What are clinical research studies?

Clinical research studies help scientists and doctors explore whether an investigational drug is safe and whether it works. Before a doctor can prescribe a new drug, it must go through several phases of clinical research:

Phase 1: first study of the investigational drug in people (often healthy volunteers).

- 96 healthy volunteers have been dosed with CIN-103, the investigational drug used in the enviva study.

Phase 2: study of the investigational drug in people with the condition the drug is for.

Phase 3: study confirming how well the investigational drug works.

Phase 4: more research after the drug is approved.

The enviva study is a Phase 2 study.

Clinical research studies rely on volunteers. Remember that taking part in the study is your choice. Know that the rules and ethics that doctors must follow to practice medicine also apply to clinical research studies.

For more information about the enviva study, contact:

Imagine the freedom of fewer IBS-D symptoms

Reach for new possibilities with the enviva study.

enviva

What is the enviva study?

- The enviva study is a Phase 2 clinical research study. Learn more about clinical research studies in the *What are clinical research studies?* section.
- The enviva study lasts about 19 weeks and includes a Screening Period, Baseline Period, Dosing Period, and Follow-up Period.
- The goal of the enviva study is to explore the effects of an investigational drug on the symptoms of irritable bowel syndrome with predominant diarrhea (IBS-D). Researchers are studying how the investigational drug may help ease unpleasant symptoms, such as abdominal pain, bloating, and stool consistency.

Who can enroll in the enviva study?

If you answer *yes* to the following questions, you may be eligible:

- Are you an adult male or female 18 years of age or older?
- Have you been diagnosed with IBS-D?
- Do you expect no changes to your lifestyle, exercise routine, and/or diet during study participation?
- Are you willing to complete a daily eDiary?

What is the investigational drug?

- CIN-103 is the investigational drug being researched in this study. It was designed to work differently from approved IBS-D treatment options.
- The investigational drug is a new formulation of a gastrointestinal drug called phloroglucinol, which relieves painful spasms within the GI tract. The investigational drug is designed to work similarly to help relieve symptoms of pain, cramping, and diarrhea.
  - *Note: phloroglucinol is not approved by regulatory agencies in all countries.*
- 8 capsules are taken orally (4 capsules in the morning and 4 at night).
- Participants are randomly assigned to a dose that may include either the investigational drug, a matching placebo, or a combination of the 2. There is a 67% chance of receiving the investigational drug.

What can study participants expect?

Once you sign the Informed Consent Form (ICF), you begin 19 weeks of study participation, divided into the following periods:

Screening Period (up to 3 weeks): complete assessments to determine if you meet the requirements to participate in the study. Use of anti-diarrheal medication is allowed.

Baseline Period (2 weeks): receive instructions for completing the daily eDiary to record your symptoms of abdominal pain and bloating, as well as your stool consistency, frequency, and urgency. Stop use of any anti-diarrheal medications, including medication used during the Screening Period.

Dosing Period (12 weeks): take your assigned dose twice daily, continue to complete the daily eDiary, and visit the study clinic 5 times for study assessments. Use of anti-diarrheal medications should be limited and discussed with the study doctor.

Follow-up Period (up to 2 weeks): talk to a member of the study team after your final dose. This visit may happen over the phone or at the study clinic.