



CHAPTER PRESIDENTS

April 5, 2012	CC: Development
<u>2012 Walk MS Pilot – Progress Report</u>	

Last fall, we introduced an important pilot with six chapters designed to help us realize the full potential of Walk MS in the future. [Click here](#) to see our progress report and update.

If you have any questions about the pilot, please contact Amy Boulas at amy.boulas@nmss.org or x15123.



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RESEARCH/CLINICAL UPDATE

cc: Chapter President, Programs, Development

April 6, 2012

MS Trial Alert:

Investigators Recruiting for Study of Daclizumab HYP Delivered in Prefilled Syringe

Summary: Investigators worldwide are recruiting 100 people with relapsing-remitting MS for a study testing the use of a prefilled syringe to administer monthly under the skin injections of the experimental therapy daclizumab high yield process (DAC HYP). Specifically, the study is looking at the immune response that is stimulated by this delivery method, and how the drug is absorbed in the body. This study – also called the OBSERVE study – is being sponsored by Biogen Idec and Abbott Biotherapeutics.

Rationale: Daclizumab is a humanized monoclonal antibody that blocks CD25 (interleukin-2 receptor-alpha, a key immune activator in MS). DAC HYP is a highly concentrated liquid formulation of daclizumab. A previous study (the SELECT trial, a double-blind, placebo-controlled study to evaluate the safety and efficacy of DAC HYP) randomly assigned 600 people with relapsing-remitting MS to receive placebo, 150 mg DAC HYP, or 300 mg DAC HYP every four weeks. The primary study endpoint, the annualized relapse rate, was reduced among people taking DAC HYP versus placebo.

DAC HYP is being tested in another phase 3 study, the DECIDE trial, comparing DAC HYP to interferon beta-1a in 1800 people with MS.

Eligibility and Details: Participants should be 18 to 55 years of age with a confirmed diagnosis of relapsing-remitting MS (<http://nationalmssociety.org/about-multiple-sclerosis/relapsing-ms/relapsing-remitting-ms-rrms/index.aspx>). Participants should have no history of malignancy, severe allergic reactions, or immune deficiency. To learn details about other enrollment criteria, please use the contact information below.

All participants will receive DAC HYP 150 mg injection delivered once subcutaneously (under the skin) using a prefilled syringe every four weeks for 24 weeks. The primary endpoint of the study is to determine the immune response that is stimulated by this delivery method, and how the drug is absorbed in the body.

Contact: To learn more about the enrollment criteria for this study, and to find out if you are eligible to participate, please email neurologyclinicaltrials@biogenidec.com.

Sites are recruiting in the following U.S. cities:

Farmington Hills, Michigan

Bradenton, Florida

Lake Barrington, Illinois

Dayton, Ohio

Franklin, Tennessee

Centennial, Colorado

[Download a brochure that discusses issues to think about when considering enrolling in an MS clinical trial \(PDF\).](#)