



Observational Study of Patients with Cutaneous T-cell Lymphoma (CTCL) treated with LYMPHIR™

LYMPHIR study

Patient Study Guide

What to Expect After Enrollment

Welcome

Thank you for joining the LYMPHIR study. This guide explains what you can expect after you join the study, what information will be collected, and how the study fits into your regular cancer care.

This study is evaluating side effects in people living with cutaneous T-cell lymphoma (CTCL) who are receiving treatment with LYMPHIR™. LYMPHIR is a treatment option for patients whose disease has returned (relapsed) or has not responded to prior therapies (refractory). Your doctor has determined that you may benefit from LYMPHIR treatment.

This is an observational study. That means the study team will collect information about your health and treatment over time, but the study will NOT decide, change, or direct your treatment. Your doctor will continue to make all medical decisions based on your usual care needs.

This study is designed to help doctors better understand why CTCL treatment with LYMPHIR may be causing certain side effects and how long those side effects may last. It looks at how LYMPHIR is used in everyday care, how patients do overtime, and how doctors may improve CTCL treatment with LYMPHIR in the future.

Study overview

About 554 people from across the United States are expected to join this study.

You will be followed for up to 24 months after your first LYMPHIR infusion. This longer follow-up helps researchers better understand how patients respond to treatment over time.

What happens after enrollment?

Your care continues as usual.

Your treatment plan is chosen by your doctor before enrollment. Joining the study does not influence which treatments you receive, how your treatment is managed, or what tests or procedures your doctor recommends as part of routine care.

Information is collected from routine care.

Most study information will come from your medical record and your doctor's usual assessments. You will also be contacted monthly by one of the study staff for a brief check-in.

You will also be asked to complete questionnaires online or answer questions via phone calls. These questionnaires ask about your physical functioning, overall health, and quality of life from your perspective.

Study data collection

The study collects information that helps researchers understand your treatment journey and outcomes in routine care. Researchers may also look at information in your medical record to understand how well your treatment is working. This may include whether you are experiencing any side effects, your taste, hearing or vision is impaired, whether the cancer has grown or spread, how long you stayed on treatment, and overall health outcomes.

Study data collection is designed to fit with your usual care visits. Information will be collected at enrollment, and every month after your first LYMPHIR infusion.

- At enrollment, the study staff will collect information about you such as your cancer diagnosis, health history, age, current health, lab test results, weight, height, and medicines you take.
- At follow-up time points, staff may collect information about weight, cancer treatment, other medicines, side effects, test results, and how your cancer is doing.
- At scheduled time points, you will be asked to answer short questions about how you are feeling and how you are doing day to day. These questions may ask about your daily activities, overall health, and quality of life.
- If you agree to optional tokenization, study staff will assign a unique identifier (minus all personal information) that will be used to link your electronic medical records data during your participation in the program.

Taking part is your choice

Taking part in this study is your choice. If you join, you can choose to stop at any time. Your regular medical care and benefits will not change if you decide to stop being in the study.

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There is no handwriting or other markings on the paper.

Hours of Operation: M – F 8:00am – 8:00pm, ET

