EUROPEAN HUNTINGTON'S DISEASE NETWORK

Advancing Research, Conducting Trials, Improving Care

Job Description

Monitor/Language Area Coordinator UK and Ireland

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

EHDN is a non-profit research network committed to advancing research, facilitating the conduct of clinical trials, and improving the care of people impacted by HD. Through EHDN, a clinical research platform has been created such that basic scientists, clinicians, and HD families can collaborate on academic and industry studies to fulfil its mission. 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 (Lancos) 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 lay associations. They are also responsible for the on-site monitoring of Enroll-HD platform study data.

What Is Huntington's Disease?

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

Main Functions of Post:

Primary responsibilities include:

- Undertaking on-site data monitoring of EHDN's core study, Enroll-HD, within the local language area (UK and Ireland) and, if necessary, providing support to other areas/countries as language capabilities permit. This will involve travelling to visit country/regional study sites on a regular basis and submitting written visit reports.
- Assisting with study site management, including regular review of relevant study site metrics, communicating study information to sites, responding to queries from personnel based at each study site, and providing general study support to the site staff.
- Initiate/train new and existing study site staff according to the study protocol and procedures: to train study sites on Enroll-HD electronic database (entry and export), assessments (training and certification), consent, and biosample collection.
- Facilitate and coordinate Enroll-HD study administration within Language Area Coordination (LAC), ensuring that project documents such as approvals, applications and consent forms are appropriately completed, filed and documented.

Additional responsibilities:

- To be familiar with the background and structure of EHDN and its core study, Enroll-HD.
- To assist with obtaining relevant Ethics Committee and institutional approvals for the Enroll-HD study.
- 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 clinical research platform.
- Facilitating the implementation and execution of study site agreements.
- Generating regular LAC Reports (monthly, quarterly, annually).
- Ensuring that all aspects of participant confidentiality are applied at all times.
- Attending LAC face-to-face meetings and regular telephone conferences.
- Supporting EHDN Working Group activities where required.
- Organising and facilitating Site Investigator Meetings if required.
- Maintaining regular contact with patient/lay associations (e.g., the national Huntington's Disease Association) as required.
- Attending patient engagement events and patient/lay association conferences. This may involve attendance at events occurring at the weekend.
- To be willing to travel regularly, nationally and sometimes within Europe.
- Capability to work effectively and independently from home.

Please note – the above list is not exhaustive, and you may be required to perform other duties not included above but consistent with the role.

Essential Criteria:

- Degree in an appropriate field.
- Previous work experience in a related field
- Awareness of ICH GCP Guidelines and local regulations for clinical trials.
- Excellent interpersonal 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/Microsoft Office skills (including Excel, Word, Email, Internet, PowerPoint).
- Meticulous and accurate in all aspects of work.
- Able to communicate effectively, orally and in writing, in the local language and in English.
- Proven ability to maintain effective working relationships remotely, and ensure clear, timely communication with remotely based colleagues
- Able to work under pressure and meet deadlines.
- Resourceful and able to act on own initiative.
- Demonstrable ability to work independently with minimal supervision
- Excellent organisational and time management skills
- Willing to travel within Europe.
- Very high level of consideration and care for patients and research participants.
- Interested in research and committed to ensuring quality in the research process.

Desirable Criteria:

- Previous experience in clinical research.
- Detailed knowledge of ICH GCP Guidelines and local regulations for clinical trials.
- Experience in data management/data entry and monitoring.

- Natural science or psychology background.
- Previous experience in an HD or neurodegenerative disease setting.

Languages:

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

You can find more information about EHDN at www.ehdn.org

Please send your application (CV and Cover Letter) in English to Adrien.Come@ehdn.org