Medannex

VACANCY: JUNIOR CLINICAL MANAGER

Medannex is an award-winning Scottish biopharmaceutical company developing new treatments for cancers and autoimmune diseases.

We recently initiated the first-in-human study of our first-in-class monoclonal antibody therapy, MDX-124. It specifically targets annexin-A1, a protein that modulates the immune system and plays a key role in the development of many cancers and autoimmune conditions. Annexin-A1 is a novel target, yet to be explored in any therapeutic context.

We are seeking a Junior Clinical Manager to join our small team. The successful candidate will work with internal team members and external vendors to ensure clinical deliverables are achieved within scope and to the required timelines. They will be required to interpret data on project issues and make good business decisions, with support from experienced team members. The role will involve a combination of working from home and from our office in Fountainbridge, Edinburgh.

Position type: Full-time, permanent

Responsibilities may include:

- Working with vendors to:
  - ensure clinical operations/quality aspects comply with ICH GCP
  - oversee set-up, organisation, content and quality of relevant sections of Study Master File (local and central)
  - ensure timely archiving of clinical documents and study materials
  - facilitate CRF completion and query resolution process
  - facilitate safety report review and processing
- Developing clinical tools eg. Monitoring Plan/Monitoring Guidelines in conjunction with Data Quality Plan
- Participating in the design and development of CRFs, CRF guidelines, patient informed consent templates, etc
- In conjunction with the study team, preparing, organising and presenting at Investigator Meetings
- Implementation and training of standardised clinical monitoring processes according to corporate standard policies
- Monitoring clinical activity timelines and metrics
- Providing regular status updates at internal meetings
- Ensuring regular project reviews and implementing appropriate recovery actions to ensure project timelines are met
- Reviewing monitoring visit reports and ensuring finalisation within contractual timelines
- Preparing and submitting packages to Regulatory Agencies
- Monitoring/co-monitoring clinical studies to assess performance and/or ensure contractual obligations are met
- Leading regular conference call meetings with monitors and other clinical team members
- Participating in bid defense meetings.

Candidate requirements:

Essential:

- Bachelor's degree or licensed certified healthcare training
- At least 3 years' experience in therapeutic areas such as Oncology/Haematology - or equivalent combination of education, training and experience (eg as a nurse or coordinator in an oncology unit)
- Significant clinical research experience (comparable to 3+ years as a CRA/monitor)
- Experience working in Phase I and II Clinical Studies
- Expert knowledge of relevant regulations eg. ICH/Good Clinical Practices, FDA guidelines etc

- Demonstrated performance management abilities and monitoring experience
- Excellent skills in organisation/prioritisation, attention to detail and communication (in English - written and verbal)
- Strong interpersonal skills, problem-solving and decision-making ability
- Ability to motivate and integrate teams and teach/mentor team members
- Good IT skills including experience of essential software (eg Microsoft Office Suite)
- Ability to travel.

Desirable:

- Experience in all phases of clinical study life cycle, including start-up, interim and close-out
- Lead Clinical Research Associate experience
- Experience working in Phase III Clinical Studies
- Valid Driver's License.

Benefits:

- Competitive salary
- Company share options
- Private medical insurance and life insurance
- Pension
- Discretionary bonus
- Family-friendly, flexible employers

Application deadline: 20 February 2023

Please email your CV and covering letter to: jenmcdowall@medannex.org