



January 2015 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff,

An Enroll-HD progress update over the past month:

Recruitment update

- As of January 1st, a total of **4,405 participants** have been enrolled at **98 sites** around the world. See below for further details regarding Enroll-HD recruitment.

Biosample reminders

- As a reminder, the Samples CRF in the EDC needs to be completed and submitted 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 integrity, necessitating a sample re-draw at the next Enroll-HD visit.

Data entry reminders

- If a participant at your site misses their annual follow-up visit, please remember to create the Phone Contact visit in the EDC and fill out the Missed Visit form. Detailed instructions have been sent to all sites regarding the process for creating this special visit. If you need further assistance, please contact IT Support (ITSupport@enroll-hd.org). Follow-up and documentation of an out of window participant visit provides the Data Safety Monitoring Committee and the Medical Monitor additional information about these participants who are not returning and ensures due diligence from you at the site.
- 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. Once you have received IRB approval, please remember to forward the documentation and approved ICFs to Quintiles.
- 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>). This information is required in order to sign off on the page and the visit.
- 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.
- 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.
- When submitting the Samples form in the EDC, site staff are reminded to **press the button only once**. 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.**
- **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.

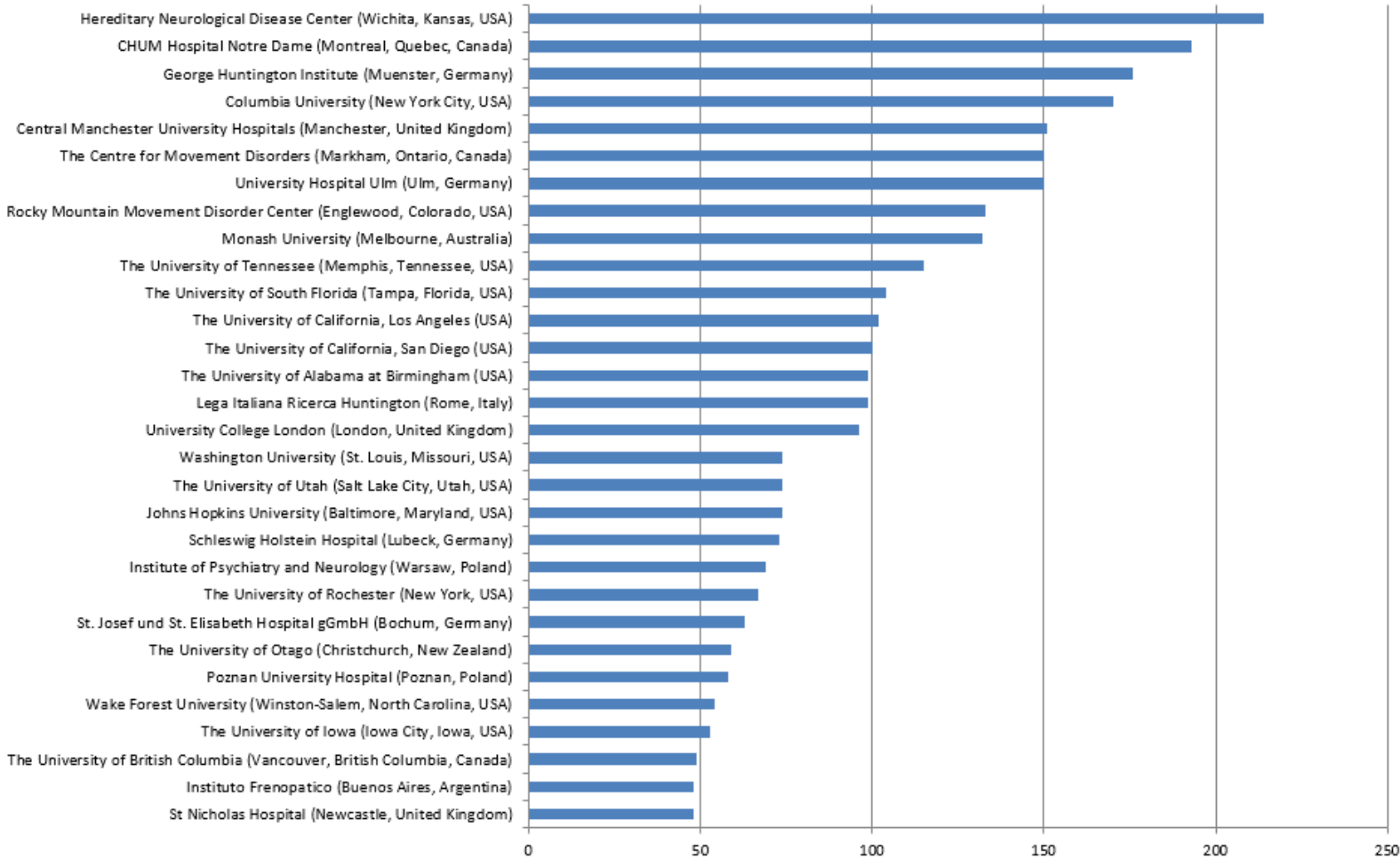
Financial reminders

- 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 eClinical GPS training materials if you are unsure of the process for submitting an invoice for fees <https://studies.enroll-hd.org/training/greenphire>

Recruitment materials reminder

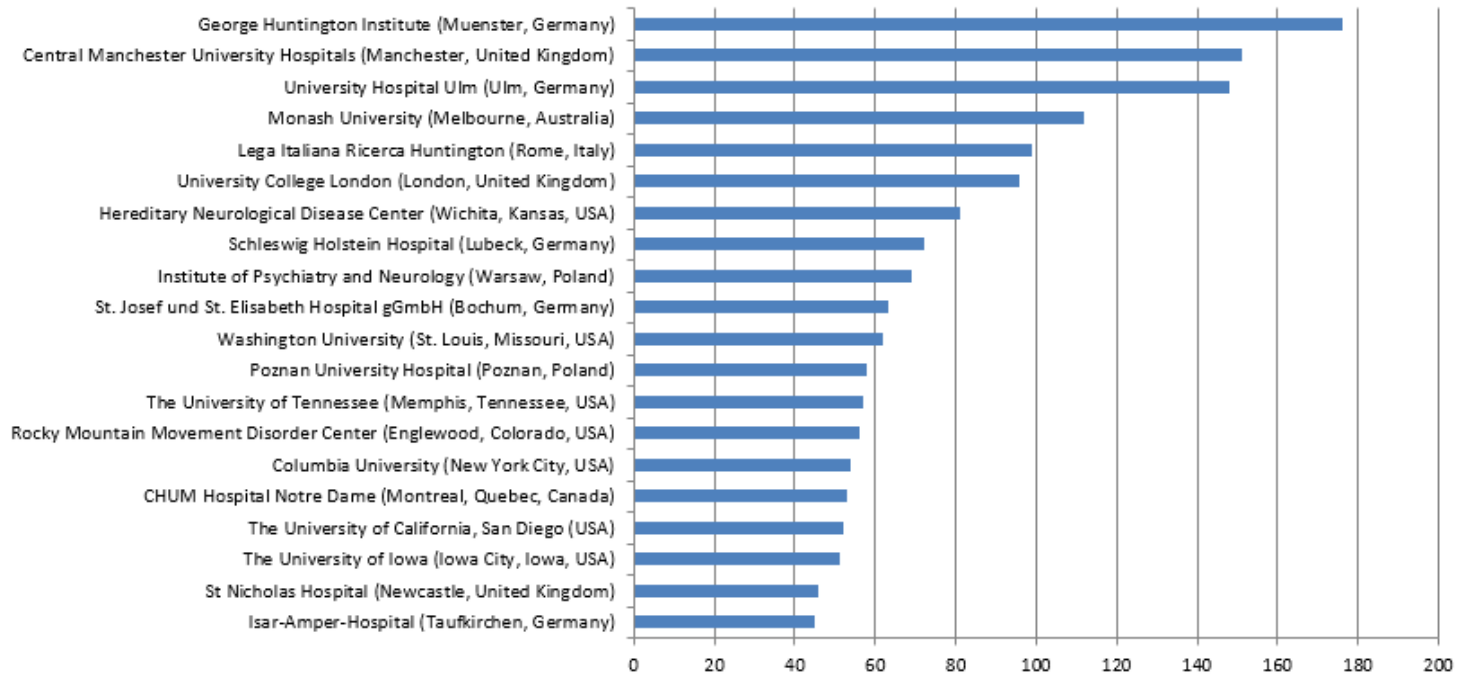
- Printed recruitment materials in different languages are now available for use at your site – for further details and/or high-quality print copies please contact Woody Kongsamut for English versions in North America/Australasia (woody.kongsamut@chdifoundation.org) and Katrin Barth for all language 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

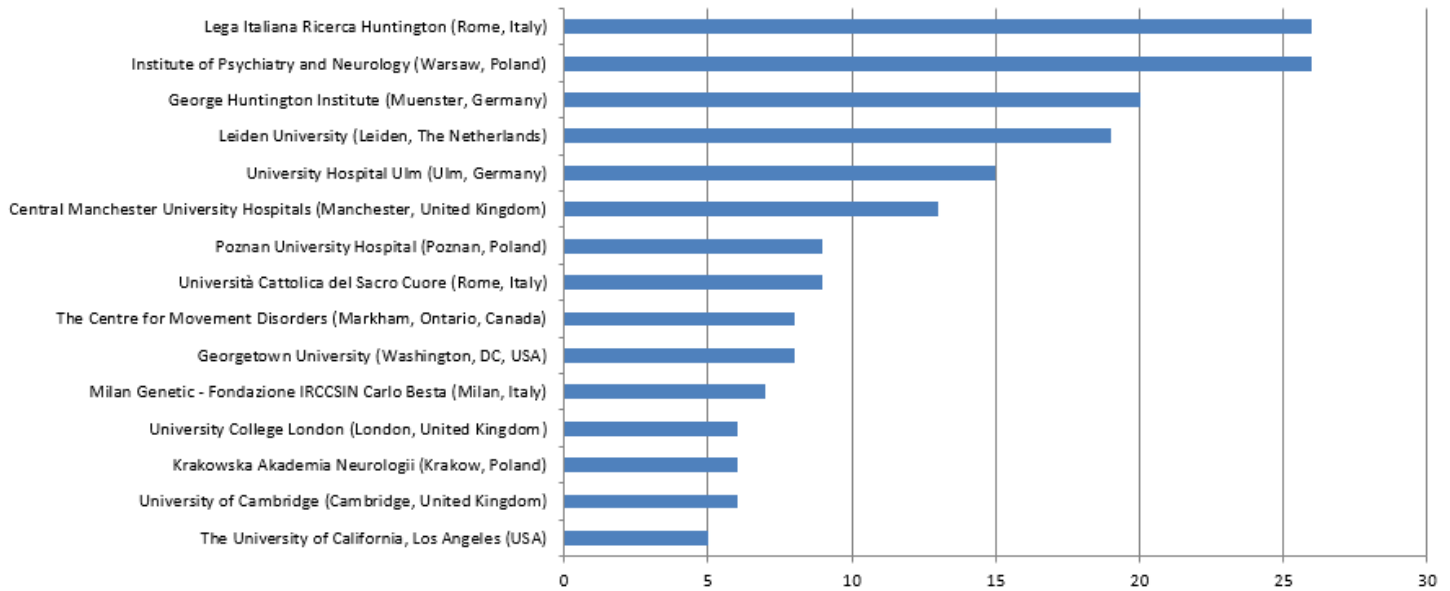


★ The top enrolling site is Hereditary Neurological Disease Center (Wichita, Kansas) with **214 participants** enrolled!

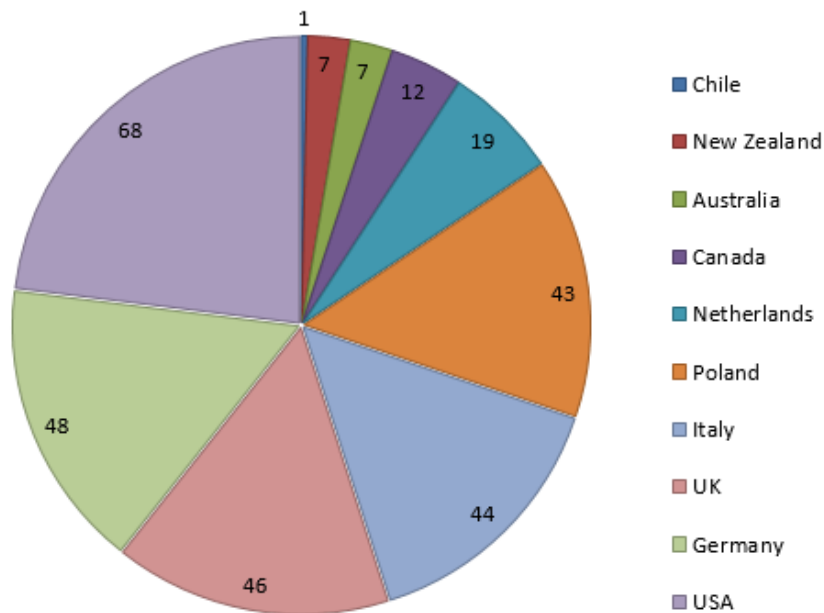
Top Enrolling Sites - Year to Date 2014



Top Enrolling Sites - Previous Month (December 2014)



Participants Enrolled in December 2014 (By Country)



Regional Startup and Enrollment Updates

NORTH AMERICA:

- 2,063 participants have been enrolled at 48 active sites.
- An additional 10 sites have begun the site start-up process.

AUSTRALIA & NEW ZEALAND:

- 250 participants have been enrolled at 4 active sites.
- Three additional sites have begun the start-up process, one site will be initiated in February 2015

LATIN AMERICA:

- 75 participants have been enrolled at 2 active sites.
- Start-up efforts continue at 10 sites in Argentina, Brazil, Chile, and Peru.

EUROPE:

- 1,565 participants have been enrolled at 38 sites in Germany, Poland, Italy, Netherlands, and the UK.
- 74 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

