November 2012 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of November 12th, a total of 106 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 following sites have completed their two-part site initiation and are now active sites:
  - The University of Alabama at Birmingham (USA)
  - The University of California at San Diego (USA)
  - Kansas University Medical Center (Kansas City, Kansas, USA)

- The following sites are scheduled for initiation next:
  - The University of South Florida (Tampa, Florida, USA)
  - The University of Utah (Salt Lake City, Utah, 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)
  - Virginia Commonwealth University Parkinson's and Movement Disorder Center (Richmond, Virginia, USA)

- The Data Safety Monitoring Committee (DSMC) meeting scheduled for November 2nd in New York City was cancelled due to Hurricane Sandy. A teleconference has been scheduled for November 14th to discuss the next steps for the DSMC.

- The Enroll-HD Steering Committee held a teleconference on November 7th. The Site Council and Scientific Planning Committee charters were approved during this meeting. The approved charters will be available on the Enroll-HD web portal.

- The Scientific Publication Review Committee (SPRC) kick-off meeting is scheduled for November 13th. The draft SPRC charter will be discussed. Members of the SPRC were elected by each region at the Dublin Investigator Meeting.

- A bio-specimen and repository Frequently Asked Questions log that can help answer Institutional Review Board/Ethics Committee and other site questions has been added to the www.enroll-hd.org website within the Operations Manual working group folder.

Training

Once sites have IRB approval and their contract has been executed, you will undergo a two-part site initiation visit (SIV).

Part One is conducted remotely, via WebEx, and includes the following training:

- Review of the protocol
- Investigator responsibilities
- Review of study assessments and study procedures

The remote portion of the SIV is expected to take no more than 2 hours.

Part Two of the SIV is conducted onsite and includes the following:

- Review of the Investigator Site File Binder
- Provide a thorough training on the Enroll-HD Electronic Data Capture (EDC) system
- Confirmation that all personnel have the correct system access
- Training of site personnel on the packaging and shipping of biosamples

The onsite portion of the SIV is expected to be about a 4-hour visit

Occasionally there may be a need to train new site personnel. Arrangements will be made by the Lead Clinical Research Associate (CRA) in your region (Anne Peterson in North America/Caron Hookway in Australia/New Zealand, Lorraine Chapot in Europe, and Ariel Fariña in Latin America) to conduct this training as soon as possible. The training will consist of a thorough review of all study assessments, the Greenphire financial compensation system, Enroll-HD EDC, protocol review, reportable event reporting and processing. The CRA will confirm that any new site personnel have been trained and that the training log is up to date.

Regional Updates

- NORTH AMERICA:
  - The following sites have enrolled their first participant since our last bulletin:
    - 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 following sites have enrolled the most participants to date:
    - The Centre for Movement Disorders (Markham, Ontario, Canada) with 38 participants enrolled

- Columbia University (New York City, NY, USA) with 25 participants enrolled
- Colorado Neurological Institute (Englewood, Colorado, USA) with 13 participants enrolled

- 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:
  - The regional CRA coordinating the Enroll-HD efforts in Australia and New Zealand, Caron Hookway, continues to be in close contact with the sites to collect their regulatory documents and work towards Ethic Committee submissions.
  - Investigator Site Binders containing the protocol, guidance documents and template regulatory documents have been sent to all 4 Australian sites and to both of the New Zealand sites.
  - Site contracts are currently in negotiation.

- LATIN AMERICA:
  - The Argentinean ICFs and Assents templates are finalized and ready for regulatory submission.
  - The submission to the Data Protection Authority is scheduled to occur on November 12th.
  - Argentina will be the first country to submit to authorities, subsequent regulatory submissions for Chile and Peru will be completed this year and Brazil is scheduled for submission in Q1 2013.

- EUROPE:
  - A two-day workshop covering all aspects of the Registry to Enroll-HD transition was held in New York City on November 4-5th. The Team discussed detailed plans for regulatory submissions, contract and ethics review board submissions and met with information technology comany2MT to discuss the data migration process. The planning for this important transition is well underway - further details will be presented during the next round of EHDN regional investigator meetings.

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

The Enroll-HD Study Team