WHAT IS A CLINICAL RESEARCH STUDY?

A clinical trial, also called a clinical research study, is a carefully designed scientific evaluation of an investigational medication or treatment. Clinical trials are conducted by doctors and researchers.

The Importance of Diversity in Clinical Research Studies

Research has shown that certain diseases, treatments and medications may impact people differently based on their age, gender, and genetic background, including race and ethnicity. Racial and ethnic minorities continue to be under-represented in clinical research. Increasing diversity in our clinical study can help ensure that potential medications and treatments are generally safe and work for diverse types of people, especially those most impacted by the disease or illness.

Why Is Clinical Research Important?

Clinical research helps doctors and scientists determine if an investigational medicine or therapies are safe and/or effective for use in humans to potentially treat a condition, disease or disorder. Clinical research studies often require a large number of volunteers to participate in a single study; sometimes thousands are needed to obtain reliable information.

CAN I CHANGE MY MIND?

Yes. You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

See if you may be eligible to participate

To learn more about this clinical research study, please contact the site at:

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DAHLIAS
SJÖGREN'S SYNDROME STUDY

THE DAHLIAS STUDY

A clinical study to evaluate an investigational medicine in adults with primary Sjögren's Syndrome (pSS) is now enrolling

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WHAT IS INFORMED CONSENT?

"Informed consent" is a process of information exchange before an adult agrees to participate in research. Potential research participants will be asked to read and sign an informed consent document, but will also be given instructions, verbally and in writing, question/answer sessions and other reading materials to assure the potential study participants' understanding of and willingness to voluntarily enroll in the research.

So, before you agree to volunteer for the study, the study doctor or staff is required to explain all the details of the study, which will include any risks, and address your questions. After all of your questions have been answered, and if you wish to participate, then you will sign a document called the Informed Consent Form to ensure:

- You agree to volunteer
- You understand the study, including the study procedures, risks and potential side effects
- You understand that you can leave the study at any time, for any reason

If you don't understand what is expected of you or the document, you should continue to ask questions and talk with the study doctor, your family or others that you trust, until you feel you understand.

The images depicted contain models and are being used for illustrative purposes only.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the safety and effectiveness of an investigational medicine and whether it may help improve symptoms in adults with Sjögren's Syndrome.

Am I Eligible?

You may be eligible to participate if you:

- Are between the ages 18 and 75
- Have been diagnosed with primary Sjögren's Syndrome
- Are experiencing symptoms that include fatigue, dry eyes or dry mouth

Additional eligibility criteria will be assessed by the study doctor or staff during the screening process prior to being enrolled in the study and receiving any investigational medicine. Not all individuals may qualify to participate in this research.

WHAT CAN I EXPECT IF I JOIN THE STUDY?

If you qualify and choose to join the study and sign the Informed Consent Form, you will be asked to attend a screening visit with the study doctor. At this visit, you will undergo tests and procedures to determine if you are a good match for continuing in the study.

- **If eligible, you will be in the study for up to 36 weeks (9 months) and visit the study doctor or clinical research staff approximately 15 times.**
- **You will be randomly assigned to one of three study treatment groups. This means you may either receive one of two different doses of the active investigational medicine or a placebo (which contains no active medicine).**
- **Neither you nor the study team will know which study treatment group you are in.**
- **You will be given the active investigational medicine or placebo intravenously (into the vein) and closely monitored for up to 1 hour after each dose.**
- **Qualified subjects will receive study-required medical care and the active investigational medicine or placebo at no cost. The study will not pay for other medical care or current medication(s) needed to support your daily health care routine.**