



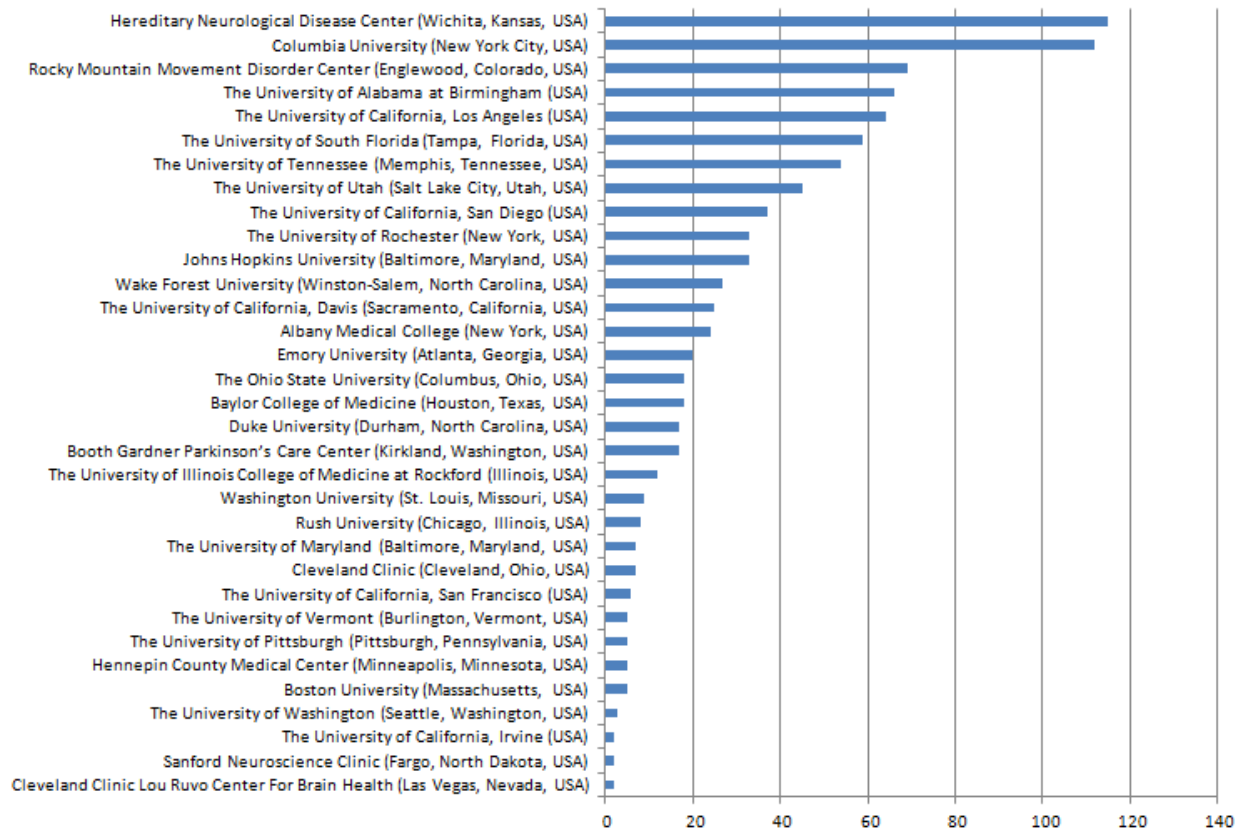
November 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

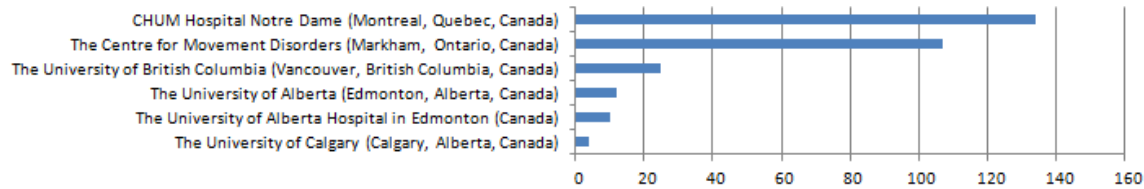
An Enroll-HD progress update over the past month:

- As of November 1st, a total of **1298 participants** have been enrolled at the following 44 sites:

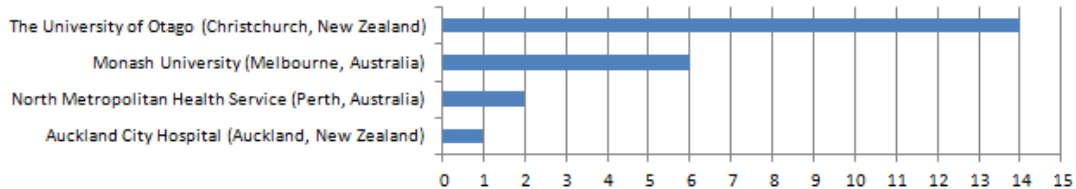
US Sites - Total Enrollment



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 **134 participants** enrolled!

- The following sites have completed their two-part site initiation:
 - CETRAM (Santiago, Chile)
 - Georgia Regents University (Augusta, Georgia, USA)
 - Kansas University Medical Center (Kansas City, Kansas, USA)
 - The University of Chicago (Illinois, USA)
 - The University of Cincinnati (Ohio, USA)
 - The University of Iowa (Iowa City, Iowa, USA)
 - Virginia Commonwealth University (Richmond, Virginia, USA)

Process Reminders and Updates

- The Operations Manual is available on the Enroll-HD 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.
- When shipping your biosamples, please remember to include 5 copies of the completed proforma invoice per the instructions found in the Enroll-HD Operations Manual (<https://studies.enroll-hd.org/manual/biosampling>). Also remember the Airway Bill shipping label is placed on top of the sleeve that is affixed to the box to hold the proforma invoice.
- As a reminder, sites are encouraged to use direct data entry whenever possible to enter study data into the Enroll-HD EDC. Paper source documentation is required for the HDID creation page, Cognitive assessments, the PBA-s assessment, and any extended assessments that are filled out by the participant. All other assessments do not require a paper source document if the direct data entry method is used.
- All site fees outlined in your site contract, like start-up and IRB review fees, must be requested through the Greenphire eClinical GPS system. The invoices must be uploaded into the Greenphire system so CHDI

can process the payments. Please review the eClinicalGPS training materials if you are unsure of the process for submitting an invoice for site 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 134 participants
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 115 participants
 - Columbia University (New York City, USA) with 112 participants
- Three “top-up training sessions” were held the week of October 7th. Thank you to all sites who participated in the training. It was a good opportunity to review some of the protocol procedures and address your questions. We hope to continue to offer these sessions throughout next year.

AUSTRALIA & NEW ZEALAND:

- North Metropolitan Health Service (Perth, Australia) and Auckland City Hospital (Auckland, New Zealand) enrolled their first participants in October.
- The protocol and informed consent have been submitted for review for the remaining 2 sites in Australia.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires has enrolled 48 participants to date.
- The Brazilian Investigator Meeting took place in Rio de Janeiro, Brazil on September 18th and 19th following the World Congress on HD.
- CETRAM in Santiago, Chile has completed their Site Initiation Visit and is scheduled to begin enrolling participants this month.
- Regulatory Submissions for Brazil are scheduled for December 2013.

EUROPE:

- 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. Twenty-three site contracts have been fully executed.
- Sites in Austria, France, Spain, Norway, Poland, Sweden and Switzerland have received their starter packets and contracts.
- Regulatory submissions are planned for France and Austria.
- The University of Ulm in Germany expects to enroll their first participant this month!
- The IT team is completing an extensive User Acceptance Testing process for the next version of the Enroll-HD EDC – this version will enable the process of transitioning participants and data from REGISTRY to Enroll-HD.

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

The Enroll-HD Study Team

