



NEW PHASE 2 CLINICAL TRIAL FOR SYMPTOMATIC CELIAC DISEASE PATIENTS LAUNCHES

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ImmunogenX, a California company focused on developing celiac disease treatments and diagnostics, received a second grant from the NIAID branch of the National Institutes of Health (NIH), in support of a new clinical trial. The trial launched in December 2019, with four sites: The Mayo Clinic (Rochester, MN), Columbia University (New York, NY), along with two private practice sites in Chesterfield, MI, and Nashville, TN.

The trial will continue testing ImmunogenX's drug candidate [latiglutenase](#) (IMGX003), a drink-based medication made up of a combination of two enzymes that degrade gluten in the stomach. The study will monitor how well latiglutenase relieves symptoms and improves quality of life in people with celiac disease. The two Principal Investigators on the study are Joe Murray, M.D., of the Mayo Clinic and Jack Syage, Ph.D., of ImmunogenX.

Latiglutenase has been under investigation as a potential treatment for celiac disease for several years, and is designed to be used along with the gluten-free diet. ImmunogenX acquired latiglutenase from Alvine Pharmaceuticals in 2016, and has continued the development of the drug, including an ongoing "gluten challenge" clinical trial, the Celiac Shield Study, which launched in May 2019.

This upcoming "real-world" trial will look more closely at celiac disease patients following a strict gluten-free diet who still have gluten-induced antibodies in their blood. This group had significantly reduced symptom severity and frequency while taking latiglutenase compared to placebo in the 2015 Phase 2B CeliAction study. Gluten-induced antibodies are most commonly measured in blood as a diagnostic test for celiac disease. In some people with celiac disease, the antibodies do not return to a normal level even while following a strict gluten-free diet. These people are referred to as "seropositive."

The goal of this upcoming NIAID-funded study is to understand if latiglutenase reduces symptoms significantly more than placebo in people who are still seropositive while on the gluten-free diet, as was seen in the 2015 CeliAction study. Studies show that even while following a strict gluten-free diet, many people with celiac disease are still [regularly exposed to gluten](#). Latiglutenase is designed to be used in conjunction with the gluten-free diet. Participants in the trial will keep a daily symptom diary, the Celiac Disease Symptom Diary (CDSD[®]), while they continue their normal daily routines and consume either latiglutenase or placebo with each daily major meal.

Many people with celiac disease do not want to voluntarily consume gluten as a requirement of a clinical trial. This specific clinical trial does not require any intentional gluten consumption. Rather, the investigators are researching the ongoing symptoms many people with celiac disease have while following a gluten-free diet. At our 2018 Research Symposium, Dr. Ciaran Kelly noted that this clinical method is somewhat preferred by the FDA because it is more reflective of real-world patient experience.

Beyond Celiac is working with ImmunogenX to recruit for this clinical trial as part of our commitment to helping accelerate research. If you are interested in participating, you can learn more and see if you qualify at [SolutionsforCeliac.com](https://www.solutionsforceliac.com). You can also learn more about the study at [ClinicalTrials.gov](https://www.clinicaltrials.gov).