EUROPEAN MULTIPLE SCLEROSIS PLATFORM

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Terms of Reference for Consultant to develop e-learning and face-to-face training modules for patients and their caregivers on "Real-World Data: How Sharing and Analysis Can Benefit You?"

Project title:

More-EUROPA - More Efficient Use of RWD for the Development, Registration and Assessment of Medicinal Products in Europe

Funding
This project has received funding from the European Union's Horizon Europe Research and Innovation Actions, under grant no. 101095479 (More-EUROPA).

1. Purpose of assignment

The primary goal of this assignment is to develop training modules to educate and empower patients and their caregivers through a comprehensive understanding of Real-World Data (RWD) and its vital role in healthcare decision-making. A key focus will be on the significance of data registries as a rich source of RWD, which are instrumental in tracking patient outcomes, treatment efficacy, and disease progression in real-world settings. By demystifying how RWD and data registries contribute to patient-centric healthcare, this training aims to enable patients and caregivers to become more informed and active participants in their care. This empowerment through knowledge not only enhances their ability to make well-informed decisions regarding treatments but also fosters a deeper understanding of how their own data can contribute to broader medical research and knowledge, ultimately leading to improved health outcomes and advancements in healthcare.

We require an external methodological expert to develop a strong thematic approach and develop the training materials based on the training concepts suggested by the EMSP and agreed by the More-EUROPA consortium partners.

Target audience for the trainings:

- Patients (people living with chronic conditions)
- Informal and formal patient caregivers (parents, spouse, partner, other family members, social workers, personal assistants, etc.)
- Clinical staff (to enable better communication with patients)
- Patient organisations' staff and members

The course will be open to any other stakeholders interested in the topic.

2. Background

While randomized controlled trials (RCTs) remain the mainstay in drug development, approval, and reimbursement, the potential of real-world data (RWD) to contribute to the understanding of drug effects is increasingly acknowledged.

Real World Evidence (RWE) can contribute significantly to support decision-making throughout all phases of clinical drug development, as well as improve efficiency in the design and conduct of clinical trial programs.

The project (More-EUROPA) focuses on the more effective and ethical use of registry data to support patient-centered decisions by drug regulators and Health Technology Assessment (HTA) agencies. The project is funded by the Horizon Europe framework programme, the main EU fund for research and innovation. The project involves 14 public and private organisations from seven EU countries (including EMSP).

The aim of this project is to develop, implement and establish evidentiary standards and methods to address the data and evidentiary needs of regulatory authorities and HTA bodies

towards a more efficient use of RWD for the development, registration and assessment of medicinal products in Europe.

The main objectives of the More-EUROPA project are:

- To generate a qualitatively generalizable account of patient and stakeholder perspectives on SWOTs of RWD use in regulatory/HTA decision-making.
- To explain to patients how data from other sources than clinical trials can be used to generate additional knowledge on medicines and medical devices: a training module on the analysis of data obtained from other sources than clinical trials, their limits, their potential contribution to scientific and medical knowledge.
- To assess the representativeness of the patient population in registries.
- To explore patient-relevant information and the current practices regarding PROs and patient-reported outcome measures (PROMs) of the case studies in More-EUROPA.
- To share More-EUROPA's developments and findings with medical coordinators of ERNs and European Patient Advisory Groups, in the context of patient and disease registries created by ERNs.
- To develop a framework for the "Ethics of RWD decision-making".

3. Scope of services and estimated timeline

The Consultant will provide the following services working closely with EMSP Project Coordinator.
The successful Consultant will be comprehensively briefed by the EMSP Project Coordinator in an initial meeting where the various elements of the different tasks will be agreed, and the definitive timetable will be set.

Scope of Work	Timeline
Review the training modules Concepts and Roadmaps (suggested by the Work Package 4, project More-EUROPA)	**March 2024**
Modules' Content Development **(**e-learning and face-to-face training modules): - Based on the six topics outlined in the Concept, develop the content for the training sessions. - Ensure the content is concise, clear, and engaging, incorporating relevant examples and case studies. - Design interactive activities and discussions to promote active learning and facilitate knowledge application (for face-to-face training). - Development of the learning path/guideline for the user	**March-April 2024**
Review of the e-learning recordings	**May 2024**
Development of supporting professional PPT slides for the e-learning module	**May 2024**
Evaluate and reviews of feedback on Test module sessions: setting up a feedback survey for 15 patients, analysis and report on results.	**June 2024**

4. Deliverables

Deliverable	Deadline
E-learning and face-to-face training modules including the reading materials, hand-outs, slides and pre- and post-tests	**May 2024**
Video-recordings developed based on the e-learning module	**June 2024**
Report based on the completed activities and the modules evaluation	**June 2024**

5. Terms and conditions

Payment schedule - Payments for this consultancy are structured as a delivery-based compensation model.

The total amount of the fees allocated for this assignment is €4,500, including administrative overheads and VAT.

This sum will be disbursed upon satisfactory submission and approval of the deliverables as outlined in section 4. It is important to note that any deliverable not meeting the required specifications will need to be reworked and resubmitted at no additional cost.

The duration of the assignment is approximately 3 months, to commence in early March 2024.

The detailed breakdown of the payment schedule is as follows:

First Instalment (20%):

The initial payment of €900 will be made when the consultant initiates the project and begins the assigned tasks. This upfront instalment is intended to support the consultant during the initial phase of the project.

Second Instalment (80%):

The remaining amount of €3,600 will be disbursed upon the satisfactory submission and approval of all deliverables outlined in section 4. This final instalment is contingent on the successful completion of the project and meeting the specified requirements.
It is important to note that any deliverable not meeting the required specifications will need to be reworked and resubmitted at no additional cost to EMSP.

Supervision - The consultant/consultants will work under supervision of the Project Coordinator/appointed team member. The supervisor will have regular interactions with the consultant(s) in order to brief the consultant on the assignment; agree on the process and clarify the deliverables; provide feedback and comments on intermediary products; and track the progress made by the consultant. The supervisor will evaluate the consultants' work and certify delivery of work.

6. Qualifications and specialised knowledge/experience required

- Advanced university degree (Master) or PhD in data sciences, public health or related field; AND Minimum two years of experience in research, health statistics; Previous work experience with patient communities and/or with EMSP is an asset.
- In case of a consultancy firm application, health and data research project experience is an asset.
- Personal/organisational Competencies
- High level of attention to details.
- An excellent command of the English language – both written and oral.
- Ability to produce quality work within a deadline and under pressure.
- Highly developed communication skills.
- Motivated and has the ability to work independently as well as in a team environment.
- Interest in patients' empowerment and engagement in research design and process

7. How to Apply

Qualified candidates (same applies for applications from consultancy firms) are requested to submit a cover letter explaining experience and knowledge relating to the scope of work, CV and an example of the previous work (e.g. a training module) related to the given topic to projects@emsp.org **by 29 February, 2024 (23:59 CEST).**