CLINICAL TRIAL ASSISTANT

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Erkenningsnummer
VG. 1690/BO B-AB10.018.

A biotechnology company specializing in the development of cell therapy products for bone fracture repair and fracture prevention. To support our Clinical Team, we are looking for a **Clinical Trial Assistant**:
Reporting to the Chief Medical Officer, you will ensure the administrative and logistics management of the clinical trials, what includes their implementation, follow-up and closure in compliance with the regulations in force, Good Clinical Practice (GCP) and Standard OperatingProcedures (SOPs).

JOB DESCRIPTION

- Ensure the administrative support of the clinical studies in compliance within the agreed-upontimelines ;
- Ensure the study documentation complies with the Standard Operating Procedures (SOPs) ;
- Maintain the communication between the Investigators and the Sponsor in the absence of the ClinicalResearch Associate (CRA) ;
- Ensure the stock management and shipment of the investigational drugs and study material in theabsence of the Clinical Research Associate (CRA) ;
- Preparation and shipment to the clinical sites of any information document ; review of sites and CRO invoices
- Preparation and coordination of the Investigator Meetings and other clinical department meetings ;
- Participation and support to the implementation of Standard Operating Procedures (SOPs) ;
- Creation and update of the permanent study record (Study & Site TMFs) ;
- Support to the creation of the clinical and regulatory documentation (study plan and study protocol,summary, CRF, IB, monitoring plan, IND/IMPD, etc.) ;
- Support the Clinical Study Manager with the development, follow up and submission of all publications being developed as a result of clinical department activities ;
- Filing, coding and archiving of the study-related documentation ;
- Continuous update of the Sponsor documentation and responsible for ensuring the traceability of theclinical development documents ;
- Update of the site tracking tools and preparation of status reports

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- Responsible together with the Clinical Research Associate for handling the phone calls andcorrespondence from the clinical sites ;
- Documentation of any monitoring activity (phone call report, correspondence, etc.) ;
- Transfer of information to the Clinical Study Manager and to Regulatory Manager
- Organization of the site visits together with the Clinical Study Manager and/or CRO (co-monitoring visit);
- Assessment of the inventory stock status to assist CRO and /or internal clinical supplies department
- Management of the material orders (labs kits, etc), verification of the on-site shipment and receipts status when applicable.

SKILLS

- Higher education degree or degree in the paramedical field and/or administrativemanagement. An equivalent professional experience is a strong asset;
- Notions of clinical trial administrative management ;
- The knowledge of ICH-GCP and SOPs used in clinical research is a strong asset;
- French and English fluent.
- Being aware of the Quality Assurance principles ;
- Being able to use commonly the Microsoft Office suite (Word, Excel, Power Point) andInternet search tools ;
- Accuracy and rigor ;
- Good work organization, speed of operation ; proactivity
- Sense of initiative and observation, team spirit ;
- Analytical and problem solving skills ;
- Adaptability, autonomy and flexibility ;
- Being able to adapt to different interlocutors.

OFFER

- Immediate start
- 3 days per week
- 6 months renewable
- Position based Wallonia partially (+ home based)