

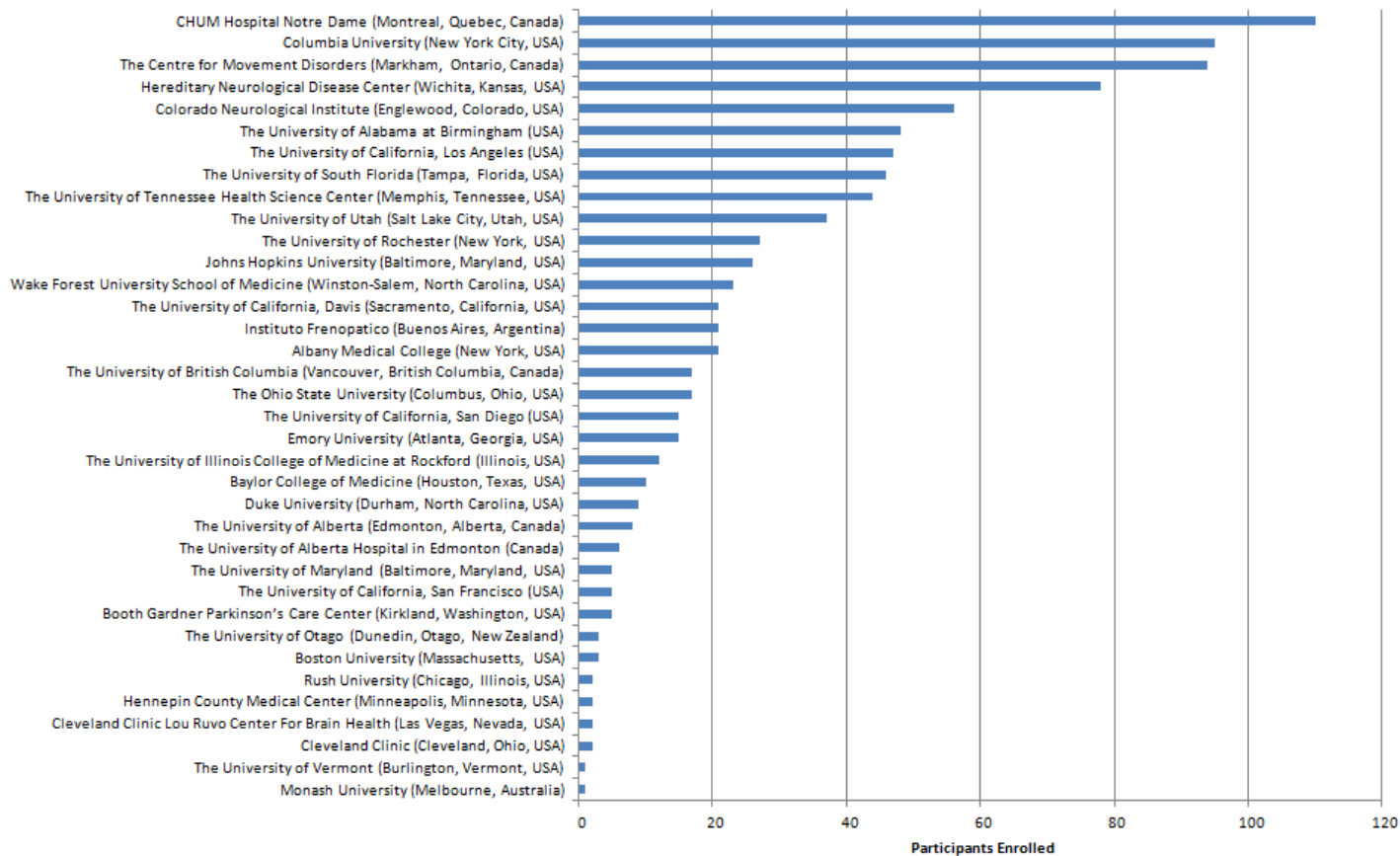


## August 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of August 12<sup>th</sup>, a total of **962 participants** have been enrolled at the following 36 sites:



★ 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)

## Process Reminders and Updates

- The Enrollment Case Report Form (CRF) in the Electronic Data Capture (EDC) system contains a space for the COHORT ID, if applicable. If a participant had multiple COHORT IDs, one created by the Clinical Trials Coordination Center (CTCC) and one by the European Huntington's Disease Network (EHDN), please enter the CTCC HDID in the COHORT ID field. All participants must have their Enroll-HD HDID created through the Enroll-HD EDC.
- 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 data entry of forms should be completed within 10 business days of a participant's enrollment date. Forms cannot be reviewed and finalized for payment until they are signed off and submitted through the EDC.

## 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 95 participants
  - The Centre for Movement Disorders (Markham, Ontario, Canada) with 94 participants

### AUSTRALIA & NEW ZEALAND:

- The first participant was enrolled at the University of Otago on July 27<sup>th</sup>
- Monash University in Australia had their site initiation visit on July 23<sup>rd</sup> and enrolled their first participant on August 8<sup>th</sup>.
- North Metropolitan Health in Perth has their site initiation visit scheduled for August 23<sup>rd</sup>.
- 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:

- An Investigator Meeting is scheduled for September 18-19, 2013 in Rio de Janeiro, Brazil. Activities will include an overview of the Enroll-HD protocol, Problem Behavior Assessment (PBA) training, and an overview of the Enroll-HD EDC.
- The regulatory submissions in Peru, Brazil and Chile are anticipated in August.

### EUROPE:

- Starter packets and site contracts have been sent to the sites in the countries that began regulatory submissions in the 1<sup>st</sup> quarter of 2013; Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom. Thirteen site contracts have been fully executed.
- The sites in France, Spain, Poland and Sweden have started to receive their starter packets. Contracts have been sent to sites in France, Spain and Poland.

- Regulatory submissions have been completed for Germany, Italy and Spain and are planned for France, Poland, and Austria.

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

**The Enroll-HD Study Team**

