Clinical Development Medical Manager

Job ID
REQ-10017429
Juli 29, 2024
China

Zusammenfassung

About the role:

In this role, you will be responsible for the quality of medical expertise clinical trials(s) run in China and takes on the medical responsibilities at the China program level.

About the Role

Key Responsibilities

• Responsible for China clinical development strategy in one or several development programs; Leads medical feasibility at indication level, often prior to the development of study concept, may responsible for providing study concept sheet

• Responsible for preparing Clinical Overview (CO), Summary of Clinical Safety (SCS), Summary of Clinical Efficacy (SCE), China CSR Appendix, Briefing Book (BB) for pre-IND meeting, medical responses to China regulatory authority

• Ensures the accurate translation of medical documents in CTA and NDA dossier (e.g., protocol, IB, CO, SCE, SCS, China CSR Appendix, BB, responses to China regulatory authority questions)

• Plans and executes publication and clinical communication strategy in coordination with Medical Affairs (MA), and provide input into key external presentations; Leads interactions with local external medical experts (e.g., regulatory authorities, key opinion leaders) at authority consultation, advisory boards, patient advocacy groups and investigator meetings

• Responsible for developing Post Approval Safety Surveillance (PASS) protocols and PASS Reports; May take on some responsibilities of China Associate Clinical Development Medical Director (aCDMD), under global aCDMD or China Development Unit Head

• Contributes to talent and career development of China CD associates through on-boarding, coaching, and/or mentoring support; May act as Clinical Development Physician (CDP) in China when required

• Takes on special task assigned by the line manager

Commitment to Diversity and Inclusion / EEO:

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

Essential Requirements:

• 3 - 5 years relevant industry experience

• Established disease knowledge is preferred with proven ability to interpret, discuss and present efficacy and safety data

• Strategic thinking by actively seeking information and understanding the impact of the external environment and internal business priority on project/study level

• Working knowledge of Good Clinical Practice (GCP), clinical trial design, statistics, and regulatory and clinical development processes

Desirable Requirements:

• MD required, 2-4 years' experience in clinical practice preferred

• Excellent verbal and written communication skill in Chinese and English

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