

## Two large HD observational studies – COHORT and Registry – merge to create ENROLL-HD



Merger of two major Huntington's Disease observational trials creates ENROLL-HD

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*When it comes to studying a disease that progresses slowly, like HD, there is strength in numbers. Studying many patients repeatedly over several years can give us powerful insights that can't be gained through other research techniques. That's why two of the largest observational studies, COHORT and REGISTRY are joining forces to form ENROLL-HD, the world's largest ever study of HD patients.*

### Observational trials

HD is a complicated disease. Scientists can study aspects of the disease in cells, flies, worms and mice, but ultimately the only thing that matters is what goes wrong in people. People with HD, and those who carry the HD mutation, are our best source of information for what goes wrong in HD.

When physicians are examining HD patients, it's difficult to know in advance what kinds of information might be informative to scientists, so often the best strategy is to collect as much information as possible, and have this information accessible to the widest possible variety of HD researchers.

'Observational' trials are studies in which HD-affected people volunteer their information or biological samples for the sake of research. No drugs or other therapies are tested, and the only goal is to learn as much about HD as possible.



COHORT and REGISTRY already involve thousands of subjects – and ENROLL-HD will be even bigger

A number of these observational trials are studying people affected by HD. Some studies involve in-depth assessments like brain imaging, biological samples, detailed questionnaires and other tests. PREDICT-HD and TRACK-HD are examples of such studies.

But day-long assessments and detailed testing isn't something everyone can commit to, and studies like PREDICT-HD and TRACK-HD can't enrol more than a few hundred volunteers.

### COHORT and REGISTRY

There are two long-term studies which aim to collect as much information from as many HD families as possible, whatever of a person's genetic testing status. COHORT is an HD observational trial running at 42 research sites in the USA, Canada and Australia, and is an effort of the Huntington Study Group. COHORT has enrolled over 1500 HD-affected people and their close relatives. These participants visit a research site once a year, donate blood, undergo a basic neurological and medical exam and have the option of giving other information.

A similar study, based primarily in Europe is known as REGISTRY, and is an effort of the European Huntington Disease Network (EHDN). Registry, like COHORT, is collecting as much data as possible on HD-affected families. Over 7,000 volunteers have enrolled in REGISTRY so far. REGISTRY includes basic questionnaires, a neurological examination and the option of donating of biological samples (blood and urine), which can be analyzed by a variety of techniques to look for changes associated with HD. REGISTRY aims to collect and integrate all this data for a large portion of the European HD community.

## ENROLL-HD

Clearly, COHORT and Registry have very similar goals, but currently different geographical coverage. But HD is the same in Pittsburgh, Prague and Perth, so linking these studies makes sense. That's just what these investigators have agreed to do. The new study, **ENROLL-HD**, is a merger of COHORT and REGISTRY, and will result in an even larger database of information for scientists to study. Participants' experience the study will be very similar to COHORT and REGISTRY visits, but behind the scenes, the database of patient information will be much larger.



By combining the power of COHORT and REGISTRY, ENROLL-HD will enable scientific discoveries about HD

As an example of why large sample sizes are critical in these kinds of trials, we could think about aspirin. Studies have shown that the immune systems of HD patients are in a higher state of readiness than non-HD people. Is this a good or bad thing? One way to find out would be to look at people with the HD mutation that take a drug that dampens the immune response, like aspirin, every day and compare their HD symptoms to people who don't. If people who take aspirin have a later age of onset of HD symptoms, or a slower disease course, we could guess that the immune reaction observed in HD patients is a bad thing. But to answer this question we'd need a **huge** number of subjects who take aspirin, and another huge group of people who are similar in every way except they don't take aspirin - these are the "controls". With ENROLL-HD, finding people who match these criteria is easier as we have more people to sample from. These are exactly the kinds of questions that HD scientists would like to be able to ask.

## Data access

A question for the HD community is the handling of personal information after donation. First, there are privacy concerns - people are donating sensitive information and it must be protected. All the studies mentioned have robust procedures for protecting and anonymizing the data of

participants. Secondly, there are concerns about ensuring the information is as useful as it can be. The databases of both REGISTRY and COHORT are open to researchers requests for asking scientific questions. In practice, both projects require qualified scientists to make an application to a review board to access information. As the rules for ENROLL-HD become more clear, we hope that appropriately anonymized information is as widely available as possible, in hopes allowing scientists to make new discoveries.

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*The authors have no conflicts of interest to declare. For more information about our disclosure policy see our FAQ...*

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## **Glossary**

**observational** A study in which measurements are made in human volunteers but no experimental drug or treatment is given

**cohort** a group of participants in a clinical research study

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