

What is OPTIMA?

OPTIMA is a phase IV clinical trial. A clinical trial is a research study in human volunteers designed to answer specific health questions. Clinical trials are conducted in phases that have different purposes. Phase IV clinical trials are conducted after a drug is approved for use, and are designed to identify additional information such as the drug's benefits, risks, and optimal use.

OPTIMA is designed to compare the safety and effectiveness of 2 different treatment regimens in patients with early rheumatoid arthritis (RA): combination therapy consisting of the TNF-blocking drug **HUMIRA**[®] (adalimumab) taken along with methotrexate (MTX), or therapy with MTX alone.

HUMIRA and MTX are already commonly used to treat RA; they are not "experimental" drugs. A TNF-blocking drug, such as **HUMIRA**, taken in combination with MTX, is currently the most effective available therapy for moderate to severe RA. The **OPTIMA** trial is designed to help clinicians understand the most effective way to use these therapies to obtain the maximal benefit for patients.



Optimizing Treatment in Rheumatoid Arthritis



Optimizing Treatment in Rheumatoid Arthritis

For site information



OPTIMA Clinical Trial— Another Choice

Understanding OPTIMA. Information to help you better understand this clinical trial and if OPTIMA might be the right choice for you.



The OPTIMA Clinical Trial:

Optimizing Treatment for Rheumatoid Arthritis



OPTIMA Clinical Trial—
Another Choice

Why would I want to participate in OPTIMA?

Participating in a clinical trial helps answer important medical questions that can benefit many people.

As an **OPTIMA** participant, you will receive well-studied medication that your doctor would have been likely to prescribe to you. All study participants will receive at least 1 active study medication; no patient in the study will receive only placebo (a placebo is an inactive substance with no treatment value). All participants will be followed closely throughout the study.

The study is designed so that all patients in the **OPTIMA** trial will be able to receive beneficial treatment.

What happens during OPTIMA?

The **OPTIMA** trial will last 18 months, and will include 2 consecutive parts, or treatment periods (one 6-month and one 1-year). See chart below.

At the start of the study, patients will be screened to determine eligibility for the study. The screening process includes a physical exam, a medical history, x-rays of chest, hands, and feet, and urine and blood tests. Eligible patients will be enrolled in **OPTIMA**.

At the first study visit, study medications will be distributed for Treatment Period 1.

Patients will return for follow-up visits every 2 to 10 weeks (See OPTIMA Study Visit Schedule). At each visit, vital signs and joints will be assessed, urine and blood samples will be collected for laboratory tests, and patient questionnaires will be completed.

At Week 26, patients will have x-rays of chest, hands, and feet, in addition to the usual study procedures. At this time, patients will be assigned to treatment groups for Treatment Period 2. Treatment Period 2 will last 1 year.

OPTIMA Study Visit Schedule	
Treatment Period 1	Treatment Period 2
Day 1	Week 26 +/- 5 days
Week 2	Week 30
Week 4	Week 36
Week 8	Week 44
Week 12	Week 52
Week 22 +/- 5 days	Week 66
	Week 78

How do I know if I am eligible for OPTIMA?

All clinical trials have guidelines—known as inclusion and exclusion criteria—about who can participate. These criteria are used to identify appropriate patients for the study.

To be considered for participation in **OPTIMA**, a patient must:

- Be at least 18 years old
- Have been told by a physician less than 1 year ago that he or she has RA
- Have not previously used anti-TNF medication, including infliximab, etanercept, or adalimumab
- Have not previously used more than 2 disease-modifying anti-rheumatic drugs or have not previously used MTX
- Be able to attend a minimum of 14 office visits

In addition, other criteria apply. Your doctor will determine your eligibility based on physical assessments, laboratory tests, and your medical history.

Where can I find out more about OPTIMA?

For more information about the **OPTIMAp** trial, or to find out if you might be eligible, ask your doctor.

To learn more about clinical trials in general, a good source of information on the Internet is the National Institutes of Health/ National Library of Medicine Web site on clinical trials.

<http://clinicaltrials.gov/info/resources>