« Clinical Study Monitor » (M/F)

Promethera Biosciences is a global innovator in liver cell-based medicines whose mission is to help patients overcome acute and chronic liver diseases. Our lead clinical program, derived from our patented cell technology platform HepaStem, is designed to benefit from its immune-modulatory and anti-fibrotic properties. We are a team of international experts operating out of R&D and GMP facilities in Mont-Saint-Guibert, Belgium, and Durham, NC, USA.

If you are sharing our vision of becoming the world leader in regenerative medicine in the liver space by developing innovative advanced therapies for acquired liver diseases and if you are looking for new challenges amongst a dynamic and international team, consider a collaboration with our fast-growing company. Promethera Biosciences is currently hiring a "**Clinical Study Monitor**".

MAIN RESPONSIBILITIES

The responsibilities of the Clinical Study Monitor are the following:

- Responsible Person for coordinating all operational aspects of a clinical trial.
- Be part of the product development department - which include clinical, medical and pre-clinical activities- and with all other departments in the overall study management of a clinical trial.
- Write or contribute to preparation of clinical protocols, amendments, informed consent forms, study guides, case report forms, and any other clinical research related documents
- Assist in identification and hiring of appropriate CROs and third-party study vendors
- Negotiate and manage the budget and payments for investigative sites, CROs and other third-party vendors
- Oversee performance of CROs, third party vendors, and field CRAs including co-monitoring, to ensure compliance with study protocol and in accordance with scope of work; identify areas of concern and escalate to Director or CRO as appropriate
- Assist with CRA and third-party vendor training on protocols and practices
- Perform initial review of CRO and other third-party study vendor invoices to ensure that work is performed in accordance with scope of work
- Identify, select, and monitor performance of investigational sites for clinical studies
- Develop and maintain good working relationships with investigators and study staff
- Prepare accurate and timely visit reports from all site interaction visits
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study specific manuals and procedures
- Plan, organize and lead internal and external meetings and conference calls
- Track and report on progress of study including site activation, patient enrollment, monitoring visits

- Review key study quality metrics (e.g., eligibility, primary endpoint data, etc.), provide reports as required to upper management and determine appropriate action in conjunction with study team (autonomy may vary with experience)
- Oversee the global study budget of a clinical trial
- Investigate queries, monitor discrepancies
- Perform clinical data review of data listings and summary tables, including query generation

QUALIFICATIONS/REQUIREMENTS

- Scientific Background: master's degree, PhD
- Previous experience as CRA or Clinical Study Manager
- ICH-GCP training
- Good skills in Microsoft Office (Word, Excel, Power Point, Outlook) and experience in EDC systems.
- Excellent English and French knowledge (oral and written).
- Planning and leading projects
- Well organized, willingness to travel.

REPORTING

- Will report to the head of clinical operations and to the Chief Scientific & Medical Officer
- Will have informal interactions with senior management

LOCATION

- At our headquarters in Mont-Saint-Guibert, Belgium

You may apply for this position by sending your CV and application letter to HR@promethera.com

Please note that, due to the high number of applications we receive, only retained candidates for interview will be contacted.

For information, resumes and application letters received will be retained as long as the employment's offer is valid and will be destroyed as soon as the position is filled. We will contact you in case we wish to keep your CV after the recruitment period.