# Medical Expert

Job ID
REQ-10047664

Apr 08, 2025

India

## Summary

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 represents 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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部門
Biomedical Research

部門
Pharma Research

国
India

勤務地
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

## 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.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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