Clinical Trial Assistant » (F/M):

Bone Therapeutics SA is a biotechnology company specializing in the development of cell therapy products for bone fracture repair and fracture prevention. At the forefront of science and medicine and leader in its field, the Company is developing innovative regenerative products, containing bone-forming cells, using its proprietary stem cell-based technology platform. With its strong portfolio of clinical programs (Phase II and Phase III) and preclinical programs, Bone Therapeutics is organized as a "mini-pharma", with departments for preclinical research, clinical studies, production, quality control, quality assurance, regulation and administration.

To strengthen our growing organization, Bone Therapeutics is looking for a **« Clinical Trial Assistant » (F/M):**

Reporting to the Chief Medical Officer (CMO), 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 Operating Procedures (SOPs).

You will be in charge of :

- Ensure the administrative support of the clinical studies in compliance within the agreed-upon timelines ;
- Creation and updating of the permanent study file (general file and center files) and files intended for investigators ;
- Ensure the study documentation complies with the Standard Operating Procedures (SOPs) ;
- Updating and maintaining documentation and ensuring the traceability of documents related to clinical development ;
- Preparation and shipment to the clinical sites of any information document ;
- Preparation and coordination of the Investigator, experts 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) as well as Investigator Site Files (ISFs) ;
- 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 the clinical development documents ;
- Update of the site tracking tools ;

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- Support in the management of clinical contracts and invoices ;
- Preparation and sending of all information documentation to the investigating centers ;
- Maintain the communication between the Investigators and the Sponsor in the absence of the Clinical Research Associate (CRA) ;
- Responsible together with the Clinical Research Associate for handling the phone calls and correspondence from the clinical sites ;
- Documentation of any monitoring activity (minutes, phone call, reports, correspondence, etc.) ;
- Transfer of information to the Clinical Study Manager ;
- Organisation of the site visits together with the Clinical Study Manager and Clinical Research Associate ;
- Assessment of the inventory stock status and refill of the investigational drugs and site material together with the CRA ;
- Management of the investigational drug and material orders, verification of the on-site shipment and receipt status.

Expected experience:

- Higher education degree or degree in the paramedical field and/or administrative management. 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. Dutch and German are an asset;
- Being aware of the Quality Assurance principles ;
- Being able to use commonly the Microsoft Office suite (Word, Excel, Power Point) and Internet search tools ;
- Accuracy and rigour ;
- Good work organisation, speed of operation ;
- 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 ;
- Full-time ;
- Long-term contract (CDI) ;
- Position based in Gosselies (Wallonia) but moving premises (Brabant-Wallon)

This opportunity to join a dynamic quickly growing company sounds appealing to you? You want to be involved in the development of innovative research products with medical applications? Then, do not hesitate further, and send your detailed CV and an application letter to Mrs. Roels: hr@bonetherapeutics.com

Deadline for applications: March 15, 2021

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Notice to Agency and Search Firm Representatives

Bone Therapeutics is not accepting unsolicited resumes from agencies and/or search firms for this job posting. Resumes submitted to any Bone Therapeutics employee by a third party agency and/or search firm without a valid written & signed search agreement, will become the sole property of Bone Therapeutics. No fee will be paid if a candidate is hired for this position as a result of an unsolicited agency or search firm referral. Thank you.

Si vous publiez vos données personnelles en tant que demandeur d'emploi, vos Données Personnelles seront utilisées pour:

- le recrutement et l'emploi;
- à des fins de référence et de correspondance des profils en vue de pourvoir les postes vacants;
- vous informer des futures opportunités d'emploi.

Veuillez noter que Bone Therapeutics traitera vos données en conformité avec les lois applicables sur les données privées. À moins que vous ne demandiez à le supprimer plus tôt, vos données seront stockées dans notre système de recrutement pour une durée maximale de neuf mois, jusqu'à trois ans si vous avez été invité à un entretien par Bone Therapeutics ou l'une de ses sociétés affiliées. Vos données seront stockées dans notre système de recrutement et pourront être transférées via un système intranet sécurisé, et conformément aux lois applicables sur les données privées, à toute société affiliée à Bone Therapeutics. Si votre demande est acceptée, vos données seront traitées et incluses dans votre dossier d'emploi. Bone Therapeutics peut transmettre vos Données Personnelles à des Tiers se situant hors de l'Europe; toutefois, Bone Therapeutics prendra toutes les mesures nécessaires pour assurer la confidentialité de vos données personnelles et de votre traitement, conformément à la présente politique et aux lois applicables en matière de confidentialité des données. Bone Therapeutics peut également devoir divulguer vos données personnelles si cela est requis par les lois applicables, les ordonnances judiciaires ou la réglementation gouvernementale. Il vous appartient de mettre à jour vos données personnelles contenues dans le système de Bone Therapeutics. Toutefois, Bone Therapeutics peut de temps en temps vous demander de mettre à jour vos données. Vous avez le droit, sans coût, d'accéder, de modifier ou de demander la suppression de vos données à tout moment en nous contactant par e-mail: dataprivacy@bonetherapeutics.com.

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