EUROPEAN HUNTINGTON'S DISEASE NETWORK

Advancing Research, Conducting Trials, Improving Care

Job Description

Clinical Research Associate/Language Area Coordinator: UK

Employer Profile

EHDN is a non-profit research network committed to advancing research, facilitating the conduct of clinical trials, and improving clinical care in Huntington's disease (HD) (please see https://ehdn.org/). Through EHDN, a platform has been created such that basic scientists, clinicians, patients and families can collaborate on academic and industry studies. 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 (LACs) because they speak the local language of their region and have the capability to support their local clinical sites and interact with local researchers and lay associations. They are also responsible for the on-site monitoring of Enroll-HD (https://www.enroll-hd.org/) study data.

Primary Responsibilities

1) Undertake on-site data monitoring of EHDN's core study (Enroll-HD) within the local language area

2) Provide site management and support for study sites

3) Work with local family associations to strengthen community engagement

As required, it may also be necessary to provide support to other areas/countries as language capabilities permit. Future duties may also involve assisting with other EHDN-endorsed projects, site management activities for clinical trials, and other research projects.

Further Requirements

• Working remotely (home-based) and undertaking regular travel nationally and within Europe

• Familiarity with the background and structure of EHDN and its core study Enroll-HD

• Undertaking regular on-site monitoring for Enroll-HD in line with the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) and standard operating procedures (SOPs), including the verification of source documentation. This will involve visiting country/area study sites on a regular basis and submitting written visit reports

• Facilitating and coordinating Enroll-HD site-level study administration within EHDN Language Area Coordination to ensure project documents such as Ethics Committee approvals, applications, consent forms, and other relevant regulatory documents are appropriately completed and filed on-site

• Assisting with obtaining relevant Ethics Committee and Institutional approvals for the Enroll-HD study

• Facilitating the implementation of study site agreements

• Assisting with study site management by communicating study information to sites and responding to queries from personnel in addition to providing general study support to the site staff

• Initiating/training new and existing study site staff according to the study protocol and procedures. This will include training study sites on the Enroll-HD database (entry and export), assessments (training and certification), consent, biosamples, etc.

• Generating regular LAC Reports (monthly, quarterly, and annual)

• Ensuring that an understanding of the importance of confidentiality is applied when undertaking all duties

• Attending LAC face-to-face meetings and regular telephone conferences

• Supporting EHDN Working Group activities (https://ehdn.org/about-ehdn/ehdn-working-groups/) where required

• Organising and facilitating Site Investigator Meetings, as requested

• Maintaining regular contact with lay HD associations, as requested

• Occasionally performing other duties not included above but consistent with the role

Essential Criteria

• Educated to degree level in an appropriate field

• Previous experience in clinical research

• Awareness of ICH GCP Guidelines and local regulations for clinical trials

• Excellent interpersonal skills with an ability to work cooperatively in a multidisciplinary setting, and in particular, the ability to effectively liaise with a variety of individuals across study sites, professional bodies, lay associations, and so on.

• Excellent PC skills (including Excel, Word, email, Internet, PowerPoint)

• Meticulous and accurate approach to all aspects of work

• Able to communicate effectively orally and in writing in local language and English

• Able to work under pressure and meet deadlines

• Resourceful and able to act on own initiative

• Willing to travel within Europe

• Empathic and sensitive approach to working with research participants and their families

• Clear interest in research and commitment to quality in the research process

Desirable Criteria

• Detailed knowledge of ICH GCP Guideline and local regulations for clinical trials

• Experience in data management/data entry and monitoring

• Natural science or psychology background

• Previous experience in an HD/neurodegenerative disease setting

Language Requirements

Fluency in both written and spoken English is a necessity for the position. Any other European language(s) would be a benefit.

Please send your application (CV and Cover Letter) in English to Adrien.Come@enroll-hd.org. Informal enquiries are also welcome.