

# Clinical Development Medical Manager

Job ID  
REQ-10009757  
May 30, 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

**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.

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<https://www.novartis.com/about/strategy/people-and-culture>

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: [https://www.novartis.com/sites/novartis\\_com/files/novartis-life-handbook.pdf](https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf)

**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.china@novartis.com](mailto:diversityandincl.china@novartis.com) 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  
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Employment Type  
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Shift Work  
No  
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## Clinical Development Medical Manager

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