Genentech Joins Funders of OPT-UP Clinical Study

On October 7, Genentech became a Founding Sponsor for the Optimizing Treatment - Understanding Progression (OPT-UP) clinical study that Accelerated Cure Project for MS hopes to launch in the coming year. If you are a regular reader of this newsletter, you have read about this initiative in previous issues. OPT-UP is a U.S.-based, multicenter longitudinal clinical research study that will enroll 2,500 people with MS, and follow them for up to five years. The goals of the study are to generate a robust evidence base of factors affecting treatment outcomes in MS to guide the choice of treatments for MS patients, and to produce knowledge and tools for developing strategies and/or medicines to slow, arrest, or reverse MS progression.

Recognizing that the unpredictability of treatment responses for individual patients can be demoralizing for people with MS and their clinicians, ACP has designed a clinical research study to address the most critical medical needs in MS today. We are delighted that Genentech, an emerging leader in MS therapeutics, has chosen to participate. In doing so, Genentech joins OPT-UP’s Lead Founding Sponsor, EMD Serono, and the National MS Society in providing funding for the OPT-UP study. ACP expects that other MS stakeholders will soon join the OPT-UP Founding Sponsors group and that this important study will begin enrolling patients in 2016.

People with MS will be enrolled in OPT-UP at up to 20 MS clinics located throughout the U.S. and will be followed for a minimum of two years and up to five years as they make choices of DMTs and any subsequent switches to other DMTs. Using validated and standardized in-clinic assessments and online questionnaires, the OPT-UP study will collect high-quality data on treatment outcomes, along with biological samples and imaging data collected under standardized protocols and processed by commercial vendors under standardized operating procedures. These comprehensive resources will be analyzed by the ACP network investigators and partner organizations, as well as shared widely with research groups that can help accomplish the goals of OPT-UP.

Despite the availability of many DMTs, physicians and patients still make many treatment decisions based on trial and error. The primary OPT-UP study objective is to provide robust evidence that can enable physicians and their patients to decide on the optimal treatment strategy for each individual person living with MS. The study exemplifies a new generation of clinical studies designed to enable personalized, or precision, medicine. In addition to standard clinic-based assessments from the OPT-UP study, researchers will also have access to critically important patient-reported outcomes that will be captured online at regular intervals. ACP believes that the substantial amount of data and biosamples
generated by the OPT-UP study will also be enormously valuable in furthering researchers' understanding of MS disease progression.

As of October 2015, nine clinical sites are participating in OPT-UP, including the University of California San Diego, University of Texas Southwestern Medical Center, University of Massachusetts Medical School, Tisch MS Research Center of New York, Johns Hopkins School of Medicine, Ohio State University Medical Center, the Shepherd Center in Atlanta, University of Colorado School of Medicine, and Stanford University School of Medicine. ACP is currently seeking additional qualified clinical sites for the study. Stay connected with Accelerated Cure Project for MS to hear about future progress on OPT-UP, including when the study is ready to enroll participants. In the meantime, if you have questions, please contact Hollie Schmidt of Accelerated Cure Project for MS at hollie@acceleratedcure.org.