

From: [EnrollHD](#)
To: [EnrollHD](#)
Subject: Enroll-HD June Bulletin
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June 2013 Monthly News Bulletin

Dear Enroll-HD Investigators and Site Staff:

An Enroll-HD progress update over the past month:

- As of June 7th, a total of **706 participants** have been enrolled at the following 30 sites:
 - Albany Medical College (New York, USA)
 - Baylor College of Medicine (Houston, Texas, USA)
 - Booth Gardner Parkinson's Care Center (Kirkland, Washington, USA)
 - Boston University (Massachusetts, USA)
 - The Centre for Movement Disorders (Markham, Ontario, Canada)
 - CHUM Hospital Notre Dame (Montreal, Quebec, Canada)
 - Colorado Neurological Institute (Englewood, Colorado, USA)
 - Columbia University (New York City, USA)
 - Duke University (Durham, North Carolina, USA)
 - Emory University (Atlanta, Georgia, USA)
 - Hennepin County Medical Center (Minneapolis, Minnesota, USA)
 - Hereditary Neurological Disease Center (Wichita, Kansas, USA)
 - Instituto Frenopatico (Buenos Aires, Argentina)
 - Johns Hopkins University (Baltimore, Maryland, USA)
 - The Ohio State University (Columbus, Ohio, USA)
 - The University of Alabama at Birmingham (USA)
 - The University of Alberta (Edmonton, Alberta, Canada)
 - The University of Alberta Hospital in Edmonton (Canada)
 - The University of British Columbia (Vancouver, British Columbia, Canada)
 - The University of Calgary (Alberta, Canada)
 - The University of California, Davis (Sacramento, California, USA)
 - The University of California, Los Angeles (USA)
 - The University of California, San Francisco (USA)
 - The University of Illinois College of Medicine at Rockford (Illinois, USA)

- The University of Maryland (Baltimore, Maryland, USA)
- The University of Rochester (New York, USA)
- The University of South Florida (Tampa, Florida, USA)
- The University of Tennessee Health Science Center (Memphis, Tennessee, USA)
- The University of Utah (Salt Lake City, Utah, USA)
- Wake Forest University School of Medicine (Winston-Salem, North Carolina, USA)

Top enrolling site is CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 109 participants enrolled!

- o The following sites have completed their two-part site initiation:
 - Cleveland Clinic (Cleveland, Ohio, USA)
 - Cleveland Clinic – Lou Ruvo Center for Brain Health (Las Vegas, Nevada, USA)
 - Kansas University Medical Center (Kansas City, Kansas, USA)
 - Rush University (Chicago, Illinois, USA)
 - The University of California, San Diego (USA)
 - The University of Vermont (Burlington, Vermont, USA)

Process Reminders and Updates

- o The Data Safety Monitoring Committee (DSMC) met in Paris, France on May 15th to review and approve the DSMC charter, CAG Discrepancy Reporting, Reportable Event Process and the SOP for Harm to Self or Others. The committee also reviewed reportable events (of which there was only one). The approved DSMC Charter will be available on the website. We would like to thank Arvid Heidberg, MD (Chair), Sandrine Andrieu, MD, PhD, Ken Cheung, PhD, Susan Fox, MD and Daniel Weintraub, MD for all their work over the past months setting up the DSMC processes.

Regional Updates

NORTH AMERICA:

- o The following sites have enrolled the most participants to date:
 - CHUM Hospital Notre Dame (Montreal, Quebec, Canada) with 109 participants
 - Columbia University (New York City, USA) with 87 participants
 - The Centre for Movement Disorders (Markham, Ontario, Canada) with 82 participants
- o As previously reported, the NIH has issued Enroll-HD a Certificate of Confidentiality (CoC). All informed consent forms (ICFs) for North American sites must be updated to include NIH-specified CoC language. If your ICFs are approved without CoC language, they must be amended to reflect this change. Amanda Klock at CHDI (Amanda.klock@chdifoundation.org) will help facilitate this process. Please note, the CoC language is required by the NIH and cannot be changed. If you have not amended your ICFs yet, your Quintiles/Outcome site management specialist will be contacting you in the coming week.

AUSTRALIA & NEW ZEALAND:

- Four of the five sites in Australia have submitted the study protocol and informed consents to their Ethics Committee.
- The study protocol was submitted to the Ethics Committee in New Zealand on June 3rd.
- An Investigator Meeting is scheduled for June 13th and 14th in Melbourne, Australia for the Australian and New Zealand site personnel.

LATIN AMERICA:

- The 1st participant was enrolled in Latin America at the Instituto Frenopatico in Buenos Aires, Argentina on May 30th.
- 1 of the 2 sites in Chile has submitted the study protocol to the Ethics Committee in May. The remaining site is expected to submit to the Ethics Committee in June.
- The regulatory submissions in Peru and Brazil are anticipated by the end of June.

EUROPE:

- The vast majority of starter packs and site contracts have been sent to the sites in the countries that began regulatory submissions in the 1st quarter (Belgium, Denmark, Germany, Ireland, Italy, Netherlands and the United Kingdom). Four site contracts have been executed.
- Regulatory submissions have been completed for Germany, Italy and Spain. The sites in France, Spain and Poland, scheduled for regulatory submission in the 2nd quarter, have started to receive their starter packets. The contracts will be distributed to these sites in June.

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

The Enroll-HD Study Team

