# **U** NOVARTIS

# **Clinical Development Medical Manager**

Job ID REQ-10017429 Jul 29, 2024 China

### Summary

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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#### 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 <u>diversityandincl.china@novartis.com</u> 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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Division

Development **Business Unit Innovative Medicines** Location China Site 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 Apply to Job

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# Clinical Development Medical Manager

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