DIRECTOR, CLINICAL RESEARCH

Onxeo is a French clinical-stage biotechnology company designing and developing novel oncology drugs targeting tumor DNA-binding functions.

Our therapeutic strategy focuses on fighting tumor resistance to treatments which poses ever-greater therapeutic challenges, further more so in aggressive or rare cancers. Our approach is based upon unique mechanisms of action on DNA Damage Response and immune response. We focus on bringing first-in-class and disruptive compounds from translational research to proof-of-concept in man in cancer indications with high unmet needs.

We are looking for our new DIRECTOR, CLINICAL RESEARCH, based in Boston (MA).

MISSIONS

The primary role of the Director, Clinical Research is to provide scientific expertise to clinical development programs including development support for study protocols. This role will work on cross-functional study teams for the design and execution of clinical studies, as well as analysis, interpretation, and communication of clinical study data.

His/her responsibilities:

- Provide clinical research input for early clinical drug candidates and support Target Product Profile development
- Contribute to the clinical development strategy, clinical development plans, and prepare clinical protocols for compounds assigned to Company
- Be responsible of the medical documentation associated with the clinical study(ies) (e.g. protocol, clinical study report, etc)
- Co-Develop the SAP in collaboration with other CRDs and bio stats
- Close and productive communication with clinical sites to ensure patient eligibility, treatment, and appropriate reporting of clinical data
- Assist in the composition and review of clinical study reports, Investigational Drug Brochures, manuscripts, abstracts, and other relevant documents
- Identify risks and recommend potential mitigation strategies that can impact the successful execution of a clinical study
- Assisted by related functions (e.g. clinical operations, project management, and procurement), responsible for timelines, budgets and contingency/risk management plans to assure successful execution of the clinical trials in compliance with Good Clinical Practice (GCP), applicable laws and regulations as well as applicable standard operating procedures (SOPs)
- Analytical support of clinical trial data (safety and, efficacy, and biomarkers), including gathering, analyzing, reviewing, interpreting, and providing preliminary assessments and recommendations
- Responsible for the clinical study(ies) plans and corresponding clinical sections of integrated development plans (IDP)
- Lead, support and oversee the execution of clinical study(ies) activities
- Provide medical support to clinical operation team during the clinical feasibility
- Review and provide clinical input across different study documents written subject information, CRF, e-diary, monitoring plan
- Composing internal and external presentations for scientific meetings (eg, investigator meetings, advisory boards, data presentations)
- Support and mentor Clinical Science/Medical staff on all projects assigned to company
- Provide review of clinical development plans and strategic initiative (e.g. task forces, protocol review committees).

EDUCATION / EXPERIENCE

- Advanced degree in a scientific discipline preferred; ideally PhD, PharmD, MD, or equivalent. Master's degree may be considered if candidate has substantial industry experience.
- 5+ years of relevant industry experience such as working for biotechnology or pharmaceutical company in clinical development or clinical research group with knowledge of drug development process, including conducting Phase 1 to 3 clinical studies and submission of Investigational New Drug Applications.

OTHER QUALIFICATIONS

- Ability to work effectively in a fluid, fast-paced, team-based environment
- Self-motivated, self-disciplined and able to function independently as well as part of a team
- Contribute to the development and use of novel strategies to improve the efficiency of clinical studies
- Demonstrated capability to challenge decision and status quo with a risk-management approach
- Ability to negotiate to ensure operational resources are available for continued clinical conduct
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- Ability to negotiate to ensure operational resources are available for continued clinical conduct
- Highly organized with attention to detail, clarity, accuracy, and conciseness.
- Strategic agility, strong critical and logical thinking with ability to analyze problems and computer skills
- Strong presentation and written/verbal communication skills

Please send your details at careers@onxeo.com reference: US-AA-2022