



National MS Society Information Sourcebook

www.nationalmssociety.org/sourcebook

Clinical Trial Participation

Many people with MS want to participate in clinical trials for new or experimental forms of therapy. Clinical trials are studies to see if a promising new drug or other medical therapy is actually safe and effective. The studies must be carefully controlled to make sure that the results are valid and not due to factors other than the drug or therapy being tested. This means that clinical trials must have strict criteria for participation. Not everyone who wants to participate in a particular study may be eligible to do so.

Most well controlled clinical trials involve two groups: one group receives the experimental treatment and the other group receives either a placebo (inactive substance) or a previously-approved treatment. Patients in these types of studies should realize that there is a 50/50 chance that they will not receive the treatment under study. Other trial designs involve a “crossover” of treatment, generally meaning that the type of treatment given to each group is switched during the course of the trial. In these types of trials, all groups eventually receive the active treatment under study. The actual design and circumstances of the trial are explained by the investigators before you are asked to give your consent to participate.

General Eligibility Guidelines

Requirements that must often be met for participation in a clinical trial include the following:

- The patient should reside close to the research facility (usually within a radius of 150 miles).
- The patient must have a specific type of MS. Often trials specify which clinical type of MS is under study – relapsing-remitting, secondary-progressive, primary progressive or progressive-relapsing.
- The patient must fall within the study guidelines relating to age, sex, level of disability, and duration of disease.
- Previous or current treatment with certain drugs (such as drugs that suppress the immune system) may exclude a patient from a study, although not necessarily.

Find Out About Potential Risks and Benefits

Patients who are eligible and who choose to enter clinical trials should be fully aware of the potential risks and benefits of the study. All aspects of a clinical trial should be discussed with the patient’s neurologist, so that a well-informed decision may be made. Physicians may also be able to help patients locate appropriate clinical research programs.

Before participating in a clinical trial, patients must complete an informed consent process that includes reviewing the study and signing the consent form indicating that they know and understand the purpose of the trial, how it will be conducted, as well as possible risks associated with the trial. Patients are also free to leave a clinical trial at any time, for any reason.

Finding Clinical Trials Recruiting Patients

There are a number of good resources individuals can use to find clinical trials in their area, including speaking to their MS physician and consulting:

- The National MS Society Web site (www.nationalmssociety.org/ClinicalTrials) has a state-by-state listing of trials that are recruiting participants.
- NARCOMS: The North American Research Consortium on MS has created a patient registry and database of individuals willing to participate in MS research, including clinical trials.
Denise Campagnolo, MD, NARCOMS Program Director
NARCOMS Registry, Barrow Neurological Institute
St. Joseph's Hospital and Medical Center
500 W. Thomas, Suite 300
Phoenix, AZ 85013
Phone: (602) 406-6286; 800-253-7884
E-mail: narcoms@chw.edu
Website: www.narcoms.org
- Center Watch: an information service providing listings of clinical trials on many diseases. <http://www.centerwatch.com/patient/trials.html>

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See also...

Sourcebook

- Clinical Trials
- Placebo Response
- Research

Society Web Resources

- Clinical Trials
www.nationalmssociety.org/ClinicalTrials
- Research Fact Sheet
www.nationalmssociety.org/ResearchFactSheet
- Research FAQs
www.nationalmssociety.org/ResearchFAQ

Book

Kalb R. (ed.) *Multiple Sclerosis: The Questions You Have; The Answers You Need* (3rd ed.). New York: Demos Medical Publishing, 2004.
—Ch. 3 Treatments

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

To contact your chapter, call **1-800-FIGHT-MS** (1-800-344-4867) or visit the National MS Society web site: www.nationalmssociety.org.

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