

October 2012 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An update on progress within Enroll-HD over the past month:

- As of October 15th, a total of 63 participants have been enrolled at the following sites:
 - The University of Tennessee Health Science Center (Memphis, Tennessee, USA)
 - Columbia University (New York City, NY, USA)
 - The Centre for Movement Disorders (Markham, Ontario, Canada)
 - Colorado Neurological Institute (Englewood, Colorado, USA)
- The University of Alabama at Birmingham (USA) and Wake Forest University School of Medicine (Winston-Salem, North Carolina, USA) have completed their two-part site initiation and are now active sites.
- The following sites will be initiated next:
 - Hereditary Neurological Disease Center (Wichita, Kansas, USA)
 - Kansas University Medical Center (Kansas City, Kansas, USA)
 - The Ohio State University (Columbus, Ohio, USA)
 - The University of Illinois College of Medicine at Rockford (Rockford, Illinois, USA)
- The Data Safety Monitoring Committee (DSMC) is meeting in New York City on November 2nd. The finalization and approval of the DSMC charter and the processes for reviewing and addressing reportable events will be discussed. The members of the Enroll-HD DSMC are:
 - Arvid Heiberg, MD, Chairperson, Oslo University Hospital, Oslo, Norway
 - Sandrine Andrieu, MD, PhD, Toulouse Hospital University, Toulouse, France
 - Ken Cheung, PhD, Columbia University, New York, New York, USA
 - Susan Fox, MD, University of Toronto, Toronto, Canada
 - Daniel Weintraub, MD, University of Pennsylvania, Philadelphia, PA, USA

Regional Updates

- NORTH AMERICA:
 - Colorado Neurological Institute enrolled their first participant on Monday, October 1st.
 - Please continue to contact Maggie Seay [(609) 945-9057 or maggie.seay@chdifoundation.org] and Meherazade Sumariwalla [(609) 945-9795 or meherazade.sumariwalla@chdifoundation.org] at CHDI for all informed consent negotiations and issues.
- AUSTRALIA & NEW ZEALAND:
 - The regional Clinical Research Associate coordinating the Enroll-HD efforts in Australia and New Zealand, Caron Hookway, is working with the participating sites on planning Ethics Committee submissions and other start-up activities. In addition, test shipments to and from Milan, Italy for the blood sample collection and packaging kits and bio-specimens will be completed by the end of the month.

- LATIN AMERICA:
 - The Enroll-HD protocol has been translated into Spanish and Portuguese.
 - Argentina will be the first country to submit to authorities, subsequent regulatory submissions for Chile and Peru will be completed this year and Brazil in Q1 2013.

- EUROPE:
 - A two-day workshop on the Registry to Enroll-HD transition will be held in New York City on October 31st and November 1st. We are assembling stakeholders from the EHDN, 2MT, CHDI and Outcome/Quintiles to develop and map-out the technical details for the transition. Our goal is to begin activities in early 2013 so that we are ready to transition the first participants in July 2013.

Thank you for your support in helping Enroll-HD achieve its goals.

The Enroll-HD Study Team

