



December 2012 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of December 20th, a total of 177 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)
 - Hereditary Neurological Disease Center (Wichita, Kansas, USA)
 - The University of California at Los Angeles (USA)
 - Wake Forest University School of Medicine (Winston-Salem, North Carolina, USA)
 - The University of Alabama at Birmingham (USA)
 - ☆ Top enrolling site is The Centre for Movement Disorders (Markham, Ontario, Canada) with 43 participants enrolled!

- The following sites have completed their two-part site initiation:
 - The University of California at San Diego (USA)
 - Kansas University Medical Center (Kansas City, Kansas, USA)
 - The University of Utah (Salt Lake City, Utah, USA)
 - The University of South Florida (Tampa, Florida, USA)
 - Emory University (Atlanta, Georgia, USA)
 - CHUM Hospital Notre Dame (Montreal, Canada)
 - The Ohio State University (Columbus, Ohio, USA)
 - The University of Illinois College of Medicine at Rockford (Rockford, Illinois, USA)
 - The University of Rochester (Rochester, New York, USA)

- The following sites are scheduled for initiation:
 - Johns Hopkins (Baltimore, Maryland, USA)
 - Virginia Commonwealth University Parkinson's and Movement Disorder Center (Richmond, Virginia, USA)
 - The University of California, Davis (USA)
 - Albany Medical College (Albany, New York, USA)
 - Rush University (Chicago, Illinois, USA)
 - The University of British Columbia (Vancouver, Canada)

- Duke University (Durham, North Carolina, USA)
- The Steering Committee (SC) held a teleconference on December 5th to discuss the draft CAG Assessment Protocol and to discuss future meeting dates.
- The Scientific Publication Review Committee (SPRC) held a teleconference on December 12th to discuss the Data Access proposal, Publication Policy as well as the process for electing the SPRC chairperson.

Training

- Training for the participant ClinCard® travel cost deferment and eClinical GPS® site payment system provided by Greenphire is available on the www.enroll-hd.org website. The information includes training videos, quick reference guides and FAQs. They can be found at - <https://www.enroll-hd.org/html/wg/greenphire/docs>
- A listing of the fifty (50) most commonly used International Statistical Classification of Diseases and Related Health Problems (ICD10 codes) is currently being developed and will be distributed to sites. We hope this guide will help expedite the data entry and coding of the co-morbid conditions.

Q: What should you do if you do not have documentation for predictive testing results?

A: You should attempt to obtain the documentation from the participant or the participant's previous health care provider. If it cannot be obtained please insert comments in the CAG form in the following fields: Date of Report, CAG analysis results, smaller allele, larger allele and analyzing laboratory indicating that the results are not available. When inserting comments, please change the value state for the eCRF page to "non-plausible but correct".

Regional Updates

NORTH AMERICA:

- The following sites have enrolled the most participants to date:
 - The Centre for Movement Disorders (Markham, Ontario, Canada) with 43 participants
 - Columbia University (New York City, NY, USA) with 42 participants
 - Colorado Neurological Institute (Englewood, Colorado, USA) with 22 participants
- We are happy to announce that the NIH/NINDS has issued a Certificate of Confidentiality (CoC) for the Enroll-HD study. This only applies to US sites and investigators. There are several sites that have included "interim" CoC language in their consent forms; these forms will need to be updated. Please contact Maggie or Meherazade regarding the need to update your ICFs.
- Please continue to contact Maggie Seay [(609) 945-9057 maggie.seay@chdifoundation.org] or Meherazade Sumariwalla [(609) 945-9795 meherazade.sumariwalla@chdifoundation.org] at CHDI for all informed consent negotiations and issues.

AUSTRALIA & NEW ZEALAND:

- Four of the five sites in Australia are prepared to submit to their Ethics Committee with the first submission expected to occur in December 2012.
- A Clinical Research Associate has been identified for New Zealand, Tony Mann; Tony is working with the two selected sites to prepare Ethics Committee submissions.

LATIN AMERICA:

- The Argentine Data Protection Authority (DPA) approval was received on 22 November 2012.
- The study is currently under the review of the Ethics Committee for the first site in Argentina.
- The next countries to begin Enroll-HD in Latin America are Chile and Peru.

EUROPE:

- Regulatory submissions are scheduled to begin in Q1 2013 for the following countries in Europe: Belgium, Denmark, Germany, Ireland, Italy, Netherlands and United Kingdom. On December 4th & 5th there were meetings of the Enroll-HD study team and EHDN Language Area Coordinators (Lancos) to begin planning for these important activities.

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

The Enroll-HD Study Team

