

Clinical Program Leader

Job ID
REQ-10006941
Jun 14, 2024
USA

Summary

About the role:

To provide strategic medical guidance for and to lead the development of experimental oncology agents in the TCO portfolio, beginning with the candidate selection phase of preclinical development and continuing through clinical proof-of-concept and transition to full development.

About the Role

Key Responsibilities:

- Leads the EPT, reports to clinical site head
- Provides strategic medical guidance for the development of new oncology agents (both small molecules, biologics, cell therapies and radioligand therapies) that are in preclinical development, typically beginning at the candidate selection phase.
- The CPL is specifically responsible for creating a clinical development strategy for new oncology agents that are within the candidate selection to proof-of-concept (PoC) and transition to full development timeframe. The development strategy combines the CPL's medical knowledge with the expertise of colleagues in a wide range of other disciplines (e.g., Clinical Pharmacology, Biostatistics) to optimize the clinical development strategy.
- Although registration studies are not within the responsibility of TCO, the CPL in TCO must provide an early clinical development strategy that foresees and supports subsequent registration trials
- The CPL integrates preclinical information (pharmacology, toxicology, pharmacokinetics) and interprets its implications for clinical development, as articulated in the Investigator's Brochure and first-in-human protocol.
- The CPL collaborates with clinical scientists to develop clinical protocols for TCO compounds and to develop the instruments needed to implement, interpret and report them (e.g., case report forms, report and analysis plans, clinical study reports).
- The CPL applies his or her medical knowledge to guide the safe, ethical and efficient conduct of the trials under his or her responsibility. He or she is knowledgeable in Good Clinical Practice guidelines and Novartis Standard Operating Procedures and strives to maintain compliance with them.
- The CPL liaises with outside experts, investigators, and regulatory authorities in the field of oncology, and represents his or her projects to those groups and authorities.
- The CPL writes and reviews abstracts/manuscripts, etc. for presentation/publications at internal/external meetings.
- The CPL participates in task forces to support continuous improvement and other management objectives.

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The pay range for this position at commencement of employment is expected to be between \$257,600 and \$386,400 / year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Essential Requirements:

- MD or DO Degree required; MD PhD preferred.
- Board certification in Hematology, Medical Oncology or both.
- 3-5 pharma/biotech industry experience in heme/onc clinical trials and the equivalent term experience in the academic setting. In case of no industry experience, substantially longer academic experience in translational oncology and substantial clinical study experience.
- Must have facility with the interpretation of preclinical data in heme/oncology (molecular biology, pharmacology, pharmacokinetics, and toxicology)
- Working knowledge of the application of PK/PD and biostatistics to clinical development and clinical trials
- Proven ability to analyze and interpret efficacy and safety data relating to oncology
- Knowledge of GCP and world-wide regulatory requirements relating to clinical trials and oncology
- Excellent medical/scientific writing skills
- Effective written and oral communication skills
- Proven ability to manage and develop a team
- Excellent personal ethical integrity and a commitment to improving the outcomes for patients with malignancies

Benefits and rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?
<https://www.novartis.com/about/strategy/people-and-culture>

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Functional Area
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Job Type
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Employment Type
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Shift Work
No
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