July 2014 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

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

\begin{itemize}
\item CHUM Hospital Notre Dame (Montreal, Quebec, Canada)
\item Hereditary Neurological Disease Center (Wichita, Kansas, USA)
\item Columbia University (New York City, USA)
\item The Centre for Movement Disorders (Barrie, Ontario, Canada)
\item Rocky Mountain Movement Disorder Center (Englewood, Colorado, USA)
\item The University of Tennessee (Memphis, Tennessee, USA)
\item University Hospital Ulm (Ulm, Germany)
\item The University of Alabama at Birmingham (USA)
\item The University of South Florida (Tampa, Florida, USA)
\item The University of California, San Diego (USA)
\item Monash University (Melbourne, Australia)
\item The University of California, Los Angeles (USA)
\item Central Manchester University Hospitals (Manchester, United Kingdom)
\item The University of Utah (Salt Lake City, Utah, USA)
\item Johns Hopkins University (Baltimore, Maryland, USA)
\item George Huntington Institute (Wuerzburg, Germany)
\item Washington University (St. Louis, Missouri, USA)
\item Instituto Pampa (Buenos Aires, Argentina)
\item The University of Rochester (New York, USA)
\item University College London (London, United Kingdom)
\item The University of Otago (Christchurch, New Zealand)
\item Wake Forest University (Winston-Salem, North Carolina, USA)
\item The University of British Columbia (Vancouver, British Columbia, Canada)
\item Baylor College of Medicine (Houston, Texas, USA)
\item The University of California, Davis (Sacramento, California, USA)
\item Duke University (Durham, North Carolina, USA)
\item The Ohio State University (Columbus, Ohio, USA)
\item Albany Medical College (New York, USA)
\item Booth Gardner Parkinson’s Care Center (Kirkland, Washington, USA)
\item The University of Iowa (Iowa City, Iowa, USA)
\end{itemize}

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\item Top enrolling site is CHUM Hospital Notre Dame (Montreal, Quebec) with 174 participants enrolled!
\end{itemize}
## Top Enrolling Sites - Year to Date 2014

1. University Hospital Ulm (Ulm, Germany)
2. Central Manchester University Hospitals (Manchester, United Kingdom)
3. George Huntington Institute (Munster, Germany)
4. Monash University (Melbourne, Australia)
5. University College London (London, United Kingdom)
6. Rocky Mountain Movement Disorder Center (Englewood, Colorado, USA)
7. Washington University St. Louis, Missouri, USA
8. Hereditary Neurological Disease Center (Wichita, Kansas, USA)
9. CHUM Hospital Notre Dame (Montreal, Quebec, Canada)
10. The University of Tennessee (Memphis, Tennessee, USA)
11. The University of Iowa (Iowa City, Iowa, USA)
12. Johns Hopkins University (Baltimore, Maryland, USA)
13. Columbia University (New York City, USA)
14. Schilling Hospital (Ludwigshafen, Germany)
15. Isar-Ampel Hospital (Taufkirchen, Germany)
16. The University of Otago (Christchurch, New Zealand)
17. Birmingham NHS Trust (Birmingham, United Kingdom)
18. The University of Alabama at Birmingham (USA)
19. The University of Washington (Seattle, Washington, USA)

## Top Enrolling Sites - Previous Month (June 2014)

1. University College London (London, United Kingdom)
2. Central Manchester University Hospitals (Manchester, United Kingdom)
3. George Huntington Institute (Munster, Germany)
4. Pomeranian University Hospital (Poznan, Poland)
5. Monash University (Melbourne, Australia)
6. Birmingham NHS Trust (Birmingham, United Kingdom)
7. University Hospital Ulm (Ulm, Germany)
8. Hereditary Neurological Disease Center (Wichita, Kansas, USA)
9. CETRAM (Buenos Aires, Argentina)
10. Johns Hopkins University (Baltimore, Maryland, USA)
11. Mayo Clinic (Scottsdale, Arizona, USA)
12. St. James University Hospital (Leeds, United Kingdom)
13. University Hospital Aachen (Aachen, Germany)
14. The University of Otago (Christchurch, New Zealand)
15. Wake Forest University (Winston-Salem, North Carolina, USA)
16. The University of South Florida (Tampa, Florida, USA)
17. The University of Iowa (Iowa City, Iowa, USA)
18. The University of California, San Diego (USA)
19. The University of Alabama at Birmingham (USA)
20. Rocky Mountain Movement Disorder Center (Englewood, Colorado, USA)
21. Cooper Health (Camden, New Jersey, USA)
22. Leicestershire Partnership NHS Trust (Leicester, United Kingdom)

## Participants Enrolled in June 2014 (By Country)

- **Italy**: 1
- **New Zealand**: 5
- **Chile**: 6
- **Canada**: 6
- **Australia**: 9
- **Poland**: 11
- **Germany**: 30
- **UK**: 48
- **USA**: 55
Regional Updates

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

LATIN AMERICA:
  o Instituto Frenopatico in Buenos Aires, Argentina has enrolled 48 participants to date.
  o CETRAM in Santiago, Chile has enrolled 18 participants to date.

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

Process Reminders and Updates

  o 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.

  o 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](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”.

  o 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!

  o 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](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