September 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff,

An Enroll-HD progress update over the past month:

Recruitment update

- As of September 1st, a total of **3,050 participants** have been enrolled at 84 sites. See below for further details regarding Enroll-HD recruitment.

Enroll-HD participants taking part in other clinical studies/trials

- Enroll-HD is an observational study intended to be a platform that facilitates HD clinical research. Ideally, research participants should be in Enroll-HD in addition to any other studies or trials they may choose so that they are not lost to follow-up at the end of the co-study, but that is up to the individual and their family.

There are a number of important issues to consider regarding study co-participation, including participant burden, practice/training effects, and, if the co-study is at the same site and visits can be combined, the order that testing is administered and scored. To address these important issues we suggest that investigators consider the following options and implement appropriate strategies to minimize participant burden and maintain the integrity of all studies:

1. Site staff should be trained on a combined assessment battery whenever possible; in other words, when the co-study is at the same site as Enroll-HD, make sure that data fields required for both studies are captured at the same combined study visit and do not unnecessarily repeat assessments.
2. During their combined study visit, participants can first complete the study assessments for the clinical trial and then administer any additional Enroll-HD Core Assessments at the end of the study visit, keeping in mind to minimize burden on the participant.
3. For Enroll-HD participants who are also in a clinical trial at a different site, work with the participant to appropriately schedule visits. There is a +/- 3-month window for the Enroll-HD annual follow-up (so within 9 and 15 months of previous visit), so try to structure Enroll-HD and the co-study visits so that they take place at least 6 months apart, dependent on clinic availability and participant burden.

As Enroll-HD becomes the central clinical research platform for lots of studies and trials these issues may become more commonplace. The Enroll-HD Team will work with other studies/trials to address issues of co-participation and develop clear instructions for investigators and participants. If any issues arise regarding co-participation in any other studies or if you have any questions, please contact Joe Giuliano at joe.giuliano@chdifoundation.org.

Data entry reminders

- 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 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.

- 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 approved for payment.** Several sites have large numbers of unsigned visits; please review your visit dashboard today!

- 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.

Financial updates

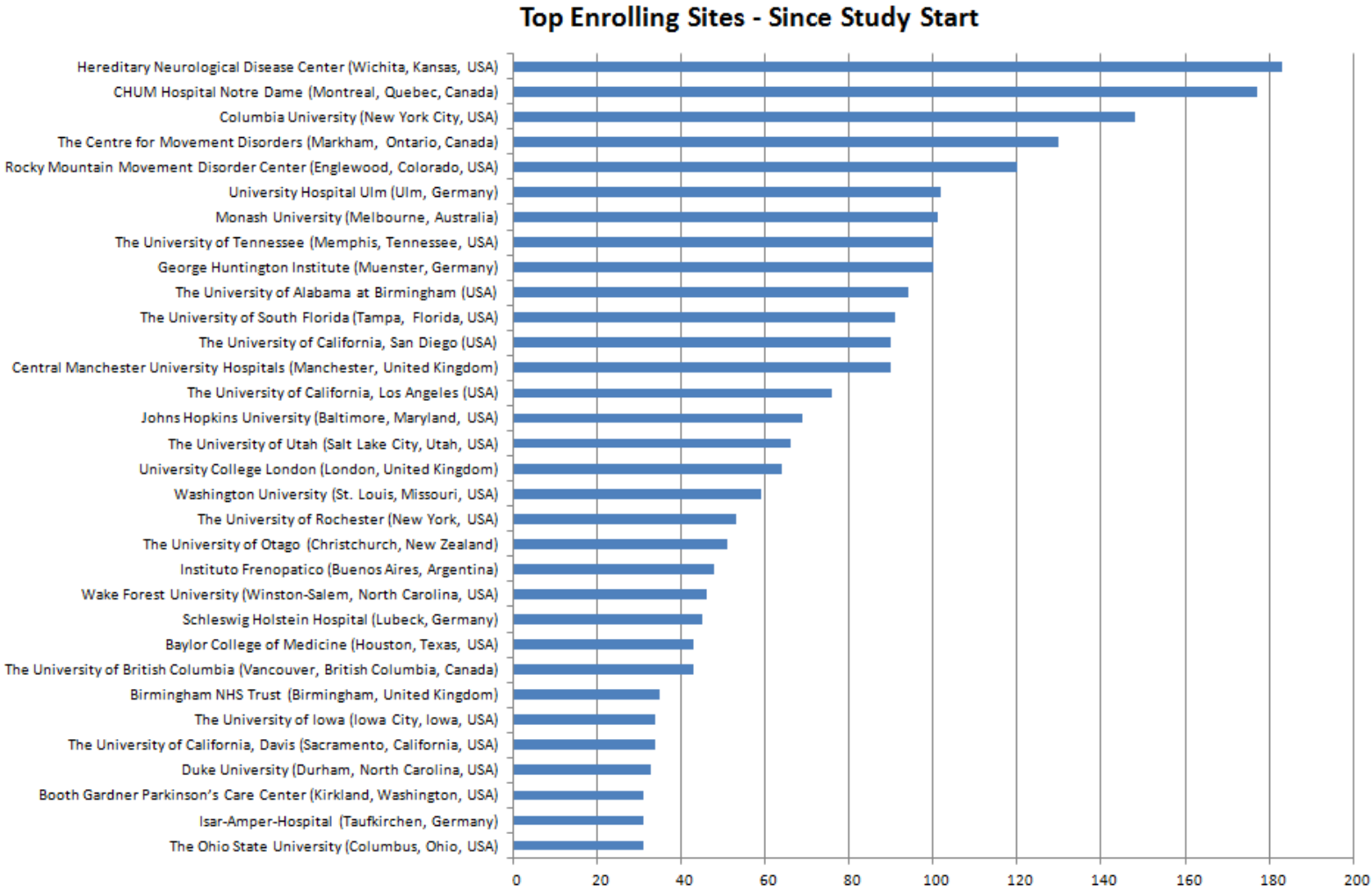
- Prior to enrolling participants, sites are required to set up their eClinical GPS account in Greenphire which will allow sites to be paid.

- 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

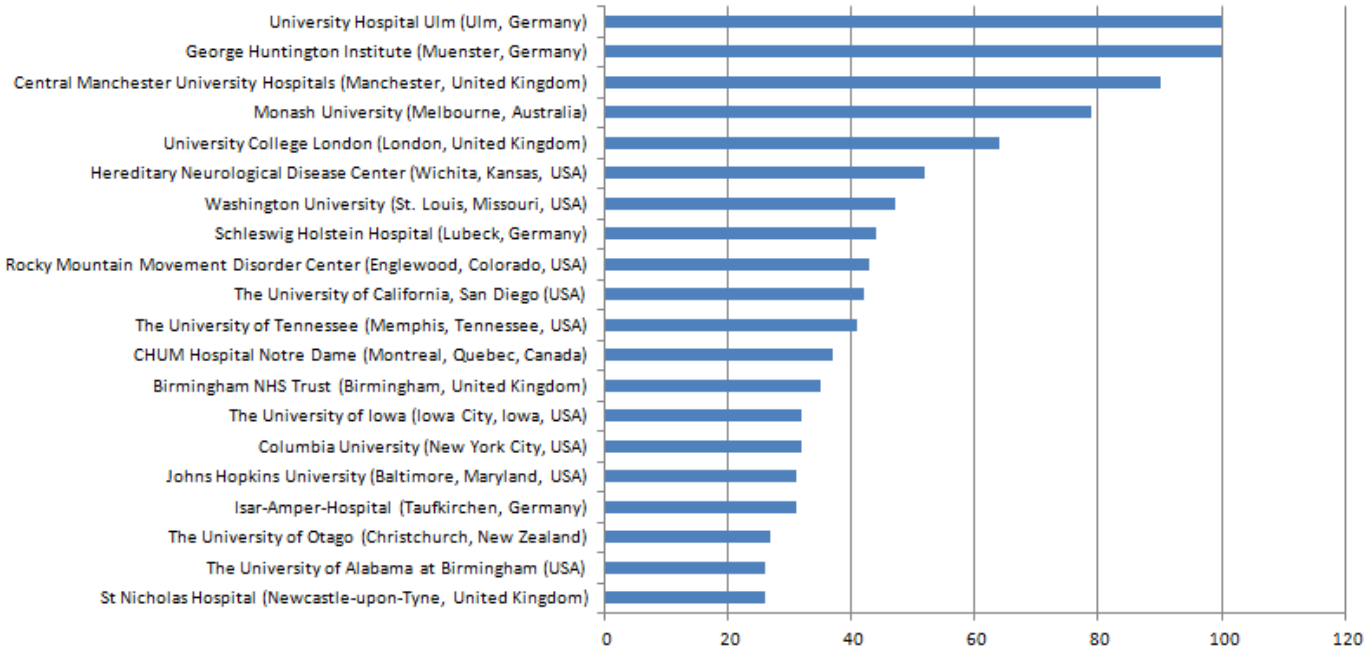
- Printed recruitment materials in different languages are now available for use at your site – for further details and/or high-quality print copies please contact Woody Kongsamut for English versions in North America/Australasia (woody.kongsamut@chdifoundation.org) and Katrin Barth for language versions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

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

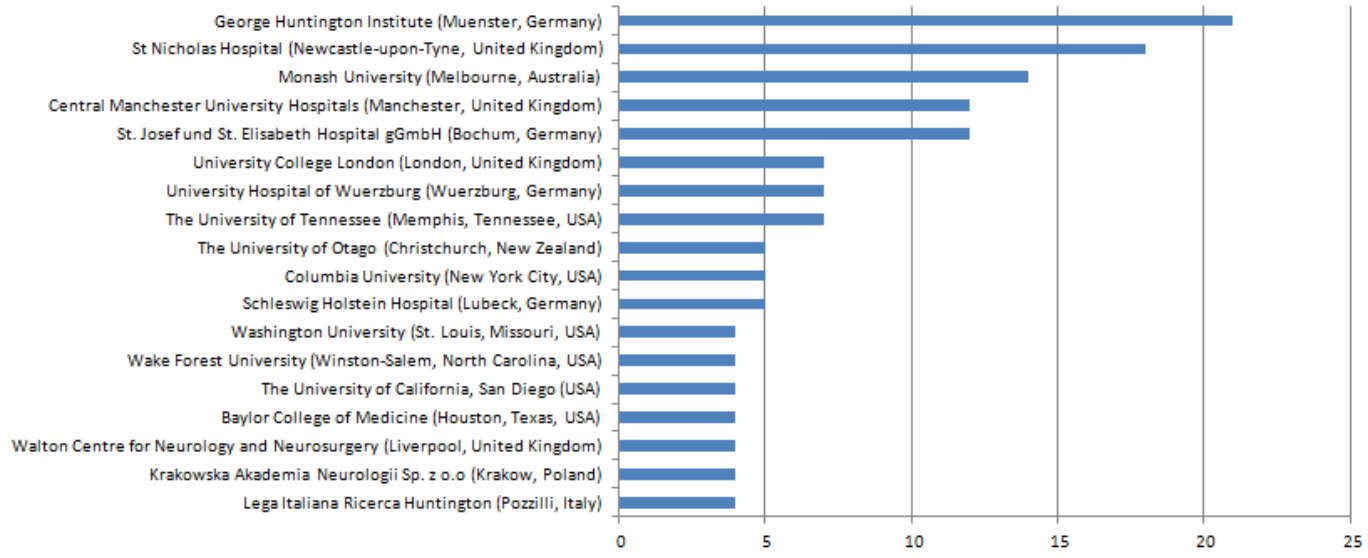


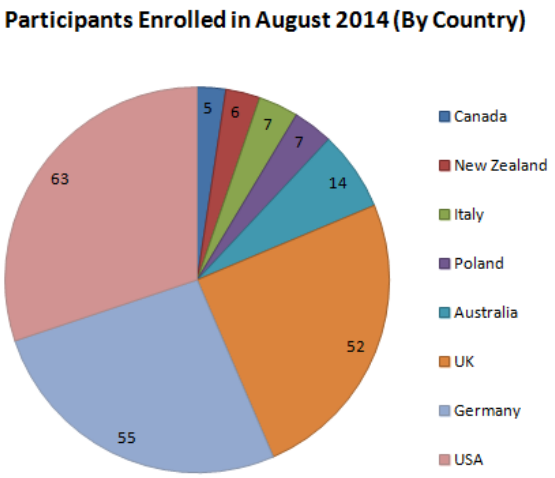
☆Top enrolling site is Hereditary Neurological Disease Center (Wichita, Kansas) with **183 participants** enrolled!

Top Enrolling Sites - Year to Date 2014



Top Enrolling Sites - Previous Month (August 2014)





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 183 participants.
  - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 177 participants.
  - Columbia University (New York City, USA) with 143 participants.

AUSTRALIA & NEW ZEALAND:

- Monash University is the leading enroller in Australia with 101 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 19 participants to date.

EUROPE:

- University Hospital of Ulm is the leading enroller in Europe with 102 participants enrolled to date.
- Over 670 participants are currently enrolled at 26 active sites in the UK, Germany, Poland and Italy.
- Nine additional sites started the initiation process and will be activated by the end of September
- 64 of the European sites, which are 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