



October 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff,

An Enroll-HD progress update over the past month:

Recruitment update

- As of October 1st, a total of **3,336 participants** have been enrolled at **89** sites around the world. See below for further details regarding Enroll-HD recruitment.

Enroll! quarterly newsletter for participants, families, and site staff

- The Autumn 2014 issue of *Enroll!* is being 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). Please ensure that you follow all local rules and regulations that apply to your site 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.

Enroll-HD governance committee updates

- The Care Improvement Committee's most recent meeting took place on September 25th, 2014. The committee would like to remind sites that have not yet done so to please complete the site survey sent to all sites. If you have questions regarding the site survey, please contact Quintiles (EnrollHD@quintiles.com)
- The Data Safety Monitoring Committee (DSMC) met on September 9th, 2014 to review Enroll-HD genetic data and study safety. The DSMC recommended continuation of Enroll-HD with no changes to the protocol. A signed letter with the DSMC's recommendation has been sent to all sites. If you did not receive a copy of the letter, please contact Quintiles.
- An email was sent to all sites in North America from Scientific Planning Committee member Dr. Karen Anderson of Georgetown University regarding PBA-s training at the upcoming Huntington Study Group meeting. Sites are reminded to please send all feedback and questions to Dr. Anderson by October 17th. If you did not receive the e-mail, please contact Quintiles.

Data entry reminders

- If changes are required on your site's informed consent forms, please remember to send **all changes** to Cheryl Knipe at CHDI (Cheryl.Knipe@chdifoundation.org) for approval prior to submitting to your IRB.

- Please remember to complete ICD-10 coding for all comorbid conditions captured on the Comorbid CRF. A list of common ICD-10 codes can be found in the Enroll-HD Operations Manual (<https://studies.enroll-hd.org/manual/assessments/general>).
- Sites are reminded to complete the coding for all participant occupations captured on the Variable form using the SNOMED dictionary. If you are unsure of the process for coding occupation, please contact IT Support (ITSupport@enroll-hd.org).
- If a participant has a history of suicidal ideation or attempt, or has mentioned suicidal ideation or attempts during the current visit, the Columbia Suicide Severity Rating Scale (CSSRS) assessment should be completed. This assessment should not be completed for participants who have no history of suicidal ideation or suicide attempts.
- At each visit please remember to review and discuss with participants whether any reportable events have occurred since their last study visit.
- As a reminder, the Samples CRF in the EDC needs to be filled out and completed before blood samples are shipped. The notification in the Samples form is required to retrieve the samples from Customs in Italy. Failure to submit the Samples form will cause delays and could lead to issues with sample processing, necessitating a sample re-draw at the next Enroll-HD visit.
- When submitting the Samples form in the EDC, sites are reminded to not press the button multiple times. It may take up to 30 seconds for the form to refresh after you hit the enter button. Hitting the button multiple times can lead to errors in the interface between the EDC and the central lab in Italy.
- 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 subsequently approved for payment.** Several sites have large numbers of unsigned visits; please review your visit dashboard today!
- **It can take up to 8 weeks to receive payment after you have submitted your forms for remote data review and queries have been answered – please be sure to check your dashboard and query inbox often to ensure all queries have been answered.**
- 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 payments; it is important to familiarize yourself with these processes to ensure data and biosample integrity.

Financial updates

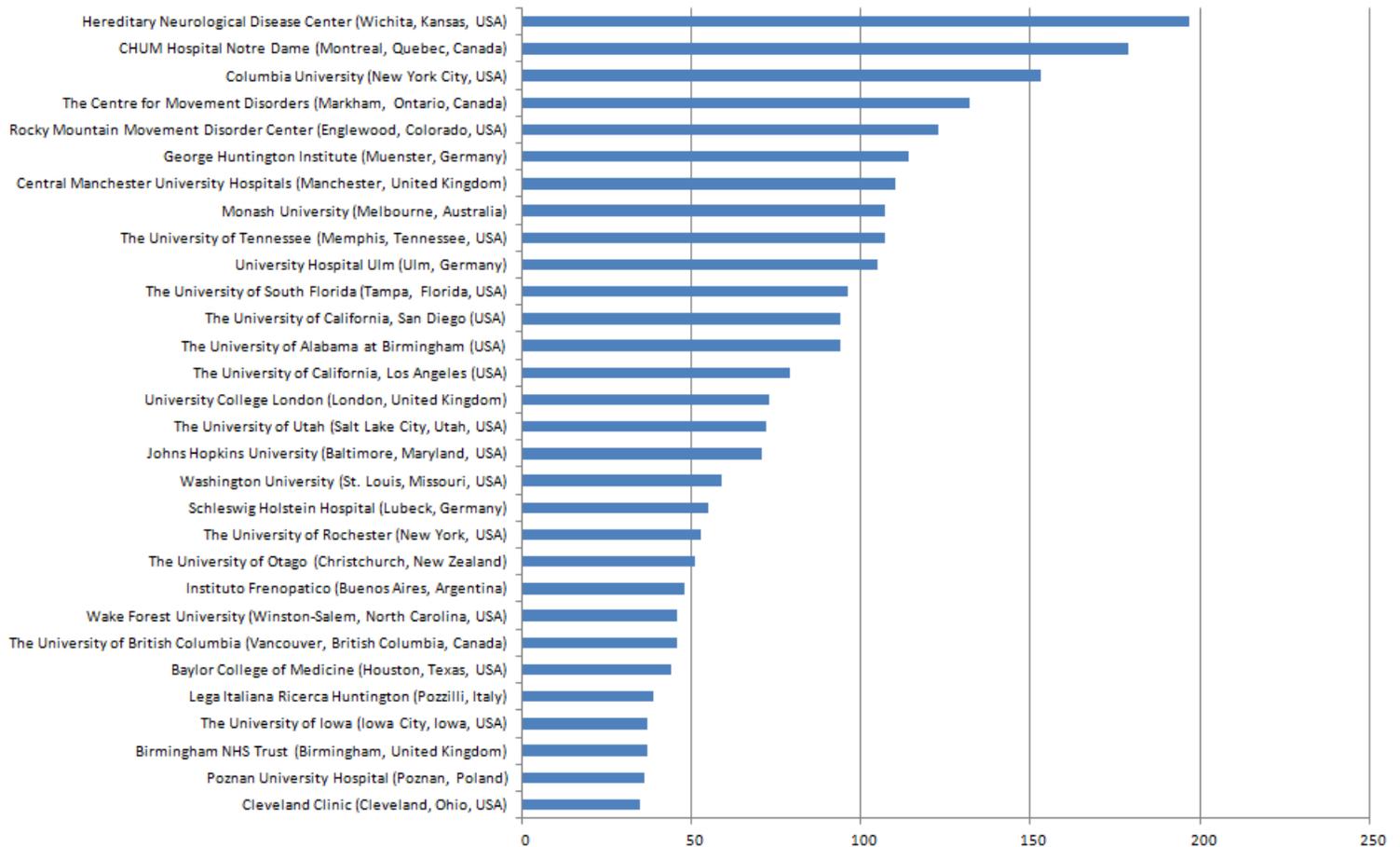
- Prior to enrolling participants, sites are required to set up their eClinical GPS account in Greenphire which will allow sites to be paid.
- All fees outlined in your site's contract, including start-up and IRB approval fees, must be requested through the Greenphire eClinical GPS system. **CHDI cannot 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>

Recruitment materials update

- Printed recruitment materials in different languages are now available for use at your site – for further details and/or high-quality print copies please contact Woody Kongsamut for English versions in North America/Australasia (woody.kongsamut@chdifoundation.org) and Katrin Barth for all language versions for active countries in Europe (katrin.barth@uni-ulm.de). These have been approved by Western IRB for use in the US and Canada and by local ERBs in Europe for all active countries, but you should check that all local IRB/ERB requirements have been met. All local

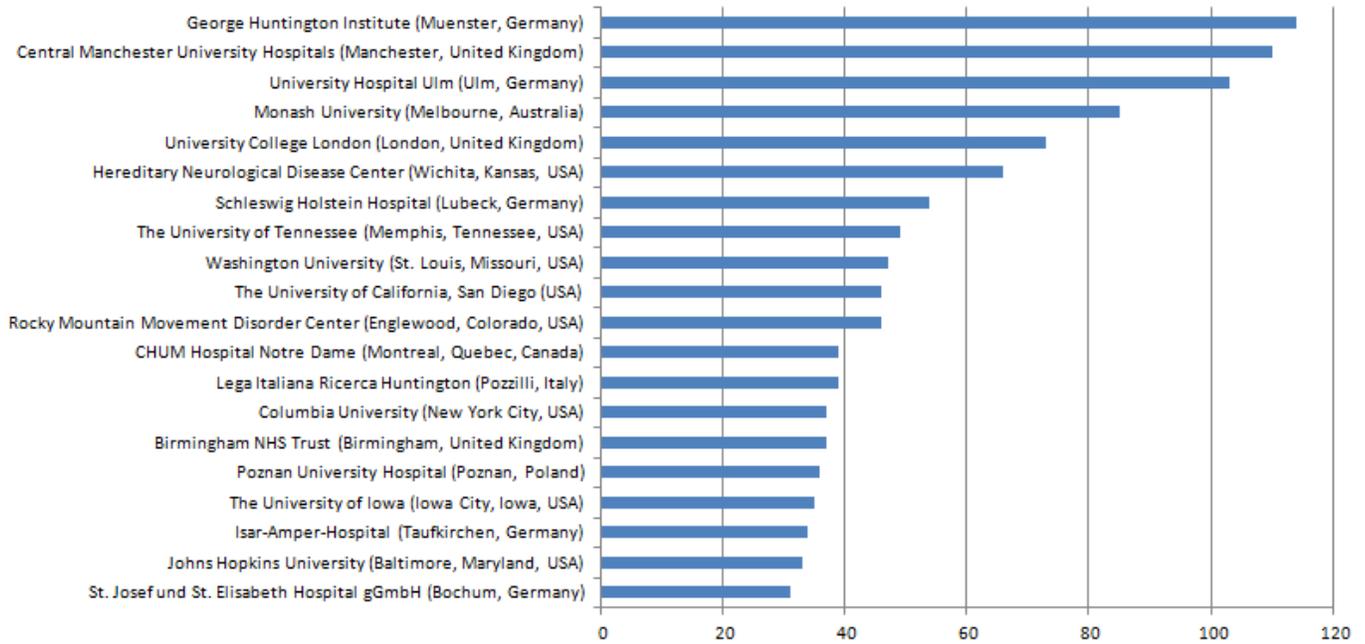
language translations of these materials are currently in process for European and Latin American sites and will be available soon.

Top Enrolling Sites - Since Study Start

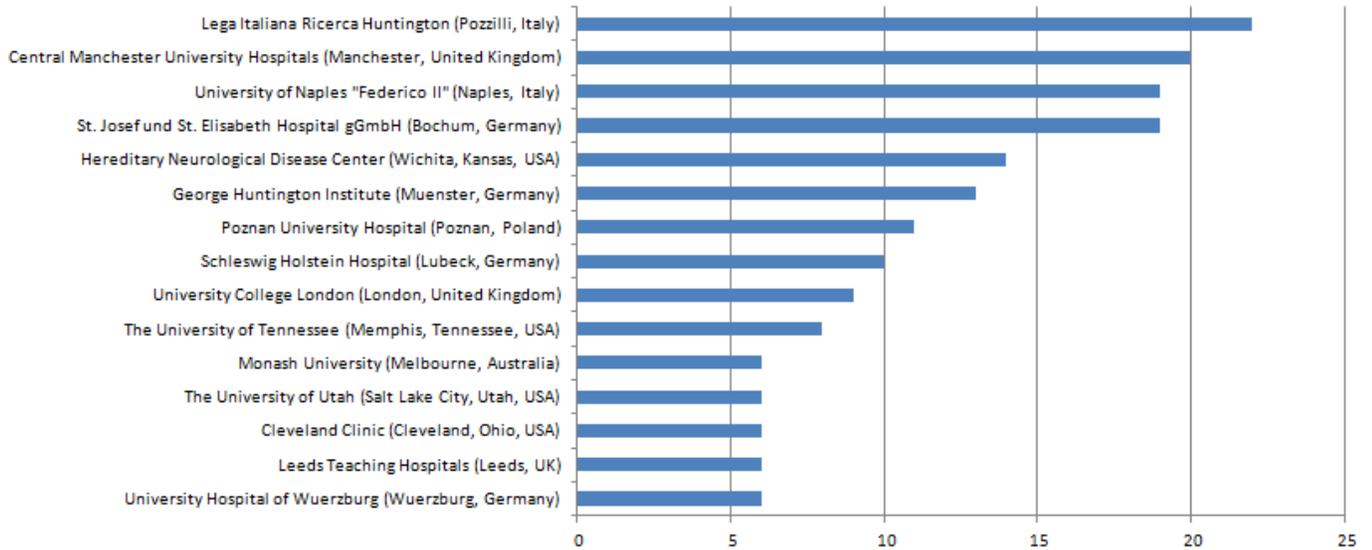


★ Top enrolling site is Hereditary Neurological Disease Center (Wichita, Kansas) with **197** participants enrolled!

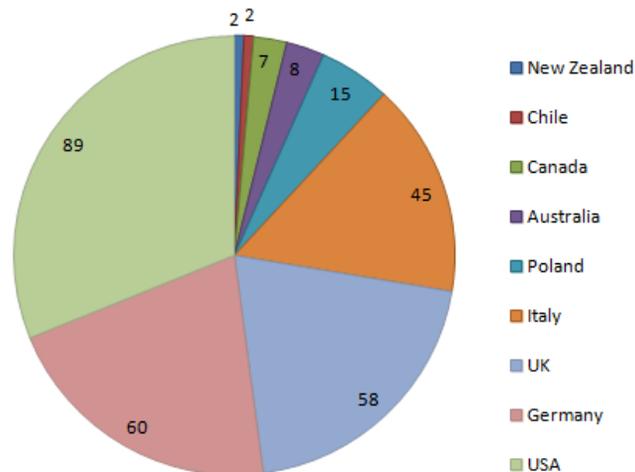
Top Enrolling Sites - Year to Date 2014



Top Enrolling Sites - Previous Month (September 2014)



Participants Enrolled in September 2014 (By Country)



Regional Startup and Enrollment Updates

NORTH AMERICA:

- The following sites have enrolled the most participants to date:
 - Hereditary Neurological Disease Centre (Wichita, Kansas, USA) with 197 participants.
 - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 179 participants.
 - Columbia University (New York City, USA) with 153 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 107 participants.
- The University of Otago at Christchurch is the leading enroller in New Zealand with 51 participants.

LATIN AMERICA:

- Instituto Frenopatico in Buenos Aires, Argentina has enrolled 48 participants to date.
- CETRAM in Santiago, Chile has enrolled 21 participants to date.

EUROPE:

- George Huntington Institute is the leading enroller in Europe with 114 participants enrolled to date.
- Over 850 participants are currently enrolled at 29 active sites in the UK, Germany, Poland and Italy.
- Nine additional sites started the initiation process and will be activated by the end of October.
- 70 of the European sites that will participate in Enroll-HD now have fully executed contracts.

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

The Enroll-HD Study Team

