## What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about an investigational medication, such as:

- Does it work?
- What amount, or dose, may work best?
- How safe is it?
- Are there side effects?

All medications must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these studies, we would have no new medications.

## About the contRAst-2 Study

The contRAst-2 Study will involve between 1500 and 1800 patients worldwide with moderate-to-severe rheumatoid arthritis (RA). This study is looking at whether an investigational medication works and how safe it is in combination with certain conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) for slowing the progression of RA in patients whose current treatment with csDMARDs is not working well enough.

**Deciding to take part in a clinical research study is your decision. If you have any questions, you can contact the study team using the information provided in this brochure.**

## Why is the contRAst-2 Study important?

RA is a chronic autoimmune disease that mainly affects the joints. In an autoimmune disease, the immune system (which normally protects the body from infections) works against itself and produces antibodies that attack certain tissues in the body. This results in inflammation, which in RA causes symptoms such as painful, swollen joints, stiffness, and fatigue.

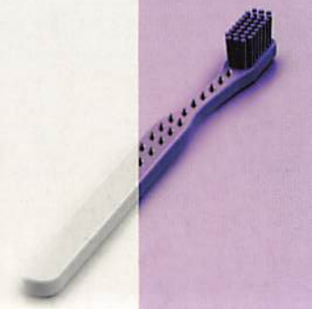
A substantial proportion of patients with RA don't respond well to currently available RA therapies. Therefore, there is a medical need for more effective RA treatments that work in different ways.

The investigational medication in the study is a biological medication and has been developed to block a substance in your body called 'GM-CSF'. GM-CSF is thought to contribute to inflammation in our bodies and higher levels of GM-CSF are found in the joints of people with RA. It is hoped that blocking GM-CSF will reduce symptoms and slow progression of RA.

## What will the contRAst-2 Study involve?

If you take part, you will be in the contRAst-2 Study for up to 1 year and 3 months, and visit the study center at least 15 times and up to once a week. You will:

- receive investigational medication, tofacitinib (an approved RA medication), or placebo (which looks the same as the investigational medication or tofacitinib but contains no actual medication).
- have a 4-in-6 chance of receiving investigational medication, a 1-in-6 chance of receiving tofacitinib, and a 1-in-6 chance of receiving placebo for the first 12 weeks.
    - After 12 weeks, if you are assigned to receive placebo, you will be switched to receive either the investigational medication or tofacitinib for the remainder of the treatment period.
- receive study medication as a sub-cutaneous (under the skin) injection at the study center and as a capsule twice a day at home.
- continue to take one or two of your current csDMARDs for the duration of the study.



tudy is made up of 3 parts.

### Screening period
**(up to 6 weeks)**

u will visit the study center to see
he study is suitable for you and
ether you want to take part.

### Treatment period
**(about 52 weeks)**

u will visit the study center at least
times for study assessments.
u will receive the study medication
ection at the study center or self-
minister it at home* once every
ek. You will take a study medication
psule twice a day at home.

u may have the opportunity to
ke part in a long-term extension
udy once you have completed the
eatment period.

### Follow-up period
**(about 8 weeks)**

you don't take part in the long-
rm extension study, you will visit
e study center once for study
sessments about 8 weeks after
ur last dose of study medication.

tudy doctor will let you know whether this option
ilable. If you self-administer the study medication
on at home, the study doctor will call you once
1 to 4 weeks to ask you questions about your
ations and how you are feeling.

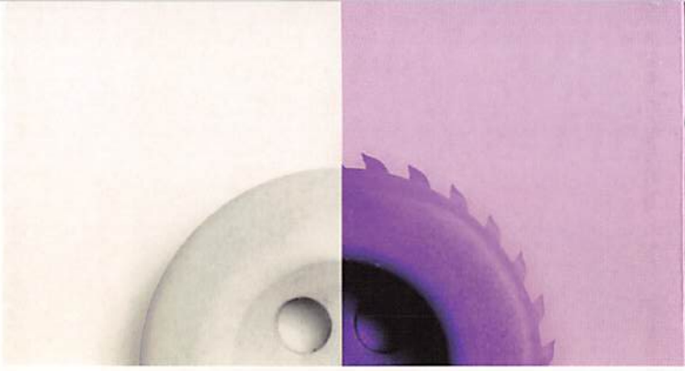
## Who can take part?

You may be able to take part if you:

- are 18 years of age or older
- have been diagnosed with rheumatoid arthritis
- have swollen and painful joints despite taking one or two of the following csDMARDs for at least the past 12 weeks: methotrexate, hydroxychloroquine, chloroquine, sulfasalazine, leflunomide, bucillamine, or iguratimod.

## What else do I need to consider?

- If you choose to take part in the study, you can stop participating at any time.
- You will not be paid to take part in this study, but you may be reimbursed for reasonable travel costs during your participation.
- All study medications and study-related tests will be provided at no cost to you.
- A team of doctors and nurses will monitor your health carefully during the study.



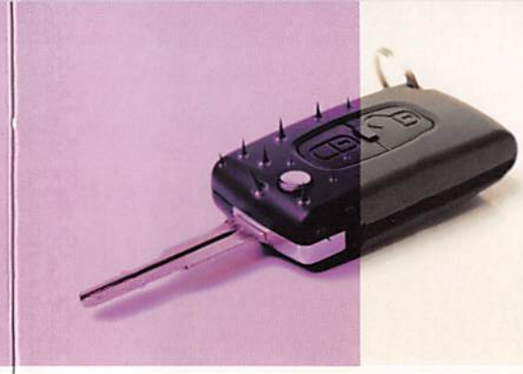
## How do I get more information?

To find out if you may be eligible to take part in the contRAst-2 Study, visit our patient website: **www.contrastraprogram.com**.

If you have any questions, contact the study team using the information provided here. Study participation is voluntary. By contacting us, you are under no obligation to take part in the study.

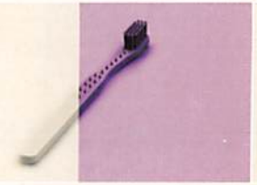

Four Rivers Clinical Research
225 Medical Ctr., Dr., Suite 305
Paducah, KY 42003
270-441-4606

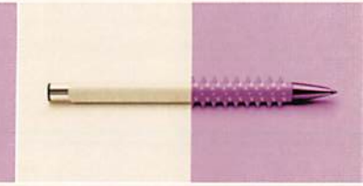

Patient Brochure (ePR), 04 Apr 2019 (V01 USA)



# Patient Information

This brochure contains information about the contRAst-2 Study for people with rheumatoid arthritis. This information should help you decide whether you or someone you know may want to take part in the study.





contRA²st
INVESTIGATING A NEW DRUG FOR RA
www.contrastraprogram.com