NOVARTIS

Clinical Program Leader

Job ID
REQ-10077698
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Швейцария

Сводка

Location: Basel

Experience will determine which level 6 (Senior CPL or CPL) after interview process.

CPL: Provides strategic medical guidance and leads the development of experimental oncology agents in the TCO portfolio, beginning with PE / DC (Portfolio Entry / Drug Candidate) of preclinical development and continuing through TDP (Transition Decision Point).

About the Role

Major Accountabilities

- Provides strategic medical and scientific leadership and expertise to all line functions on the project team for the development of new oncology agents (e.g., small molecules, biologics, radioligand therapies) that are in preclinical development, typically beginning at the PE / DC
- Creates clinical development strategies for new oncology agents within the PE/ DC to TDP 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. Delivers solutions within functions, across functions, and on global projects, developing independent approach to TCO strategy.
- Although registration studies are not within the responsibility of TCO, the CPL must provide an early clinical development strategy that foresees and supports subsequent registration trials. Development of the Integrated Development Plan Approval (IDPA) in alignment with CPL Disease Area Leads (DALs), Development (DEV), Strategy & Growth (S&G), and Commercial teams
- Lead Biomedical Research Early Program Teams (BPTs) to enable the start of clinical development and continuing through clinical trials needed to support TDP. May lead multiple global project teams
- Integrates preclinical information (pharmacology, toxicology, and pharmacokinetics) and interprets 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 develop the instruments needed to implement, interpret and report them (e.g., case report forms, report and analysis plans, clinical study reports)
- Applies own medical knowledge to guide the safe, ethical and efficient conduct of the trials under own responsibility. 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 oncology, and represents own projects to those groups and authorities
- 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. Operational responsibility for quality and compliance
- May provide informal mentorship to less experienced CPLs

Qualifications:

Education:

MD or DO degree

Board-certification in an oncology specialty and PhD-level science is preferred

Languages:

Fluent English – Oral and written

Experience/Professional requirement:

- At least 5 years of pharmaceutical/biotech industry experience in oncology clinical trials plus the equivalent duration experience from an academic medical center. If limited or no Pharmaceutical industry experience, then substantially longer senior academic experience in translational oncology with substantial clinical study experience
- Recognized as an expert in your field by external medical experts and regulatory authorities. External candidates have a substantial record of publication and international recognition
- Excellent interpretation of oncology preclinical data (molecular biology, pharmacology, pharmacokinetics, and toxicology)
- Strong 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 for clinical trials and oncology
- Excellent medical/scientific writing skills
- Successful track record of strategic thinking: created major innovations with successful outcomes for patients
- Proven ability to develop and inspire project/line/matrix multidisciplinary teams in a global environment
- Excellent personal ethical integrity and a commitment to improving the outcomes for patients with malignancies
- Excellent written and oral English communication/presentation skills
- Strong office IT skills

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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Biomedical Research
Business Unit
Development
Место
Швейцария
Сайт
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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Clinical Program Leader

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