

History of Changes for Study: NCT02407236

**A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderat
Severely Active Ulcerative Colitis (UNIFI)**[Latest version \(submitted January 3, 2023\) on ClinicalTrials.gov](#)

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of th
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in green.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	☐	☐	March 30, 2015	None (earliest Version on record)
2	☐	☐	April 20, 2015	Study Status
3	☐	☐	May 11, 2015	Study Status
4	☐	☐	June 1, 2015	Study Status
5	☐	☐	July 14, 2015	Study Status
6	☐	☐	August 11, 2015	Study Status and Contacts/Locations
7	☐	☐	September 23, 2015	Contacts/Locations and Study Status
8	☐	☐	October 16, 2015	Recruitment Status, Contacts/Locations and Study Status
9	☐	☐	November 6, 2015	Contacts/Locations and Study Status
10	☐	☐	November 27, 2015	Contacts/Locations and Study Status
11	☐	☐	December 21, 2015	Contacts/Locations and Study Status
12	☐	☐	January 12, 2016	Contacts/Locations and Study Status
13	☐	☐	February 2, 2016	Contacts/Locations and Study Status
14	☐	☐	February 23, 2016	Contacts/Locations and Study Status
15	☐	☐	March 15, 2016	Contacts/Locations and Study Status
16	☐	☐	April 5, 2016	Contacts/Locations and Study Status
17	☐	☐	April 22, 2016	Contacts/Locations and Study Status
18	☐	☐	May 13, 2016	Contacts/Locations and Study Status
19	☐	☐	June 1, 2016	Contacts/Locations and Study Status
20	☐	☐	June 22, 2016	Contacts/Locations and Study Status
21	☐	☐	July 13, 2016	Contacts/Locations and Study Status
22	☐	☐	August 3, 2016	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
23	☐	☐	August 24, 2016	Contacts/Locations and Study Status
24	☐	☐	October 14, 2016	Contacts/Locations and Study Status
25	☐	☐	November 12, 2016	Contacts/Locations, Study Status and Oversight
26	☐	☐	December 12, 2016	Contacts/Locations and Study Status
27	☐	☐	February 10, 2017	Contacts/Locations and Study Status
28	☐	☐	March 10, 2017	Study Status and Contacts/Locations
29	☐	☐	March 21, 2017	Contacts/Locations and Study Status
30	☐	☐	April 20, 2017	Contacts/Locations, Study Status and Oversight
31	☐	☐	May 16, 2017	Study Status and Contacts/Locations
32	☐	☐	June 13, 2017	Contacts/Locations and Study Status
33	☐	☐	July 11, 2017	Study Status and Contacts/Locations
34	☒	☐	August 8, 2017	Contacts/Locations and Study Status
35	☐	☒	September 6, 2017	Recruitment Status, Contacts/Locations, Study Status and Study Design
36	☐	☐	November 28, 2017	Study Status and Contacts/Locations
37	☐	☐	February 26, 2018	Study Status and Contacts/Locations
38	☐	☐	March 21, 2018	Study Status and Study Design
39	☐	☐	August 13, 2018	Study Status and Study Design
40	☐	☐	October 3, 2018	Study Status
41	☐	☐	October 31, 2018	Study Design and Study Status
42	☐	☐	November 28, 2018	Study Status and Study Design
43	☐	☐	March 21, 2019	Study Status and Study Design
44	☐	☐	April 18, 2019	Study Status and Contacts/Locations
45	☐	☐	May 16, 2019	Study Status and Study Design
46	☐	☐	June 13, 2019	Study Status
47	☐	☐	August 8, 2019	Study Status
48	☐	☐	August 26, 2019	Arms and Interventions and Study Status
49	☐	☐	October 31, 2019	Study Status
				► Results Submission Events
50	☐	☐	December 20, 2019	Outcome Measures, Study Status, More Information, Document Section, Adverse Events, Baseline Characteristics, Participant Flow and Study Design
51	☐	☐	January 21, 2020	Study Status
52	☐	☐	February 18, 2020	Study Status and Contacts/Locations
53	☐	☐	March 17, 2020	Study Status
54	☐	☐	April 14, 2020	Study Status and Contacts/Locations
55	☐	☐	May 12, 2020	Study Status
56	☐	☐	July 7, 2020	Study Status
57	☐	☐	September 29, 2020	Study Status and Contacts/Locations
58	☐	☐	October 27, 2020	Study Status

Version	A	B	Submitted Date	Changes
59	☐	☐	November 24, 2020	Study Status
60	☐	☐	December 22, 2020	Contacts/Locations and Study Status
61	☐	☐	January 19, 2021	Study Status
62	☐	☐	March 16, 2021	Study Status
63	☐	☐	April 12, 2021	Study Status
64	☐	☐	May 11, 2021	Study Status
65	☐	☐	June 7, 2021	Study Status
66	☐	☐	July 6, 2021	Study Status
67	☐	☐	August 3, 2021	Contacts/Locations and Study Status
68	☐	☐	August 31, 2021	Study Status
69	☐	☐	September 28, 2021	Study Status
70	☐	☐	October 26, 2021	Study Status
71	☐	☐	November 23, 2021	Study Status
72	☐	☐	February 2, 2022	Recruitment Status and Study Status
73	☐	☐	August 2, 2022	Study Status and Contacts/Locations
74	☐	☐	November 29, 2022	Adverse Events, Participant Flow, Baseline Characteristics, Study Status, Document Section and More Information
75	☐	☐	January 3, 2023	Study Status

Compare

Comparison Format: ☒ Merged
☐ Side-by-Side

[Scroll up to access the controls](#)

Compare v33 to v34

Changes (Merged) for Study: NCT02407236
August 8, 2017 (v34) -- September 6, 2017 (v35)

Compar

Changes in: [Study Status](#), [Study Design](#) and [Contacts/Locations](#)

☐ Show only changed modules

▼ Study Identification

Unique Protocol ID: CR106920

Brief Title: A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI)

Official Title: A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy Ustekinumab Induction and Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis

Secondary IDs: 2014-005606-38 [EudraCT Number]
CNT01275UCO3001 [Janssen Research & Development, LLC]

▼ Study Status

Record Verification: ~~August 2017~~ September 2017

Overall Status: ~~Recruiting~~ Active, not recruiting

Study Start: July 10, 2015

Primary Completion: April 12, 2018 [Anticipated]

Study Completion: October 13, 2021 [Anticipated]

First Submitted: March 30, 2015

First Submitted that March 30, 2015

Met QC Criteria:

First Posted: April 2, 2015 [Estimate]

Last Update Submitted that ~~August 8, 2017~~ September 6, 2017

Met QC Criteria:

Last Update Posted: ~~August 9~~ September 8, 2017 [Actual]

▼ Sponsor/Collaborators

Sponsor: Janssen Research & Development, LLC

Responsible Party: Sponsor

Collaborators:

▼ Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device: No

Data Monitoring: Yes

▼ Study Description

Brief Summary: The purpose of this study is to evaluate the efficacy and safety of ustekinumab as intravenous (IV: into the vein) infusion in induction in participants with moderately to severely active Ulcerative Colitis (UC) and as subcutaneous (SC) administration in maintenance : participants with moderately to severely active Ulcerative Colitis (UC) who have demonstrated a clinical response to Induction treat with IV ustekinumab.

Detailed Description: This is a Phase 3, randomized (assignment of study drug by chance), double-blind (neither the participant or study staff will know the identity of study drugs), placebo-controlled (placebo is an inactive substance that is compared with a drug to test whether the drug has a real effect in a clinical trial), parallel-group (a medical research study comparing the response in 2 or more groups of participants receiving different interventions), multi-center (more than one clinical site will work on a medical research study), protocol of ustekinumab. The protocol will consist of 2 studies: an Induction study and a Maintenance study with unique endpoints. Screening period will be up to 4 Weeks. Induction study will be at least 8 weeks duration for each participant. Participant with clinical response in the Induction study will be eligible for the Maintenance study. The Maintenance study will be 44 weeks duration. After completion of the maintenance study term extension will follow eligible participants for an additional 3 years. Clinical remission will be evaluated at Week 8 in the Induction study. Clinical remission among ustekinumab Induction responders will be evaluated at week 44 in the Maintenance study. Participant safety will be monitored throughout.

▼ Conditions

Conditions: Colitis, Ulcerative
Inflammatory Bowel Diseases

Keywords: Ustekinumab
Inflammatory Bowel Diseases (IBD)
Colitis, Ulcerative

▼ Study Design

Study Type: Interventional

Primary Purpose: Other

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 10

Masking: Double (Participant, Investigator)

Allocation: Randomized

Enrollment: ~~951 [Anticipated]~~ 966 [Actual]

▼ Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Induction Study - Placebo Intravenous (IV) Participants will be randomized to receive single dose of placebo as Intravenous (IV: into the vein) infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study, but will not be randomized.	Drug: Placebo IV Placebo will be administered as intravenous infusion.
Experimental: Induction Study - Ustekinumab 130 milligram (mg) IV Participants will be randomized to receive single dose of ustekinumab 130 mg as IV infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infusion Week 0 or Week 8 in Induction Study.
Experimental: Induction Study - Ustekinumab 6 mg/kg IV Participants will be randomized to receive ustekinumab approximating 6 mg/kg of body weight, as intravenous infusion at Week 0. Participants with clinical response at Week 8 will be eligible to enter the Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infusion Week 0 or Week 8 in Induction Study.
Induction Study- Placebo- Nonresponders at Week 8 Participants without clinical response to placebo at Week 8 will receive a single IV infusion of ustekinumab approximating 6mg/kg along with matching subcutaneous (SC) placebo (to maintain the blind). Participants in clinical response at Week 16 will be eligible to enter Maintenance study and will be randomized.	Drug: Ustekinumab IV Ustekinumab will be administered as intravenous infusion Week 0 or Week 8 in Induction Study.
Induction study-Ustekinumab Nonresponders at Week 8 Participants without clinical response to ustekinumab (130 mg or 6 mg/kg [IV]) at Week 8 will receive a single dose of ustekinumab 90 mg subcutaneously along with matching placebo intravenously (to maintain the blind). Participants in clinical response at Week 16 (that is, delayed responders) will be eligible to enter Maintenance study, but will not be randomized.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Placebo Comparator: Maintenance Study - Placebo Subcutaneous (SC) Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44.	Drug: Placebo SC Placebo will be administered Subcutaneously.
Experimental: Maintenance Study - Ustekinumab 90mg SC every 12 weeks Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive ustekinumab 90 mg subcutaneously every 12 weeks, beginning Week 0 of Maintenance study through Week 44.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Experimental: Maintenance Study - Ustekinumab 90mg SC every 8 weeks (q8w) Participants in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab will be randomized to receive ustekinumab 90 mg subcutaneously every 8 weeks, beginning Week 0 of Maintenance study through Week 44.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.
Maintenance Study - Placebo IV - Responder - Placebo SC Participants in clinical response to Induction treatment with IV Placebo will receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44. Participants are not randomized.	Drug: Placebo SC Placebo will be administered Subcutaneously.
Maintenance Study-Delayed Responder-Ustekinumab 90mg SC q8w Participants without clinical response to induction treatment ustekinumab (130 mg or 6 mg/kg [IV]) at Week 8 but in clinical response at Week 16 after receiving Induction Ustekinumab at week 8 (delayed responders) will receive ustekinumab 90 mg subcutaneously every 8 weeks, beginning Week 0 of Maintenance study through Week 44. Participants are not randomized.	Drug: Ustekinumab SC Ustekinumab will be administered as subcutaneously.

▼ Outcome Measures

Primary Outcome Measures:

1. Induction Study - Number of Participants With Clinical Remission
[Time Frame: Week 8]

The global definition of Clinical remission is defined as Mayo score less than or equal to ($\leq$) 2 points, with no individual subscore than ($>$) 1, for countries outside the United States (US). For the US, Clinical remission is defined as absolute stool number $\leq$ 3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis. The Mayo score ranges from 0 to 12 points and consists of 4 subscores (stool frequency, rectal bleeding, finding flexible sigmoidoscopy and physician's global assessment), each subscore is graded from 0 to 3 with the higher score indicating r severe disease activity.

2. Maintenance Study - Number of Participants with Clinical Remission Among Participants in Clinical Response to IV Ustekinumab Induction Treatment
[Time Frame: Week 44]

The global definition of Clinical remission is defined as Mayo score less than or equal to ($\leq$) 2 points, with no individual subscore than ($>$) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number $\leq$ 3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis. The Mayo score ranges from 0 to 12 points and consists of 4 subscores (stool frequency, rectal bleeding, finding flexible sigmoidoscopy and physician's global assessment), each subscore is graded from 0 to 3 with the higher score indicating r severe disease activity.

Secondary Outcome Measures:

1. Induction Study - Number of Participants with Clinical Response
[Time Frame: Week 8]

Clinical response is defined as a decreased from Induction baseline in the Mayo score by greater than or equal to ($\geq$) 30 percent and $\geq$ 3 points, with either a decrease from induction baseline in the rectal bleeding subscore $\geq$ 1 or rectal bleeding subscore = (

2. Induction Study - Number of Participants With Endoscopic Healing
[Time Frame: Week 8]

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It will be defined as Mayo endoscopic subscore 1.

3. Induction Study - Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Score
[Time Frame: Week 8]

The IBDQ is a 32-item questionnaire for participants with Inflammatory Bowel Disease (IBD) that will be used to evaluate the disease specific health-related quality of life across 4 dimensional scores: bowel (loose stools, abdominal pain), systemic (fatigue, altered pattern), social (work attendance, need to cancel social events), and emotional (anger, depression, irritability). The total score ran from 32 to 224 with higher scores indicating better quality of life.

4. Maintenance Study - Number of Participants with Clinical Response Among Participants in Clinical Response to IV Ustekinumab Induction Treatment
[Time Frame: Through Week 44]

Clinical response is defined as a decreased from Induction baseline in the Mayo score by greater than or equal to ($\geq$) 30 percent and $\geq$ 3 points, with either a decrease from Induction baseline in the rectal bleeding subscore $\geq$ 1 or rectal bleeding subscore = (

5. Maintenance Study - Number of Participants with Endoscopic Healing Among Participants in Clinical Response to IV Ustekinumab Induction Treatment
[Time Frame: Week 44]

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It will be defined as Mayo endoscopic subscore 1.

6. Maintenance Study - Number of Participants with Clinical Remission Among those who Achieved Clinical Remission at Maintenance Study Baseline
[Time Frame: Through Week 44]

The global definition of Clinical remission is defined as Mayo score less than or equal to ($\leq$) 2 points, with no individual subscore than ($>$) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number $\leq$ 3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis.

7. Maintenance Study - Number of Participants with Clinical Remission and not Receiving Concomitant Corticosteroids Among those Receiving Concomitant Corticosteroids at Maintenance Baseline
[Time Frame: Week 44]

The global definition of Clinical remission is defined as Mayo score less than or equal to ($\leq$) 2 points, with no individual subscore than ($>$) 1, for countries outside the United States (US). For the US Clinical remission is defined as absolute stool number $\leq$ 3, a bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1. The Mayo score is a tool designed to measure disease activity ulcerative colitis.

▼ Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Has a clinical diagnosis of Ulcerative Colitis (UC) at least 3 months before Screening
- Has moderately to severely active UC, defined as a Baseline (Week 0) Mayo score of 6 to 12, including a Screening endoscopy subscore of the Mayo score greater than or equal to ($\geq$) 2 as determined by a central reading of the video endoscopy
- Have failed biologic therapy, that is, have received treatment with 1 or more tumour necrosis factor (TNF) antagonists or vedolizumab at a dose approved for the treatment of UC, and have a documented history of failure to respond to or tolerate $\leq$ treatment; OR Be naïve to biologic therapy (TNF antagonists or vedolizumab) or have received biologic therapy but have not demonstrated a history of failure to respond to, or tolerate, a biologic therapy and have a prior or current UC medication history includes at least 1 of the following: a. Inadequate response to or failure to tolerate current treatment with oral corticosteroids or immunomodulators (6-mercaptopurine [6-MP] or azathioprine [AZA]) OR b. History of failure to respond to, or tolerate, at least the following therapies: oral or IV corticosteroids or immunomodulators (6-MP or AZA) OR c. History of corticosteroid dependence (that is, an inability to successfully taper corticosteroids without a return of the symptoms of UC)
- Before the first administration of study agent, the following conditions must be met: vedolizumab must have been discontinued at least 4 months and anti-tumor necrosis factors (TNFs) for at least 8 weeks

Exclusion Criteria:

- Has severe extensive colitis and is at imminent risk of colectomy
- Has UC limited to the rectum only or to < 20 centimeters (cm) of the colon
- Presence of a stoma or history of a fistula
- Participants with history of extensive colonic resection (for example, less than 30 cm of colon remaining) that would prevent adequate evaluation of the effect of study agent on clinical disease activity
- Participants with history of colonic mucosal dysplasia. Participants will not be excluded from the study because of a pathological finding of "indefinite dysplasia with reactive atypia"

▼ **Contacts/Locations**

Central Contact Person: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions: Email: JNJ.CT@sylogent.com

Study Officials: Janssen Research & Development, LLC Clinical Trial
Study Director
Janssen Research & Development, LLC

Locations: **United States, Alabama**University of Alabama Liver Center[Recruiting]Birmingham, Alabama, United States, 35294Mobile Medical And Diagnostic Center[Withdrawn]Mobile, Alabama, United States, 36617**United States, Arizona**Adobe Clinical Research LLC[Withdrawn]Tucson, Arizona, United States, 85712**United States, California**Scripps Clinic La Jolla[Withdrawn]La Jolla, California, United States, 92037**United States, California**Biovin Enterprises LLC dba Medvin Clinical Research[Recruiting]La Mirada, California, United States, 90638Cedars Sinai Medical Center[Recruiting]Los Angeles, California, United States, 90048

~~Surinder Saini M.D., Inc~~~~[Recruiting]~~~~Newport Beach, California, United States -02660~~~~Weisman Medical Group~~~~[Withdrawn]~~~~Palo Alto, California, United States, 94304~~~~South Bay Gastroenterology~~~~[Recruiting]~~~~Torrance, California, United States -00505~~~~Vallejo Hospital and Medical Offices~~~~[Recruiting]~~~~Vallejo, California, United States -04589~~**United States, Colorado**~~South Denver, PC~~~~[Recruiting]~~~~Lone Tree, Colorado, United States -80124~~**United States, Connecticut**~~Connecticut Gastroenterology Institute at Bristol Hospital~~~~[Withdrawn]~~~~Bristol, Connecticut, United States, 06010~~**United States, Connecticut**~~Connecticut GI~~~~[Recruiting]~~~~Farmington, Connecticut, United States -06032~~~~Chase Medical Research LLC~~~~[Withdrawn]~~~~Waterbury, Connecticut, United States, 06708~~**United States, District of Columbia**~~Georgetown Univ Hospital~~~~[Recruiting]~~~~Washington, D.C., District of Columbia, United States -20007~~**United States, Florida**~~Zasa Clinical Research~~~~[Withdrawn]~~~~Atlanta, Florida, United States, 33462~~~~Clinical Trials Management of Boca Raton Inc.~~~~[Withdrawn]~~~~Boca Raton, Florida, United States, 33428~~**United States, Florida**~~University of Florida~~~~[Active, not recruiting]~~~~Gainesville, Florida, United States -32610~~~~Florida Center For Gastroenterology~~~~[Recruiting]~~~~Largo, Florida, United States -33777~~~~A Plus Research~~~~[Recruiting]~~~~Miami, Florida, United States -33144~~~~Advanced Medical Research Center~~~~[Recruiting]~~~~Port Orange, Florida, United States -32127~~~~Univ. of South Florida Med. Group~~~~[Recruiting]~~~~Tampa, Florida, United States -33606~~~~Shafran Gastroenterology Center~~~~[Recruiting]~~

Winter Park, Florida, United States ~~-32789~~

~~Florida Medical Clinic, P.A.~~

~~[Recruiting]~~

Zephyrhills, Florida, United States ~~-33542~~

United States, Georgia

~~Emory University~~

~~[Recruiting]~~

Atlanta, Georgia, United States ~~-30322~~

~~Atlanta Gastroenterology Associates~~

~~[Recruiting]~~

~~Atlanta, Georgia, United States, 30342~~

~~Atlanta Center For Gastroenterology~~

~~[Recruiting]~~

Decatur, Georgia, United States ~~-30033~~

~~Gastroenterology Associates of Central GA~~

~~[Recruiting]~~

Macon, Georgia, United States ~~-31201~~

~~Atlanta Gastroenterology Specialists, PC~~

~~[Recruiting]~~

Suwanee, Georgia, United States ~~-30024~~

United States, Idaho

~~Grand Teton Gastroenterology~~

~~[Active, not recruiting]~~

Idaho Falls, Idaho, United States ~~-83404~~

United States, Illinois

~~Northwest Gastroenterologists S.C.~~

~~[Withdrawn]~~

Arlington Heights, Illinois, United States, 60005

United States, Illinois

~~Rush University Medical Center~~

~~[Recruiting]~~

Chicago, Illinois, United States ~~-60612~~

~~NorthShore University Health System, Evanston Hospital~~

~~[Recruiting]~~

Evanston, Illinois, United States ~~-60201~~

~~Loyola University Medical Center~~

~~[Withdrawn]~~

Maywood, Illinois, United States, 60153

~~Digestive Health Research Center - The Carle Foundation~~

~~[Suspended]~~

Urbana, Illinois, United States, 61801 Urbana, Illinois, United States

United States, Indiana

~~Indianapolis Gastroenterology Research Foundation~~

~~[Recruiting]~~

Indianapolis, Indiana, United States ~~-46237~~

United States, Iowa

~~University of Iowa Hospital and Clinic~~

~~[Withdrawn]~~

Iowa City, Iowa, United States, 52242

United States, Kansas

~~Health Science Research Center~~

~~[Recruiting]~~

Pratt, Kansas, United States ~~-67124~~

United States, Kentucky

~~Tri-State Gastroenterology Assoc~~

~~[Active, not recruiting]~~

~~Crestview Hills, Kentucky, United States -41017~~

~~University of Kentucky~~

~~[Recruiting]~~

~~Lexington, Kentucky, United States -40506~~

~~University of Louisville 627 South Preston Street~~

~~[Recruiting]~~

~~Louisville, Kentucky, United States -40202~~

United States, Louisiana

~~Houma Digestive Health Specialists LLC~~

~~[Recruiting]~~

~~Houma, Louisiana, United States -70360~~

~~Louisiana Research Center~~

~~[Recruiting]~~

~~Shreveport, Louisiana, United States -71103~~

United States, Maryland

~~Gastro Center Of Maryland~~

~~[Recruiting]~~

~~Columbia, Maryland, United States -21045~~

United States, Massachusetts

~~Massachusetts General Hospital- Boston~~

~~[Recruiting]~~

~~Boston, Massachusetts, United States -02114~~

United States, Michigan

~~University of Michigan~~

~~[Recruiting]~~

~~Ann Arbor, Michigan, United States -48109~~

~~Clinical Research Institute of Michigan, LLC~~

~~[Recruiting]~~

~~Chesterfield, Michigan, United States -48047~~

~~Center for Digestive Health~~

~~[Withdrawn]~~

~~Troy, Michigan, United States -48068~~

~~Center for Digestive Health~~

~~[Recruiting]~~

~~Troy, Michigan, United States, 48068~~

~~Saint Joseph Mercy Hospital~~

~~[Recruiting]~~

~~Ypsilanti, Michigan, United States -48197~~

United States, Minnesota

~~Mayo Clinic~~

~~[Recruiting]~~

~~Rochester, Minnesota, United States -55905~~

United States, Mississippi

~~University of Mississippi Medical Center~~

~~[Recruiting]~~

~~Jackson, Mississippi, United States -39216~~

United States, Missouri

~~Washington University School of Medicine~~

~~[Withdrawn]~~

~~Saint Louis, Missouri, United States, 63110~~

United States, New Jersey

~~South Jersey Gastroenterology~~

~~[Active, not recruiting]~~

~~Marlton, New Jersey, United States -08053~~

~~Morristown Memorial~~

~~[Recruiting]~~

~~Morristown, New Jersey, United States ,07962~~

~~United States, New York~~

~~Albany Medical Center~~

~~[Withdrawn]~~

~~Albany, New York, United States, 12208~~

~~United States, New York~~

~~NY Scientific~~

~~[Active, not recruiting]~~

~~Brooklyn, New York, United States ,11235~~

~~Winthrop University Hospital~~

~~[Recruiting]~~

~~Mineola, New York, United States ,11504~~

~~Beth Israel Medical Center~~

~~[Withdrawn]~~

~~New York, New York, United States ,10003~~

~~Manhattan Medical Research~~

~~[Withdrawn]~~

~~New York, New York, United States, 10016~~

~~New York University Langone Medical Center~~

~~[Recruiting]~~

~~New York, New York, United States, 10016~~

~~NYU Langone Long Island Clinical Research Associates~~

~~[Recruiting]~~

~~New York, New York, United States, 10016~~

~~Weill Medical College of Cornell University~~

~~[Recruiting]~~

~~New York, New York, United States, 10021~~

~~Columbia University Medical Center~~

~~[Recruiting]~~

~~New York, New York, United States, 10032~~

~~Lenox Hill Hospital~~

~~[Recruiting]~~

~~New York, New York, United States, 10075~~

~~Premier Medical Group of the Hudson Valley~~

~~[Active, not recruiting]~~

~~Poughkeepsie, New York, United States ,12604~~

~~University of Rochester~~

~~[Recruiting]~~

~~Rochester , New York, United States , 14642~~

~~Stony Brook University Medical Center - NY~~

~~[Withdrawn]~~

~~Stony Brook, New York, United States, 11794~~

~~Montefiore Medical Center~~

~~[Suspended]~~

~~The Bronx, New York, United States ,10467~~

~~United States, Ohio~~

~~Greater Cincinnati Gastroenterology Association, Inc.~~

~~[Recruiting]~~

~~Cincinnati, Ohio, United States ,45249~~

~~Great Lakes Gastroenterology~~

~~[Active, not recruiting]~~

~~Mentor, Ohio, United States ,44060~~

~~United States, Oklahoma~~

~~Oklahoma Foundation for Digestive Research~~

~~[Withdrawn]~~

~~Oklahoma City, Oklahoma, United States, 73102~~

~~United States, Oregon~~

~~Northwest Gastroenterology Clinic~~~~[Recruiting]~~~~Portland, Oregon, United States ,07210~~**United States, Pennsylvania**~~Central Bucks Specialists~~~~[Recruiting]~~~~Doylestown, Pennsylvania, United States ,18901~~~~Penn State Hershey Medical Center~~~~[Recruiting]~~~~Hershey, Pennsylvania, United States ,17033~~~~University of Pennsylvania - Perelman School of Medicine~~~~[Recruiting]~~~~Philadelphia, Pennsylvania, United States ,19104~~~~Jefferson Digestive Disease Service~~~~[Withdrawn]~~~~Philadelphia, Pennsylvania, United States, 19107~~~~Temple University Hospital~~~~[Recruiting]~~~~Philadelphia, Pennsylvania, United States, 19140~~~~Guthrie Medical Group, PC~~~~[Recruiting]~~~~Sayre, Pennsylvania, United States ,18840~~**United States, South Carolina**~~Seacoast Medical Research~~~~[Withdrawn]~~~~North Charleston, South Carolina, United States, 29406~~**United States, Tennessee**~~Chattanooga Medical Research~~~~[Withdrawn]~~~~Chattanooga, Tennessee, United States, 37404~~**United States, Tennessee**~~Gastro One~~~~[Recruiting]~~~~Germantown, Tennessee, United States ,38138~~~~Quality Medical Research- Nashville~~~~[Completed]~~~~Nashville , Tennessee, United States ,37211~~~~Vanderbilt~~~~[Recruiting]~~~~Nashville, Tennessee, United States, 37232~~**United States, Texas**~~Austin Gastroenterology, PA~~~~[Withdrawn]~~~~Austin, Texas, United States, 78745~~~~Research Concepts~~~~[Withdrawn]~~~~Bellaire, Texas, United States, 77401~~**United States, Texas**~~Texas Digestive Disease Consultants~~~~[Recruiting]~~~~Dallas, Texas, United States ,75231~~~~Brooke Army Medical Center~~~~[Withdrawn]~~~~Fort Sam Houston, Texas, United States, 78234~~~~Baylor College of Medicine Univ. Hosp.~~~~[Recruiting]~~

~~Houston, Texas, United States ,77030~~

~~Houston Methodist Hospital~~

~~[Recruiting]~~

~~Houston, Texas, United States, 77030~~

~~The University Of Texas Medical School At Houston~~

~~[Recruiting]~~

~~Houston, Texas, United States, 77030~~

~~Texas Digestive Disease~~

~~[Recruiting]~~

~~Irving, Texas, United States ,75030~~

~~Barnall Army Comm Hospital Internal Medicine~~

~~[Withdrawn]~~

~~Killeen, Texas, United States, 76544~~

~~Gastroenterology Clinic Of San Antonio P A~~

~~[Active, not recruiting]~~

~~San Antonio, Texas, United States ,78220~~

~~University of Texas Health Science Center – Medical Education~~

~~[Withdrawn]~~

~~San Antonio, Texas, United States, 78220~~

~~Texas Digestive Disease Consultants~~

~~[Active, not recruiting]~~

~~Southlake, Texas, United States ,76002~~

~~Digestive Health Specialists of Tyler~~

~~[Recruiting]~~

~~Tyler, Texas, United States ,75704~~

United States, Utah

~~Aspen Clinical Research~~

~~[Withdrawn]~~

~~Orem, Utah, United States, 84058~~

United States, Utah

~~Wasatch Clinical Research~~

~~[Recruiting]~~

~~Salt Lake City, Utah, United States ,84102~~

~~Advanced Clinical Research~~

~~[Recruiting]~~

~~West Jordan, Utah, United States ,84088~~

~~Advanced Clinical Research~~

~~[Withdrawn]~~

~~West Jordan, Utah, United States, 84088~~

United States, Vermont

~~University Of Vermont – Fletcher Allen Healthcare~~

~~[Withdrawn]~~

~~Burlington, Vermont, United States, 05404~~

United States, Virginia

~~Gastroenterology Associates of Tidewater~~

~~[Recruiting]~~

~~Chesapeake, Virginia, United States ,23320~~

~~Gastroenterology Associates of Northern Virginia~~

~~[Active, not recruiting]~~

~~Fairfax, Virginia, United States, 22034~~ ~~Fairfax, Virginia, United States~~

~~Carilion Clinic Dept of Med.~~

~~[Recruiting]~~

~~Roanoke, Virginia, United States ,24046~~

United States, Washington

~~Virginia Mason Medical Center~~

~~[Recruiting]~~

~~Seattle, Washington, United States ,98104~~

~~University of Washington~~	
~~[Recruiting]~~	
~~Seattle, Washington, United States, 98105~~	
~~UW Medicine – Harborview Medical Center~~	
~~[Completed]~~	
~~Seattle, Washington, United States, 98105~~	
~~Australia~~	
~~University of NSW – Bankstown-Lidcombe Hospital~~	
~~[Withdrawn]~~	
~~Bankstown, Australia, 2200~~	
~~Australia~~	
~~Flinders Medical Centre~~	
~~[Completed]~~	
~~Bedford, Australia, 5042~~	
~~BOX HILL~~	
~~[Withdrawn]~~	
~~Box Hill, Australia, 3128~~	
~~Nambour General Hospital~~	
~~[Withdrawn]~~	
~~Central Queensland M-C, Australia, 4560~~	
~~Monash Health, Monash Medical Centre~~	
~~[Active, not recruiting]~~	
~~Clayton, Australia, 3168~~	~~Clayton, Australia~~
~~Concord Hospital~~	
~~[Active, not recruiting]~~	
~~Concord N/A, Australia, 2137~~	
~~Saint Vincent's Hospital – Melbourne~~	
~~[Recruiting]~~	
~~Fitzroy, Australia, 3065~~	~~Fitzroy, Australia~~
~~Centre For Digestive Diseases~~	
~~[Completed]~~	
~~Five Dock, Australia, 2046~~	
~~Canberra Hospital – Australia~~	
~~[Active, not recruiting]~~	
~~Garran, Australia, 2605~~	~~Garran, Australia~~
~~Austin Hospital~~	
~~[Active, not recruiting]~~	
~~Heidelberg, Australia, 3084~~	~~Heidelberg, Australia~~
~~Liverpool Hospital~~	
~~[Active, not recruiting]~~	
~~Liverpool, Australia, 2170~~	~~Liverpool, Australia~~
~~The Alfred Hospital – Clinical Research Unit – Infectious Diseases~~	
~~[Active, not recruiting]~~	
~~Melbourne, Australia, 3004~~	~~Melbourne, Australia~~
~~Royal Melbourne~~	
~~[Withdrawn]~~	
~~Parkville, Australia~~	
~~Mater Hospital Brisbane~~	
~~[Active, not recruiting]~~	
~~South Brisbane, Australia, 4101~~	~~South Brisbane, Australia~~
~~Austria~~	
~~Landeskrankenhaus Salzburg, Universitätsklinik f. Innere Medizin III~~	
~~[Completed]~~	
~~Salzburg, Austria, 5020~~	~~Salzburg, Austria~~
~~Krankenhaus der Barmherzigen Brüder St. Veit~~	
~~[Withdrawn]~~	
~~St Veit An Der Glan, Austria, 9300~~	

~~Akh Wien~~	
~~{Active, not recruiting}~~	
~~Wien, Austria, 1090~~	~~Wien, Austria~~
~~Hartmannspital~~	
~~{Withdrawn}~~	
~~Wien, Austria, A-1050~~	
Belgium	
~~GZA Ziekenhuizen~~	
~~{Active, not recruiting}~~	
~~Antwerpen, Belgium, 2018~~	~~Antwerpen, Belgium~~
~~UZ Gent~~	
~~{Active, not recruiting}~~	
~~Gent, Belgium, 9000~~	~~Gent, Belgium~~
~~Az Groeninge~~	
~~{Active, not recruiting}~~	
~~Kortrijk, Belgium, 8500~~	~~Kortrijk, Belgium~~
~~University Hospitals Leuven~~	
~~{Recruiting}~~	
~~Leuven, Belgium, 3000~~	~~Leuven, Belgium~~
~~UZ Leuven~~	
~~{Active, not recruiting}~~	
~~Leuven, Belgium, 3000~~	
~~CHC-Cliniques Saint-Joseph~~	
~~{Active, not recruiting}~~	
~~Liège, Belgium, 4000~~	~~Liège, Belgium~~
~~CHU de Liège~~	
~~{Active, not recruiting}~~	
~~Liège, Belgium, 4000~~	
~~AZ-Delta-VZW~~	
~~{Active, not recruiting}~~	
~~Roeselaere, Belgium, 8800~~	~~Roeselaere, Belgium~~
Bulgaria	
~~University Multiprofile Hospital for Active Treatment – UMHAT-Dr. Georgi Stranski~~	
~~{Active, not recruiting}~~	
~~Pleven, Bulgaria, 5800~~	~~Pleven, Bulgaria~~
~~MHAT Rousse~~	
~~{Active, not recruiting}~~	
~~Rousse, Bulgaria, 7002~~	~~Rousse, Bulgaria~~
~~Medical Center 1-Sevlievo-EOOD~~	
~~{Active, not recruiting}~~	
~~Sevlievo, Bulgaria, 5400~~	~~Sevlievo, Bulgaria~~
~~2nd MHAT~~	
~~{Active, not recruiting}~~	
~~Sofia, Bulgaria, 1202~~	~~Sofia, Bulgaria~~
~~St. Ivan Rilski Hospital~~	
~~{Active, not recruiting}~~	
~~Sofia, Bulgaria, 1431~~	
~~MHAT Tokuda Hospital Sofia~~	
~~{Recruiting}~~	
~~Sofia, Bulgaria, 1527~~	
~~Medical Center Asklepiion~~	
~~{Active, not recruiting}~~	
~~Sofia, Bulgaria, 1606~~	
~~MHAT 'Doverie' {Gastroenterology}~~	
~~{Active, not recruiting}~~	
~~Sofia, Bulgaria, 1632~~	

~~MC "Synexus Sofia" EOOD~~~~[Recruiting]~~~~Sofia, Bulgaria, 1784~~~~Medical Center Mladost Med 1~~~~[Active, not recruiting]~~~~Sofia, Bulgaria, 1784~~~~MHAT St Marina~~~~[Recruiting]~~~~Varna, Bulgaria, 9040~~**Canada, British Columbia**~~GIRI Gastrointestinal Research Institute~~~~[Active, not recruiting]~~~~Vancouver, British Columbia, Canada, V6Z 2K5~~

Vancouver, British Columbia, Canada

~~PerCuro Clinical Research Ltd.~~~~[Active, not recruiting]~~~~Victoria, British Columbia, Canada, V8V 3M9~~

Victoria, British Columbia, Canada

Canada, Manitoba~~Brandon Medical Arts Clinic~~~~[Recruiting]~~~~Brandon, Manitoba, Canada, R7A 0N7~~~~Winnipeg Health Sciences Centre~~~~[Active, not recruiting]~~~~Winnipeg, Manitoba, Canada, R3A 1R9~~

Winnipeg, Manitoba, Canada

Canada, Ontario~~London Health Sciences Centre - University Campus~~~~[Active, not recruiting]~~~~London, Ontario, Canada, N6A 5A5~~

London, Ontario, Canada

~~London Health Sciences Center~~~~[Recruiting]~~~~London, Ontario, Canada, N6A 5W9~~~~Office of Kimberley S. Tilbe, MD~~~~[Active, not recruiting]~~~~Sudbury, Ontario, Canada, P3C 5N3~~

Sudbury, Ontario, Canada

Canada, Quebec~~Maisonneuve Rosemont - Gastroenterology~~~~[Not yet recruiting]~~~~Montreal, Quebec, Canada, H1T 2M4~~

Montreal, Quebec, Canada

~~McGill University - Health Centre - Montreal General Hospital~~~~[Active, not recruiting]~~~~Montreal, Quebec, Canada, H3G 1A4~~**Czechia**~~Hepato-gastroenterologie HK s.r.o.~~~~[Active, not recruiting]~~~~Hradec Kralove, Czechia, 500 12~~

Hradec Kralove, Czechia

~~Fakultni nemocnice Plzen~~~~[Active, not recruiting]~~~~Plzen, Czechia, 304 60~~

Plzen, Czechia

~~HKEM~~~~[Recruiting]~~~~Prague 4, Czechia, 140 24~~~~Fakultni nemocnice v Motole~~~~[Recruiting]~~~~Praha 5, Czechia, 150 06~~

Praha 5, Czechia

~~ISCARE I.V.F. a.s.~~~~[Active, not recruiting]~~~~Praha 7, Czechia, 170 04~~

Praha 7, Czechia

NH Hospital, a.s.[Withdrawn]Praha 8, Czechia, 180 84Medicon a.s.[Active, not recruiting]Praha 9, Czechia, 100 00Praha 9, Czechia**Denmark**Aarhus Universitetshospital[Active, not recruiting]Aarhus, Denmark, 8000Aarhus, DenmarkOdense Universitetshospital[Recruiting]Odense, Denmark, 5000Odense, Denmark**France**CHU Amiens Hopital Nord[Active, not recruiting]Amiens, France, 80054Amiens, FranceCHU de Bordeaux – Hôpital Saint André[Active, not recruiting]Bordeaux, France, 33076Bordeaux, FranceCHRU de Lille – Hôpital Claude Huriez[Active, not recruiting]Lille, France, 59037Lille, FranceClinique de la Sauvegarde[Active, not recruiting]Lyon, France, 69009Lyon, FranceAphm – Hopital Nord[Active, not recruiting]Marseille, France, 13015Marseille, FranceCHRU Montpellier – Hopital Saint-Eloi[Active, not recruiting]Montpellier, France, 34295Montpellier, FranceHopital Saint Antoine[Withdrawn]Paris, France, 75012Hôpital Necker[Withdrawn]Paris, France, 75743CHU Lyon Sud[Active, not recruiting]Pierre-Benite, France ,69495Hôpital Robert Debré[Active, not recruiting]Reims, France, 51092Reims, FranceCHRU Hôpital de Pontchaillou[Active, not recruiting]Rennes, France, 35033Rennes, FranceCHU Hôpital Nord[Active, not recruiting]Saint Etienne, France, 42055Saint-Etienne, FranceHopital de Rangueil[Active, not recruiting]Toulouse, France, 31059Toulouse, France**Germany**Universitätsklinikum Charité, Campus Virchow-Klinikum[Active, not recruiting]Berlin, Germany, 13353Berlin, Germany

<u>Klinikum Dresden</u>	
<u>[Withdrawn]</u>	
<u>Dresden, Germany, 01307</u>	
<u>St Josef Krankenhaus</u>	
<u>[Active, not recruiting]</u>	
<u>Essen, Germany, 45257</u>	<u>Essen, Germany</u>
<u>Universitätsklinikum Freiburg</u>	
<u>[Active, not recruiting]</u>	
<u>Freiburg, Germany, 79106</u>	<u>Freiburg, Germany</u>
<u>Medizinische Hochschule Hannover</u>	
<u>[Active, not recruiting]</u>	
<u>Hannover, Germany, 30626</u>	<u>Hannover, Germany</u>
<u>Universitätsklinikum Schleswig-Holstein Campus Kiel</u>	
<u>[Active, not recruiting]</u>	
<u>Kiel, Germany, 24105</u>	<u>Kiel, Germany</u>
<u>Gastroenterologie und Hepatologie am Johannisplatz</u>	
<u>[Active, not recruiting]</u>	
<u>Leipzig, Germany, 04103</u>	<u>Leipzig, Germany</u>
<u>Städtisches Klinikum Lüneburg</u>	
<u>[Active, not recruiting]</u>	
<u>Lüneburg, Germany, 21339</u>	<u>Lüneburg, Germany</u>
<u>Medizinische Fakultät Mannheim der Universität Heidelberg</u>	
<u>[Active, not recruiting]</u>	
<u>Mannheim, Germany, 68167</u>	<u>Mannheim, Germany</u>
<u>Gastroenterologische Gemeinschaftspraxis Minden</u>	
<u>[Active, not recruiting]</u>	
<u>Minden, Germany, 32423</u>	<u>Minden, Germany</u>
<u>MVZ Portal 10</u>	
<u>[Active, not recruiting]</u>	
<u>Münster, Germany, 48155</u>	<u>Münster, Germany</u>
<u>Gemeinschaftspraxis Germania Campus</u>	
<u>[Completed]</u>	
<u>Münster, Germany, 48159</u>	
Hungary	
<u>DRG Gyógyszervizsgáló Központ Kft.</u>	
<u>[Active, not recruiting]</u>	
<u>Balatonfüred, Hungary, H-8230</u>	<u>Balatonfüred, Hungary</u>
<u>Semmelweis Egyetem</u>	
<u>[Active, not recruiting]</u>	
<u>Budapest, Hungary, 1088</u>	<u>Budapest, Hungary</u>
<u>Pannónia Magánorvosi Centrum Kft</u>	
<u>[Active, not recruiting]</u>	
<u>Budapest, Hungary, 1136</u>	
<u>Réthy Pál Kórház Rendelőintézet</u>	
<u>[Active, not recruiting]</u>	
<u>Békéscsaba, Hungary, 5600</u>	<u>Békéscsaba, Hungary</u>
<u>Vasútegészségügyi Nonprofit Közhasznú Kft., Debreceni Egészsé</u>	
<u>[Active, not recruiting]</u>	
<u>Debrecen, Hungary, 4025</u>	<u>Debrecen, Hungary</u>
<u>Debreceni Egyetem Klinikai Központ</u>	
<u>[Active, not recruiting]</u>	
<u>Debrecen, Hungary, H-4012</u>	
<u>Miskolci Semmelweis Kórház és Egyetemi Oktatókórház</u>	
<u>[Completed]</u>	
<u>Miskolc, Hungary, 3529</u>	<u>Miskolc, Hungary</u>
<u>Karolina Kórház Rendelőintézet</u>	
<u>[Active, not recruiting]</u>	

Mosonmagyaróvár, Hungary, 9200	Mosonmagyaróvár, Hungary
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Tolna Megyei Önkormányzat Balassa János Kórháza

[Active, not recruiting]

Székeszárd, Hungary, 7100	Székeszárd, Hungary
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Vas Megyei Markusovszky Lajos Általános Rehabilitációs
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[Active, not recruiting]

Szombathely, Hungary, H 9700	Szombathely, Hungary
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Fejér Megyei Szent György Kórház I. Sz. Belgyógyászat

[Recruting]

Székesfehérvár, Hungary, 8000	Székesfehérvár, Hungary
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Jávorszky Ödön Kórház

[Completed]

Vac, Hungary, 2600	Vac, Hungary
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Israel

Ha'Emek Medical Center

[Withdrawn]

Afula, Israel, 18104

Israel

Soroka University Medical Center

[Active, not recruiting]

Beersheba, Israel, 84104	Beersheba, Israel
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Bnai Zion Medical Center

[Active, not recruiting]

Haifa, Israel, 31048	Haifa, Israel
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The Edith Wolfson Medical Center

[Recruting]

Holon, Israel, 58100	Holon, Israel
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Shaare Zedek Medical Center

[Recruting]

Jerusalem, Israel, 91034	Jerusalem, Israel
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Meir Medical Center

[Active, not recruiting]

Kfar Saba, Israel, 44284	Kfar Saba, Israel
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Western Galilee Hospital

[Recruting]

Nahariya, Israel, 22400	Nahariya, Israel
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Rabin Medical Center, Beilinson Hospital
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[Active, not recruiting]

Petach Tikvah, Israel, 49100	Petach Tikvah, Israel
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Tel Aviv Sourasky Medical Center

[Active, not recruiting]

Tel Aviv, Israel, 64239	Tel Aviv, Israel
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The Chaim Sheba Medical Center

[Recruting]

Tel Hashomer, Israel, 52624	Tel Hashomer, Israel
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Japan

Ohmori Toshihide Gastrointestinal Clinic
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[Recruting]

Ageo-Shi, Japan, 362-0075	Ageo-Shi, Japan
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Asahikawa City Hospital

[Recruting]

Asahikawa, Japan, 070-8640	Asahikawa, Japan
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Tokyo Medical and Dental University Hospital
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[Recruting]

Bunkyo-Ku, Japan, 113-8549	Bunkyo-Ku, Japan
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Chiba University Hospital

[Recruting]

~~Chiba, Japan, 260-8677~~	Chiba, Japan
~~Fukuoka University Chikushi Hospital~~	
~~[Active, not recruiting]~~	
~~Chikushinoshi, Japan, 818-8502~~	Chikushinoshi, Japan
~~Sai Gastroenterology, Proctology~~	
~~[Recruiting]~~	
~~Fujiidera, Japan, 583-0027~~	Fujiidera, Japan
~~Kitakyushu Municipal Medical Center~~	
~~[Recruiting]~~	
~~Fukuoka-Ken, Japan, 802-0077~~	Fukuoka-Ken, Japan
~~Mito Medical Center~~	
~~[Recruiting]~~	
~~Higashi-Ibaraki, Japan, 311-3193~~	
~~Hirosaki National Hospital~~	
~~[Recruiting]~~	
~~Hirosaki, Japan, 036-8545~~	Hirosaki, Japan
~~Hiroshima University Hospital~~	
~~[Recruiting]~~	
~~Hiroshima, Japan, 734-8551~~	Hiroshima, Japan
~~Isesaki Municipal Hospital~~	
~~[Recruiting]~~	
~~Isesaki, Japan, 372-0817~~	Isesaki, Japan
~~Iwate Medical University Hospital~~	
~~[Recruiting]~~	
~~Iwate, Japan, 020-8505~~	Iwate, Japan
~~Shimane University Hospital~~	
~~[Recruiting]~~	
~~Izumo, Japan, 693-8501~~	Izumo, Japan
~~Kagawa Prefectural Central Hospital~~	
~~[Recruiting]~~	
~~Kagawa, Japan, 760-8557~~	Kagawa, Japan
~~Sameshima Hospital~~	
~~[Recruiting]~~	
~~Kagoshima, Japan, 892-0846~~	Kagoshima, Japan
~~Nanpuh Hospital~~	
~~[Recruiting]~~	
~~Kagoshima, Japan, 892-8512~~	
~~Kanazawa Medical University Hospital~~	
~~[Active, not recruiting]~~	
~~Kahoku, Japan, 920-0293~~	Kahoku, Japan
~~Ibaraki Prefectural Central Hospital~~	
~~[Withdrawn]~~	
~~Kasama, Japan, 309-1703~~	
~~Aoyama Naika Clinic~~	
~~[Recruiting]~~	
~~Kobe-Shi, Japan~~	
~~Kochi National Hospital~~	
~~[Active, not recruiting]~~	
~~Kochi, Japan, 780-8077~~	Kochi, Japan
~~Kurume University Hospital~~	
~~[Active, not recruiting]~~	
~~Kurume, Japan, 830-0011~~	Kurume, Japan
~~Hidaka Coloproctologic Clinic~~	
~~[Recruiting]~~	
~~Kurume, Japan, 839-0809~~	
~~NHO Kyoto Medical Center~~	
~~[Active, not recruiting]~~	
~~Kyoto, Japan, 612-8555~~	Kyoto, Japan

~~Tokitokai Tokito Clinic-Coloproctology Center~~	
~~[Recruiting]~~	
~~Midori-Ku, Japan, 336-0963~~	~~Midori-Ku, Japan~~
~~Nagasaki University Hospital~~	
~~[Recruiting]~~	
~~Nagasaki, Japan, 852-8402~~	~~Nagasaki, Japan~~
~~Kenseikai Dongo Hospital~~	
~~[Recruiting]~~	
~~Nara, Japan, 635-0022~~	~~Nara, Japan~~
~~Hyogo College of Medicine Hospital~~	
~~[Recruiting]~~	
~~Nishinomiya, Japan, 663-8504~~	~~Nishinomiya, Japan~~
~~Oita Red Cross Hospital~~	
~~[Active, not recruiting]~~	
~~Oita, Japan, 870-0033~~	~~Oita, Japan~~
~~Osaka City General Hospital~~	
~~[Recruiting]~~	
~~Osaka, Japan, 534-0024~~	~~Osaka, Japan~~
~~Osaka City University Hospital~~	
~~[Recruiting]~~	
~~Osaka, Japan, 545-8586~~	
~~Saga University Hospital~~	
~~[Active, not recruiting]~~	
~~Saga, Japan, 849-8504~~	~~Saga, Japan~~
~~Kojinkai Himeji Central Hospital~~	
~~[Recruiting]~~	
~~Saga-Ken, Japan~~	~~Saga-Ken, Japan~~
~~Tenmakai Chikuba Hospital~~	
~~[Recruiting]~~	
~~Saitama, Japan, 362-0075~~	~~Saitama, Japan~~
~~Toho University Sakura Medical Center~~	
~~[Recruiting]~~	
~~Sakura, Japan, 285-8744~~	~~Sakura, Japan~~
~~Sapporo Kosei General Hospital~~	
~~[Active, not recruiting]~~	
~~Sapporo, Japan, 060-0033~~	~~Sapporo, Japan~~
~~KKR Sapporo Medical Center~~	
~~[Recruiting]~~	
~~Sapporo, Japan, 062-0934~~	
~~National Hospital Organization Sendai Medical Center~~	
~~[Active, not recruiting]~~	
~~Sendai, Japan, 083-8520~~	~~Sendai, Japan~~
~~Matsuda Hospital~~	
~~[Recruiting]~~	
~~Shizuoka, Japan, 432-8064~~	~~Shizuoka, Japan~~
~~Shizuoka Medical Center~~	
~~[Recruiting]~~	
~~Sunto-Gun, Japan, 411-8644~~	~~Sunto-Gun, Japan~~
~~Takamatsu Red Cross Hospital~~	
~~[Recruiting]~~	
~~Takamatsu, Japan, 760-0047~~	~~Takamatsu, Japan~~
~~The Jikei University Hospital~~	
~~[Withdrawn]~~	
~~Tokyo, Japan, 105-8474~~	~~Tokyo, Japan~~
~~Kitasato Institute Hospital-Biomedical Research Center, Clinical Trial Unit~~	
~~[Active, not recruiting]~~	
~~Tokyo, Japan, 108-8642~~	

<u>Juntendo University Hospital</u>	
<u>[Recruiting]</u>	
<u>Tokyo, Japan, 113-8431</u>	
<u>NTT Medical Center Tokyo</u>	
<u>[Recruiting]</u>	
<u>Tokyo, Japan, 141-8625</u>	
<u>Kyorin University Hospital</u>	
<u>[Recruiting]</u>	
<u>Tokyo, Japan, 600-8492</u>	
<u>Saiseikai Toyama Hospital</u>	
<u>[Recruiting]</u>	
<u>Toyama, Japan, 931-8533</u>	Toyama, Japan
<u>Ieda Hospital</u>	
<u>[Active, not recruiting]</u>	
<u>Toyota, Japan, 470-1210</u>	Toyota, Japan
<u>Mie University Hospital</u>	
<u>[Active, not recruiting]</u>	
<u>Tsu, Japan, 514-8507</u>	Tsu, Japan
<u>JA Tsuchiura Kyodo General Hospital</u>	
<u>[Recruiting]</u>	
<u>Tsuchiura, Japan, 300-0053</u>	Tsuchiura, Japan
<u>Wakayama Medical University Hospital</u>	
<u>[Active, not recruiting]</u>	
<u>Wakayama, Japan, 644-8510</u>	Wakayama, Japan
<u>Yamanashi Prefectural Central Hospital</u>	
<u>[Recruiting]</u>	
<u>Yamanashi, Japan, 400-8506</u>	Yamanashi, Japan
Korea, Republic of	
<u>Keimyung University Dongsan Medical Center</u>	
<u>[Recruiting]</u>	
<u>Daegu, Korea, Republic of, 700-712</u>	
<u>Kyungpook National University Hospital</u>	
<u>[Active, not recruiting]</u>	
<u>Daegu, Korea, Republic of, 700-724</u>	
<u>Hanyang University Guri Hospital</u>	
<u>[Completed]</u>	
<u>Guri-Si, Korea, Republic of, 471-704</u>	
<u>Asan Medical Center</u>	
<u>[Active, not recruiting]</u>	
<u>Seoul, Korea, Republic of, 05505</u>	
<u>Kyung Hee University Medical Center</u>	
<u>[Active, not recruiting]</u>	
<u>Seoul, Korea, Republic of, 102-1703</u>	
<u>Severance Hospital, Yonsei University Health System</u>	
<u>[Active, not recruiting]</u>	
<u>Seoul, Korea, Republic of, 120-752</u>	
<u>Samsung Medical Center</u>	
<u>[Active, not recruiting]</u>	
<u>Seoul, Korea, Republic of, 135-710</u>	
<u>The Catholic University of Korea</u>	
<u>[Active, not recruiting]</u>	
<u>Suwon-Si, Korea, Republic of, 16247</u>	
Netherlands	
<u>Academisch Medisch Centrum Universiteit van Amsterdam</u>	
<u>[Active, not recruiting]</u>	
<u>Amsterdam, Netherlands, 1105-AZ</u>	Amsterdam, Netherlands

Academisch Ziekenhuis Maastricht[Active, not recruiting]Maastricht, Netherlands, 6220 HXMaastricht, Netherlands**New Zealand**Auckland City Hospital[Active, not recruiting]Auckland, New Zealand, 1142Auckland, New ZealandChristchurch Hospital[Active, not recruiting]Christchurch, New Zealand, 8140Dunedin Hospital[Active, not recruiting]Dunedin, New Zealand, 9016Dunedin, New ZealandHutt Hospital[Active, not recruiting]Lower Hutt, New Zealand, 5010Shakespeare Specialist Group Ian Wallace Ltd[Completed]Milford, New Zealand, 0620Milford, New Zealand**Poland**Copernicus Podmiot Leczniczy Sp z o.o[Completed]Gdansk, Poland, 80-462Gdansk, Poland5-Wojskowy Szpital Kliniczny z Poliklinika SP ZOZ[Completed]Krakow, Poland, 30-901Krakow, PolandSzpital Uniwersytecki w Krakowie[Withdrawn]Krakow, Poland, 31-531Uniwersytecki Szpital Kliniczny nr 1 im. N. Barlickiego[Active, not recruiting]Lodz, Poland, 90-153Lodz, PolandCentrum Medyczne Med-Gastr[Active, not recruiting]Lodz, Poland, 01-034KO-MED Centra Kliniczne Pulawy[Active, not recruiting]Pulawy, Poland, 24-100Pulawy, PolandEndoskopia Sp z o.o.[Active, not recruiting]Sopot, Poland, 81-756Sopot, PolandTwoja Przychodnia - Szczecińskie Centrum Medyczne[Not yet recruiting]Szczecin, Poland, 71-270Szczecin, PolandCentrum Badawcze Współczesnej Terapii[Active, not recruiting]Warszawa, Poland, 01-337Warszawa, PolandCentrum Onkologii - Instytut im. Marii Skłodowskiej-Curie[Active, not recruiting]Warszawa, Poland, 02-781NZOZ Vivamed Zespół Lekarzy Specjalistów[Active, not recruiting]Warszawa, Poland, 03-580Melita Medical[Active, not recruiting]Wroclaw, Poland, 50-440Wroclaw, Poland

Lexmedica{Active, not recruiting}Wroclaw, Poland, 53-025ARS-MEDICA Rybak Maria, Rybak Zbigniew, s.c.{Active, not recruiting}Wroclaw, Poland, 53-333**Romania**MedLife-Grivita{Active, not recruiting}Bucuresti, Romania, 010719Bucuresti, RomaniaCentrul Medical SANA{Recruiting}Bucuresti, Romania, 011025Spitalul Universitar de Urgenta Bucuresti{Completed}Bucuresti, Romania, 050098Spitalul Universitar de Urg Militar Central Dr.Carol Davila{Recruiting}Bucuresti, Romania, 050728Cabinet Medical Dr Fratila{Active, not recruiting}Oradea, Romania, 410167Oradea, RomaniaCentrul Medical de Diagnostic, Tratament Ambulator si Medicina Preventiva Bucurest{Completed}Romania, Romania, 061011Romania, RomaniaCabinet Particular Policlinic Algomed{Active, not recruiting}Timisoara, Romania, 300002Timisoara, RomaniaMed Life{Recruiting}Timisoara, Romania, 300166**Russian Federation**Scientific Centre for Reconstructive and Restorative Surgery{Active, not recruiting}Irkutsk, Russian Federation, 664003Irkutsk, Russian FederationKazan State Medical University{Active, not recruiting}Kazan, Russian Federation, 420012Kazan, Russian FederationCentral Clinical Hospital of RAS{Recruiting}Moscow, Russian Federation , 117593Central Clinical Hospital of RAS{Active, not recruiting}Moscow, Russian Federation, 119333City Clinical Hospital #51{Withdrawn}Moscow, Russian Federation, 121309GU 'Moscow Regional Research Clinical Institute n.a. M.F.Vla{Active, not recruiting}Moscow, Russian Federation, 120110Novosibirsk State Medical University{Active, not recruiting}Novosibirsk, Russian Federation, 630004Novosibirsk, Russian FederationFederal State Budgetary Institution 'Scientific Research Institute'{Active, not recruiting}Novosibirsk, Russian Federation, 630117

~~Omsk state medical academy~~	
~~[Withdrawn]~~	
~~Omsk, Russian Federation, 644000~~	
~~City Hospital #20~~	
~~[Active, not recruiting]~~	
~~Rostov-On-Don, Russian Federation, 344004~~	
~~Ryazan Regional Clinical Hospital~~	
~~[Active, not recruiting]~~	
~~Ryazan, Russian Federation, 390030~~	Ryazan, Russian Federation
~~Military Medical Academy~~	
~~[Active, not recruiting]~~	
~~Saint Petersburg, Russian Federation, 194016~~	
~~Elizavetinskaya hospital~~	
~~[Active, not recruiting]~~	
~~Saint Petersburg, Russian Federation, 195257~~	
~~City Clinical Hospital # 26~~	
~~[Active, not recruiting]~~	
~~St Petersburg, Russian Federation, 196247~~	
~~Northern Western State Medical University n.a. I.I. Mechnikov~~	
~~[Active, not recruiting]~~	
~~St. Petersburg, Russian Federation, 195067~~	St.-Petersburg, Russian Federation
~~Stavropol State Medical University (StSMU) - State Institution Clinic of Mental Disorders Borderline~~	
~~[Recruiting]~~	
~~Stavropol, Russian Federation, 355017~~	Stavropol, Russian Federation
~~City Clinical Hospital # 24~~	
~~[Active, not recruiting]~~	
~~Ufa, Russian Federation, 450074~~	Ufa, Russian Federation
Serbia	
~~Clinical Center Serbia~~	
~~[Recruiting]~~	
~~Belgrade, Serbia, 11-000~~	Belgrade, Serbia
~~Zvezdara University Medical Center~~	
~~[Active, not recruiting]~~	
~~Belgrade, Serbia, 11000~~	
~~Clinical Center Zemun~~	
~~[Withdrawn]~~	
~~Belgrade, Serbia, 11080~~	
~~Clinical Hospital Center Bezanijaska Kosa~~	
~~[Active, not recruiting]~~	
~~Belgrade, Serbia, 11080~~	
~~Clinical Center of Kragujevac~~	
~~[Recruiting]~~	
~~Kragujevac, Serbia, 34000~~	Kragujevac, Serbia
~~Clinical Center Nis~~	
~~[Active, not recruiting]~~	
~~Nis, Serbia, 18000~~	Nis, Serbia
~~Clinical Center of Vojvodina~~	
~~[Recruiting]~~	
~~Vojvodina, Serbia, 24000~~	Vojvodina, Serbia
Slovakia	
~~IBDeentrum s.r.o.~~	
~~[Recruiting]~~	
~~Bratislava, Slovakia, 831-04~~	Bratislava, Slovakia
~~GASTRO I. s.r.o.~~	
~~[Active, not recruiting]~~	
~~Presov, Slovakia, 080-01~~	Presov, Slovakia

UVN SNP Ruzomberok – FN	
{Withdrawn}	
Ruzomberok, Slovakia, 034 26	
Ukraine	
Bukovinian State Medical University	
{Withdrawn}	
Chernivtsi, Ukraine, 58001	
Ukraine	
Dnipropetrovska derzhavna medychna akademiya	
{Recruiting}	
Dnipropetrovsk, Ukraine, 49044	Dnipropetrovsk, Ukraine
Ivano-Frankivsk National Medical University	
{Active, not recruiting}	
Ivano-Frankivsk, Ukraine, 76008	Ivano-Frankivsk, Ukraine
KZOZ Kharkivska miska klinichna likarnia #13	
{Active, not recruiting}	
Kharkiv, Ukraine, 61035	Kharkiv, Ukraine
Kharkiv City Clinical Hospital	
{Active, not recruiting}	
Kharkiv, Ukraine, 61037	
Kyiv Regional Clinical Hospital	
{Recruiting}	
Kyiv, Ukraine, 04107	Kyiv, Ukraine
Kyivska miska klinichna likarnia 18	
{Active, not recruiting}	
Kyiv, Ukraine, 01030	Kyiv, Ukraine
Natsionalna medychna akademiia pisladyplomnoi osvity imeni	
{Active, not recruiting}	
Kyiv, Ukraine, 04201	
Danylo Halytsky Lviv National Medical University	
{Active, not recruiting}	
Lviv, Ukraine, 79010	Lviv, Ukraine
Lvivskiy natsionalnyi medychnyi uni. imeni D. Galytskogo	
{Recruiting}	
Lviv, Ukraine, 79010	
Odeska oblasna klinichna likarnia	
{Active, not recruiting}	
Odessa, Ukraine, 65025	Odessa, Ukraine
Komunalnyi zaklad Sumskoi oblasnoi rady " sumska oblasna kli	
{Active, not recruiting}	
Sumy, Ukraine, 40022	Sumy, Ukraine
Transcarpathian Regional Clinical Hospital	
{Active, not recruiting}	
Uzhgorod, Ukraine, 88000	Uzhgorod, Ukraine
Vinnytska Oblasna klinichna likarnia imeni M.1	
{Active, not recruiting}	
Vinnytsia, Ukraine, 21018	Vinnytsia, Ukraine
Priv male pidpr, medychnyi tsentr 'Puls'	
{Recruiting}	
Vinnytsia, Ukraine, 21020	
Slaomed - Khels Klinik	
{Active, not recruiting}	
Vinnytsia, Ukraine, 21020	
KU 6 miska klinichna likarnia ZMR	
{Active, not recruiting}	
Zaporizhzhia, Ukraine, 69035	Zaporizhzhia, Ukraine

~~Miska likarnia №7~~	
~~{Active, not recruiting}~~	
~~Zaporizhzhia, Ukraine, 69118~~	
~~Zaporizhzhia Medical University~~	
~~{Active, not recruiting}~~	
~~Zhaporozhia, Ukraine, 69000~~	~~Zhaporozhia, Ukraine~~
United Kingdom	
~~Jameside Hospital NHS Foundation Trust~~	
~~{Withdrawn}~~	
~~Ashton Under Lyne, United Kingdom, OL6 9RW~~	
United Kingdom	
~~Queen Elizabeth Hospital~~	
~~{Recruiting}~~	
~~Birmingham, United Kingdom, B15 2TH~~	
~~Addenbrookes Hospital~~	
~~{Active, not recruiting}~~	
~~Cambridge, United Kingdom, CB2 2QQ~~	~~Cambridge, United Kingdom~~
~~University Hospital Coventry & Warwickshire NHS Trust~~	
~~{Active, not recruiting}~~	
~~Coventry, United Kingdom, CV2 2DX~~	~~Coventry, United Kingdom~~
~~Doncaster and Bassetlaw Hospitals NHS Foundation Trust~~	
~~{Recruiting}~~	
~~Doncaster, United Kingdom, DN2 5LT~~	~~Doncaster, United Kingdom~~
~~Centre for Genomic and Experimental Medicine~~	
~~{Recruiting}~~	
~~Edinburgh, United Kingdom, EH4 2XU~~	~~Edinburgh, United Kingdom~~
~~Royal Liverpool University Hospital~~	
~~{Active, not recruiting}~~	
~~Liverpool, United Kingdom, L7 8XP~~	~~Liverpool, United Kingdom~~
~~University College Hospital~~	
~~{Active, not recruiting}~~	
~~London, United Kingdom, NW1 2PG~~	~~London, United Kingdom~~
~~Guy's and St Thomas' Hospital~~	
~~{Active, not recruiting}~~	
~~London, United Kingdom, SE1 7EH~~	
~~Chelsea And Westminster Hospital~~	
~~{Withdrawn}~~	
~~London, United Kingdom, SW10 9NH~~	
~~Royal Gwent Hospital~~	
~~{Withdrawn}~~	
~~Newport, United Kingdom, NP20 2UB~~	
~~Norfolk and Norwich University Hospital~~	
~~{Withdrawn}~~	
~~Norwich, United Kingdom, NR4 7UY~~	
~~Hope Hospital~~	
~~{Recruiting}~~	
~~Salford, United Kingdom, M6 8HD~~	
~~Southampton University Hospitals NHS Trust~~	
~~{Active, not recruiting}~~	
~~Southampton, United Kingdom, SO16 6YD~~	~~Southampton, United Kingdom~~
~~Kings Mill Hospital~~	
~~{Active, not recruiting}~~	
~~Sutton In Ashfield, United Kingdom, NG17 4JL~~	

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