



The Next Frontier: Optimizing Treatment-Understanding How MS Progresses

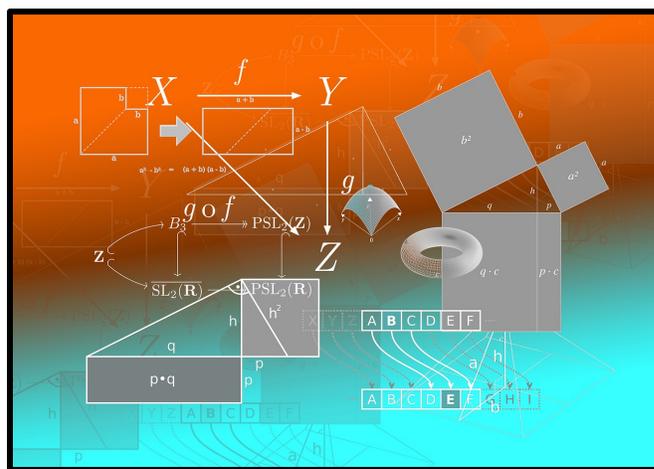
As has been described, MS treatment choices involve a process of trial and error. Furthermore, the available disease-modifying therapeutics (DMTs) have been approved based on their ability to reduce relapse rates in relapsing types of MS; none has yet proven able to control progressive forms of MS. An inadequate understanding of what causes the increasing disability seen in progressive MS has substantially blocked the development of therapies to slow, arrest, or reverse it.

To address these challenges, ACP and the collaborating investigators that make up the ACP Clinical Research Network have developed a longitudinal study, Optimizing Treatment-Understanding Progression, or OPT-UP. The goals of OPT-UP are to (1) generate robust evidence to guide the choice of treatments and other interventions that will have the greatest benefit with fewest adverse effects for each individual MS patient, and (2) produce essential knowledge and tools for developing strategies and/or medicines to slow, arrest, or reverse the relentless decline in abilities that is referred to as progressive MS.

One pharmaceutical company, EMD Serono, has signed on to be the Lead Founding Sponsor of the study. We are in negotiations with another, and optimistic that it too, will become a Founding Sponsor and that other companies will join the Founding Sponsors group. The National MS Society has provided generous support to the effort as well.

Study Details

In the OPT-UP study, the ACP Clinical Research Network will enroll a large cohort of people with MS and follow them for up to 5 years, collecting high-quality biosamples, data on treatment outcomes, and imaging data at pre-specified intervals under standardized protocols. These samples and data will be added to the ACP Repository, not only to be analyzed by the ACP network investigators and partner organizations, but to be shared widely with research groups that can help accomplish the goals of OPT-UP.



The OPT-UP study will enroll 2500 participants, including 2000 people with relapsing forms of MS who are starting an FDA-approved DMT and 500 people with primary progressive MS

who are either starting or not using a DMT. Subjects will be enrolled at up to 20 MS clinics located throughout the U.S. Participants will be followed for a minimum of 2 years and up to 5 years.

Study visits will occur at enrollment, immediately before DMT initiation, 3 and 6 months post-DMT initiation, and every 6 months thereafter. Study visits will allow for the collection of clinically assessed outcomes, biosamples, and imaging scans. In addition, patient-reported outcomes will be captured at regular intervals via an Internet portal.

Impact of OPT-UP

This cohort is novel in its combination of features: broad enrollment (20 sites nationwide), comprehensive and highly standardized acquisition of data and biosamples, and focus on two critical unmet needs (optimizing treatment and understanding progression).

Successful completion of this project will result in guidance that will help people with MS and their clinicians select treatments based on robust evidence. Findings from this study and associated analyses will also shed light on the factors influencing progression in MS and point to treatments or strategies that may preserve function in people with MS.

