

# Frequently asked Questions...

## ABOUT E4402: A CLINICAL TRIAL FOR PATIENTS WITH NON-HODGKIN'S LYMPHOMA

*The Eastern Cooperative Oncology Group (ECOG) prepared this fact sheet to help you understand this cancer clinical trial and the treatment for Non-Hodgkin's Lymphoma using rituximab.*

### **What is a clinical trial?**

A clinical trial is a study conducted by doctors to test new medications or new combinations of medications. This trial – ECOG Trial E4402 – is what is called a “phase three” trial. That means that the new treatment has already been tested in different doses for safety and to see if it is effective against the cancer.

### **What is the purpose of this trial?**

In this trial, researchers will compare the effect of giving the drug rituximab (an already approved drug) in a single dose every 12 weeks to giving it once a week for four weeks on a varying schedule.

This trial also includes a laboratory study that will examine the rituximab levels in the blood and the effect it has on lymphoma.

### **What is Rituximab?**

Rituximab is a drug called a “monoclonal antibody” that reacts against a very specific disease-causing element called an “antigen” found on lymphoma cells. In this way, rituximab destroys the lymphoma cells.

### **What should I know about the trial treatments?**

If, after the initial four doses of rituximab, your condition does not improve, your doctor will discuss other treatment options with you and your participation in the trial will end.

If your condition improves with the initial four doses of rituximab, you will be assigned at random, to one of two groups. Being assigned “at random” means that you will not have a choice about which schedule of Rituximab you take. Each group will continue to receive rituximab, but on different schedules to see if there is any benefit related to the timing of the dose.

### **What are some of the side effects caused by these medications?**

Rituximab is given “intravenously,” with a needle injected into a vein. The most common side effects with rituximab are most likely to occur as it is given. Side effects may include fever, chills, nausea and vomiting, headache, low blood pressure, tiredness, joint pain, abdominal pain, skin rash, hives, or pain at the tumor site. Medication can be given to relieve the side effects.

### **What will I have to do on the clinical trial?**

If you decide to participate in this trial, your doctor will perform several tests before you begin taking your medication. These include:

- Blood and urine tests;
- Bone marrow biopsy; and
- Bone x-rays.

You would most likely need to have these tests anyway as part of your routine care for Non-Hodgkin's Lymphoma. These tests will be repeated occasionally during the trial. Your doctor or nurse will help you set up a schedule for your tests.

### **Will insurance cover the cost of this trial?**

Medicare covers the routine costs of care required in clinical trials. Many other insurers also cover these costs. Coverage may not, however, be the same from plan to plan. The cost of the rituximab, doctor's visits, and certain tests may or may not be covered. Please discuss these issues with your healthcare provider and your insurer.

### **Is this trial right for me?**

To be accepted into this trial, you must have had a biopsy to diagnose that you have a non-aggressive form of lymphoma called Indolent Non-Hodgkin's Lymphoma. If you have not yet been treated, you may be eligible for this trial. Men and women of all ethnic groups can participate.

If you would like to participate in this trial, let your doctor know. Your doctor can tell you whether this trial is right for you. If you decide to participate, your doctor will help you enroll.



***What if I change my mind after enrolling in the trial?***

You may stop treatment at any time – please discuss your concerns with your doctor.

***Would my doctor stop my participation for any reason?***

Your doctor will carefully observe your health throughout the trial. Your doctor may stop your participation if:

- Your disease progresses;
- You have serious side effects;
- New information on treating Non-Hodgkin's Lymphoma becomes available that may affect your health or welfare.

***Who is conducting the trial?***

The Eastern Cooperative Oncology Group (ECOG) is conducting this trial. ECOG is one of the largest cancer research organizations in the United States. It has a network of researchers, physicians, and healthcare professionals at public and private institutions across the country. ECOG conducts clinical trials in all types of adult cancers. It receives funding from the National Cancer Institute (NCI) and other sources. ECOG's goal is to control, effectively treat, and ultimately cure cancer. ECOG provides research results to individuals and the medical community through scientific publications and professional meetings.

***Where can I get more information?***

For more information about ECOG, visit <http://www.ecog.org>.

For more information about cancer and clinical trials, visit:

The Coalition of National Cancer Cooperative Groups:  
[www.CancerTrialsHelp.org](http://www.CancerTrialsHelp.org)

The National Cancer Institute (NCI) Cancer Information Service:  
1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615,  
[http://cancer.gov/clinical\\_trials](http://cancer.gov/clinical_trials) for clinical trial information and  
[http://cancer.gov/cancer\\_information](http://cancer.gov/cancer_information) for more information about cancer.

