



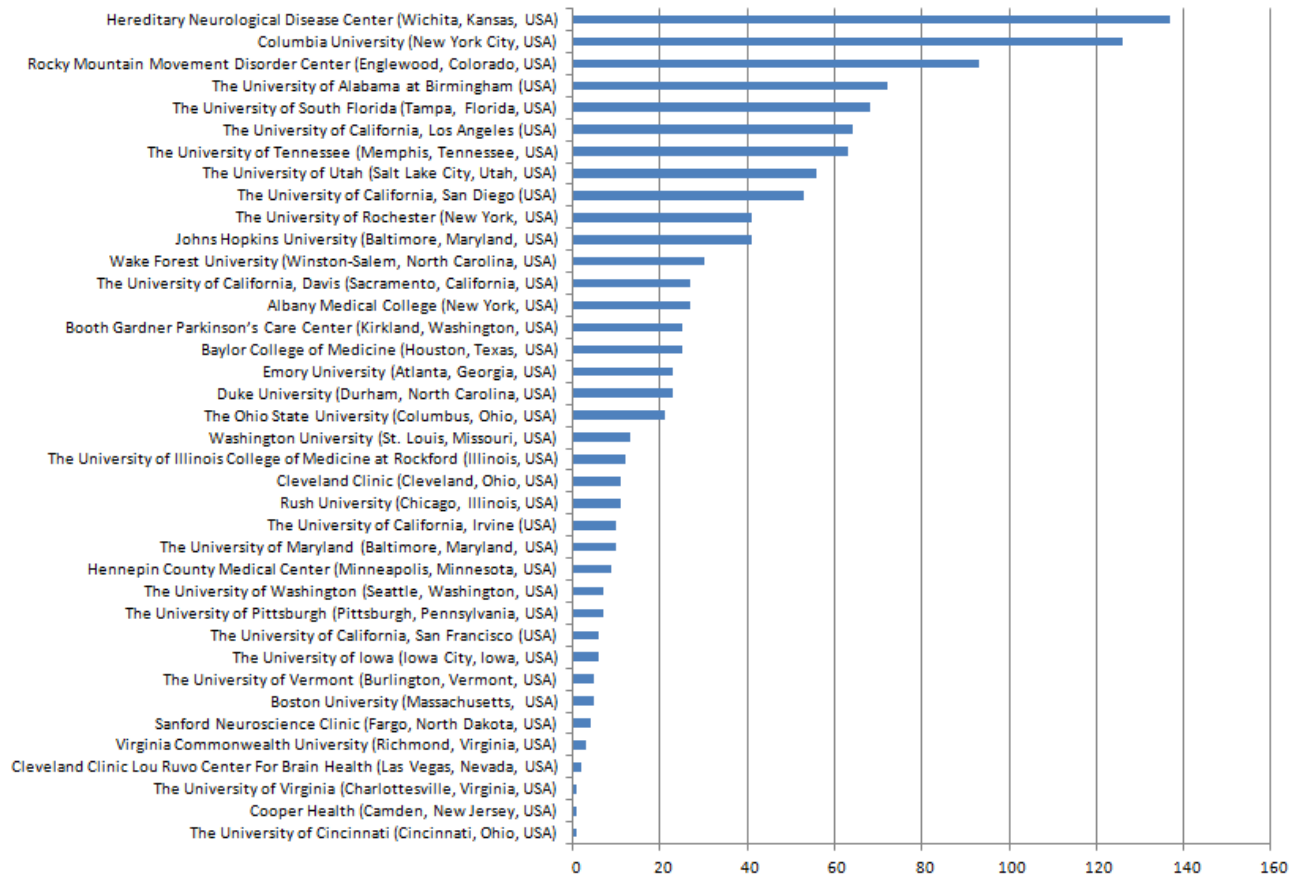
February 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

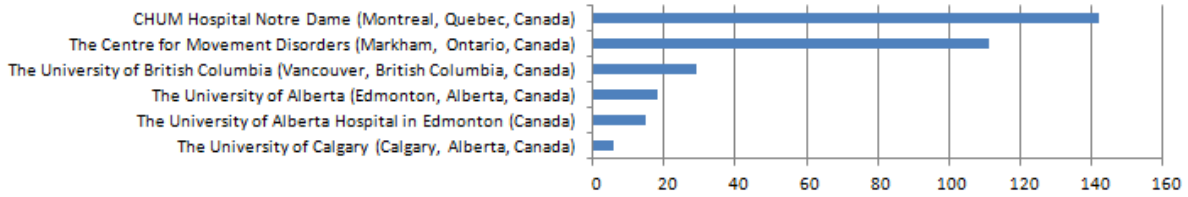
An Enroll-HD progress update over the past month:

- As of February 1st, a total of **1592 participants** have been enrolled at the following 52 sites:

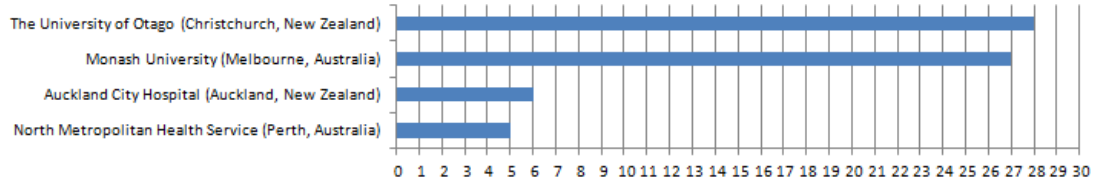
US Sites - Total Enrollment



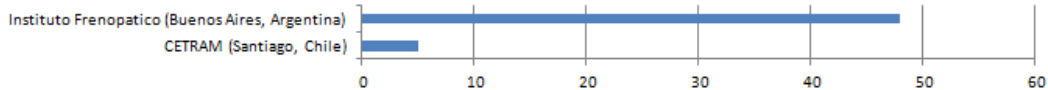
Canadian Sites - Total Enrollment



Australia/New Zealand Sites - Total Enrollment



Latin American Sites - Total Enrollment



European Sites - Total Enrollment



★ Top enrolling site is CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with **142 participants** enrolled!

- The following sites have completed their two-part site initiation:
 - Georgia Regents University (Augusta, Georgia, USA)
 - Kansas University Medical Center (Kansas City, Kansas, USA)
 - Loma Linda University (Loma Linda, California, USA)
 - The University of Chicago (Chicago, Illinois, USA)

Process Reminders and Updates

- Please review the Safety and Event Reporting section of the Operations Manual and ensure that you are asking your participants about Reportable Events during each study visit. <https://studies.enroll-hd.org/manual/reporting>
- The window to complete follow-up visits is plus or minus 3 months from the baseline date. Sites are reminded to check the Visit Dashboard, located on the left side bar of the Enroll-HD EDC, to ensure follow-up visits are scheduled accordingly. If a participant is not able to attend for their next scheduled follow-up visit, the missed visit form should be completed. An email communication was sent to all sites on January 31st explaining the process for completing the missed visit form.
- Quintiles Outcome will be conducting monthly Question and Answer sessions for sites, with the first session scheduled for Wednesday, February 19th at 2:00pm EST. These monthly meetings are meant to address questions that sites have regarding any aspect of Enroll-HD, including but

not limited to data entry, informed consent, safety reporting, biosampling procedures and monitoring. A meeting reminder along with WebEx details will be sent out one week prior to each meeting, and sites are encouraged to send their questions to the Quintiles Outcome at that time.

- A modification to the “Date of shipment” field on the Samples CRF has been implemented in the EDC. Sites are now able to enter a date up to 7 days in the future (from the current date) when completing the form, if they are aware that they will have to wait to ship the samples to BioRep.
- The Operations Manual (available on the Enroll-HD EDC under the Operations Manual tab) provides detailed instructions on all aspects of the study, including biosampling, data entry, the informed consent process and Greenphire. The “I Have a Question” document circulated by the Quintiles Outcome Site Management team on December 13th, 2013 has been added to the FAQ sidebar link in the Operations Manual. (<https://studies.enroll-hd.org/manual/faqs>)
- 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 142 participants.
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 137 participants.
 - Columbia University (New York City, USA) with 122 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 25 participants.
- The University of Otago at Christchurch is the leading enroller in New Zealand with 28 participants.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires has enrolled 48 participants to date.
- CETRAM in Santiago, Chile has enrolled 5 patients to date.
- Regulatory submissions for Brazil are scheduled for February 10th.

EUROPE:

- The University of Ulm in Germany has enrolled 20 participants to date.
- Four sites started the initiation process in January: two in the UK and two in Germany.
- Three additional sites will be initiated in February: two in Germany and one in the UK.
- 131 of the 136 confirmed sites in Europe have received their starter packets. 26 site contracts have been fully executed.

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

The Enroll-HD Study Team

