

## About clinical trials

Clinical trials aim to answer specific questions about how medicines work in the participants who take them. You should feel fully informed about what to expect from your participation in a clinical trial.

During the study, you will collaborate with a professional research team of study doctors, study nurses, and other research staff. Without your help and the commitment of the study team, the development of new medication choices would not be possible to help MS patients in the future.



## Why are clinical trials conducted?

Clinical trials may help researchers, doctors, and healthcare providers find new ways to prevent, detect, or treat diseases, syndromes, or conditions.

Clinical trials may include the study of:

- Investigational drugs or new drug combinations
- New surgical procedures or devices.
- New ways to use existing treatments to relieve symptoms and/or slow a disease from getting worse.

The goal of a clinical trial is to learn the effects of an investigational procedure, medication, or device under controlled conditions.



# GEMINI 1

## EFC16033

The Gemini 1 clinical trial is part of the MyMSTrials symposium of multiple sclerosis clinical trials.

 **MyMSTrials.com**

MyMSTrials.com is a collection of phase III clinical trials designed to determine the efficacy, safety and tolerability of the study drug in patients with various forms of Multiple Sclerosis.

## Who can I contact to learn more about MyMSTrials?

For more information about MyMSTrials and the possible risks and benefits of participation, please visit:

**[www.MyMSTrials.com](http://www.MyMSTrials.com)**



## Seeking Participants with Relapsing Forms of Multiple Sclerosis (RMS) for Clinical Trial



 **MyMSTrials.com**

## We appreciate your interest in the Gemini 1 Trial!

The information provided is intended to assist in your decision to participate in this clinical trial opportunity.



### About relapsing forms of multiple sclerosis (RMS)

A large majority (approximately 85%) of people with multiple sclerosis are initially diagnosed with a relapsing form of multiple sclerosis, making it the most common form of the disease.

Those who experience relapsing forms of multiple sclerosis—including relapse-remitting multiple sclerosis (RRMS)—may have attacks (relapses) when symptoms flare up.

Relapses are typically preceded by a period of recovery (remission) when symptoms lessen or alleviate altogether. Remission can last from weeks to months, sometimes longer.

Common symptoms of relapsing forms of multiple sclerosis include—but are not limited to—numbness and tingling, eye pain and vision problems, bowel or bladder problems, dizziness, difficulty maintaining balance, and muscle stiffness.

## What is the purpose of the Gemini 1 Trial?



The Gemini 1 Trial is a Phase III clinical trial designed to assess the efficacy and safety of the study drug against an existing treatment medication, teriflunomide. The efficacy and safety of the study drug is measured by annualized adjudicated relapse rate in patients diagnosed with relapsing forms of multiple sclerosis (RMS). Patients will be randomly selected to receive the study drug or the existing treatment medication.

Additional goals of the trial will be to test the effect of the study drug on disability progression, magnetic resonance imaging (MRI) lesions, the ability to learn and process information, and quality of life, as well as the safety and tolerability of the study medication.

### You may be eligible for the trial if:

- You are a man or woman between the ages of 18 and 55
- You have a current diagnosis of relapsing multiple sclerosis (RMS)

Additional requirements will be discussed with a study team's representative. Qualified patients may receive study-related care at no cost.

### What are the benefits and risks of taking part in this study?

This study is experimental research and there is no guarantee that you will get any benefit from participating in.

All medications and treatments have risks. One of the risks is that you might experience discomfort or side effects with the use of the SAR442168 or teriflunomide (Aubagio) or procedures. For SAR442168, these risks are still unknown at this stage. In some cases, side effects can be serious, long-lasting, permanent, or life-threatening. The study doctor is trained to take the appropriate measures to reduce risks and limit any discomforts you may experience. The study doctor will discuss with you risks in more detail such as those associated with drugs similar to the study drug and those that may be associated with study procedures.

## What will I be required to do to join the trial?

Participation in the Gemini 1 Trial consists of three stages:

- 1 SCREENING**  
to determine eligibility to participate
- 2 TREATMENT**  
receive either the investigational drug or the existing treatment medication
- 3 COMMON EOS VISIT**  
final procedures/assessments

*After the end of this study, and after completing this trial successfully, you may be offered the option to participate in the long-term extension study for an additional 2 years, or until the drug is approved in your respective country, whichever comes first. For more information, please discuss with your study doctor.*

### How long will participation last?

The duration of treatment (investigational drug or teriflunomide) will be between 18 to 36 months. For patients completing the treatment per protocol, you may be offered to take part of an optional Long-Term extension study during which you will continue to receive the study drug.



The Gemini 1 clinical trial is part of the MyMSTrials symposium of multiple sclerosis clinical trials. To learn more about this trial and find out if you qualify, visit [www.MyMSTrials.com](http://www.MyMSTrials.com).