



Enroll-HD - A Prospective Registry Study in a Global HD Cohort

New York, NY, November 19 2010; CHDI Foundation, Inc., today announced the start of a planning and consultation process to combine the existing REGISTRY and COHORT longitudinal clinical observation studies of Huntington's disease (HD) into a worldwide initiative called Enroll-HD. The new initiative is the next phase of the CHDI-sponsored REGISTRY and COHORT studies that currently operate in Europe and North America/Australia, respectively, and will build on their many successes and strengths. Enroll-HD will launch on July 1st 2011 and will also include sites from the nascent Latin American network, Red Latinamericana de Huntington (RLAH), as well as facilitate participation of specific sites in other countries such as Singapore, South Africa, and South Korea.

The active collaboration of HD patients, individuals born at risk for HD (regardless of whether they have been tested genetically), and their families is greatly valued and vital to the development of HD therapeutics. All research participants and clinical sites currently taking part in the REGISTRY and COHORT studies are welcome and encouraged to continue into the new unified Enroll-HD initiative. It is anticipated that the large majority of research participants will see little difference at their clinical visits as the REGISTRY and COHORT studies transition into Enroll-HD.

The overarching objective of Enroll-HD is to accelerate the development of therapies for HD by

- compiling uniform clinical data and biological samples critical to better understanding the natural history of HD,
- building an even more comprehensive database of HD information—including biologic samples—that will be available for use by any HD investigator worldwide,
- making available larger datasets from a greater number of research participants, thereby enhancing the power of data-mining and computational biology projects,
- serving as a platform to facilitate clinical sub-studies and the development and validation of novel assessment tools for HD, and
- expediting recruitment into global clinical trials of candidate therapeutics in the coming years.

Professor Ira Shoulson, Chair of the Huntington Study Group (HSG) and Principal Investigator of the COHORT study, said "COHORT has benefited considerably from the talents, experience, and efforts of the participating HSG sites and investigators. Amalgamating COHORT, REGISTRY, and

the Latin American effort into a broader, unified study will have great research potential for informing us about the nature of HD and for developing treatments that make a difference for HD. The leadership of COHORT and the HSG are committed to cooperative participation in the planning and conduct of Enroll-HD.”

The Principal Investigator of the global study will be Professor G. Bernhard Landwehrmeyer of the University of Ulm, Germany, who currently serves as a co-principal investigator of the REGISTRY study and is Chair of the European Huntington’s Disease Network (EHDN). “It’s a natural progression to combine the successful HD observational clinical studies into one worldwide effort that will harness the power of greater numbers of research participants,” said Landwehrmeyer. “The unified Enroll-HD initiative will make each individual participant’s contribution more meaningful by helping us to develop and validate novel assessment tools for HD and to conduct exploratory sub-studies. It will also accelerate the path to effective treatments for HD by providing a means for sites to more efficiently recruit volunteers for future clinical trials.”

Rodrigo Osorio, President of RLAH, said “The Red Latinamericana de Huntington is very excited to become a part of the global Enroll-HD initiative and collaborate in this way with the international HD research community to better understand and treat Huntington’s disease.”

A planning process will now begin in which all stakeholders within the global HD community—clinicians, research participants, families, investigators, advocates—will be invited to participate. For future information updates on Enroll-HD, please send an email to Info@EnrollHD.org; email updates of progress and plans will be sent out periodically and a dedicated website is planned. See also the FAQs below.

About CHDI Foundation, Inc.

CHDI Foundation, Inc. is a privately-funded, not-for-profit, virtual biotech company that is exclusively dedicated to rapidly discovering and developing therapies that slow the progression of Huntington’s disease (HD). As a collaborative enabler, CHDI seeks to bring the right partners together to identify and address critical scientific issues and move drug candidates to clinical evaluation as quickly as possible. Our scientists work closely with a network of more than 600 researchers in academic and industrial laboratories around the world in the pursuit of these novel therapies, providing project management to ensure that our common goals remain in focus. More information about CHDI can be found at www.chdifoundation.org.

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Frequently Asked Questions about Enroll-HD

By Research Participants:

1. What will happen between now and July 1st 2011 – do I still attend my REGISTRY/COHORT visit?

Yes. Please attend your scheduled REGISTRY or COHORT visit. Your continued participation in HD clinical research is important to finding treatments and we greatly appreciate your effort!

2. Will I still see the same doctor for my study visit?

Yes in all likelihood. All REGISTRY and COHORT study sites are most welcome to continue to participate in Enroll-HD. If for some reason the study site you are attending does not continue in the study every effort will be made to facilitate your participation at another convenient study site.

3. What will happen to my samples and the information collected about me?

They will continue to be available to advance HD research. Your samples will continue to be safely stored in the same biorepositories where they are now kept and all information about you will be securely stored in accordance with applicable local laws and regulations regarding the protection of your privacy.

4. Can my other family members still take part in the study?

Of course, we hope they do! No need to wait until next July to start. Anyone who enrolls in REGISTRY or COHORT before then will be automatically welcome to continue in Enroll-HD.

5. If my current site does not participate in Enroll-HD can I go to another site?

Yes. During the transition period you will be given information on exactly how you can access a participating site should your current site choose not to participate.

By Investigators:

1. As an investigator in REGISTRY or COHORT, what do I do from now until July 2011?

You should continue to see your participants in COHORT and REGISTRY without interruption. We will communicate on a regular basis with all the COHORT and REGISTRY sites to outline the steps needed to make the transition to Enroll-HD. We want this to be a smooth transition for you and your study participants.

2. Will I need to get IRB/ERB approval for Enroll-HD? How about informed consent?

It is intended that Enroll-HD- will incorporate the best of COHORT and REGISTRY, which will result in a new protocol and informed consent. This means that reapproval by your IRB/ERB will be necessary and research participants will need to re-consent at their first Enroll-HD study visit. Every effort will be made by the transition team to make this as simple as possible for the site investigator and coordinator.

3. Will I have to re-negotiate my contract? Will I receive the same reimbursement?

Yes, in most cases a new contract will be necessary. Because there will be changes to the study and the administration of the contracts, new contracts will need to be signed. We do not anticipate major changes to the site budgets or payments. There may be some changes in how payments are broken down by the actual work performed at each visit – this will provide for more flexibility and consistency across all the regions.

4. I submitted a data/sample request to COHORT/REGISTRY – what will happen to my request?

Your request will be processed according to the steps outlined for the COHORT and REGISTRY studies. Eventually, a new process for handling the requests for samples and data access will be implemented for Enroll-HD. The new process will take the best practices from COHORT and REGISTRY to ensure the data and samples collected in Enroll-HD are put to their best scientific use and there is the same rigorous ethical scrutiny.

5. How can I get involved in the planning process for Enroll-HD?

To facilitate the combination of REGISTRY and COHORT studies, working groups will be formed to address the following topics: protocol development, ethics/regulatory, site management, participant/site recruitment, data management, bio-repositories, data and sample sharing, and publication and communication. If you are interested in participating in one or more of these working groups please send an email to that effect to Joseph.Giuliano@CHDIFoundation.org.

6. How can I receive more information about Enroll-HD?

Send an email to Info@EnrollHD.org. Email updates of progress and plans will be sent out periodically, and a dedicated website for Enroll-HD is planned.