July 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of July 2nd, a total of **806 participants** have been enrolled at the following 31 sites:
  - Albany Medical College (New York, USA)
  - Baylor College of Medicine (Houston, Texas, USA)
  - Booth Gardner Parkinson’s Care Center (Kirkland, Washington, USA)
  - Boston University (Massachusetts, USA)
  - The Centre for Movement Disorders (Markham, Ontario, Canada)
  - CHUM Hospital Notre Dame (Montreal, Quebec, Canada)
  - Cleveland Clinic (Cleveland, Ohio, USA)
  - Colorado Neurological Institute (Englewood, Colorado, USA)
  - Columbia University (New York City, USA)
  - Duke University (Durham, North Carolina, USA)
  - Emory University (Atlanta, Georgia, USA)
  - Hennepin County Medical Center (Minneapolis, Minnesota, USA)
  - Hereditary Neurological Disease Center (Wichita, Kansas, USA)
  - Instituto Frenopatico (Buenos Aires, Argentina)
  - Johns Hopkins University (Baltimore, Maryland, USA)
  - The Ohio State University (Columbus, Ohio, USA)
  - The University of Alabama at Birmingham (USA)
  - The University of Alberta (Edmonton, Alberta, Canada)
  - The University of Alberta Hospital in Edmonton (Canada)
  - The University of British Columbia (Vancouver, British Columbia, Canada)
  - The University of Calgary (Alberta, Canada)
  - The University of California, Davis (Sacramento, California, USA)
  - The University of California, Los Angeles (USA)
- The University of California, San Francisco (USA)
- The University of Illinois College of Medicine at Rockford (Illinois, USA)
- The University of Maryland (Baltimore, Maryland, USA)
- The University of Rochester (New York, USA)
- The University of South Florida (Tampa, Florida, USA)
- The University of Tennessee Health Science Center (Memphis, Tennessee, USA)
- The University of Utah (Salt Lake City, Utah, USA)
- Wake Forest University School of Medicine (Winston-Salem, North Carolina, USA)

Top enrolling site is CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 110 participants enrolled!

- The following sites have completed their two-part site initiation:
  - Cleveland Clinic – Lou Ruvo Center for Brain Health (Las Vegas, Nevada, USA)
  - Kansas University Medical Center (Kansas City, Kansas, USA)
  - Rush University (Chicago, Illinois, USA)
  - The University of California, San Diego (USA)
  - The University of Vermont (Burlington, Vermont, USA)

Process Reminders and Updates

- The biokit ordering interface is now available in the Electronic Data Capture (EDC) system. You can order additional biokits by clicking on the “Sample Kits” link on the left navigation pane in the EDC. After clicking the link, simply fill out your phone number where you can be reached, and then confirm your shipping address is correct before pressing the “Order Now” button. As a reminder, it takes approximately 10 business days for a new kit shipment to arrive. Instructions are also available in the Operations Manual tab of the EDC (https://studies.enroll-hd.org/manual/biosampling)

- When preparing to send biosamples to BioRep, it is essential that you complete the Samples form in the EDC the same day the samples are sent. The completion of this form sends a notification to BioRep that samples have been shipped and allows BioRep to complete the coding of the samples in the EDC upon receipt.

- The Care Committee met on May 31st to discuss the finalization of a Standard of Care Survey. This survey will be rolled out to Enroll-HD sites to better understand the care systems used for delivering care to HD patients and their families. You will receive more details regarding the distribution and completion of the survey in August.

Quarterly Newsletter Update

- Enroll! is a recently-launched quarterly newsletter about Enroll-HD for current and potential participants, their families, and site staff – a PDF of the latest issue is attached. This has been approved for distribution in the United States and Canada by the central IRB being utilized for Enroll-HD, Western Institutional Review Board (WIRB). Please ensure that you follow all local rules and regulations prior to distribution (including any submission and/or review requirements by your local IRB/EC).
For logistical reasons print copies will not be distributed, but you are encouraged to print locally (in color if possible) so that participants and their family members can take a copy with them. Please contact the Enroll-HD Study Team with any questions.

Regional Updates

NORTH AMERICA:
- The following sites have enrolled the most participants to date:
  - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 110 participants
  - Columbia University (New York City, USA) with 88 participants
  - The Centre for Movement Disorders (Markham, Ontario, Canada) with 84 participants

AUSTRALIA & NEW ZEALAND:
- Four of the five sites in Australia have submitted the study protocol and informed consents to their Ethics Committee and two sites have received preliminary approval.
- The study protocol was approved by the Ethics Committee in New Zealand on June 20th.
- An Investigator Meeting was held on June 13th and 14th in Melbourne, Australia for the Australian and New Zealand site personnel.
- The 1st participant is expected to be enrolled in Australia and New Zealand in July.

LATIN AMERICA:
- The first participant was enrolled in Latin America at Instituto Frenopatico in Buenos Aires on May 30th.
- The regulatory submissions in Peru and Brazil are anticipated in July.

EUROPE:
- The vast majority of starter packs and site contracts have been sent to the sites in the countries that began regulatory submissions in the 1st quarter (Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom). Ten site contracts have been executed.
- Regulatory submissions have been completed for Germany, Italy and Spain. The sites in France, Spain and Poland have started to receive their starter packets. The remaining contracts will be distributed to these sites in July.

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

The Enroll-HD Study Team