

Medical Expert

Job ID
REQ-10047664

4月 08, 2025

India

摘要

The Medical Expert in TCO (Translational Clinical Oncology) is the medical leader for assigned global, roll-over and long-term follow-up studies, and studies in the close-out phase. They may also provide medical co-leadership for assigned aspects of one or more global, active, TCO study, under the leadership of a Clinical Program Leader (CPL)

TCO (Translational Clinical Oncology) is a department under Biomedical Research division, and is responsible for designing and executing out early phase (first in human) clinical studies in patients with cancer. It acts as a bridge between drug discovery and late phase clinical development and strives to deliver transformative new medicines for oncology conditions.

About the Role

Major accountabilities:

- Provides medical support to Clinical Program Leader (CPL) leading the program. Medical support may include, but is not limited to, contributing to clinical sections of protocols and/or amendments, Informed Consents, publications, regulatory documents such as Investigator Brochures, responses to Health Authority questions and conducting ongoing review of clinical trial data, with oversight of TCO deliverables.
- May act as the medical monitor to support overall program safety reporting (e.g., Drug Safety Update Reports (DSURs), and other safety related documents) in collaboration with Patient Safety Team.
- May represent CPL at project team meetings (e.g. CTT) and may provide inputs to project strategy
- May represent CPL at Investigator teleconferences including dose escalation meetings and site initiation visits.
- Oversees the clinical/scientific elements of TCO - related submission documents, including preparation and review of project documentation for Health Authority submission, including briefing books, IBs, Annual Safety Reports, responses to Health Authority questions etc.
- Leads the ongoing clinical trial data medical/scientific review across assigned TCO studies and coordinates data analysis and interpretation
- Accountable for assigned close-out, roll-over and long-term follow-up studies, ensuring Clinical Study Report review, consistency and quality of clinical study reports (CSR) in collaboration with CSR medical writing team, and publication of studies across assigned TCO projects - either directly as lead author or by providing leadership to the medical writing team
- Manages stakeholder engagements internally and externally
- Mentors and coaches junior TCO team members in India
- Maintains expert knowledge of ICH-GCP, external regulations and procedures, and supplements by training and practice of Novartis SOPs and internal policies. Leads or assists with relevant trainings across TCO India
- Advocate continuous improvement of quality
- Ensure all activities of associates comply with company standards and local regulations

Key performance indicators:

- Management of assigned studies to ensure execution according to timelines, and with high quality, ensuring adherence to international and local regulations.
- Demonstrates excellent scientific writing skills to enable the development of quality trial reporting, and regulatory documents.
- Strong evidence of quality medical review of trial data and quality contributions to clinical sections of e.g. protocols, IBs, DSURs and CSRs
- Contribution towards objectives set for the department.
- Feedback from external and internal stakeholders.
- Clearly demonstrates Novartis Values and Behaviors.

Minimum Requirements:

Education:

- MD or equivalent medical degree required. Advanced knowledge and clinical training in a medical/scientific area (e.g., internal medicine / pharmacology etc.) with medical council certification required.
- Experience in hematology / oncology preferred

Work Experience:

- At least 5 years of pharmaceutical/biotech industry experience
- At least 2 years of clinical practice experience in the hospital setting.
- Experience with oncology clinical trials
- Experience with early development clinical trials
- Knowledge of Good Clinical Practice (GCP).
- Strong operational project experience including excellent planning, prioritization, problem solving and organizational skills. Used to managing multiple priorities.
- Demonstrated operational excellence and scientific contribution to both clinical and preclinical projects.
- Strategic thinking: ability to network with and influence key stakeholders, clear and logical presentation of complex strategic issues.
- Clear written and verbal expression of ideas, an active/proactive communicator.
- Well-developed interpersonal skills, with a proven record of accomplishment of successfully interacting with, influencing and building strong positive relationships.
- Used to working independently and in a team, being flexible and adapting in a changing environment.

Skills:

- Clinical Monitoring.
- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.
- Decision Making Skills.
- Drug Development.
- Health Sciences.
- Lifesciences.
- Medical Strategy.
- Regulatory Compliance.

Languages :

- English.

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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部门

Biomedical Research

Business Unit

Pharma Research

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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



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