



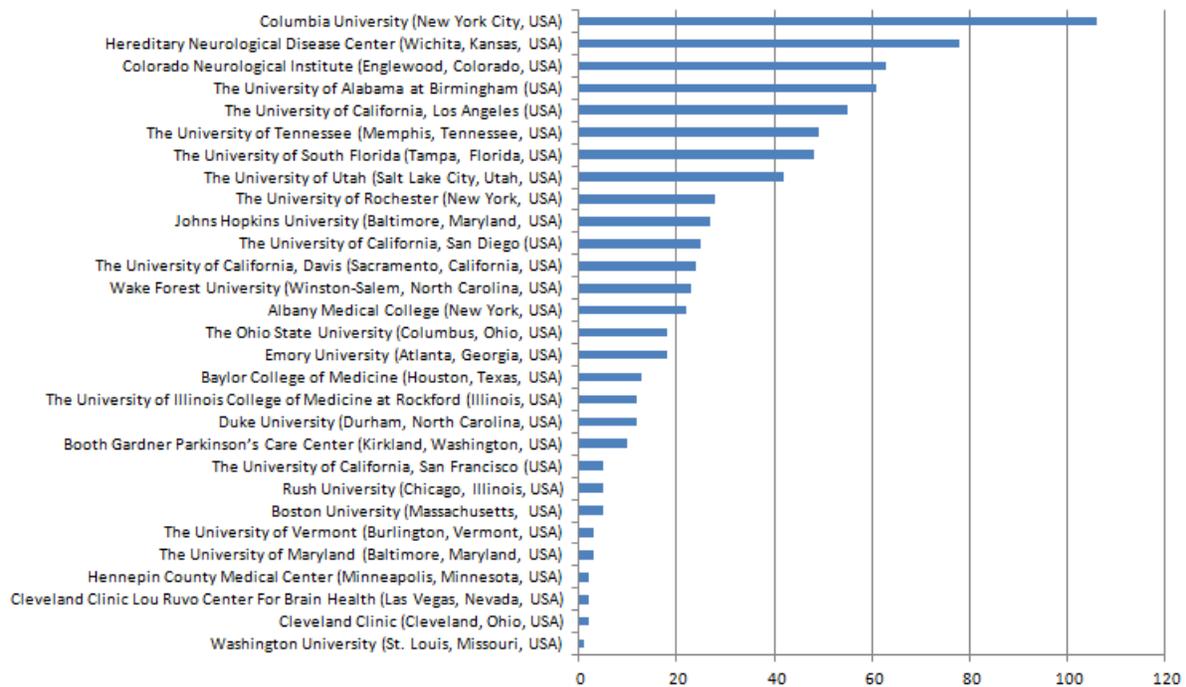
## September 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

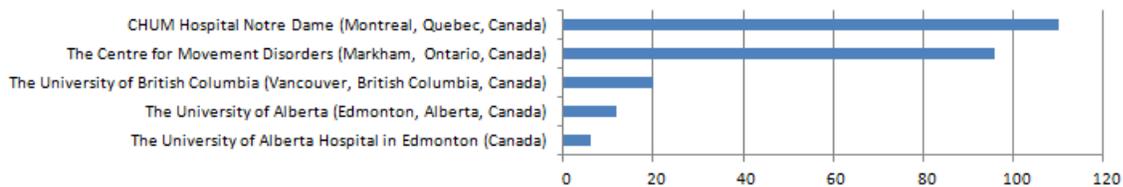
An Enroll-HD progress update over the past month:

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

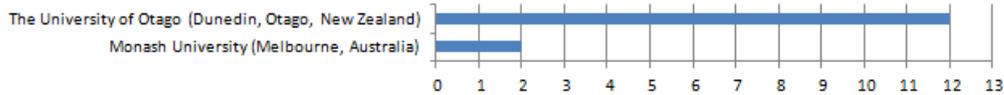
### US Sites - Total Enrollment



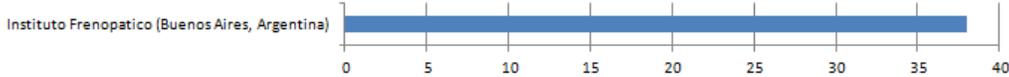
### Canadian Sites - Total Enrollment



### Australia/New Zealand Sites - Total Enrollment



### Latin American Sites - Total Enrollment



★ 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 Greenphire 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>

### 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 23<sup>rd</sup> 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:

- Instituto Frenopatico in Buenos Aires has enrolled 38 participants to date.
- 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.
- The regulatory submissions in Peru and Chile are anticipated in September

#### 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. Eighteen site contracts have been fully executed.
- Sites in France, Spain, Poland and Sweden have started to receive their starter packets and contracts.
- Regulatory submissions have been completed for Germany, Italy and Spain and are planned for France, Poland, and Austria.
- 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**

