



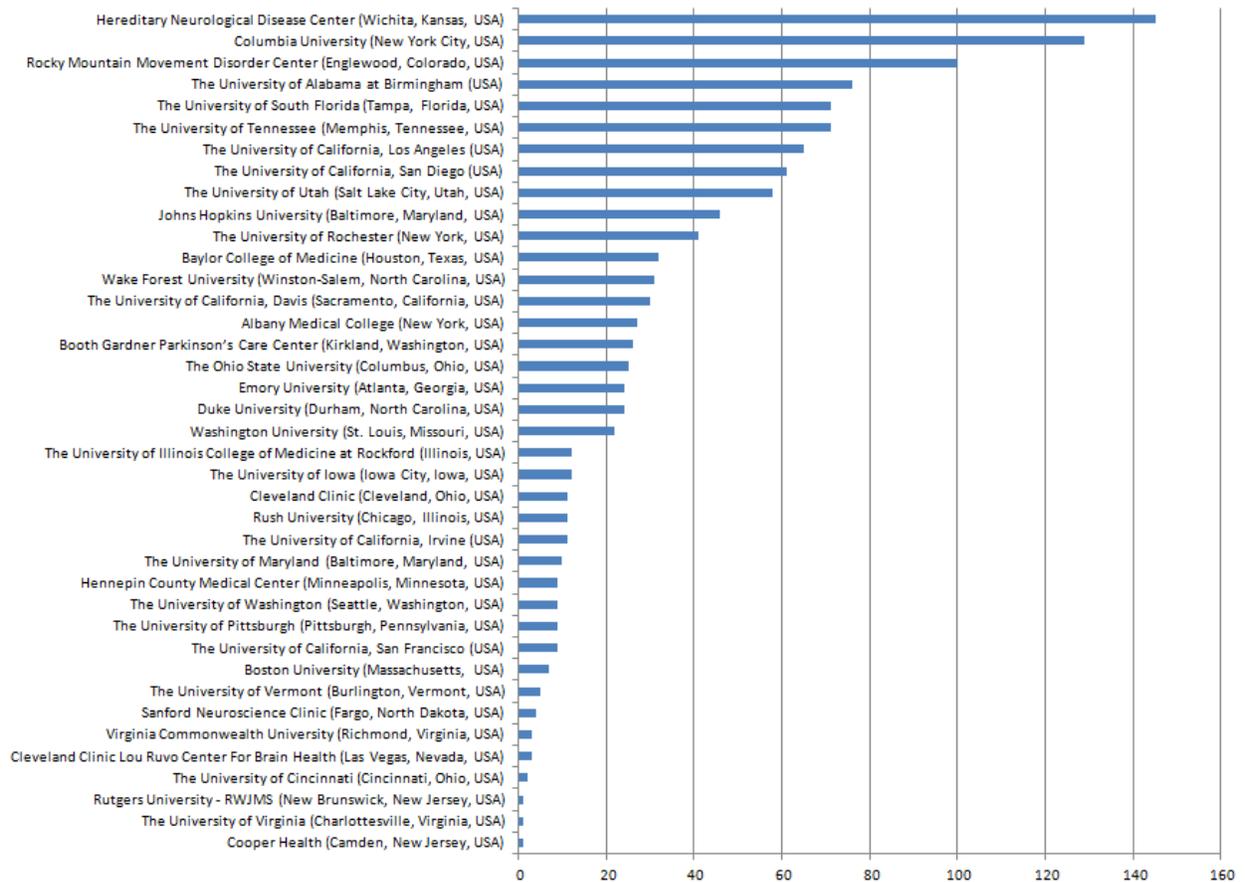
March 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

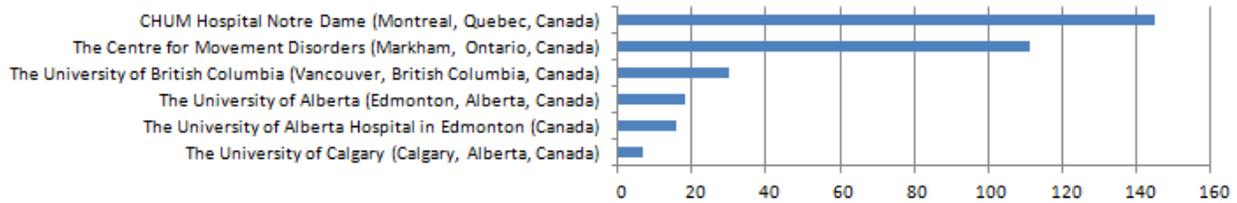
An Enroll-HD progress update over the past month:

- As of March 1st, a total of **1735 participants** have been enrolled at the following 57 sites:

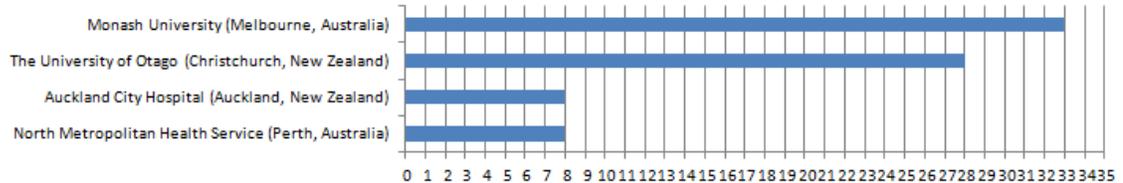
US Sites - Total Enrollment



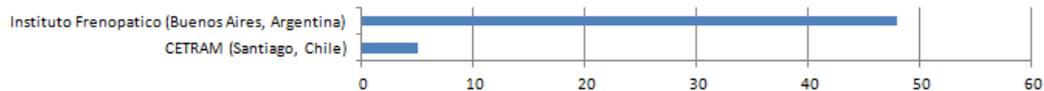
Canadian Sites - Total Enrollment



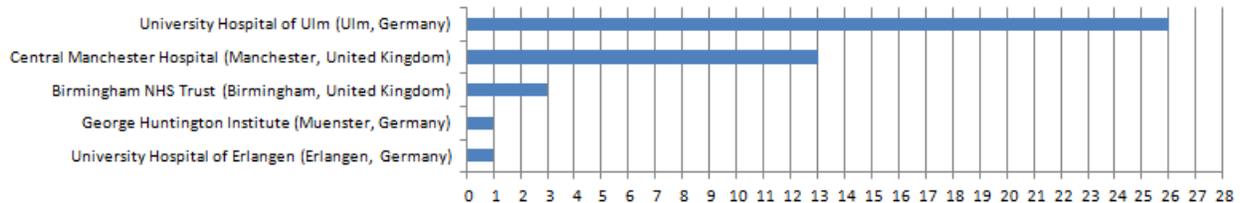
Australia/New Zealand Sites - Total Enrollment



Latin American Sites - Total Enrollment



European Sites - Total Enrollment



★ Top enrolling sites are CHUM Hospital Notre Dame (Montreal, Quebec, Canada) and Hereditary Neurological Disease Center (Wichita, Kansas, USA) with **145 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)

Communications Materials

- *Enroll!* - the quarterly Enroll-HD newsletter for current and potential participants, their families, and site staff - is also available for distribution at your site; see the attached March issue PDF. This has been approved for distribution in the United States and Canada by the central IRB being utilized for Enroll-HD, the Western Institutional Review Board (WIRB). Please ensure that you follow all local rules and regulations prior to distribution (including any submission and/or review requirements by your local IRB/EC). If you'd like to be added to the distribution list for future issues please email Woody Kongsamut (woody.kongsamut@chdifoundation.org).

- For logistical reasons print copies of *Enroll!* will not be distributed, but you are encouraged to print locally (in color if possible) so that participants and their family members can take a copy with them. Please contact the Enroll-HD Study Team with any questions.
- Printed recruitment materials in English are also 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 also need to be approved by your local IRB. Local language translations of these materials are currently in process for European and Latin American sites.
- The new Enroll-HD website is currently under construction and will go live in the next month or two. The Enroll-HD Communications Working Group is an integral part of this process.

Process Reminders and Updates

- As a reminder, when creating HDIDs, the field “Birth Name” asks for only the participant’s LAST NAME at birth. The participant’s full name at birth should NOT be entered. Please reference the help text on the HDID creation page, as well as the section of the Operations Manual covering HDID creation (<https://studies.enroll-hd.org/manual/assessments/enrollment>) if you have any questions.
- When a Site Controller sets up their bank account information in the Greenphire eClinicalGPS system they must select an option from the drop-down list for the ‘MEMO LINE’ field. The choices to choose from are:
 - Custom text (this selection requires the entry of custom text, alpha numeric is allowed)
 - Protocol and Sponsor
 - PI Last Name and Protocol
 - Study Name

The information selected for the ‘MEMO LINE’ is included in the information that Greenphire passes to the receiving bank for all EFTs as well as populated on the memo line for each check. The Site Controller can alter the selection at any time and the updated information will be used for future payments. Please note, while Greenphire passes this information along to all receiving banks, how and whether the bank displays this information to the account holder is out of Greenphire’s control. Additionally, Greenphire sends a payment initiation email to the designated Site Controller(s) alerting them to the amount of the transfer and the account to which it is being transferred.

- If at the baseline visit you are unable to draw blood but you have already opened the kit and used one of the vacutainers (and you have not yet associated the barcodes in the EDC nor has a lab ID been created for this kit) you can simply substitute one from the extra spare kit parts bag that comes in the kit package (for practice or needed items) and use it for the next participant. If a barcode labeled tube has been used then the kit should be destroyed and this should be logged at the site.
- Please keep in mind that BioRep needs 10 business days to ship biokits from the time they receive an order; delivery can take up to an additional 5 business days. Sites are reminded to regularly monitor the number of kits they have in stock and ensure an adequate supply is always maintained.
- 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.
- 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 145 participants.
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 145 participants.
 - Columbia University (New York City, USA) with 129 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 33 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.
- The Scientific Review Board has approved the study in Brazil. Submission to the Local ERB will take place in March.

EUROPE:

- Six sites have now been initiated in the UK and Germany and participant enrollment has commenced in both countries.
- Two sites started the initiation process in February: 1 in UK and 1 in Germany. Full site activation will be within the next 10 days.
- Two further sites will be initiated in March: 1 in UK and 1 in Germany.
- The next countries due to start Enroll-HD are the Netherlands, Poland, Italy and Denmark.
- In total, 137 sites have been confirmed for participation in Enroll-HD in Europe and 29 of these have fully executed contracts.

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

The Enroll-HD Study Team

