Last Name	First Name	Middle Name	Signature/Date:
McKenzie	Mark	Montgomery	

Credentials: MD	**Title:** Medical Director, Investigator
Study Site Address(es): WR-ClinSearch, LLC 6035 Shallowford Rd, Suite 109 Chattanooga, TN, 37421	**Contact Information** **Phone:** 423-698-4584 **Fax:** 423-698-4577 **Email:** mmckenzie@clinsearch-us.com

License No: State of Tennessee #35982

Education and Training:
Medical College of Ohio, Doctor of Medicine, Toledo, OH, 1995-2000
Southern Adventist University, Bachelor of Science, Medical Technology, Collegedale, TN, 1994
Florida Hospital School of Medical Technology, Clinical Laboratory Internship, Orlando, FL, 1991-1992
Southern Adventist University, Bachelor of Arts, Biology, Collegedale, TN, 1986-1991

Positions and Employment:

Date(s)	Title	Institution/Company
2017-Present	Medical Director, Primary Investigator	WR-ClinSearch, LLC, Chattanooga, TN
2009-2017	Sub-Investigator	WR-ClinSearch, LLC, Chattanooga, TN
2009-2017	Physician/Owner	The McKenzie Center for Internal Medicine PLLC, Chattanooga, TN
2012-2014	Medical Director	Cigna-HealthSpring, Chattanooga, TN
2008-2009	Physician	Internal Medicine Group of Cleveland, Cleveland, TN
2006-2008	Physician	Peerless Medical Associates, Cleveland, TN
2002-2006	Physician	Galen Medical Group, Cleveland, TN
1999-2002	Resident Physician	Medical College of Ohio, Toledo, OH
1997-1999	Medical Technologist	Riverside Hospital-Hematology Department, Toledo, OH
1992-1995	Medical Technologist	Florida Hospital, Orlando, FL

Professional Certification/Licensure:
CITI Program-Good Clinical Practice for Investigators Certificate
Certificate for completion of Internal Medicine Residency, 2000, 2002
Certification from the American Society of Clinical Pathologists, Medical Technologist

Society Membership:
American College of Physician Executives
American Society of Clinical Pathologists
American Medical Association
American College of Physicians -ASIM

Clinical Study Phase Experience: *I, II, III, IV*

Clinical Research Experience:

Diabetes Studies:

- An Open-Label, Randomized, Multicenter, Phase III Study To Compare The Immunogenicity, Efficacy, And Safety Of XXXX Insulin XXXX Injection To XXXX (Insulin XXXX Injection) In Adult Subjects With Type 1 Diabetes Mellitus
- An Open-Label, Randomized, Multicenter, Phase III Study To Compare The Immunogenicity, Efficacy, And Safety Of XXXX Insulin XXXX Injection XXXX (Insulin XXXX Injection) In Adult Subjects With Type 2 Diabetes Mellitus
- A Randomized, Double-blind, Placebo-controlled, Parallel-group, 52-week Multicenter Study to Evaluate the Efficacy and Safety of XXXX in Patients With Type 2 Diabetes Who Have Inadequate Glycemic Control on Basal Insulin Alone or in Addition to Oral Antidiabetes Drugs (OADs)

- A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Clinical Trial to Evaluate the Efficacy and Safety of the Initial Combination of XXXX (XXXX) With XXXX in the Treatment of Subjects With T2DM With Inadequate Glycemic Control on Diet and Exercise
- A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of the Addition of XXXX During XXXX in Up-titration Compared With XXXX Up-titration Alone in Subjects With Type 2 Diabetes Mellitus
- XXXX to Reduce Cardiovascular Outcomes by Reducing Triglycerides IN patients With diabetes (XXXX)
- A randomized, double-blind, Phase 3b proof-of-concept study to evaluate the efficacy and safety of XXXX vs placebo in combination with Metformin in subjects with hypertension and Type 2 Diabetes
- A Phase 2, multicenter, randomized, double-blind, placebo-controlled study of the safety and efficacy of XXXX w/Metformin in Type 2 Diabetes subjects w/inadequate glycemic control on Metformin Monotherapy
- A randomized, double-blind, Phase 3b proof-of-concept study to evaluate the efficacy and safety of XXXX vs placebo when used with Metformin in subjects with hypertension and Type 2 Diabetes
- A randomized, double-blind, placebo-controlled multicenter Phase 2 study to evaluate the safety and efficacy and dose response of 28 days of once-daily dosing of the oral Motilin Receptor Agonist XXXX, in Type 1 and 2 Diabetic male and female subjects with Gastroparesis
- A single-arm, open-label, multicenter study evaluating Triglyceride changes in subjects with Type 2 Diabetes and Dyslipidemia following treatment conversion from XXXX to XXXX with stable statin therapy

Health/Nutrition Studies:

- Double-blind, multi-center, randomized, parallel-group, 16 week study of XXXX of administered orally once-a-day with without a low calorie diet lead in obese adults with OLE of 6 months
- A 2 year study (1 year weight loss, 1 year regain prevention) to assess the safety, tolerability and efficacy of XXXX in obese patients
- A double-blind, randomized, placebo-controlled, multicenter study to assess the safety, tolerability, and efficacy of XXXX in patients
- A double-blind, randomized, placebo-controlled, multicenter study to assess the safety ,tolerability, and efficacy of XXXX in patients

Dermatology Studies:

- A Phase 3 Multi-Center, Randomized, Double-Blinded, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy, Tolerability and Safety of XXXX and Vehicle Gel Once Daily in the Treatment of Acne Vulgaris
- A Phase 3 Multi-Center, Open Label Study Evaluating the Long Term Safety of XXXX Once Daily in the Treatment of Acne Vulgaris
- A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel Group Study Comparing XXXX Cream 0.01% to XXXX (XXXX) Cream 0.1% and Both Active Treatments to a Vehicle Control in the Treatment of Acne Vulgaris
- A Randomized, Double-Blind Study to Compare the Efficacy, Safety and Long-Term Safety of Topical Administration of XXXX for 1 Year in the Treatment of Moderate-to-Severe Acne Vulgaris
- A Randomized, Double-blind, Placebo-controlled, Phase 2b Study to Assess the Efficacy and Safety of Orally Administered XXXX in Patients with Moderate to Severe Atopic Dermatitis
- An Open-Label Study of XXXX in Patients with Atopic Dermatitis who Participated in Previous XXXX Clinical Trials
- A Multicenter, Randomized, Double-Blind, Parallel-Group, Vehicle-Controlled Study of the Safety and Efficacy of XXXX Lotion in the Treatment of Acne Vulgaris for 12 Weeks
- A Randomized, Double-Blind, Placebo Controlled Study Of The Efficacy, Safety, And Tolerability Of XXXX For The Treatment Of Pruritus In Adults And Adolescents With A History Of Atopic Dermatitis
- A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence of a Generic XXXX, 1% (XXXX.) to the Marketed Product XXXX (XXXX) Cream, 1% (XXXX) in the Treatment of Mild to Moderate Atopic Dermatitis.
- A Phase 3, double-blind, randomized, vehicle-controlled, multicenter study of the safety and bioequivalence of XXXX cream in subjects with Mild to Moderate Atopic Dermatitis
- A Phase 3, randomized, double-blind, placebo-controlled study investigating the efficacy and safety of multiple XXXX dose regimens for maintaining treatment response in patients with atopic dermatitis
- A Phase 3, confirmatory study investigating the efficacy and safety of XXXX administered to adult patients with moderate to severe atopic dermatitis
- A double-blind, randomized, parallel-group, vehicle-controlled, multicenter study to evaluate the safety and bioequivalence of XXXX cream in the treatment of mild to moderate atopic dermatitis

Cardiovascular Studies:

- XXXX to reduce cardiovascular outcomes by reducing triglycerides in diabetic patients
- A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of XXXX and XXXX Combination Therapy to XXXX and XXXX Monotherapy in Subjects with Mixed Dyslipidemia

- A Randomized, Double-Blind, Placebo Controlled, Phase 3 Study of XXXX in the Prevention of CV Events Among Subjects with Low Levels of LDL-Cholesterol and Elevated Levels of C-Reactive Protein
- A randomized, double-blind, multi-center, multifactorial, placebo controlled, parallel group study to evaluate the efficacy and safety of XXXX and XXXX and alone in hypertensive patients
- A 52-week open-label extension to the randomized, double-blind, multifactorial, placebo-controlled, parallel group study to evaluate efficacy and safety of XXXX and XXXX combined and alone in hypertensives

Neurology Studies:

- A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Single Attack Study to Evaluate the Efficacy, Safety, and Tolerability of Oral XXXX in the Acute Treatment of Migraine
- A Multicenter, Randomized, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Oral XXXX in the Acute Treatment of Migraine with or Without Aura
- Study to Evaluate the Efficacy and Safety of XXXX in Migraine Prevention
- A Parallel Group, Double-Blind, Randomized, Placebo Controlled, Trial to Evaluate the Efficacy and Safety of XXXX Administered Intravenously in Patients With Frequent Episodic Migraines
- An Open Label Trial to Evaluate the Safety of XXXX Administered Intravenously in Patients With Chronic Migraine
- A Parallel Group, Double-Blind, Randomized, Placebo Controlled Phase 3 Trial to Evaluate the Efficacy and Safety of XXXX Administered Intravenously in Patients With Chronic Migraine
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of XXXX in Patients With Episodic Migraine - the XXXX Study
- A Randomized, Double-Blind, Placebo Controlled Proof of Concept Study of XXXX in Patients With Migraine
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Efficacy, Tolerability, and Safety Study of XXXX in Episodic Migraine With or Without Aura
- A Study of Three Doses of XXXX (50 mg, 100 mg and 200 mg) Compared to Placebo in the Acute TReaTment of MigrAiNe: A Randomized, Double-blind, Placebo-controlled Parallel Group Study (XXXX)
- A Phase 2a, Randomized, Double-Blind Placebo-controlled, Parallel-group Study to Assess the Analgesic Efficacy and Safety of XXXX in Subjects With Fibromyalgia
- A Phase 2, randomized, double-blind, placebo-controlled study of XXXX in patients with migraine
- A Phase 2b, multicenter, randomized, double-blind, placebo-controlled, dose-finding study of XXXX in the treatment of acute Migraine
- Double-Blind, randomized, placebo controlled, dose-ranging trial of XXXX for acute treatment of migraine
- A randomized, double-blind comparison of 5 mg of XXXX, 15 mg of XXXX, and placebo in the treatment of patients with Primary Insomnia
- A Phase 2, double-blind, randomized, placebo-controlled, parallel-group, multicenter proof-of-concept study to evaluate the safety and efficacy of XXXX taken in combination with XXXX for the treatment of subjects with Chronic Insomnia
- A randomized, double-blind, placebo-controlled study to assess the subjective response to treatment with XXXX in adult subjects with Chronic Insomnia by utilizing an interactive voice response system (IVRS) for collecting diary data
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled, outpatient study to assess the efficacy and safety of a modified release formulation of XXXX in adult primary insomnia patients with sleep maintenance difficulties
- A Phase 3, randomized, double-blind, placebo-controlled, outpatient study to assess the long-term safety and efficacy of two dose levels of a modified release formulation of XXXX in adult patients with primary insomnia

Hepatology Studies:

- Open-label Rollover Study of XXXX for the Treatment of Liver Fibrosis in Adult Subjects With Nonalcoholic Steatohepatitis (NASH)
- A Multicenter, Randomized, Double-Blind, Placebo-controlled Trial of XXXX (XXXX), an Oral Caspase Inhibitor, in Subjects With Non-alcoholic Steatohepatitis (NASH) Fibrosis
- A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of XXXX in Subjects With Nonalcoholic Steatohepatitis
- A Phase 2 Double-blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Tolerability and Efficacy of XXXX, an XXXX (XXXX) in Adults With Nonalcoholic Steatohepatitis (NASH)
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of XXXX in Subjects With Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH)
- The XXXX XXXX Test for Monitoring Liver Disease and Treatment Effects by Measuring Liver Function and Physiology
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of XXXX an Oral Caspase Inhibitor, in Subjects With Decompensated Non-Alcoholic Steatohepatitis (NASH) Cirrhosis
- A Phase 3 Study to Evaluate the Efficacy and Safety of XXXX for the Treatment of Liver Fibrosis in Adult Subjects With Nonalcoholic Steatohepatitis
- A Phase 2a, Randomized, Double-blind, Placebo-controlled, Dose-ranging, Parallel Group Study To Evaluate Safety, Tolerability, And Pharmacodynamics Of XXXX Administered Daily For 16-weeks To Adult Subjects With Nonalcoholic Fatty Liver Disease

- A Multicenter Non-Alcoholic Fatty Liver Disease Biospecimen Collection
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of XXXX in Subjects With Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of XXXX in Subjects With compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH)
- A Phase 2, Randomized, Double-Blind, Placebo-Controlled Multicenter study to assess Efficacy and Safety of XXXX for prevention of complications in subjects with early decompensated liver cirrhosis
- A Phase 2 efficacy and safety study of XXXX for NASH in adult subjects with Liver Fibrosis
- A Phase 2, multicenter, randomized, double-blind, placebo-controlled trial of XXXX for NASH Fibrosis

Hematology Studies:
- A multi-center, randomized, controlled study to investigate the safety and tolerability of intravenous XXXX (XXXX) vs. Standard Medical Care in treating Iron Deficiency Anemia
- A multi-center, randomized, controlled study to investigate the safety and tolerability of IV XXXX vs. Standard Medical Care in treating Iron Deficiency Anemia in non-dialysis dependent subjects

Musculoskeletal Studies:
- A Phase 2a, randomized, double-blinded, placebo-controlled, parallel-group study to assess the analgesic efficacy and safety of XXXX in patients with Fibromyalgia
- Safety and tolerability study comparing XXXX given as an oral solution to a single blinded combination of oral tablets plus oral solution in subjects with Fibromyalgia
- A three-month, open-label, safety trial of XXXX in patients with Fibromyalgia

Respiratory Studies:
- A randomized, double-blind, parallel-group, multicenter study to compare clinical health outcomes of XXXX versus XXXX in outpatients with community acquired lower respiratory tract infections
- A comparative study of the safety, efficacy and effectiveness of XXXX extended release tablets and XXXX for the treatment of subjects with acute exacerbation of Chronic Bronchitis
- Comparative study of the safety and efficacy of XXXX QD to Penicillin V TID in the treatment of Streptococcal Pharyngitis/Tonsillitis

Rheumatology Studies:
- A double-blind, randomized, placebo-controlled, parallel group, multi-site study to evaluate the clinical equivalence of XXX Gel with XXXX Gel in patients with osteoarthritis of the knee
- A multicenter, randomized, active-control, phase 3B study to evaluate the cardiovascular safety of XXXX and XXXX in subjects with Gout and Cardiovascular Comorbidities
- A two-arm study comparing the analgesic efficacy and safety of XXXX once-a-day verses placebo for the treatment of pain due to osteoarthritis
- A randomized, double-blind, Phase 3 study to compare the efficacy and safety of XXXX in risk reduction of NSAID-associated ulcers in osteoarthritis subjects taking low dose aspirin
- A randomized, double-blind, multi-center study to evaluate the tolerability and effectiveness of XXXX vs XXXX in patients with osteoarthritis

Urology Studies:
- A multicenter, randomized, double-blind, placebo-controlled, parallel-group trial with OLE to demonstrate the efficacy and safety of XXXX orally disintegrating tablets for nocturia in adult males

STUDIES IN GASTROENTERLOGY INDICATIONS

Dyspepsia:
- Functional Dyspepsia Reduction Evaluation and Safety Trial (FDREST) A randomized, double-blind, placebo-controlled study to assess the safety and efficacy of XXXX, a medical food, in the dietary management of patients with functional dyspepsia
- A Phase 2b, multicenter, randomized, double-blind, placebo-controlled, parallel group, dose-ranging study of XXXX in subjects with functional dyspepsia
- A randomized, double-blind, placebo-controlled, dose finding, multicenter study to assess the efficacy, safety and tolerability of XXXX given orally at three dose levels and placebo in patients with functional dyspepsia (FD) and documented delayed gastric emptying
- A randomized, double-blind, placebo-controlled, dose finding, multicenter study to assess the efficacy, safety and tolerability of XXXX given orally at three dose levels and placebo in patients with functional dyspepsia (FD) and documented normal gastric emptying

Celiac Disease:

- A randomized, double-blind, placebo-controlled, multiple ascending dose study to evaluate the safety and tolerability of XXXX in patients with Celiac Disease
- A randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of different doses of XXXX for the treatment of Celiac Disease

Constipation:

- A 12-week, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Safety and Efficacy of XXXX in Patients with Diabetic Gastroparesis Constipated adults
- A Safety and Efficacy Evaluation of XXXX Laxative in Constipated Adults
- An Open Label Study of Chronic Use of XXXX Laxative in Constipated Adults
- A Phase 3, randomized, double-blind, placebo-controlled, parallel-group trial of XXXX administered orally for 12 weeks followed by a 4-week randomized withdrawal in chronic constipation
- A trial to evaluate the long-term tolerability, safety, subject satisfaction, pharmacokinetics and use patterns of oral XXXX tablets in subjects with chronic idiopathic constipation (CIC)
- A double-blind, placebo-controlled trial to evaluate the effect of dose titration on the safety and efficacy of XXXX tablets in subjects with chronic constipation
- A randomized, multicenter, double-blind, parallel-design Phase 2 trial of oral XXXX administered for 14 days once daily at 100 μg, 300 μg, 1000 μg, or placebo to patients with chronic constipation
- A randomized, multicenter, double-blind, placebo-controlled, dose-range finding, parallel-group, Phase 2 trial of oral XXXX administered to patients with chronic constipation
- Double blind, randomized, placebo-controlled, parallel group, multi-site study to evaluate the clinical equivalence of XXXX and XXXX 24 mcg capsules in treating CIC
- A multicenter, randomized, double-blind, placebo-controlled, parallel-group study of subcutaneous XXXX for treating of opioid-induced constipation (OIC) in subjects with chronic non-malignant pain
- A multicenter, randomized, double-blind, placebo-controlled, parallel-group study of oral XXXX for the treatment of opioid-induced bowel dysfunction in subjects with chronic non-malignant pain

Gastroparesis:

- A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Phase 2 Study to Assess the Efficacy, Safety, and Tolerability of XXXX for the Treatment of Diabetic or Idiopathic Gastroparesis
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Proof of Concept Study to Assess the Efficacy of XXXX (XXXX) in Relieving Symptoms of Gastroparesis
- A 2-Part, Randomized, Double Blind and Open-Label, Placebo and Active-Comparator Controlled Trial to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics for XXXX in Subjects With Diabetes Mellitus and Gastroparesis or With Idiopathic Gastroparesis
- An evaluation of the agreement between gastric emptying scintigraphy and the XXXX monitoring test and to assess both impact on patient management and diagnostic gain associated with the XXXX test
- A Phase 2b, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of XXXX in patients with vomiting symptoms and moderate to severe diabetic gastroparesis
- A multicenter, randomized, double-blind, placebo-controlled, parallel-group, phase 2a study or oral XXXX QD and BID for 4 weeks to patients with diabetic gastroparesis
- A Phase 1b, randomized, double-blind, placebo-controlled, crossover study to assess the effects of XXXX on gastric emptying time in diabetic subjects with gastroparesis.

Gastroesophageal Reflux Disease, Heartburn, and Reflux:

- Efficacy and safety of 10 mg of XXXX for treating heartburn in frequent sufferers
- A phase 2b, double-blind, randomized, placebo-controlled, dose-finding study to evaluate efficacy of a novel selective 5-HT4 receptor agonist, XXXX taken with a PPI in subjects with gastroesophageal reflex disease (GERD) with persistent regurgitation with or without heartburn while on PPI therapy
- Determination of minimal clinically important difference of the ReQuest Patient Self Assessment in patients with endoscopically-confirmed GERD, Grade A-D (LA class) treated with XXXX or placebo
- An open-label study of once-daily oral administration of XXXX 40 mg in patients with symptoms of GERD to investigate the relationship between the presence of erosive esophagitis (EE) at baseline and heartburn resolution after 4 weeks of treatment
- Investigation of the prevalence of clinically relevant esophageal mucosal pathology in XXXX users
- A Phase 2 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate the efficacy and safety of a four-week treatment with XXXX for the relief of heartburn with GERD
- A Phase 2 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate the efficacy and safety of a four-week treatment with XXXX for the healing of acute EE
- A double-blind, placebo-controlled study of XXXX 20mg maintenance intermittent therapy following acute treatment in patients with symptomatic GERD

- A randomized, double-blind, multicenter dose-finding Phase 2b study for up to 8 weeks' treatment with XXXX 25, 50, 75 mg and XXXX 40 mg, given orally once daily for the healing of erosive esophagitis
- A 4-week, randomized, double-blind, dose-finding phase 2b study with XXXX (20, 50 & 75 mg) and XXXX 20 mg, for the treatment of GERD without EE (per LA classification) in adults
- An open label, long term safety study of XXXX, and XXXX in study subjects with EE
- A comparative efficacy and safety study of XXXX and XXXX in study subjects with EE
- A second multi-center, double-blind, randomized, single-dose, parallel study to evaluate the efficacy of XXXX, XXXX and placebo in preventing heartburn symptoms
- A multicenter, double-blind, randomized study comparing safety and efficacy of extended release XXXX (daily and BID) and placebo in treating symptomatic, endoscopically confirmed erosive GERD

Irritable Bowel Syndrome:

- A Phase 3, International, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Efficacy and Safety Trial of XXXX Administered Orally for 12 Weeks to Patients With Irritable Bowel Syndrome With Constipation
- A Phase 2b, Randomized, Double-blind, Double-dummy, Placebo-controlled, Parallel-group, Dose-range-finding Study of Two Delayed Release Formulations of XXXX Administered Orally for 12 Weeks to Patients With Irritable Bowel Syndrome With Constipation
- A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study With a 4-Week Randomized Withdrawal Period to Evaluate the Efficacy and Safety of XXXX for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
- An Open Label Long-Term Safety Study of XXXX for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
- A Phase 4 Multicenter, Multinational, Prospective, Randomized, Placebo-Controlled, Double-Blinded Parallel Group Study to Assess Efficacy of XXXX in the Treatment of Irritable Bowel Syndrome With Diarrhea (IBS-D) in Patients Who Report Inadequate Control of IBS-D Symptoms With Prior XXXX Use (RELIEF)
- A study to assess repeat treatment efficacy and safety of XXXX 550mg TID in subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)
- A randomized, double-blind, placebo-controlled, Phase 3 study to evaluate the efficacy, safety, and tolerability of XXXX in the treatment of patients with IBS-D
- A Phase 2, multi-center, randomized, double-blind, placebo-controlled, multiple-dose study to determine the safety and efficacy of orally administered XXXX in subjects with IBS-D
- A Phase 2, multi-center, randomized, double-blind, placebo-controlled, multiple-dose study to determine the safety and efficacy of orally administered XXXX in subjects with IBS-D
- A randomized, double-blind, placebo-controlled study to assess the safety and efficacy of XXXX for the treatment of constipation-predominant irritable bowel syndrome (IBS-C)
- A randomized, double-blind, placebo-controlled, parallel-group, dose-ranging, multicenter study to evaluate the efficacy, safety, and tolerability of XXXX in the treatment of patients with IBS-C

Other Gastrointestinal Conditions:

- A Randomized, Double Blind, Placebo-controlled, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Fixed-dose Combination XXXX in Subjects With Moderately to Severely Active Crohn's Disease
- Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the
- Efficacy and Safety of XXXX in the Induction and Maintenance of Remission in Subjects With Moderately to Severely Active Crohn's Disease
- Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of XXX in the Induction and Maintenance of Remission in Subjects With Moderately to Severely Active Ulcerative Colitis
- A randomized, double-blind, placebo-controlled study of XXXX in the treatment of functional diarrhea
- Efficacy and safety study of Intra-Anal application of XXXX ointment in subjects with symptomatic internal hemorrhoids
- A Phase 3 randomized, double-blind, placebo-controlled, parallel-treatment group, multicenter efficacy and safety study of intra-anal application of XXXX ointment in subjects with symptomatic internal hemorrhoids
- Double-blind, dose response, randomized, placebo-controlled, parallel group, multi-center phase 3 study on the efficacy and tolerability of XXXX vs. placebo for the prevention of recurrence of diverticulitis
- A Phase 3, randomized, double-blind, dose-response, stratified, placebo-controlled study evaluating the safety and efficacy of XXXX versus placebo over 104 weeks in the prevention of recurrence of diverticulitis
- A Phase 2 randomized, double blind, placebo-controlled, multicenter study to assess the efficacy and safety of fixed-dose combination XXXX in subjects with moderately to severely active Crohn's Disease