U NOVARTIS

Clinical Program Leader / Senior Clinical Program Leader, Translational Clinical Oncology (Dual Posting)

Job ID REQ-10051807

6月 18, 2025

USA

摘要

About the role: #LI-Onsite

Help us ensure that safe, effective and innovative treatments reach patients as quickly as possible. The Clinical Program Leader (CPL) / Senior Clinical Program Leader (Senior CPL) will play a critical role in overseeing the planning, execution, and interpretation of clinical trials research, data collection activities and clinical operations.

About the Role

Key Responsibilities:

- Provides strategic medical guidance for the development of new oncology agents that are in preclinical development, typically beginning at the development candidate (DC) phase. Accountable for Translational Clinical Oncology (TCO) aspects of one or more global drug development programs. Establish and approve scientific methods for design and implementation of clinical protocols, data collection systems and final reports.
- · Evaluation of external opportunities for potential business development purposes
- Responsible for creating a clinical development strategy for new oncology agents. The development strategy combines the Clinical Program Leader's (CPL) medical knowledge with the expertise of colleagues in a wide range of other disciplines (e.g. Biomarkers, 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
- Leads Biomedical Research Program Teams (BPTs), beginning at the time of approval to conduct Good Laboratory Practices (GLP) toxicology studies to enable the start of clinical development, and continuing through those clinical trials. May lead multiple global project teams.
- Support new and ongoing clinical research and clinical trials and ensure efficient and timely processing of confidentiality agreements and clinical agreements.
- Responsible for development of the Integrated Development Plan (IDPA).
- 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.
- 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).
- 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.
- Liaises with outside experts, investigators, and regulatory authorities in the field of oncology, and represents his or her projects to those groups and authorities. Fosters communication with key opinion leaders and collaborating investigators. Acts as the medical monitor for one or more global clinical studies. Writes and reviews abstracts/manuscripts, etc. for presentation/publications at internal/external meetings. Participates in task forces to support continuous improvement and other management objectives. Mentors and serves as an educational resource across Novartis. Acts as a key resource for less experienced CPLs in TCO.

Essential Requirements:

- This position will be located at the Cambridge, MA site and will not have the ability to be located remotely. This position will require approximately 10% travel as defined by the business (domestic and/ or international).
- This is a dual posting. The final level & title of the offer role would be determined by the hiring team based on the skills, experience & capabilities required to perform the role at the level the role has been offered (Clinical Program Leader / Senior Clinical Program Leader):
 - Clinical Program Leader: 1-3 years of experience leading complex early phase Oncology clinical programs from the pharma/biotech industry; Experience with the

interpretation of preclinical data in oncology (molecular biology, pharmacology, pharmacology)

- Senior Clinical Program Leader: 3-5+ years of experience leading complex early phase Oncology clinical programs from the pharma/biotech industry; Experience with the interpretation of preclinical data in oncology (molecular biology, pharmacology, pharmacokinetics, and toxicology)
- MD or DO degree and additional laboratory-based training are required; Board certification (or equivalent expertise) in an Oncology sub-specialty
- Working knowledge of the application of pharmacokinetic / pharmacodynamic (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 Good Clinical Practices (GCP) and world-wide regulatory requirements relating to clinical trials and oncology
- Excellent medical/scientific writing and oral communication / presentation skills
- Proven ability to manage and develop a team; Used to working successfully across more than one indication; Excellent teamwork in multidisciplinary settings; Creative and independent leader; Innovative and fearless in designing new approaches to PoC studies and in critical thinking; Looks beyond what is evident and visible
- Inspires others and strong passion for translational science; Excellent personal ethical integrity and a commitment to improving the outcomes for patients with malignancies

Desirable Requirements:

- Experience from an academic medical center
- PhD

The pay range for this position at commencement of employment is expected to be between: \$152,600 and \$283,400 for CPL or \$236,600 and \$439,400/year for Senior CPL; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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. 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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to <u>us.reasonableaccommodations@novartis.com</u> or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门 Biomedical Research

Business Unit Universal Hierarchy Node

地点 USA

状态

站点 Cambridge (USA)

Company / Legal Entity U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Functional Area Research & Development

Job Type Full time

Employment Type Regular

Shift Work No

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