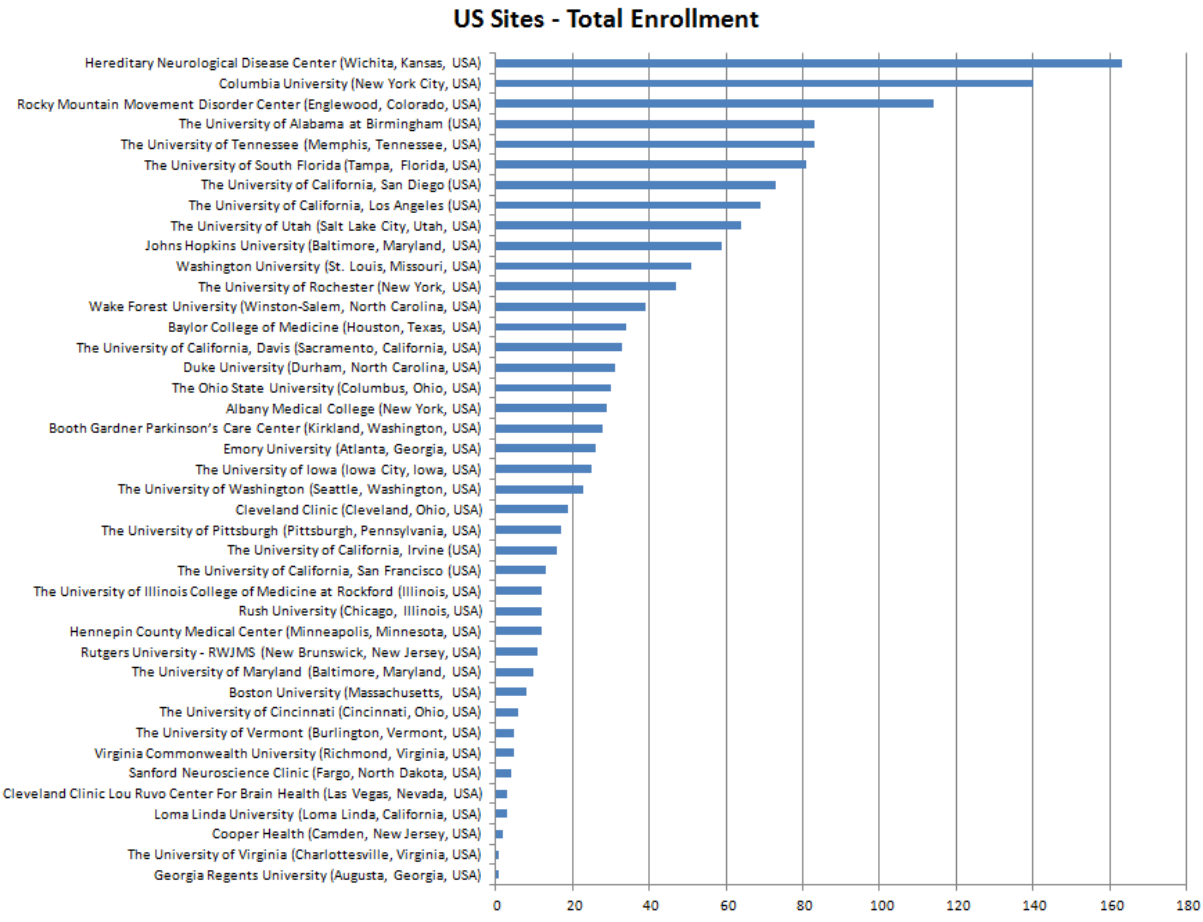
June 2014 Monthly News Bulletin

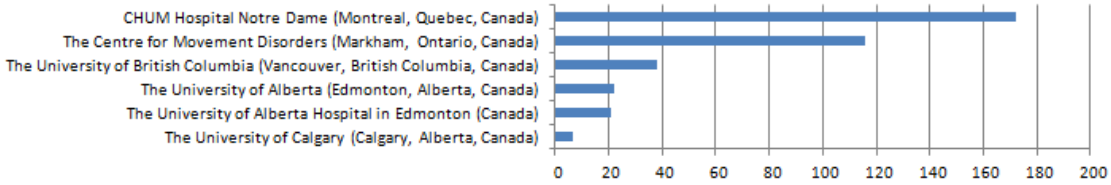
Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

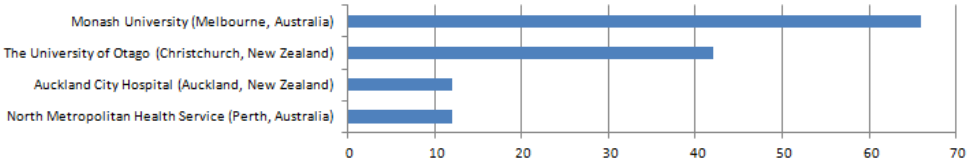
- As of June 1st, a total of **2,351 participants** have been enrolled at the following 65 sites:



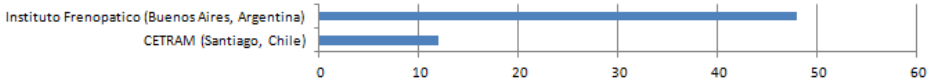
Canadian Sites - Total Enrollment



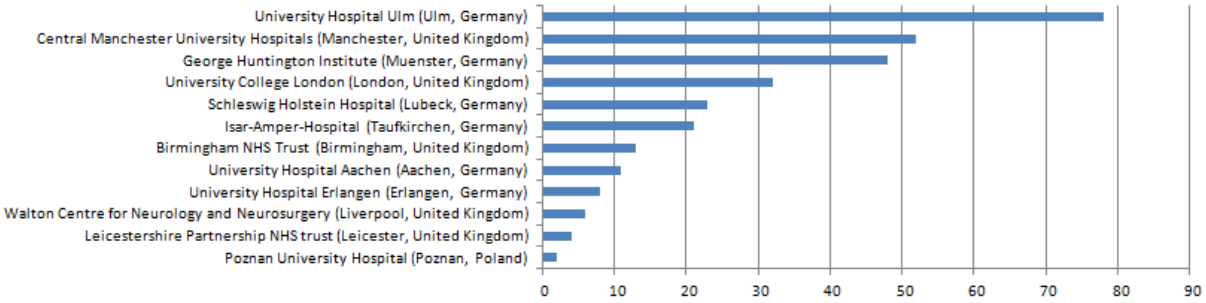
Australia/New Zealand Sites - Total Enrollment



Latin American Sites - Total Enrollment

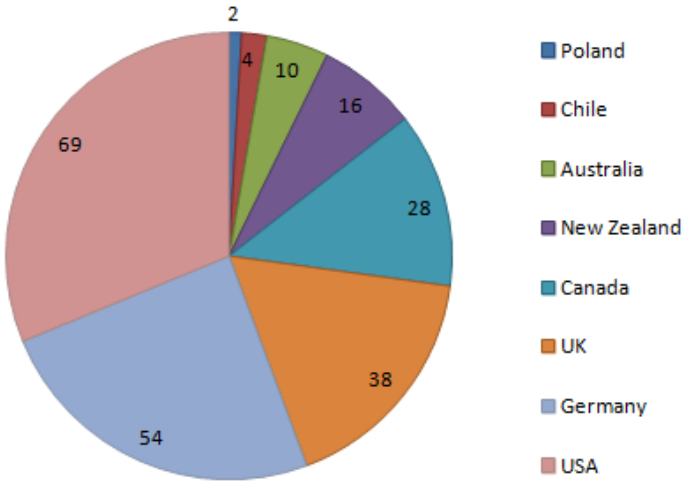


European Sites - Total Enrollment



☆Top enrolling site is CHUM Hospital Notre Dame (Montreal, Quebec) with **172 participants** enrolled!

Participants Enrolled in May 2014



Enroll-HD Quarterly Newsletter for Participants, Families, and Site Staff

- The June issue of *Enroll!* has been circulated with this month's bulletin. This has been approved for distribution in the United States and Canada by the central IRB being utilized for Enroll-HD, Western Institutional Review Board (WIRB). If you do not use 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).
- For logistical reasons print copies 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.

Process Reminders and Updates

- There is no exclusion for participants who cannot complete the core assessments. If a participant is unable to complete the core assessment(s) (some or all) due to the severity of their cognitive deficits, there is an SOP which should be implemented. As sites only receive payment for a completed core assessment, care should be used to correctly complete the case report forms; data fields should not be left blank, guidelines for completion are in the web portal, and the comments section should be utilized. If you have questions regarding how to complete the Case Report Form (CRF), please contact either your call center or your regional monitor. If the participant is not able to complete the core cognitive assessments then, for obvious reasons, the site should NOT complete the optional assessments.
- 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 and following up on the reportable event until it has been closed. https://studies.enroll-hd.org/manual/reporting

- A reminder to all sites regarding the sign-off of CRFs in the 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; some translations are completed and print copies will be available soon, more details to follow.

- 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

- 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.

Regional Updates

NORTH AMERICA:

- The following sites have enrolled the most participants to date:
  - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 172 participants.
  - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 163 participants.
  - Columbia University (New York City, USA) with 140 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 66 participants.
- The University of Otago at Christchurch is the leading enroller in New Zealand with 42 participants.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires, Argentina has enrolled 48 participants to date.
- CETRAM in Santiago, Chile has enrolled 12participants to date.

EUROPE:

- 13 sites have now been initiated in the UK, Germany and Poland and all are enrolling participants.
- Over 300 participants have now joined Enroll-HD in Europe.
- Italy has become the fourth European country to join Enroll-HD, with site initiation process started at the site in Naples.
- Eight further sites started the initiation process in May and will soon be activated in full. Five more site initiations in Italy have been confirmed for June and July.
- 38 European sites due to participate in Enroll-HD in Europe now have fully-executed contracts.

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

The Enroll-HD Study Team