

Job title: Clinical Data Manager (CDM)

Employer: Laboratório de pesquisa clínica em doenças febris agudas, Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz (INI/Fiocruz)

Location: home-based (post does not have to be based in Rio de Janeiro, Brazil)

Salary: competitive

Closing date: 30 oct 2020

Summary: INI is a technical-scientific unit of Fiocruz, a lead biomedical research institution in Latin America, devoted to clinical care, research, training, and prevention of tropical infectious diseases. The Clinical Research Laboratory in Acute Febrile Illness is focused on the clinical-epidemiological manifestations of the leading acute febrile illness; infectious diseases outbreak investigation and clinical care of affected patients. It is a reference center for malaria that occurs outside the Amazon basin and serves as a geosentinel surveillance center for travelers who return from the tropics.

The laboratory is looking for a senior clinical data manager with a solid knowledge of clinical studies/trials and a background in data analysis in infectious diseases. The CDM will be reporting to Dr. André Siqueira, head of clinical trials and clinical project manager requested by PI.

The ideal candidate will have at least five years of clinical data management experience with substantial experience in major EDC systems and epidemiologic studies. The post is open for Brazilians and non-Brazilians applicants.

Main responsibilities

- Define and manage Clinical Data Management timelines on multiple studies or programs;
- Coordinate/perform CDM activities for assigned studies/programs, including eCRF design, EDC system set up, user acceptance testing, users training, database release, data review and query generation and data coding;
- Integrate clinical and laboratory data into a unique data management system within distinct clinical projects;
- Provide data management support for the data repository and local sample biorepository;
- Prepare data management plans, data validation plans, and other study-specific procedures and guidelines in compliance with standard process and SOPs;
- Ensure appropriate study-specific training is provided to assigned study teams and documented;
- Ensure ongoing and timely data capture and data cleaning, including external data sources;

- Provide/coordinate data management support to study teams to support timely and ongoing data review and monitoring;
- Ensure study timelines are met, and data quality is according to high industry standards;
- Lock, transfer, and archive databases;
- Ensure adherence to GCP, regulatory guidelines, standard processes, and SOPs

Qualifications and Experiences

- Scientific or technical education background, ideally university level
- Experience of at least five years in clinical data management, with strong experience using major EDC systems and related tools and technologies
- Experience leading data management studies and teams to deliver quality databases that meet regulatory requirements timely
- Epidemiology experience is strongly desirable
- Good planning, organizational, and communications skills
- Ability to effectively work and collaborate in a complex matrix organization
- Fluent in English and working knowledge of Brazilian Portuguese will be an asset

Application deadline: Please e-mail a motivation letter and CV to replick@ini.fiocruz.br with the subject: CDM – AFI/INI by 30 Oct 2020. Please note that only applicants meeting the profile requirements will be contacted.