

IMPORTANCE OF CLINICAL TRIALS

A clinical research study (**also called a clinical trial**) is carefully supervised research that is done before an investigational treatment becomes available to the public.

- Clinical trials follow specific rules to protect the rights, safety, well-being, and privacy of participants.
- The results help government officials decide if a treatment or product is safe and should be available to patients.
- Clinical trials are the only way to develop new medical treatments to improve patient care.



FACTS ABOUT ECZEMA

Eczema, also known as atopic dermatitis (AD), is a non-contagious, inflammatory skin condition that is often characterized by red, itchy, dry, and cracked skin. Areas of the body commonly affected include the face, inside of the elbows, or behind the knees, but eczema can appear anywhere on the body and can range from mild to severe. As the patient scratches, this can cause skin tears, bleeding blisters, pain, and changes in the natural color of their skin.

Eczema affects people of all ages. The exact cause of eczema is unknown, but it is thought to be related to a combination of genes and dysfunction of the immune system in reaction to triggers like allergens.

Symptoms of eczema can affect a person's daily activities, mental health, interfere with sleep, and impact their overall quality of life. Currently, there is **no cure** for eczema.



ECZEMA CLINICAL TRIAL TRIV-509

Our atopic dermatitis (eczema) trial is testing the safety and effectiveness of an investigational treatment for eczema called **TRIV-509**. TRIV-509 is given as an injection under the skin (**subcutaneously**) during in-clinic visits.

WHY PARTICIPATE?

You may not directly benefit from taking part in this trial, but your participation will help us learn about the investigational treatment and could help others with eczema in the future.

If you **qualify and decide to take part**, you may:

- Have access to the investigational treatment, **TRIV-509**
- Be **reimbursed for travel-related expenses**



DO YOU QUALIFY FOR PARTICIPATION?

To participate in this trial, you must meet the following criteria:

- Be **18-75 years old**
- Have had a diagnosis of eczema **for at least 1 year**
- Have **moderate-to-severe eczema**, as evaluated by a study doctor
- Be willing to **not use other medications to treat eczema** for the duration of the study
- Be available for **14 visits over 57 weeks**

We are actively enrolling participants. For more information and to see if you qualify, please visit:

**Other criteria for eligibility apply. Trial treatment, visits, tests, and procedures will be provided at no cost to you. The study staff will tell you about any reimbursement for trial-related travel expenses.*



ABOUT OUR CLINICAL TRIAL

TRIV-509 works by blocking proteins in the skin called kallikreins (KLK-5 and KLK-7). These proteins are responsible for maintaining normal skin barrier function and have been shown to be overactive in atopic dermatitis.

Trial participation will last up to **57 weeks and includes 14 study visits**.

The duration of the study for each participant will be up to 57 weeks, including a Screening period of up to 30 days, a 32-week treatment period, and a 20-week follow-up period.

Study visits will occur for Screening and on Day 1 and Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 44, and 52. During the trial, your eczema will be assessed at every visit, and your overall health will be closely monitored.

This is a placebo-controlled trial, meaning that at the beginning of the trial, some participants will be assigned to receive **TRIV-509** and some participants will receive **placebo**, which looks like TRIV-509 but does not contain active drug. Later in the trial, participants who received TRIV-509 will "cross over" and receive placebo, and those who received placebo will "cross over" and receive TRIV-509. This allows investigators to better understand how TRIV-509 is working and ensures everyone in the trial receives TRIV-509.

*Medical photographs, full body front and back, **will be performed**. Your head and face will **not be included** in the photographs.*

*Joining this trial is completely up to you and you can decide to **leave the trial at any time** and for any reason. Deciding not to take part will not affect your usual medical care now or in the future.*