

Job Description

Monitor / Language Area Coordinator

What is the European Huntington's Disease Network (EHDN)?

The EHDN is a non-profit research network committed to advancing research, facilitating the conduct of clinical trials, and improving clinical care in HD. Through the EHDN a platform has been created such that basic scientists, clinicians, patients and families can collaborate on academic and industry studies to fulfil its mission. The EHDN is supported by and collaborates closely with CHDI Foundation, Inc.

The network has a structure of regionally based staff who are referred to as Language Area Coordinators (LAC) because they speak the local language of their region and have the capabilities to support their local clinical sites and interact with the local researchers and patient associations. They are also responsible for the on-site monitoring of the Enroll-HD study data.

What Is Huntington's Disease?

Huntington's disease (HD) is a rare, hereditary, degenerative disorder of the brain that was first described by George Huntington in 1872. Symptoms include motor (movement), behavioural (for example mood) and cognitive (for example understanding) disturbances, which in the majority of cases appear in mid-adult life. There are currently no therapies that effectively treat the underlying causes of HD, although there are treatments that can alleviate some of its symptoms and improve quality of life for those affected by it.

Main Function of Post:

Primary responsibilities are to undertake on-site data monitoring of the EHDN's core study, Enroll-HD, within the local language area and, if necessary, to provide support to other areas/countries as language capabilities permit. Future duties could also involve assisting with other EHDN endorsed projects, site management activities for clinical trials, and other research projects as defined by the EHDN Scientific Strategic plan or required by the Enroll-HD research platform.

Details of the role:

- To be familiar with the background and structure of EHDN and its core study [Enroll-HD](#).
- To undertake regular on-site monitoring of the Enroll-HD project, in line with the International Conference on Harmonisation (ICH) good clinical practice (GCP) and standard operation procedures, including verification of source documentation. This will involve visiting country/area study sites on a regular basis and submitting written visit reports.
- To facilitate and coordinate Enroll-HD study administration within Language Area Coordination (LAC): to ensure project documents such as approvals, applications and consent forms are appropriately completed, filed and documented.
- To assist with obtaining relevant Ethics Committee and Institutional approvals for the Enroll-HD study.
- To facilitate implementation of study sub-contracts.
- To assist with study site management: communicate study information to sites and respond to queries from personnel based at each study site and provide general study support to the site staff.

- To initiate/ train new and existing study sites staffs according to the study protocol and procedures: to train study sites on Enroll-HD database (entry and export), assessments (training and certification), consent, biosamples...
- To generate regular LAC Reports: monthly, quarterly, annual.
- To ensure that an understanding of the importance of confidentiality is applied when undertaking all duties.
- To attend LAC face-to-face meetings and regular telephone conferences.
- To support EHDN Working Group activities where required.
- To organise and facilitate a Site Investigator's Meeting if requested.
- To maintain regular contact with lay associations (e.g. with the national Huntington's Disease Association) as requested.
- To be willing to travel regularly, nationally and sometimes within Europe.
- To occasionally perform other duties which are not included above, but which will be consistent with the role.

Essential Criteria

- Educated to degree level in an appropriate field
- Previous experience of clinical research
- Awareness of ICH GCP Guideline and local regulation for clinical trials
- Excellent inter-personal skills with an ability to work co-operatively in a multidisciplinary setting, in particular liaison with a wide range of people including other study sites, professional bodies, lay associations etc.
- Excellent PC skills (Excel, Word, Email, Internet, PowerPoint)
- Meticulous and accurate in all aspects of work
- Able to communicate effectively orally and in writing in local language and in English
- Able to work under pressure and meet deadlines
- Resourceful and able to act on own initiative
- Willing to travel within Europe
- A very high level of consideration and care for patients and research subjects
- Interested in research and a commitment to quality in the research process

Desirable Criteria

- Detailed knowledge of ICH GCP Guideline and local regulations for clinical trials
- Experience of data management/data entry and monitoring
- Natural science or psychology background.
- Previous experience in an HD setting or neurodegenerative disease

Languages:

Fluent, written and spoken, in German and English. Any other European language is a plus.

You will be hired through University Hospital Ulm (EHDN Central Coordination).

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You can also find more information on the EHDN at www.ehdn.org
Please send you English application to katrin.barth@enroll-hd.org