September 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of September 4th, a total of **1058 participants** have been enrolled at the following 38 sites:

  **US Sites - Total Enrollment**

  - Columbia University (New York City, USA)
  - Hereditary Neurological Disease Center (Wichita, Kansas, USA)
  - Colorado Neurological Institute (Englewood, Colorado, USA)
  - The University of Alabama at Birmingham (USA)
  - The University of California, Los Angeles (USA)
  - The University of Tennessee (Memphis, Tennessee, USA)
  - The University of South Florida (Tampa, Florida, USA)
  - The University of Utah (Salt Lake City, Utah, USA)
  - The University of Rochester (New York, USA)
  - Johns Hopkins University (Baltimore, Maryland, USA)
  - The University of California, San Diego (USA)
  - The University of California, Davis (Sacramento, California, USA)
  - Wake Forest University (Winston-Salem, North Carolina, USA)
  - Albany Medical College (New York, USA)
  - The Ohio State University (Columbus, Ohio, USA)
  - Emory University (Atlanta, Georgia, USA)
  - Baylor College of Medicine (Houston, Texas, USA)
  - The University of Illinois College of Medicine at Rockford (Illinois, USA)
  - Duke University (Durham, North Carolina, USA)
  - Booth Gardner Parkinson's Care Center (Barkley, Washington, USA)
  - The University of California, San Francisco (USA)
  - Rush University (Chicago, Illinois, USA)
  - Boston University (Massachusetts, USA)
  - The University of Vermont (Burlington, Vermont, USA)
  - The University of Maryland (Baltimore, Maryland, USA)
  - Hennepin County Medical Center (Minneapolis, Minnesota, USA)
  - Cleveland Clinic Lou Ruvo Center for Brain Health (Las Vegas, Nevada, USA)
  - Cleveland Clinic (Cleveland, Ohio, USA)
  - Washington University (St. Louis, Missouri, USA)

  **Canadian Sites - Total Enrollment**

  - CHUM Hospital Notre Dame (Montreal, Quebec, Canada)
  - The Centre for Movement Disorders (Marcham, Ontario, Canada)
  - The University of British Columbia (Vancouver, British Columbia, Canada)
  - The University of Alberta (Edmonton, Alberta, Canada)
  - The University of Alberta Hospital in Edmonton (Canada)
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:
  - Kansas University Medical Center (Kansas City, Kansas, USA)
  - The University of Calgary (Alberta, Canada)
  - University of Pittsburgh (Pittsburgh, Pennsylvania, USA)

Process Reminders and Updates

- The finalization and implementation of the Global Clinical Impression form (GCI) has not yet been completed. The form is not available on the Enroll-HD Electronic Data Capture system (EDC) and should not be administered as part of the Enroll-HD study visit at this time. Further details will be provided when available.
- As a reminder, the Operations Manual is available on the EDC (under the Operations Manual tab) and provides detailed instructions on all aspects of the study, including biosampling, data entry, the informed consent process and Greenphire.
- All fees outlined in your site’s contract, including start-up and IRB approval fees must be requested through the Greenfire eClinical GPS system. CHDI cannot process payments for any paper copy invoices submitted. Please review the eClinicalGPS training materials if you are unsure of the process for submitting an invoice for fees [https://studies.enroll-hd.org/training/greenphire](https://studies.enroll-hd.org/training/greenphire)

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 106 participants
  - The Centre for Movement Disorders (Markham, Ontario, Canada) with 96 participants

**AUSTRALIA & NEW ZEALAND:**
- North Metropolitan Health in Perth had their site initiation visit on August 23rd and will enroll their first participant in the next few weeks.
- The protocol and informed consent have been submitted for review for the remaining 3 sites in Australia and the 1 remaining site in New Zealand.
LATIN AMERICA:
  o Instituto Frenopatico in Buenos Aires has enrolled 38 participants to date.
  o An Investigator Meeting is scheduled for September 18-19, 2013 in Rio de Janeiro, Brazil, immediately following the World Congress on Huntington’s Disease. Activities will include an overview of the Enroll-HD protocol, Problem Behavior Assessment (PBA) training, and an overview of the Enroll-HD EDC.
  o The regulatory submissions in Peru and Chile are anticipated in September.

EUROPE:
  o Starter packets and site contracts have been sent to the sites in the countries that began regulatory submissions in the 1st quarter of 2013; Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom. Eighteen site contracts have been fully executed.
  o Sites in France, Spain, Poland and Sweden have started to receive their starter packets and contracts.
  o Regulatory submissions have been completed for Germany, Italy and Spain and are planned for France, Poland, and Austria.
  o European enrollment is expected to begin in Germany during the month of October.

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

The Enroll-HD Study Team