JOB DESCRIPTION
MEDICAL WRITER – for medical guidelines and EU projects

INSTITUTION
Hôpitaux Universitaires de Strasbourg, Administrative HUS contact: Mme Marion PEYSSOU, marion.peyssou@chru-strasbourg.fr Medical & Scientific contacts: Pr Hélène DOLLFUS (Head of Department, coordinator of ERN-EYE)

The project team & the INSTITUTION details
Hierarchical links : - Head of department – Pr Hélène Dollfus Functional links : The Medical Writer will work under the responsibility of the head of department, ERN-EYE and SENSGENE Coordinator, Pr Dollfus. The Medical Writer works daily directly with the ERN-EYE Project Manager and SENSGENE Project Manager. The Medical Writer will work daily with: - Agencia de Calidad Sanitania de Andalucia (ACSA) representatives in charge of ERNs guidelines, provider of the guidelines template strategy appointed by the European Commission - Members of ERN-EYE workgroups for writing of medical guidelines for rare eye diseases - ERN-EYE and SENSGENE medical members - ERN-EYE and SENSGENE management teams based in Strasbourg Learned Societies - National and European bodies for guidelines Administrative representatives (Hôpitaux Universitaires de Strasbourg and in all ERN-EYE HCPs) - Patients groups and patients' organizations - European Commission spokespersons - Scientific and research stakeholders

Job description
Full time job or part time Fluent spoken and written English required Travels can be necessary on a one-time basis Salary will depend on experience and diplomas according to the Public Function salaries

Co-funded by the European Union

Project presentation

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialized treatment and concentrated knowledge and resources. Health systems in the European Union aim to provide high-quality, cost-effective care. This is particularly difficult with rare or low-prevalence complex diseases or conditions. Between 5.000 and 8.000 rare diseases affect the daily lives of around 30 million people in the EU.

ERN-EYE, dedicated to Rare Eye Diseases (RED), currently consists of 29 healthcare-providers from 13 Member States, with important interactions with patient groups and will cover RED conditions in four thematic groups: retinal RED, neuro-ophthalmology RED, pediatric ophthalmology RED & anterior segment RED; six transversal working groups are addressing common issue (genetic diagnosis, registries, research, training guidelines…).

The French network, SENSGENE, fulfils national missions around rare sensory diseases with the aim of improving the care of patients, coordinating and encouraging research and developing training and information. The six centres of reference of the network, bringing together highly specialized hospital-university teams, have an expertise role for rare diseases and have developed specific and recognized competencies in this field. SENSGENE, have as a priority to develop National Diagnostic and Care Protocols (PNDS) to explain to the professionals concerned the optimal diagnostic and therapeutic care and the care path of a patient suffering from a rare disease on the basis of the international recommendations already published. They are written by the experts of the Reference Centres Rare Diseases (CRMR) using a methodology proposed by the High Authority of Health (HAS).

For both networks, high quality medical writing is required. The writer will drive recommendations & guidelines following the national and European procedures and produced by the experts of the network. The medical writer who will manage the whole procedure, including all meetings and web conferences that will be necessary as well as ensure high quality references and writing. In addition, the writer will help the ERN-EYE members in any ERN article preparation.
In addition, the medical writer will be involved in preparation of medical and scientific articles to be published checking on the understandability and quality of the manuscripts.

ERN-EYE, www.ern-eye.com
SENSGENE, www.sensgene.com

The team

Pr Hélène DOLLFUS is Chief of Department of CARGO and the coordinator of ERN-EYE and SENSGENE networks.
On a daily basis, the medical writer will work closely with:

The local ERN-EYE team is localized in Strasbourg and composed by:

- Dorothée LEROUX (ERN-EYE Project Manager)
- Scientific Project Manager
- Communication team
- IT team (virtual clinic)
- Part-time secretary

The National French network SENSGENE is localized in Strasbourg and composed by:

- Marilyne OSWALD (SENSGENE project Manager)
- Scientific Project Manager
- Communication team
- IT specialist
- Project officers in other cities in France

Key roles of the position

Clinical guidelines and good practices recommendations are essential for professionals to ensure the best quality of care. As reference networks, the European Reference Network for Rare Eye Diseases ERN-EYE and the French network SENSGENE are in charge of producing and spreading these high-quality standards documents.

The Medical Writer will be responsible of the writing of high-quality clinical guidelines or good practices recommendations, based on the best experts' opinion in Europe and an accurate and up-to-dated literature review.
The European Guidelines will follow the rules edited by Agencia de Calidad Sanitania de Andalucia (ACSA), appointed by the European Commission recently, and the French guidelines are based on the PNDS standards, edited by the HAS.

The Medical Writer collaborates with the physicians and perimedical staff network who are members of specific working groups to prepare high-quality clinical guidelines, related regulatory documents, clinical publications, and related clinical documents within agreed-upon timelines. He/she will be responsible of organizing the work between experts, ensure the smooth running of the writing process and ensure the respect of all the quality standards of the produced documents.

Duties and responsibilities

Medical Writer Duties and Responsibilities

Follow the rules for guideline production

The Medical Writer will undertake surveillance and will follow the procedures to write guidelines: European (ACSA rules of procedures for ERNs guidelines) or French (HAS guidelines for PNDS production).
The medical writer will have to attend specific training sessions (EU training for guidelines development) and ad hoc meetings in Paris or Brussels

Organize Project Writing and Manage the Schedule

The Medical Writer will have to organise the process following the procedures (references identification and pertinence; work flow for each participant, schedule to be respected, building of the document and validation by the experts)

The Medical Writer with the Work Group leader ensures that that conflicting and/or ambiguous comments are clarified and appropriately addressed. He/she works closely with the writing working group (and specially it's lead) to reach consensus on timelines for deliverables.

Other responsibilities:

- **Maintain Documents** (archive project documents with track project progress; organize all project documents in an appropriate database or library; ensure that all documents are accurate; prepare report/notes on specific topics).
- **Identify Problems or Risks** (identify any potential issues or risks that could affect the progression of the project and demonstrate ability to utilize a balanced approach to problems).
- **Reports and monitoring** (regular report to the coordinator and the Project Managers to review progress and to discuss future steps, deliver within agreed internal and regulatory timelines).

Skills, qualifications and Experience

Core skills:

- Thorough familiarity with word processing, spreadsheet, and project scheduling computer applications
- Thorough knowledge of general medicine (if ophthalmology experience, it will be very much appreciated), clinical research concepts, practices, and regulations using medical writing standards; demonstrated ability to interpret and apply these guidelines to document writing
- Ability to work effectively as a team member and independently,
- Ability to manage multiple priorities under pressure, trouble-shoot, and to meet short- and long-term deadlines
- Excellent written and verbal communication skills, especially in English, medical English and medical French
- Excellent critical and creative thinking and analytical skills

Advanced skills:

- Experience in program administration, operating procedures, oversight and monitoring
- Ability to work with database applications
- Knowledge of medical writing procedures and guidelines
- Scientific and /or medical background fitting the field

Qualifications:

- MD, PharmD and/or PhD in Biological Science
- Working knowledge of computers and software's (Office suite: Word, Excel, PowerPoint)
- Excellent writing and verbal communication skills in English and French is mandatory; other EU language is an asset.

Experience:

- 2 to 5 years' experience in medical writing in local, national/ International Organizations.

To contact

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