Call Toll-free 1-800 856-7842 or 828-254-0881 with Extension listed

Name of Study: **A Trial to Evaluate the Frequency of Genetic Sucrase-Isomaltase Deficiency Genotypes, and the Efficacy and Safety of Sucraid® (Sacrosidase) Oral Solution in Subjects with Chronic Diarrhea and Sucrase Deficiency (GSID-E)-(QOL Medical)**

LINK: https://clinicaltrials.gov/ct2/show/NCT02784067?term=qol+sucrase&rank=1

PI: William Harlan, MD

Study Coordinator: Ann Jones x 3397 or Direct-828-350-3697

ENROLLMENT BEGINS: June 2016

ENROLLMENT ENDS: Approximately June 2017

Summary: A Multicenter, Double-Blind, Placebo-Controlled Trial to Evaluate the Frequency of Genetic Sucrase-Isomaltase Deficiency Genotypes, and the Efficacy and Safety of Sucraid® (Sacrosidase) Oral Solution in Adults with Chronic Diarrhea and Sucrase Deficiency

Inclusion:

Subject is 18 years of age or older.
2. Subject is male or female.
3. Subject has a minimum of 3 months of self-reported diarrhea (BSFS scores ≥ 5 on at least 3 days per week and ≥1 stool per day)
4. Subject has a value in the SHMBT of at least 20 ppm for hydrogen, or 12 ppm for methane or 15 ppm above a previous breath sample for the combination of both gases.
5. Subject reports that he/she experienced soft stools or diarrhea within the last 24 hours when contacted by the site 24 hours after completing the SHMBT.
6. Subject is able to read, speak, and verbally understand the English language.
7. Subject is located in the United States.
8. Subject has access to the Internet on a daily basis.
9. Subject has access to an acceptable Apple iPhone/iPad/iTouch or Android smartphone/tablet. The sponsor may choose to provide a smartphone in unusual cases.

Exclusion:

Subject has recent history of functional or chronic constipation.

2. Subject has known history of ulcerative colitis, Crohn's disease, or Celiac disease.

3. Subject has known hypersensitivity to papain, glycerol, or yeast.

4. Subject has received bovine serum in the last year.

5. Subject has previous history of Sucraid use.

6. Subject has not taken any prebiotic or probiotic within 5 days prior to Visit 2 and agrees to refrain from taking them during the study.

7. Subject is female and is pregnant, breastfeeding, or planning to become pregnant during the study.

8. Subject has known uncontrolled systemic disease.

9. Subject has prior diagnosis of Type 1 or Type 2 diabetes.

10. Subject has history of bowel resection.

11. Subject is undergoing chemotherapy for the treatment of cancer.

12. Subject has major physical or psychiatric illness within the last 6 months that in the opinion of the investigator would affect the subject's ability to complete the trial.