

## Clinical Development Medical Manager

Job ID  
REQ-10017429

7月 29, 2024

China

### 摘要

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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部门  
Development

Business Unit  
Innovative Medicines

地点  
China

站点  
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

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