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. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? 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

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 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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

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

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.
Alternative Location 1
Beijing (Beijing), China
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
REQ-10009757

Clinical Development Medical Manager

Apply to Job

Source URL: *https://qa1.novartis.us/careers/career-search/job/details/req-10009757-clinical-development-medical-manager*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. mailto:diversityandincl.china@novartis.com
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/about/strategy/people-and-culture
6. https://talentnetwork.novartis.com/network
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Shanghai-Shanghai/Clinical-Development-Medical-Manager_REQ-10009757
8. https://talentnetwork.novartis.com/network
9. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Shanghai-Shanghai/Clinical-Development-Medical-Manager_REQ-10009757