INSERM U1219 Research Center
(Inserm team HIV, hepatitis and multimorbidity/CMG-EC), located in Bordeaux, France

SEEKS A PROJECT MANAGER
for an international clinical trial evaluating vaccines against Ebola Virus Disease
Fixed term contact (CDD), 12 months

Référence: CDP 01 10-2016

The Inserm team "HIV, hepatitis and multimorbidity: clinical epidemiology and public health" includes one of the centres of methodology and clinical trial management (CMG-EC) for studies sponsored by the National Agency for HIV and Hepatitis Research (INSERM-ANRS) and by Inserm (French National Institute of Health and Medical Research). This CMG-EC is responsible for the methodological aspects of projects in the field of infectious diseases and vaccinology (protocol development, statistical analysis plan, statistical analysis), their operational management (logistical aspects, monitoring, data quality control), and contributes to their dissemination. The CMG-EC is certified ISO 9001:2008 for its clinical research activities (certificate n° QUAL-2009-33716). The CMG-EC collaborates closely with the Vaccine Research Institute (VRI) and is a component of the EUCLID/F-CRIN platform.

Role and Responsibilities

The project manager participates in the coordination of an international clinical trial evaluating preventive vaccines against Ebola Virus Infection. He/she coordinates a project team, participates in methodological and scientific aspects of the studies, is the main contact for the sponsor and collaborators regarding the study follow-up. The project manager ensures that the study is conducted according to the regulation, and the quality management rules, develops and revises quality documents corresponding to her/his responsibilities, and ensures the proper dissemination of information regarding the studies that he/she manages.

Activities conducted in biomedical research:

- Coordinate and participate in project conception
- Survey literature relevant to the project
- Plan and coordinate the set up and conduct of the study
- Participate in the development of the protocol and its amendments, the informed consent, the CRF and other trial documentation
- Organize and facilitate meetings, develop presentations, and write minutes
- Set up and manage the Biobank circuit
- Manage the outsourcing (specifications, calls for tender)
- Participate in the evaluation of budgets and submit budget requests to the sponsor
- Supervise the data collection and their quality control, as well as logistical aspects of the study
- Conduct a data review and validate event coding
- Participate in the data analyses
- Participate in the communication and dissemination of the results
- Develop or coordinate development of reports and newsletters for the participants
- Manage the non-conformities related to the study

Education

MD, Pharm D, PhD in Sciences, or MSc with substantial relevant experience

Mandatory Skills

- Expertise in Clinical conduct and methodology , documented by a degree in the relevant field (public health, epidemiology, clinical trial methodology or similar) and prior experience in conducting randomized intervention trials
- Biomedical research regulation (GCP, ICH, laws…)
- English literate, highly proficient in written and spoken English, fluent appreciated
- Spoken and written communication skills

- Previous experience in an international environment
- Thoroughness, organization, sense of team work, project team coordination
- Computer-literacy (including database management)

Job description

Full time position located in Bordeaux, South-Western France, 12 months fixed-term contract, possibly renewable (probationary period is 1 month).
You will integrate a project team and be supervised by the Head of Inserm Team. This position comes with short-term business traveling at the national and international levels.

Position is available as soon as possible

Please send all applications (Cover letter and resume) to:

Dr Christine Schwimmer
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