8 billion (FY2024, all indications, global)** FY2024, all indications (UC + CD + psoriasis + PsA), global; UC approved March 2025 US UC approval received March 2025 in US, making it the newest IL-23 entrant in UC. Joins mirikizumab and risankizumab in the IL-23 class. J&J's strong commercial infrastructure and established dermatology/rheumatology relationships support rapid uptake. Competes directly in the same moderate-to-severe UC population as NCT06598943.

Drug	Type	Manufacturer	~Annual sales
Humira / biosimilars (adalimumab)	Anti-TNF monoclonal antibody	AbbVie (originator); multiple biosimilar manufacturers	**$8.9 billion (AbbVie Humira FY2024, all indications, global; biosimilar revenues additional)** FY2024, AbbVie Humira only, all indications, global; US biosimilar market share growing rapidly Multiple adalimumab biosimilars launched in US since 2023 (Hadlima, Hyrimoz, Cyltezo, Yusimry, Simlandi, Abrilada, Hulio, Idacio, Hadlima). Significant price erosion ongoing. Still widely used as first-line biologic in UC but losing share to newer mechanisms. Patients who fail adalimumab are a core target population for NCT06598943.

Expected within 12 months

The only near-term regulatory event of direct relevance is guselkumab's supplemental NDA for Crohn's disease, with a PDUFA date anticipated in Q2 2026; UC approval for guselkumab is already in effect as of March 2025. A CD approval would extend J&J's IL-23 franchise across both major IBD indications, intensifying competition with mirikizumab—which received its own US CD approval in February 2025—and risankizumab, which already holds both UC and CD labels. This approval, if granted, would further consolidate the IL-23 class as the dominant biologic backbone in IBD and increase commercial pressure on Lilly to differentiate mirikizumab through combination strategies such as the one being evaluated in NCT06598943. No other novel mechanism approvals are expected within the next twelve months that would materially alter the competitive landscape for the biologic-experienced moderate-to-severe UC population targeted by this trial.

Drug	Type	Manufacturer	Regulatory milestone
Tremfya (UC label – already approved March 2025; CD NDA under review) (guselkumab)	Anti-IL-23p19 monoclonal antibody	Johnson & Johnson (Janssen) $3.8 billion (FY2024, all indications, global) | FY2024, all indications, global; CD-specific NDA filed; UC already approved	**Crohn's disease sNDA under FDA review; PDUFA date expected mid-2026 based on J&J investor communications** 2026-Q2

Promising pipeline

The most commercially significant near-term pipeline asset is tulisokibart (Merck's anti-TL1A), which posted striking Phase 2 remission data and is now in a Phase 3 program with primary completion expected August 2026, positioning it for a potential 2027–2028 launch that would

introduce a genuinely novel mechanism into the biologic-experienced UC population. Obefazimod, an oral RNA-modulating small molecule from Abivax, is the most advanced novel oral candidate with Phase 3 data maturing and regulatory interactions underway, and its differentiated mechanism and oral route could appeal to patients and prescribers fatigued by injectable biologics. Of particular strategic relevance to NCT06598943 is Spyre Therapeutics' SPEAR-UC platform, which is directly testing long-acting anti-integrin plus anti-IL-23 combinations—a concept that mirrors Lilly's eltrekibart plus mirikizumab hypothesis—as well as Lilly's own intra-portfolio comparator study pairing the oral integrin antagonist MORF-057 with mirikizumab, meaning the combination strategy itself will face internal and external validation pressure before any Phase 3 investment decision. Zasocitinib (Takeda's oral TYK2 inhibitor) and rosnilimab (AnaptysBio's anti-PD-1 agonist) represent mechanistically distinct Phase 2 assets that, if successful, could further fragment the advanced-therapy-experienced segment in the 2028–2030 timeframe.

Drug	Type	Manufacturer	Phase / latest readout
Tulisokibart (MK-7240 / PRA023) (tulisokibart)	Anti-TL1A (TNF-like ligand 1A) monoclonal antibody	Merck Sharp & Dohme LLC	**Phase 3** Phase 2 TUSCANY data (2023) showed ~26% clinical remission vs ~1% placebo at Week 12 in moderate-to-severe UC; Phase 3 ARTEMIS-UC program (NCT06052059) primary completion Aug 2026
Obefazimod (ABX464) (obefazimod)	RNA-modulating small molecule (miR-124 upregulator); oral anti-inflammatory	Abivax S.A.	**Phase 3** Phase 2b ABIVAX-II data showed 26.5% clinical remission at Week 8 induction vs 8.1% placebo; Phase 3 ABTECT program ongoing; OLE primary completion March 2026; EMA and FDA interactions ongoing
Rosnilimab (ANB030) (rosnilimab)	Anti-PD-1 agonist antibody (regulatory T-cell restoration)	AnaptysBio, Inc.	**Phase 2** ROSETTA Phase 2 study (NCT06127043) primary completion January 2026; data readout expected H1 2026; novel mechanism targeting Treg restoration in biologic-experienced moderate-to-severe UC; Phase 3 decision anticipated mid-2026

Drug	Type	Manufacturer	Phase / latest readout
Zasocitinib (TAK-279) (zasocitinib)	Selective TYK2 inhibitor (oral)	Takeda	**Phase 2** Phase 2 induction study (NCT06254950) in moderate-to-severe UC; primary completion September 2026; TYK2 inhibition validated in psoriasis (deucravacitinib); oral route differentiates from IV/SC biologics in same advanced-therapy-experienced UC population
SPY001 / SPY002 (long-acting anti-α4β7 / anti-IL-23 combination) (SPY001 / SPY002)	Long-acting anti-α4β7 integrin antibody (SPY001) + long-acting anti-IL-23p19 antibody (SPY002); extended half-life platform enabling infrequent dosing	Spyre Therapeutics, Inc.	**Phase 2** SPEAR-UC platform trial (NCT07012395) initiated May 2025; primary completion June 2026; tests monotherapies and combinations including anti-integrin + anti-IL-23 in moderate-to-severe UC; directly competitive with eltrekibart+mirikizumab combination concept
LY4268989 (MORF-057) + Mirikizumab (LY4268989 (MORF-057) + mirikizumab)	Oral integrin α4β7 antagonist (small molecule) + anti-IL-23p19 monoclonal antibody combination	Eli Lilly and Company	**Phase 2** Phase 2 study (NCT07186101) initiated November 2025; primary completion May 2027; tests oral integrin antagonist MORF-057 co-administered with mirikizumab vs mirikizumab alone in virtually identical UC population to NCT06598943; intra-Lilly comparator to eltrekibart+mirikizumab program
Lutikizumab (ABT-981) (lutikizumab)	Dual IL-1α/IL-1β inhibitor monoclonal antibody	AbbVie	**Phase 2** Phase 2 induction and maintenance study (NCT06257875) in moderate-to-severe UC with adalimumab active comparator arm; primary completion September 2027; novel mechanism from major IBD sponsor; Phase 3 decision expected late 2027
RO7837195 (RO7837195)	Undisclosed novel target; Phase 2b placebo-controlled induction study	Genentech / Roche	**Phase 2b** Phase 2b study (NCT06979336) initiated September 2025; primary completion August 2027; Genentech's IBD track record (etrolizumab experience, vedolizumab heritage) signals serious commercial intent; target undisclosed publicly

Drug	Type	Manufacturer	Phase / latest readout
BI 3032950 (BI 3032950)	Undisclosed novel mechanism (Boehringer Ingelheim IBD pipeline)	Boehringer Ingelheim	**Phase 2a** Phase 2a open-label induction + SC maintenance study (NCT06636656) in biologic-experienced moderate-to-severe UC; primary completion January 2026 (past); full study completion February 2028; Phase 2b decision expected 2026

Market timing view

- [S36] AbbVie Pipeline – Lutikizumab (ABT-981) IBD Program (Company website / pipeline)
- [S19] AbbVie Q4 2024 Earnings – Humira Revenue and Biosimilar Impact (Company earnings report)
- [S12] AbbVie Q4 2024 Earnings – Rinvoq Revenue (Company earnings report)
- [S8] AbbVie Q4 2024 Earnings – Skyrizi Revenue (Company earnings report)

- [S25] Abivax Press Release – Obefazimod Phase 3 ABTECT Program Update, 2024 (Company press release)
- [S41] adisinsight.springer.com – Eltrekibart + Mirikizumab Phase 2 UC Trial Profile (Clinical trial registry / database)
- [S27] AnaptysBio Press Release – Rosnilimab ROSETTA Phase 2 UC Study Update (Company press release)
- [S39] clinicaltrials.eu – Eltrekibart and Mirikizumab Phase 2 UC Study (NCT06598943) (Clinical trial registry)
- [S26] ClinicalTrials.gov – NCT05177835 (Obefazimod OLE Study) (Clinical trial registry)
- [S23] ClinicalTrials.gov – NCT06052059 ARTEMIS-UC (Tulisokibart Phase 3) (Clinical trial registry)
- [S28] ClinicalTrials.gov – NCT06127043 ROSETTA (Rosnilimab Phase 2 UC) (Clinical trial registry)
- [S30] ClinicalTrials.gov – NCT06254950 (Zasocitinib Phase 2 UC) (Clinical trial registry)
- [S35] ClinicalTrials.gov – NCT06257875 (Lutikizumab Phase 2 UC) (Clinical trial registry)
- [S38] ClinicalTrials.gov – NCT06636656 (BI 3032950 Phase 2a UC, Boehringer Ingelheim) (Clinical trial registry)
- [S37] ClinicalTrials.gov – NCT06979336 (RO7837195 Phase 2b UC, Genentech) (Clinical trial registry)
- [S32] ClinicalTrials.gov – NCT07012395 SPEAR-UC (SPY001/SPY002 Phase 2) (Clinical trial registry)
- [S33] ClinicalTrials.gov – NCT07186101 (LY4268989/MORF-057 + Mirikizumab Phase 2 UC) (Clinical trial registry)
- [S34] Eli Lilly Pipeline – MORF-057 (LY4268989) Oral Integrin Antagonist UC Program (Company website / pipeline)
- [S5] Eli Lilly Q4 2024 Earnings – Omvoh (Mirikizumab) Revenue (Company earnings report)
- [S20] FDA – Adalimumab Biosimilar Approvals Reference List (FDA regulatory decision)
- [S15] FDA – Etrasimod (Velsipity) UC Approval, October 2023 (FDA regulatory decision)
- [S17] FDA – Guselkumab (Tremfya) UC Approval, March 2025 (FDA regulatory decision)
- [S6] FDA – Mirikizumab (Omvoh) Approval for Ulcerative Colitis, October 2023 (FDA regulatory decision)
- [S7] FDA – Mirikizumab (Omvoh) Crohn's Disease Approval, February 2025 (FDA regulatory decision)
- [S14] FDA – Ozanimod (Zeposia) UC Approval, May 2021 (FDA regulatory decision)
- [S9] FDA – Risankizumab (Skyrizi) UC Approval, June 2024 (FDA regulatory decision)
- [S11] FDA – Tofacitinib (Xeljanz) Prescribing Information and Black Box Warning Update (FDA label / prescribing information)
- [S13] FDA – Upadacitinib (Rinvoq) UC Approval, May 2022 (FDA regulatory decision)
- [S2] FDA – Ustekinumab Biosimilar Approvals (Wezlana, Selarsdi, Pyzchiva, Otulfi) (FDA regulatory decision)
- [S4] FDA – Vedolizumab (Entyvio) Prescribing Information (FDA label / prescribing information)
- [S1] J&J 2024 Annual Report / Earnings – Stelara Revenue (Company earnings report)
- [S21] J&J Investor Presentation 2025 – Guselkumab Crohn's Disease NDA Filing and PDUFA (Investor presentation)
- [S18] J&J Q4 2024 Earnings – Tremfya Revenue and UC/CD Pipeline Update (Company earnings report)
- [S22] Merck Q4 2024 Earnings – Tulisokibart (MK-7240) Phase 3 Update (Company earnings report)
- [S16] Pfizer 2024 Annual Report – Velsipity (Etrasimod) Launch Update (Company earnings report)
- [S10] Pfizer 2024 Annual Report – Xeljanz Revenue (Company earnings report)
- [S24] Sandborn WJ et al. – Tulisokibart Phase 2 TUSCANY Results, NEJM 2023 (Peer-reviewed publication)
- [S31] Spyre Therapeutics Investor Presentation – SPEAR-UC Platform Trial Design, 2025 (Investor presentation)
- [S3] Takeda FY2024 Earnings – Entyvio Revenue (Company earnings report)
- [S29] Takeda Investor Presentation 2025 – Zasocitinib (TAK-279) UC Phase 2 Update (Investor presentation)