

**« Clinical Study Manager » (M/F)**

**Bone Therapeutics S.A** is a fast growing biotech company specialized in the treatment of bone diseases using cell therapy. At the forefront of science and medicine and leader in its field, the Company develops innovative cell products for the repair and regeneration of bone tissues, using its proprietary stem cell-based technology platform. With a strong portfolio of advanced clinical programs (phase II and phase III) and preclinical programs, the Company is organized as a « mini-pharma » with departments of Preclinical Research, Production, Quality Control, Quality Assurance, Regulatory, Clinic and Administrative.

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

**You will be in charge of:**

- Management and coordination of clinical trials : phase II and III
- Participate to study design and protocol development
- Scientific and medical writing - study related documents: protocols, IB, ICF, CRF, ...
- Preparation of regulatory documents/submission files to EC (CA)
- Site Relationship: investigators, site selection, initiation visits, investigator agreement preparation, organization of investigator/meetings
- Management of CRO and monitoring activities
- Review of clinical trial data, support in preparation of clinical study reports
- Contribution to Safety Management: reporting, notification of safety events – follow up and safety report preparation
- Development of credible relationships with KoL, Investigators, and key stakeholders
- Review of medical literature and related new technologies, and close collaboration with other departments (preclinical, regulatory, production, QC, IP...)

**Expected profile**

- A minimum of an advanced scientific degree (Master or PhD level)
- Experience in clinical operations: 2-4 years
- Experience in Study Monitoring / CRA: 1-2 years
- Good knowledge of GCP - ICH principles
- And/or experience within Biotech, Pharma Industry; R&D environment,
- Autonomous team player, strong interpersonal and communication skills
- Able to work within Start up and Biotech environment in a quickly growing structure
- Reactive to deadlines, pro-active, dynamic and problem solving
- Fluent in English; Advanced level of French; Dutch is an asset

**Offer**

- Immediate start
- Full-time
- Long-term contract (CDI)
- Reporting to the Director of Clinical Operations
- Position mainly based in Gosselies (Charleroi)

This opportunity to join a dynamic quickly growing spin-off 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](mailto:hr@bonetherapeutics.com)

**Notice to Agency and Search Firm Representatives**

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