NOVARTIS

Early Clinical Development Physician (Oncology)

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REQ-10078867
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Сводка

Provides strategic and operational level medical guidance for the development of experimental oncology agents in the TCO portfolio in China, ensuring high quality medical input, scientific rigor, and regulatory compliant execution of early clinical development activities.

About the Role

Major accountabilities:

- Contribute to the BR TCO China organization in accordance with the global BR TCO clinical strategy.
- Provide medical and scientific input for compounds/modalities selected and prioritized for development in China, gathering local clinical and scientific insights (e.g., treatment landscape, patient population, standards of care) to inform early clinical strategy.
- Provide supportive medical input to early clinical due diligence in China, reviewing preclinical, translational, and clinical data to assess biological rationale and identify key risks and data gaps under senior guidance.
- Act as the primary interface between the TCO CPL and the TCO China team. Serve as the medical lead for China and provide support to global Biomedical Research Program Teams (BPTs); may be work with multiple BPTs per project assignments. Partner with the TCO China Clinical Sciences team to operationalize TCO clinical trials in China in close collaboration with Global TCO teams, Clinical Development, and other relevant functions in China.
- Provide medical guidance and support to the TCO China Clinical Operations team. Partner with Clinical Sciences on the establishment of a qualified network of TCO first-in-human and proof-of-concept sites in China; build and maintain collaborative relationships with PIs and KOLs who will be engaged long-term for advice and advocacy on the Novartis discovery and early development pipeline in China.
- Partner closely with local line functions in China development and international to ensure China's specific regulatory requirements are appropriately incorporated into early-phase study strategies and execution.
- Optimize the organization's ability to include China in late development studies in real time, leveraging the early development package to enable timely participation.
- May represent Novartis early oncology in China in interactions with the regulatory agency NMPA, with HGRAC, and with other authorities and decision-making bodies as appropriate.
- Ensure all activities comply with company standards, Good Clinical Practice, and local regulations. Ensure adequate reporting of adverse events/technical complaints/compliance issues in accordance with company procedures. Complete all required training and compliance activities within required timelines.

Key performance indicators:

- Contribute to an early clinical development strategy that foresees and supports subsequent registration trials for oncology drugs in China.
- Timely initiation of TCO trial activities in China by facilitating communication and collaboration between Global TCO and Development China.
- Successful conduct of TCO trials in China by meeting agreed timelines, enrollment targets, and quality standards.
- Effective and proactive communication with internal and external stakeholders to enable early handling of potential issues.
- Excellence in decision-making for day-to-day trial/patient management in China.
- Effective communication of risks and issues related to clinical development in China within the global BPT and to the TCO leadership team.
- Contribution to the creation of an attractive workplace embodying the Novartis global culture

Minimum requirements and skills:

- MD degree. Oncology experience required. Board certification (or equivalent) in an oncology specialty and PhD-level science is preferred. (for RLT: nuclear radiology and/or radiation oncology specialty or equivalent)
- At least 5 years of pharmaceutical/biotech industry experience in oncology clinical trials or the equivalent duration experience from an academic medical center.
- Understanding and interpretation of oncology preclinical data (molecular biology, pharmacology, pharmacokinetics, and toxicology).
- 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.
- Excellent knowledge of regulatory requirements for the conduct of clinical trials in China.
- Knowledge of GCP and worldwide regulatory requirements for clinical trials. Proven ability to develop and inspire project/line/matrix multidisciplinary teams.
- Experience working in a multi-cultural environment and in a matrixed global organization.
- Excellent personal ethical integrity and a commitment to improving outcomes for patients with cancer.

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
Research
Место
Китай

Сайт
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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