

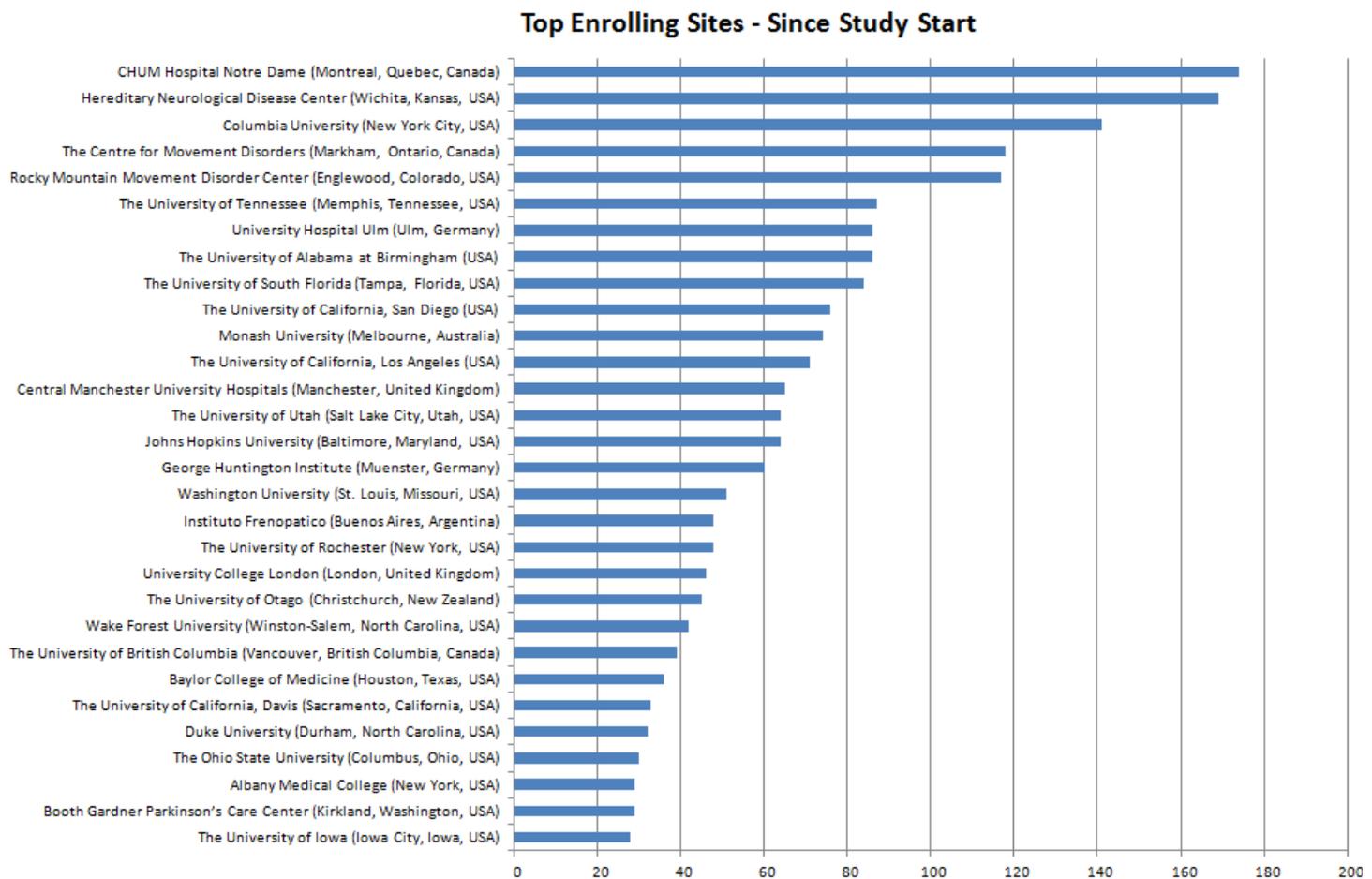


July 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

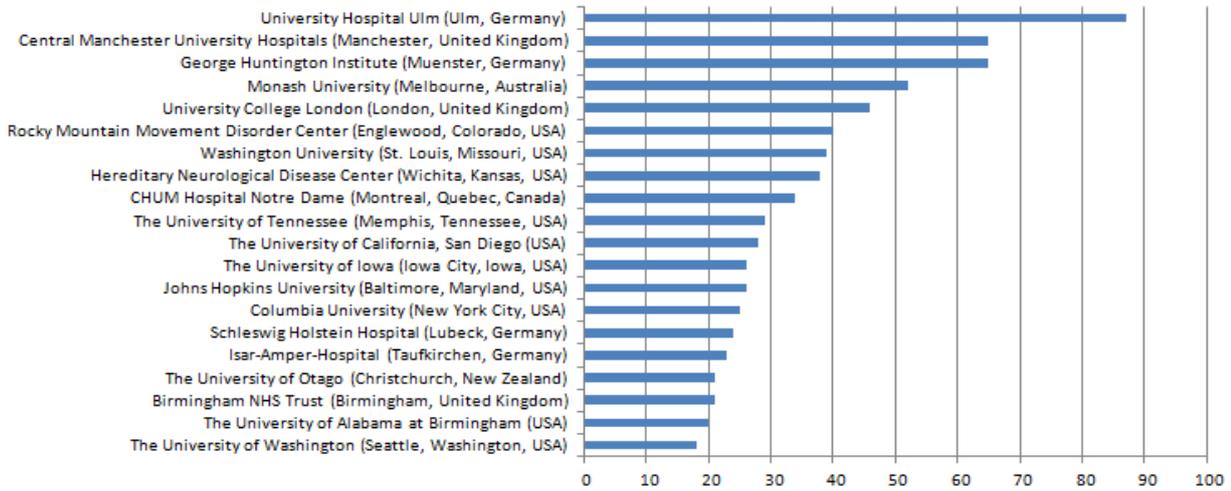
An Enroll-HD progress update over the past month:

- As of July 1st, a total of **2523 participants** have been enrolled at the following 75 sites:

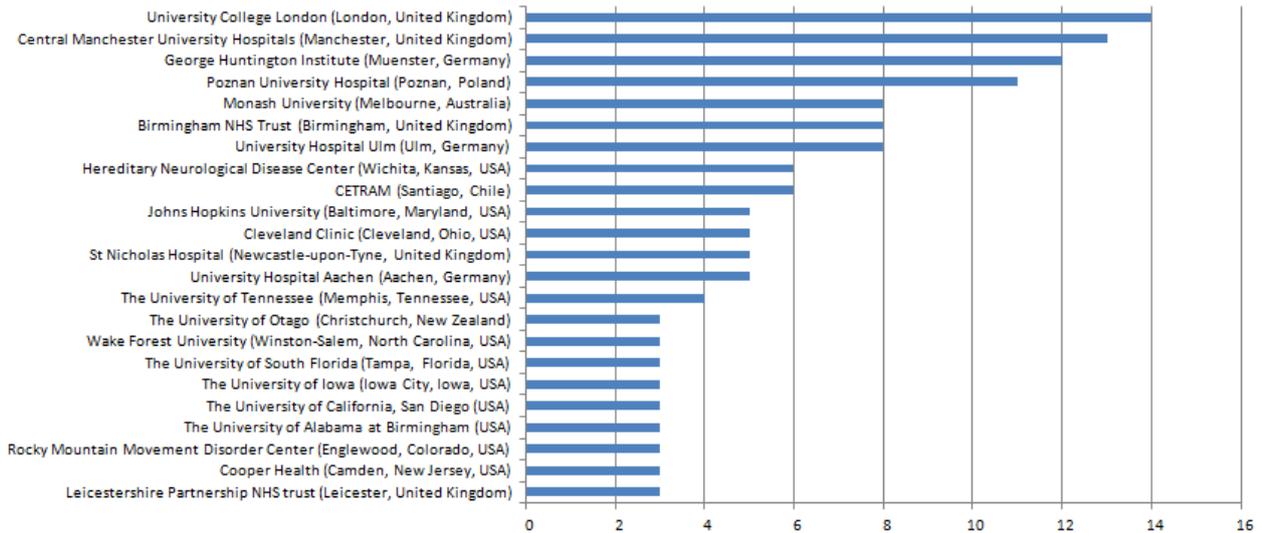


★ Top enrolling site is CHUM Hospital Notre Dame (Montreal, Quebec) with **174 participants** enrolled!

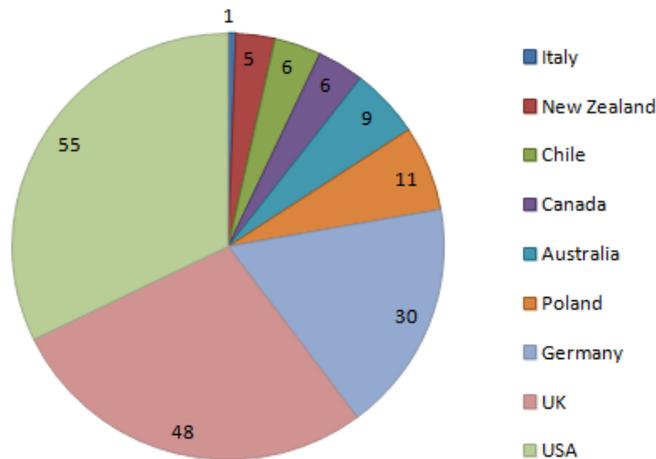
Top Enrolling Sites - Year to Date 2014



Top Enrolling Sites - Previous Month (June 2014)



Participants Enrolled in June 2014 (By Country)



Regional Updates

NORTH AMERICA:

- The following sites have enrolled the most participants to date:
 - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 174 participants.
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 169 participants.
 - Columbia University (New York City, USA) with 141 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 74 participants.
- The University of Otago at Christchurch is the leading enroller in New Zealand with 45 participants.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires, Argentina has enrolled 48 participants to date.
- CETRAM in Santiago, Chile has enrolled 18 participants to date.

EUROPE:

- This month we welcome Italy to Enroll-HD, with the first participant enrolled at the Naples site.
- Over 400 participants are currently enrolled at 19 active sites in the UK, Germany, Poland and Italy.
- Eight additional sites started the initiation process and will be activated by the end of July
- 51 of the European sites, which are due to participate in Enroll-HD in Europe, now have fully executed contracts.

Process Reminders and Updates

- All sites are reminded to regularly check their biokit inventory and always ensure they have at least 5 kits on hand. **BioRep has asked that sites place any kit re-orders by August 6th** to cover the entire month of August due to BioRep's holiday schedule.
- 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 any such reportable events until they have been closed. <https://studies.enroll-hd.org/manual/reporting>. Please monitor your reportable events until they are closed and make appropriate updates in the edc until the reportable event CRF can be made "final".
- 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 visit dashboard today!
- 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.

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

The Enroll-HD Study Team

