



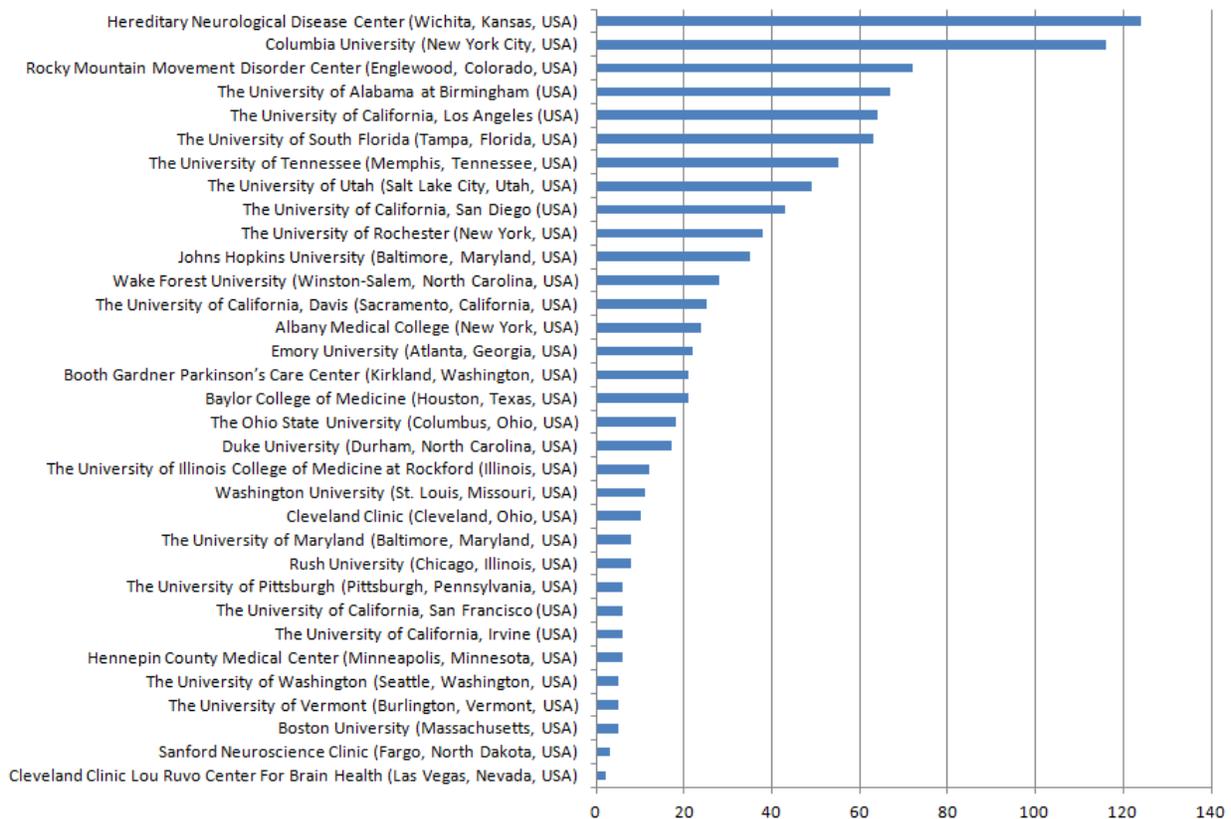
December 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

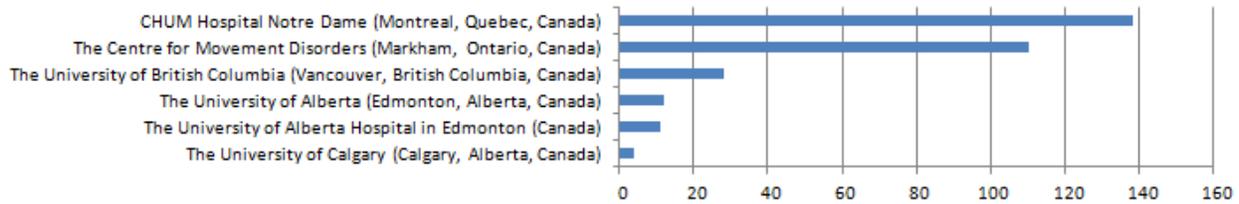
An Enroll-HD progress update over the past month:

- As of December 1st, a total of **1387 participants** have been enrolled at the following 44 sites:

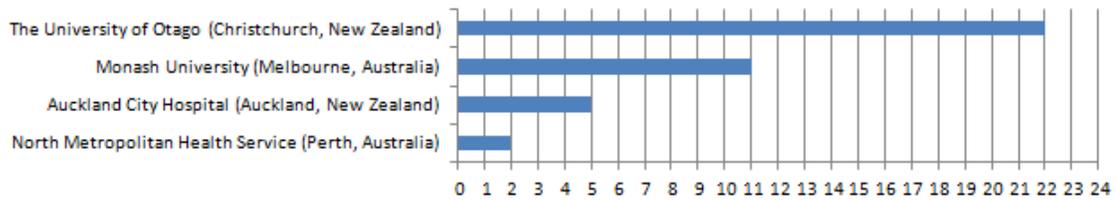
US Sites - Total Enrollment



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 **138 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 (Chicago, Illinois, USA)
 - The University of Iowa (Iowa City, Iowa, USA)
 - The University of Virginia (Charlottesville, Virginia, USA)
 - Virginia Commonwealth University (Richmond, Virginia, USA)

Process Reminders and Updates

- When communicating via email to the Support Team, please use only the first 4 digits of the HDID.
- The newest release of the Enroll-HD EDC is now live. The current release, version 1.2, includes additional languages and integration tools for sites in Europe.
- 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.
- The Visit Dashboard is available on the Enroll-HD EDC (on the left sidebar) and allows sites to determine which visits still require data entry before the review cycle can begin. After logging in, click the “Enroll!” button and select “Visit Dashboard” from the left sidebar. Filter for “Enroll-HD” in the dropdown menu and then review the status of all visits.

- 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>
- BioRep will be closed on December 25th and 26th, as well as January 1st and 6th. BioRep will continue to receive shipments during this time. If you need to order additional biokits, please do so by December 20th to prevent any delays in shipping. Biokits should be ordered through the Enroll-HD EDC via the link on the left sidebar; the process is outlined in the Operations Manual: <https://studies.enroll-hd.org/manual/biosampling>
- A new version of the Declaration of Helsinki, effective October 2013, has been approved by the World Medicine Association, and the document is now available on the Enroll-HD EDC: <https://studies.enroll-hd.org/manual/helsinki>

PREDICT-HD and Enroll-HD recruitment

- Concurrent enrollment in PREDICT-HD and Enroll-HD may confound findings resulting from PREDICT-HD, is not scientifically useful and is therefore not permitted. When participants complete their participation in PREDICT-HD they are welcome and encouraged to participate in Enroll-HD. Participants should be instructed to contact their local Enroll-HD site for more information about Enroll-HD. There are no quotas or restrictions on enrollment of PREDICT-HD participants into Enroll-HD once their participation in PREDICT-HD has ended.

Communications Materials

- Printed recruitment materials are available for use at your site (see attached PDF files) – please contact Woody Kongsamut (woody.kongsamut@chdifoundation.org) for further details and/or high-quality print copies. These have been approved by Western IRB for use in the US and Canada but may need to be approved by your local IRB.
- *Enroll!*, the Enroll-HD newsletter, is also available for distribution at your site – see the attached Autumn issue. If you'd like to be added to the distribution list for future issues please email Woody Kongsamut (woody.kongsamut@chdifoundation.org).

Regional Updates

NORTH AMERICA:

- The following sites have enrolled the most participants to date:
 - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 138 participants
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 124 participants
 - Columbia University (New York City, USA) with 116 participants

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 11 participants
- The University of Otago at Christchurch is the leading enroller in New Zealand with 21 participants
- The protocol and informed consent has been approved for the remaining site in Australia.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires has enrolled 48 participants to date.
- CETRAM in Santiago, Chile has completed their Site Initiation Visit and is scheduled to begin enrolling participants in December
- Regulatory submissions for Brazil are scheduled for December

EUROPE:

- The University of Ulm in Germany had their Site Initiation Visit on November 25th 2013 and enrolled their first participant on December 6th 2013 – Enroll-HD has now started in Europe!! Congratulations and thanks to all involved for their hard work and dedication.
- 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-five 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.

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

The Enroll-HD Study Team

