

Team Lead, Clinical Data Management for Nordic Bioscience A/S

Nordic Bioscience Clinical Development (NBCD) is an international drug development organization. We believe that personalized medicine and innovative study designs and execution is the key to developing new drugs smarter, better and faster.

NBCD was established in 2006 and is a division of the Nordic Bioscience group established in 1992. NBCD provides scientific and clinical trial services to the biotech and pharmaceutical industry in addition to developing own drug candidates. NBCD currently consists of 20 employees based in Herlev, Denmark and 6 Clinical Research Associate's based throughout Europe and Asia. We perform all aspects of pre-market clinical trials such as data management, regulatory affairs, pharmacovigilance, monitoring and trial management.

We are a niche Clinical Research Organization (CRO) specialized in clinical drug development of personalized medicine based on our proprietary biomarker-technology. We focus our efforts on innovative clinical trials in few therapeutic areas, where we can provide additional value such as osteoarthritis, rheumatoid arthritis, osteoporosis and diabetes. Nordic Bioscience is a small, but growing operation, which means we rely on, and leverage our agility and efficiency. Every team member has broad responsibilities and we strongly believe in empowerment and giving our employees freedom to operate and to innovate.

We are now looking for a Team Leader for our Clinical Data Management (DM) group to join the team in Herlev outside Copenhagen, Denmark, and be the team leader for our four data managers.

We expect you to be a hands-on team leader and contribute to our day-to-day tasks in addition to being the front figure for the DM group. The responsibilities of our DM group at NBCD is highly varied and include being involved in the creation, execution and maintenance of data management processes from study start to database lock.

DM collaborates with the Clinical Operations personnel in managing the query life cycle, and you will be responsible for the delivery of regulatory-compliant clinical study data.

Responsibilities

As Team Lead, Clinical Data Management at Nordic Bioscience your responsibilities will include;

- Hands-on management of clinical trials and human resources in the DM group.
- Providing leadership and mentorship to our internal DM staff.
- Providing leadership and direction for outsourced activities, such as biostatistics.
- Overseeing all assigned clinical trials to ensure data quality, integrity and timeliness.
- Working closely with the Clinical Operations team to set study goals and timelines.
- Create a positive work environment.
- Responsible for the global standardization of DM processes and process improvement and efficiency.

Nordic Bioscience have pioneered Risk-Based Monitoring and you will be a critical player in the continuous development of statistical and central monitoring checks.

Nordic Bioscience collaborates with external partners, such as CROs, EDC Vendors, Central Imaging and Central Labs, where you will be an important player ensuring the data flow together with the rest of the Clinical Data Management team.

Our DM group is also responsible for the data management activities of Nordic Bioscience Laboratory, which is our sister organization that performs GLP analysis of safety chemistry for our clinical trials and biomarker analysis for Nordic Bioscience's biomarker activities.

Desired skills and experience

- You have several years of clinical data management experience at a CRO, biotech or pharma company.
- You have a degree in health sciences or experience in working with clinical trials.
- SAS programming, or programming in other statistical languages, will be considered a plus.
- Prior management or leadership experience will be considered a plus.

Personal Qualifications

- You must be a responsible person who can work independently and assume accountability of your delegated responsibilities.
- You must be a creative thinker and be able to think outside the box. As a small organization, we rely on the combined creative intellect of the organization to solve issues rather than established procedures and check lists.
- We expect you to be enthusiastic about innovative research and desire to learn new approaches and expand your core skill set.
- You must have excellent communications skills and as most our communication is in English, you must be proficient in business English (spoken and written).

NBCD is offering

- An important role in a highly dynamic research-organization with world-wide reach
- An environment driven by science and good ideas, where you can truly make a difference and see your own ideas come to life
- Great opportunities for personal development
- The possibilities to broaden your efforts, being introduced to all clinical and non-clinical pre-market aspects of drug development in one place
- Voluntary contribution to our academic publication activities: Nordic Bioscience A/S publishes around 40 peer-reviewed articles each year
- A flat, tight organization in which your successes will not go unnoticed

For further information please contact Jeppe R. Andersen (jra@nordicbio.com).

To apply please send a letter of motivation and a CV to clinical@nordicbio.com