



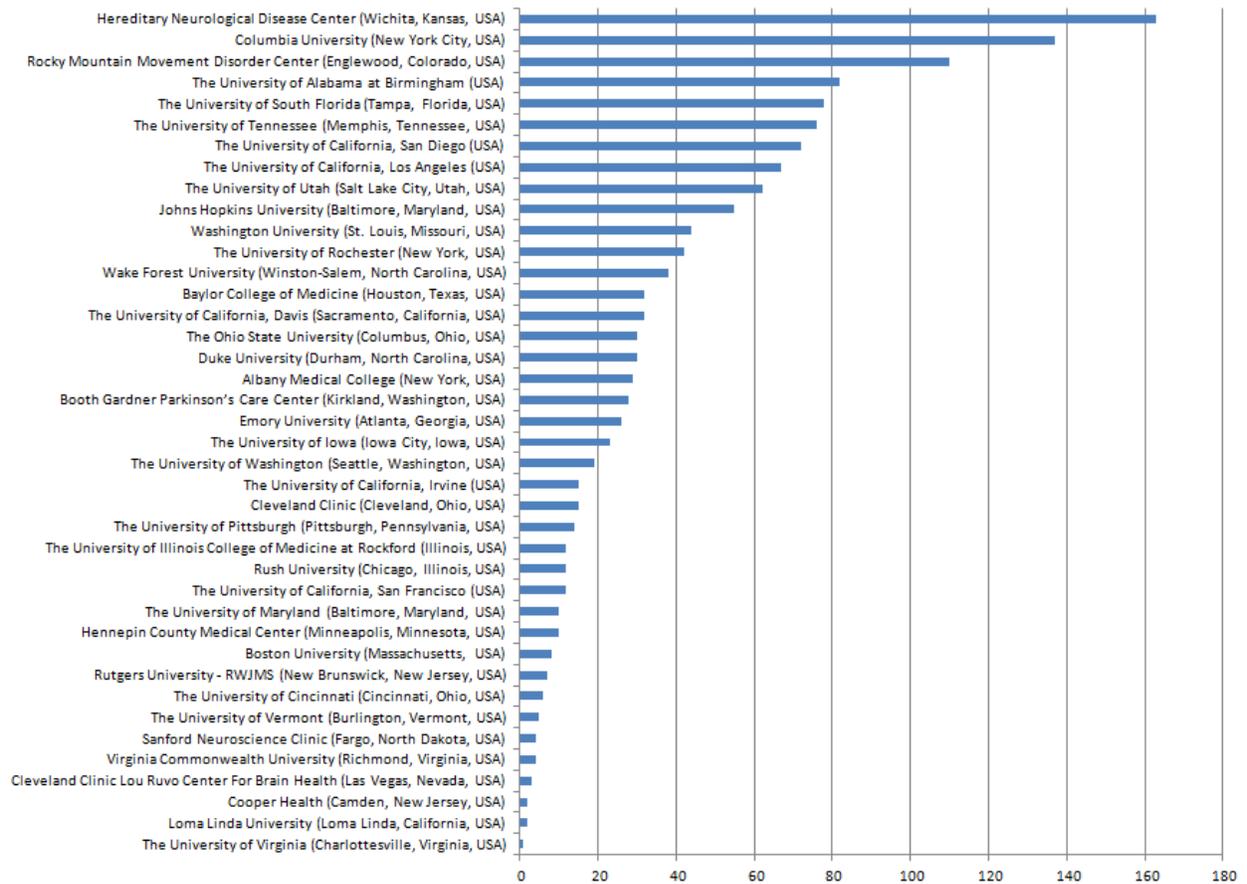
May 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

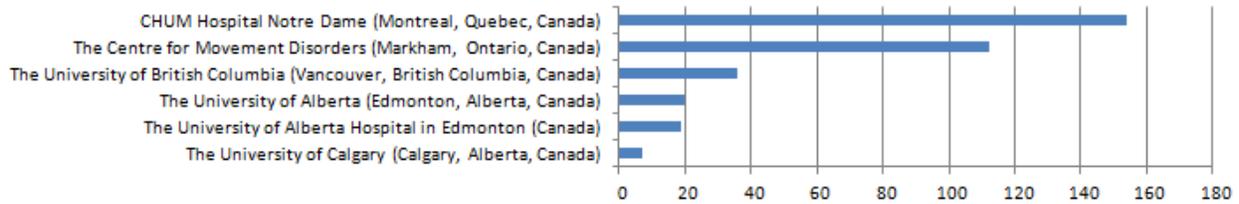
An Enroll-HD progress update over the past month:

- As of May 1st, a total of **2,138 participants** have been enrolled at the following 62 sites:

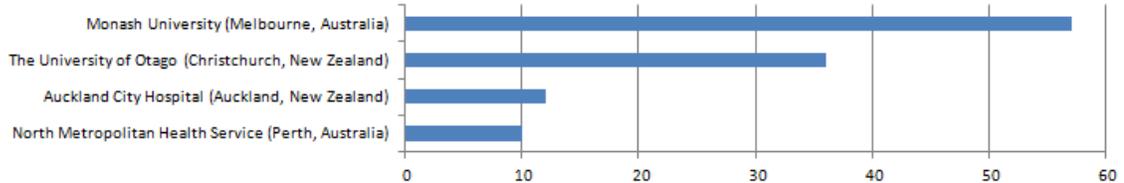
US Sites - Total Enrollment



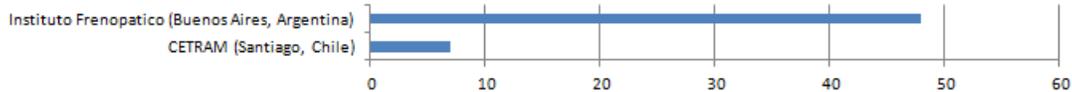
Canadian Sites - Total Enrollment



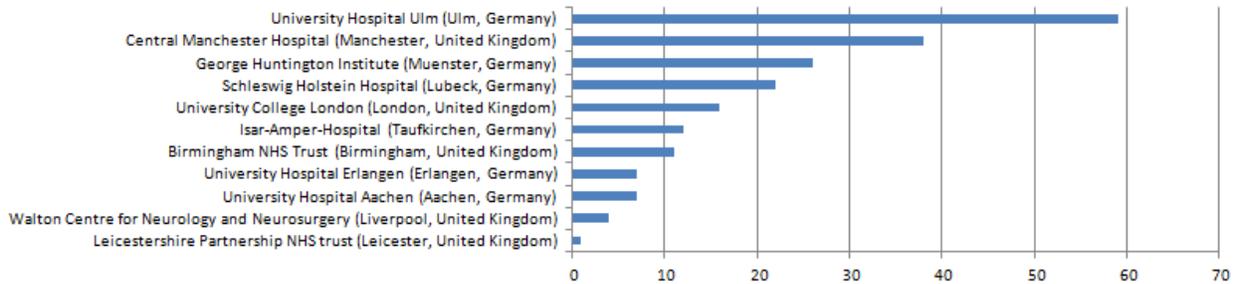
Australia/New Zealand Sites - Total Enrollment



Latin American Sites - Total Enrollment



European Sites - Total Enrollment



★ Top enrolling site is Hereditary Neurological Disease Center (Wichita, Kansas, USA) with **163 participants** enrolled!

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

Care Improvement Committee

- One of the goals for Enroll-HD is to identify and gain a better understanding of the interventions that lead to better outcomes for patients; the Care Improvement Committee, co-chaired by Mark Guttman and Martha Nance, is leading this effort. The 12-item Short Form Health Survey (SF-12), a validated measure of health-related quality of life (HRQoL), is currently part of the extended (and non-compulsory) assessment in Enroll-HD and may prove to be important in determining which interventions lead to improvement in HRQoL. **Though the form is not required, the Care Improvement Committee requests that all sites complete the SF-12 for all**

participants from now on. Data about care and well-being from a large number of participants may lead to additional studies. The SF-12 will remain an extended (and non-compulsory) assessment, and your site will receive additional compensation for its completion.

- Another important part of the Care Improvement Committee's work is to better understand how care is provided to HD patients and their families around the world - **all sites will receive an invitation to complete an online care delivery survey in May, please complete the survey at your earliest convenience.** We plan to have a preliminary analysis of these data available in September - on behalf of the Care Improvement Committee, thank you for your contribution to this important work!

Process Reminders and Updates

- A reminder to all sites regarding the sign-off of Case Report Forms (CRFs) in the Electronic Database Capture (EDC) system - **all individual CRFs must be signed by a site user after data entry is complete, and the visit itself (Baseline, Annual Follow-Up, General, Family History) must also be signed by a site user before the visit can be flagged as ready for monitoring and then approved for payment.** Several sites have large numbers of unsigned visits; please review your dashboard today!
- Sub-study proposals should be submitted for review by the Scientific Planning Committee (SPC) at StudyProposal@Enroll-HD.org. The SPC review will be based on the strength of the proposal and the scientific priorities of Enroll-HD.
- Printed recruitment materials in English are available for use at your site – 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 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; it is important to familiarize yourself with these processes to ensure data and biosample integrity.
- 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:
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 163 participants.
 - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 154 participants.
 - Columbia University (New York City, USA) with 137 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 57 participants.
- The University of Otago at Christchurch is the leading enroller in New Zealand with 36 participants.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires, Argentina has enrolled 48 participants to date.
- CETRAM in Santiago, Chile has enrolled 8 participants to date.

EUROPE:

- Eleven sites have now been initiated in the UK and Germany.
- Over 200 participants have now joined Enroll-HD in Europe.
- Poland will become the third European country to join Enroll-HD; the transition process has begun at the site in Poznan.
- Four further site initiations have been confirmed for May.
- 138 European sites are due to participate in Enroll-HD; 32 of these already have fully executed contracts.

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

The Enroll-HD Study Team

