



# ADVANCED DIGESTIVE CARE

## GASTROENTEROLOGY ASSOCIATES

Where caring for our patients is our #1 priority!

### VOLUNTEERING FOR A CLINICAL TRIAL

#### What is a clinical trial?

A clinical trial is a research study in which volunteers receive investigational treatments under the supervision of a physician and other research professionals. These treatments are developed by pharmaceutical and biotechnology companies who select qualified physicians, also known as investigators, to conduct clinical trials to determine the benefits of investigational drugs. Clinical trials are usually conducted in three phases (I, II, III). Only a small number of people participate in phase I trials while the later phases involve a larger number of volunteers.

#### Who can participate in a clinical trial?

All clinical trials have guidelines about who can participate. Before joining a clinical trial, a volunteer must qualify for the study. The factors that allow volunteers to participate in a clinical trial are called "inclusion criteria" and the factors that disallow volunteers from participating are called "exclusion criteria." These criteria can include age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Some research studies seek participants with specific illnesses or conditions to be studied in a clinical trial, while others require healthy participants. It is important to note that inclusion and exclusion criteria are used to identify appropriate participants, promote participants' safety, and ensure that researchers learn the information they need.

#### How does a clinical trial work?

In a clinical trial, a volunteer is usually assigned a specific study group. Volunteers in one study group may receive an investigational treatment or study drug while other volunteers may receive a placebo or a treatment already available. A placebo is an inactive product used to assess the experimental treatment's effectiveness. The participant, physician, and research staff may not know which volunteer receives a placebo and which receives the active treatment. Not knowing which participants are receiving the active treatment allows the physician and research staff to objectively observe the volunteers during the study. Regardless of which treatment volunteer receives, however, the level of medical attention and care that each receives is the same.

*This information was obtained from CenterWatch.*

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4<sup>th</sup> Quarter 2019

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## ACTIVE STUDIES

Do you have one of these  
medical conditions?

**Ulcerative Colitis** - Eli Lilly:  
LUCENT 1: Protocol I6T-MC-AMAN:A  
Phase 3, Multicenter, Randomized,  
Double-Blind, Parallel, Placebo-  
Controlled Induction Study of  
Mirikizumab in Conventional-Failed  
and Biologic-Failed Patients  
with Moderately to Severely Active  
Ulcerative Colitis

**Gastroesophageal Reflux  
Disease (GERD)** - Ironwood:  
Protocol C3718-302:A Phase 3,  
Randomized, Double-blind, Placebo-  
controlled, Parallel-group, Multicenter  
Trial of Oral IW-3718 Administered to  
Patients with Gastroesophageal  
Reflux Disease while receiving Proton  
Pump Inhibitors

**Clostridium difficile  
Infection** - Summit: Ri-CoDiFy:  
Protocol SMT19969/C005: A Phase  
3, randomized, double-blind, active  
controlled study to compare the  
efficacy and safety of ridinilazole (200  
mg, bid) for 10 days with vancomycin  
(125 mg, qid) for 10 days in the  
treatment of Clostridium difficile  
infection (CDI)

**Crohn's Disease** - Celgene:  
Yellowstone: Protocol RPC01-3201: A  
Phase 3, Multicenter, Randomized,  
Double-Blind, Placebo-Controlled  
Study of Oral Ozanimod as Induction  
Therapy for Moderately to Severely  
Active Crohn's

Interested in participating  
in a study?

Get in touch with our research  
team member, Gigi Willis at  
571-535-2587.

*If you are interested in research but do  
not qualify for one of the above studies,  
you may call to find out about  
additional research.*

## 12 Ways to Have a Healthy Holiday Season

Brighten the holidays by making your health and safety a priority. Take steps to keep you and your loved ones safe and healthy and ready to enjoy the holidays.

1. **Wash hands often to help prevent the spread of germs.** It's flu season. Wash your hands with soap and clean running water for at least 20 seconds.
2. **Bundle up to stay dry and warm.** Wear appropriate outdoor clothing: light, warm layers, gloves, hats, scarves, and waterproof boots.
3. **Manage stress.** Give yourself a break if you feel stressed out, overwhelmed, and out of control. Some of the best ways to manage stress are to find support, connect socially, and get plenty of sleep.
4. **Don't drink and drive or let others drink and drive.** Whenever anyone drives drunk, they put everyone on the road in danger. Choose not to drink and drive and help others do the same.
5. **Be smoke-free.** Avoid smoking and secondhand smoke. Smokers have greater health risks because of their tobacco use, but nonsmokers also are at risk when exposed to tobacco smoke.
6. **Fasten seat belts while driving or riding in a motor vehicle.** Always buckle your children in the car using a child safety seat, booster seat, or seat belt according to their height, weight, and age.
7. **Get exams and screenings.** Ask your health care provider what exams you need and when to get them. Update your personal and family history.
8. **Get your vaccinations.** Vaccinations help prevent diseases and save lives. Everyone 6 months and older should get a flu vaccine each year.
9. **Monitor children.** Keep potentially dangerous toys, food, drinks, household items, and other objects out of children's reach. Protect them from drowning, burns, falls, and other potential accidents.
10. **Practice fire safety.** Most residential fires occur during the winter months, so don't leave fireplaces, space heaters, food cooking on stoves, or candles unattended.
11. **Prepare food safely.** Remember these simple steps: Wash hands and surfaces often, avoid cross-contamination, cook foods to proper temperatures and refrigerate foods promptly.
12. **Eat healthy, stay active.** Eat fruits and vegetables which pack nutrients and help lower the risk for certain diseases. Limit your portion sizes and foods high in fat, salt, and sugar.



This information was obtained from CDC.GOV

## Gluten Free Thanksgiving Stuffing



### Ingredients

- 1 (1 pound) loaf gluten-free bread (such as Udi's(R) Millet-Chia bread)
- 3 tablespoons olive oil
- 2 onions, diced
- 3 stalks celery, diced
- 1 teaspoon chopped fresh sage
- 1 teaspoon dried thyme leaves
- 3/4 teaspoon salt
- ground black pepper to taste
- 2 cups gluten-free chicken broth
- 2 large eggs

### Directions

1. Preheat oven to 325 degrees F (165 degrees C). Grease a 3-quart baking dish.
2. Cut bread into cubes about 3/4-inch square and spread onto a baking sheet.
3. Bake in the preheated oven until crisp, 12 to 17 minutes.
4. Heat olive oil in a large skillet over medium heat. Cook and stir onions and celery in the hot oil until soft, 8 to 10 minutes. Stir sage, thyme, salt, and black pepper into the vegetables. Mix toasted breadcrumbs, chicken broth, and eggs into vegetables. Spoon dressing into the prepared baking dish and cover dish.
5. Bake in the preheated oven for 30 minutes, uncover, and bake until top of dressing is crisp and lightly browned, about 10 more minutes.

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