

Participating in Clinical Trials

A Guide for People with MS



National
Multiple Sclerosis
Society



Have you ever taken medicine for an illness? Then you have experienced the benefits of clinical research. Clinical trials help to determine if treatments are safe and effective. There is an urgent need for people with multiple sclerosis who are willing to volunteer in clinical trials testing MS therapies. Studies are enrolling diverse populations, and are monitored to ensure that the rights and safety of all participants are protected. Without the help of people with MS, it would be impossible to develop new and better therapies.

Clinical trial basics

Many factors are involved in making sure that a study is conducted properly and that the results are valid. The U.S. Food and Drug Administration requires therapies to undergo three phases of clinical trials before they can be approved to treat people with MS:

- **Phase I** – The first step is to determine safety. In a small number of healthy volunteers or persons with MS, the investigators determine how the human body reacts to the therapy.
- **Phase II** – If the therapy proves to be safe, another study is undertaken to begin to determine the effectiveness of the drug in people with MS. A phase II study may last several months or several years, and involves larger numbers of people. The study is controlled — that is, the drug

is compared with the standard treatment, or an inactive placebo. Studies in this phase are meant to determine if a larger, more definitive phase III trial is worth the large investment of funds that would be required.

- **Phase III** – If the phase II trial suggests effectiveness and safety, an even larger study is conducted in hundreds of people to definitively determine the drug's effectiveness and to gain a better understanding of the drug's possible side effects. These multi-center studies can span several years and several countries.

Following FDA approval, post-marketing studies (phase IV) might be conducted to assess long-term safety and effectiveness.

The trial follows a carefully controlled protocol — a plan that details what researchers will do in the study.

What are the benefits of participating in a clinical trial?

Clinical trials that are well-designed and well-executed are an excellent approach for eligible participants to:

- Play an active role in their own health care
- Gain access to new research treatments before they are widely available
- Help others by contributing to medical research

What are the risks of participating in a clinical trial?

- There may be unpleasant, serious or even life-threatening side effects to treatment.
- The treatment may not be effective.
- The protocol (clinical trial procedures) may require more time and attention than just receiving a standard treatment from your doctor. For example, you may have to make several trips to the study site, or undergo more treatments and tests.

How are participants protected?

Given these risks, participants in clinical trials are protected in several ways. Most clinical research is federally regulated with built-in safeguards to protect the patient. The trial follows a carefully controlled protocol — a plan that details what researchers will do in the study. An independent Data and Safety Monitoring Board follows the study closely for side effects and any unexpected outcomes. Once the trial is completed, researchers may report the results of the trial at scientific meetings, to medical journals and to various government agencies — but participants' names remain secret and are not mentioned in these reports.



Who can participate?

People who wish to enroll in clinical trials are generally required to meet the following requirements, or entrance criteria:

- Reside close to the research facility (usually within 150 miles)
- Have a specific diagnosis
- Meet the study's guidelines relating to age, sex, level of disability and duration of disease
- Be able to understand the possible risks of participating, give consent, and be able and willing to follow study instructions
- Additional requirements unique to each study

These and other entrance criteria attempt to ensure that the trial participants in the treatment and control groups are similar in terms of their MS and other characteristics at the start of the trial. This makes it easier to determine at the end of the trial whether a new treatment shows benefit from a statistical point of view.

What you need to know

If you are thinking about participating in a clinical trial, here are some key questions to ask before making a decision:

- What is the purpose of the study?
- Why do researchers believe this new treatment being tested might be effective?
- Has the treatment been tested before?
- What kinds of tests and treatments are involved?
- How often will I have to come to the study site?
- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Who will pay for the experimental treatment, or any of the tests?
- Will I be reimbursed for other expenses?
- What type of long-term, follow-up care is involved with this study?
- How will I know if the experimental treatment is working? Will results of the trial be provided to me?
- If the treatment works can I continue receiving it?
- Does this study include a placebo or another treatment already on the market? What is the probability that I will receive a placebo?
- Who else will know that I am participating in this study?



Find out how the study is controlled

Well-designed clinical trials should be “controlled” in such a way that the hopes and expectations of the participants and the researchers do not bias the trial outcomes or the interpretation of those outcomes. In most controlled studies today, one group of participants — the treatment or experimental group — receives the treatment being tested, and the other group — the control group — receives a previously-approved treatment or an inactive placebo. Whenever possible, the participants and the researchers are “blinded” to who is in each group until the trial data have been analyzed.

If you are considering becoming involved in a study in which the experimental drug is being compared to an inactive placebo, make sure that you understand your treatment options with therapies already on the market, and that you know what the probability is that you will receive the inactive placebo.

Seeking diversity

Clinical research projects today welcome cultural, ethnic and gender diversity. In fact, recent research indicates that MS affects African-Americans and Caucasians differently, underscoring the need to include diverse groups in treatment studies.

It wasn't always this way. For many years, only white males were allowed into most clinical trials. A few trials involving African-Americans were conducted in ways that would now be considered unethical. This is no longer the case. Trials today are monitored for safe and ethical treatment of volunteers.

Make sure that you understand your treatment options with therapies already on the market.

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Understand informed consent

Before you agree to participate, you will be asked to understand and sign an “informed consent” form. The form should provide a summary of the clinical trial, including its purpose, the treatment procedures and schedule, potential risks and benefits, and alternatives to participation.

Informed consent is not just a document. It’s a process that involves discussing the form before you enter the study, getting updates throughout the study, and knowing that you can ask questions of the research team at any time before, during or after the study. You also can decide to leave a clinical trial at any time. If you decide to stop participating, it’s important to let the nurse or coordinator know your reasons for leaving the study, so that they can minimize the potential impact on the study results.

Coordinate your medical care

Before participating in a clinical trial, discuss the study with your doctor. If you decide to participate, put your doctor in touch with the doctor running the study. Give your doctor permission to share medical information. That will help ensure your safety during a clinical trial. Even if your own doctor is running the



study, be sure to tell the doctor or the nurse/study coordinator if you are taking medication for a condition other than your MS. Even a routine treatment for an unrelated condition might interact with the study drug during a clinical trial. This could accidentally interfere with the study’s results, or even be harmful to you.

Know what costs are covered

Understand who is covering the costs of the study. The informed consent form should outline any costs that will be billed to you. In most cases, the research team covers the cost of the study drug and any medical care performed to fulfill the study’s goals. Contact your health insurer — with the protocol or informed consent form in hand — to find out whether treatment for any side effects or routine care will be covered so that you understand fully what you might be expected to pay.

Resources

■ CenterWatch

A publishing and information services company that provides information on clinical trials, including a list of MS studies currently recruiting patients.

www.centerwatch.com/

Address: 100 N. Washington St., Ste. 301, Boston, MA 02114 **Tel:** 1-617-948-5100; toll-free, 1-866-219-3440

■ CISCRP

The Center for Information and Study on Clinical Research Participation educates and empowers patients, medical and research professionals, the media and policymakers about clinical research participation and what it means to be an active participant in the process.

www.ciscrp.org/index.html

Address: 990 Washington Street, Suite 101S, Dedham, MA 02026 **Tel:** toll-free, 1-888-CISCRP3 (247-2773)

■ Clinical Trials in MS

Search for clinical trials in the U.S. or view a list of international trials on the Web site of the National MS Society. Also view the annual list of ongoing, planned, and recently completed studies, including study results.

www.nationalmssociety.org/ClinicalTrials

Tel: Contact your National MS Society chapter at 1-800-344-4867

■ ClinicalTrials.gov

A registry of clinical trials that are currently recruiting participants with many disorders in the United States and around the world. Searchable by disease.

www.clinicaltrials.gov/

■ MS International Federation

This site provides resources on all aspects of clinical trials related to MS, including participation and ethical issues. Information is available in several languages.

www.msif.org/en/research/clinical_trials/

Address: 3rd Floor Skyline House, 200 Union Street, London, SE1 0LX

Tel: +44 (0) 20 7620 1911

■ My Life, My MS, My Decision

Living with a disease like MS requires making many decisions, both personal and medical. This National MS Society DVD program follows three people living with MS as they make decisions about choosing doctors, deciding on medications, participating in clinical trials, and wellness.

www.nationalmssociety.org/multimedia-library/videos--dvs/index.aspx

Tel: Contact your National MS Society chapter at 1-800-344-4867

■ NARCOMS

This registry of people willing to participate in MS research was initiated by the Consortium of MS Centers to facilitate multicenter studies. As of May 2007, the number of participants surpassed 32,000. Information is available in Spanish.

www.ms-care.org/cm-sc/

[CMSC-NARCOMS-Information.html](http://www.ms-care.org/cm-sc/NARCOMS-Information.html)

Address: RPHB 414, Birmingham, AL 35294 **Tel:** 1-800-253-7884

■ ResearchMatch.org

A not-for-profit secure Web site, designed to provide people who are interested in participating in research the opportunity to be matched with studies that may be the right fit for them. ResearchMatch is a collaborative effort of the national network of medical research institutions affiliated with the Clinical and Translational Science Awards, a part of the National Institutes of Health.

www.researchmatch.org

The National MS Society addresses the challenges of each person affected by MS by funding cutting-edge research, driving change through advocacy, facilitating professional education, collaborating with MS organizations around the world, and providing programs and services designed to help people with MS and their families move their lives forward.

The National MS Society is proud to be a source of information about MS. Our comments are based on professional advice, published experience and expert opinion, but do not represent individual therapeutic recommendation or prescription. For specific information and advice, consult your personal physician.

Studies show that early and ongoing treatment with an FDA-approved therapy can reduce future disease activity and improve quality of life for many people with multiple sclerosis. The National MS Society's medical advisers recommend that people with MS talk with their health care professionals about using these medications and about effective strategies and treatments to manage symptoms. If you or someone you know has MS, please contact the National MS Society at nationalMSSociety.org or 1-800-344-4867 (1-800-FIGHT-MS) to learn more.

**WE ARE PEOPLE WHO WANT TO
DO SOMETHING ABOUT MS NOW.
NATIONALMSSOCIETY.ORG**

nationalMSSociety.org

For Information:

1 800 FIGHT MS (1 800 344 4867)

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