



March 2015 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff,

An Enroll-HD progress update over the past month:

Recruitment update

- As of March 1st, a total of **5,081 participants** have been enrolled at **104** sites around the world. See below for further details regarding Enroll-HD recruitment.

Enroll-HD website update

- The **new Enroll-HD website is now live** – go to www.Enroll-HD.org to find lots of information about how Enroll-HD is structured and the people who keep it running, from site staff to participants to clinicians to researchers, plus links to lots of information sources. Please share the link with your site staff and participants and check back often for new updates and announcements.

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.
- 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.
- 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.

IRB/ERB 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. Once you have received IRB approval, please remember to forward the documentation and approved ICFs to Quintiles.
- For sites that are submitting for re-approval, if ICFs do not require changes you still need to send copies of your ICFs to Quintiles after they have been re-approved by your IRB.

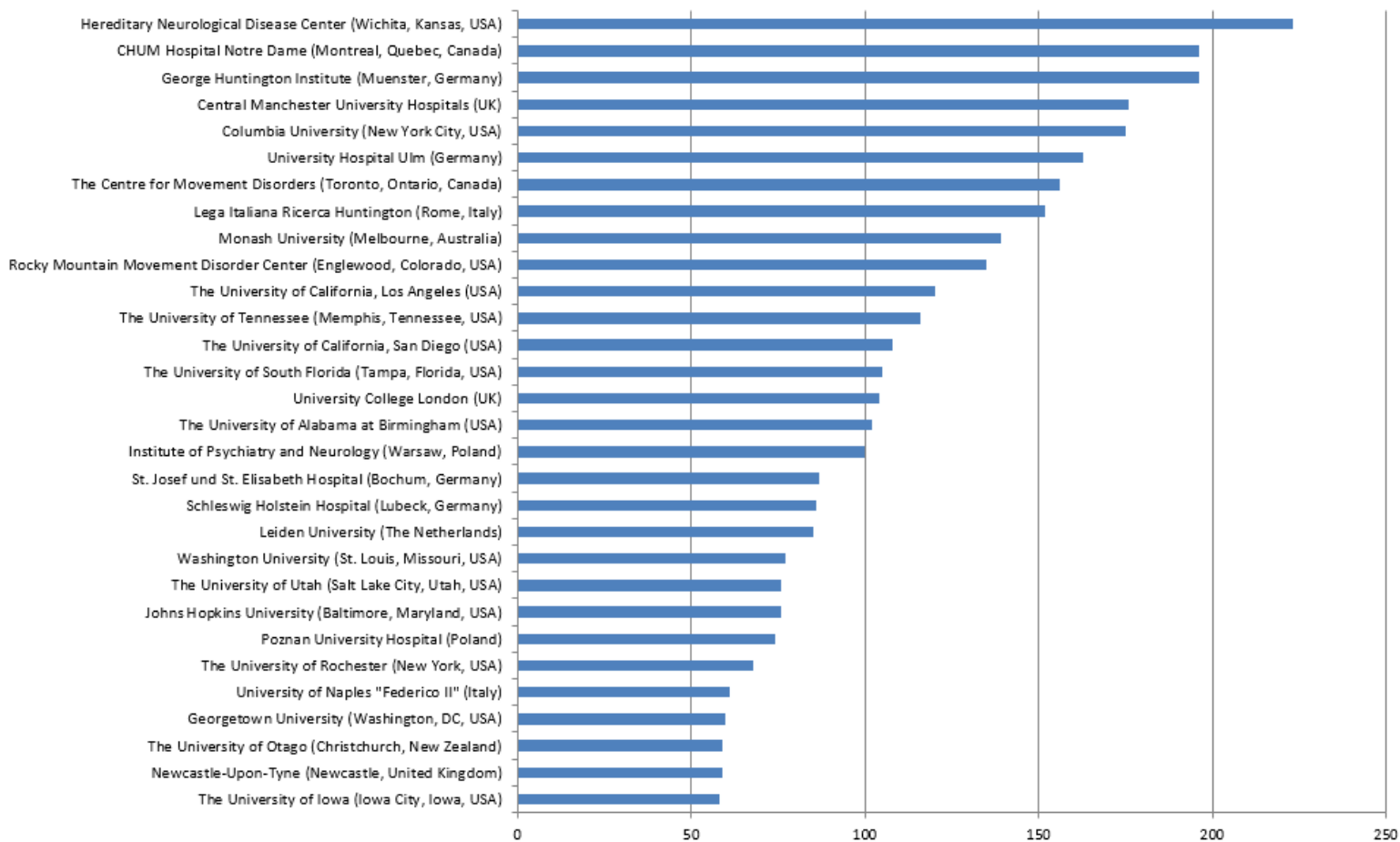
Financial reminders

- Prior to enrolling participants, **sites are required to set up their eClinical GPS account in Greenphire which will allow sites to be paid.** If your financial information is not entered into the eClinical GPS system, payment cannot be made to your site for data entry, start-up and IRB costs.
- 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

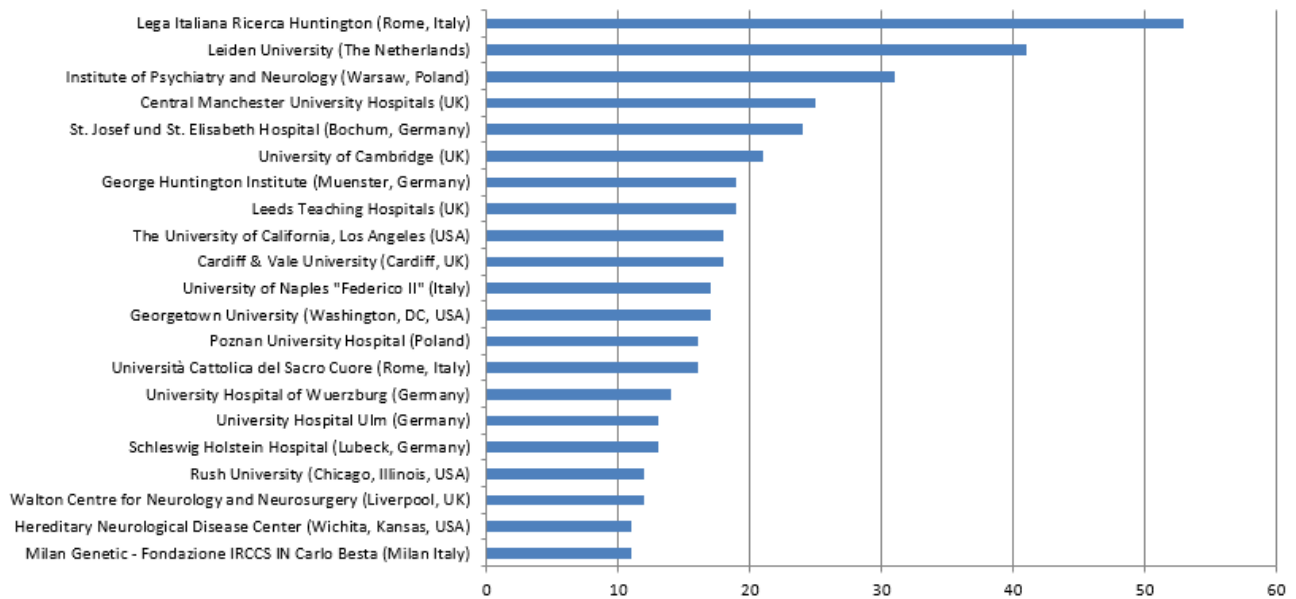
- Printed recruitment materials in different languages are now available for use at your site – for further details and/or high-quality print copies please contact Woody Kongsamut for English versions in North America/Australasia (woody.kongsamut@chdifoundation.org) and Katrin Barth for all language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

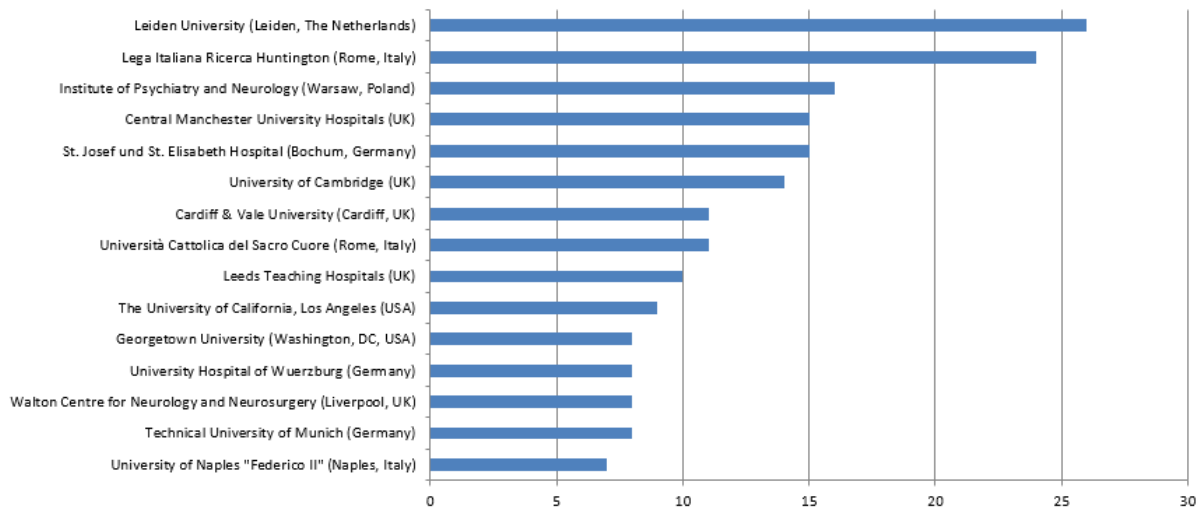


★ The top enrolling site is Hereditary Neurological Disease Center (Wichita, Kansas) with **223 participants** enrolled!

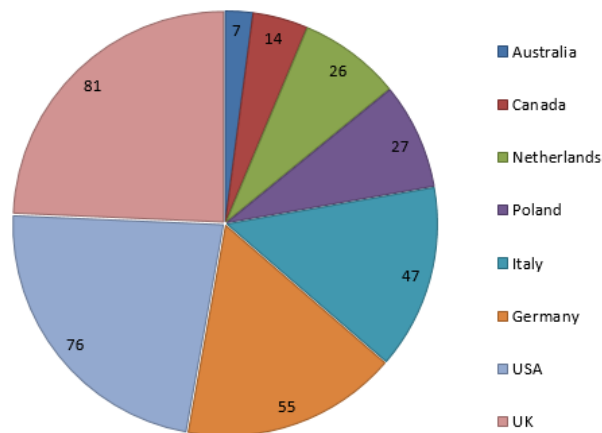
Top Enrolling Sites - Year to Date 2015



Top Enrolling Sites - Previous Month (February 2015)



Participants Enrolled in February 2015 (By Country)



Regional Startup and Enrollment Updates

NORTH AMERICA:

- 2,709 participants have been enrolled at 56 active sites.
- An additional 12 sites have begun the site start-up process.

AUSTRALIA & NEW ZEALAND:

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

LATIN AMERICA:

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

EUROPE:

- 2,086 participants have been enrolled at 43 sites in Germany, Poland, Italy, Netherlands, and the UK.
- 81 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

