Associate Medical Expert

Job ID
REQ-10047661
May 12, 2025
India

Summary

The Associate 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 support for assigned aspects of a global, active, TCO study, under the leadership of a Clinical Program Leader (CPL) and / or Medical Expert

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) and / or Medical Expert. 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.
- Contributes to 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.
- Contributes to the ongoing clinical trial data medical/scientific review across assigned TCO studies and coordinates data analysis and interpretation
- Supports conduct of dose escalation meetings, investigator teleconferences and site initiation visits etc.
- 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
- Maintains expert knowledge of ICH-GCP, external regulations and procedures, and supplements by training and practice of Novartis SOPs and internal policies.
- Advocate continuous improvement of quality

Key performance indicators:

- Evidence of high-quality medical input to assigned studies to ensure execution according to timelines and ensuring adherence to international and local regulations.
- Evidence of quality medical and scientific review of clinical trial data
- Demonstrates excellent scientific writing skills to enable the development of high-quality documents including but not limited to clinical trial protocols, trial reporting (e.g. CSR), and regulatory documents (e.g. IB, DSUR).
- Contribution towards objectives set for the department.
- Feedback from external and internal stakeholders.
- Clearly demonstrates Novartis Values and Behaviors.

Minimum Requirements:

- 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 2 years of pharmaceutical/biotech industry experience or at least 4 years of clinical practice experience in the hospital setting
- 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 clinical or preclinical projects.
- 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.
- 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

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: https://www.novartis.com/careers/benefits-rewards

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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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