Associate Clinical Development Medical Director

Job ID
REQ-10020080
Ago 22, 2024
China

Resumen

About the role:
In this role, you will be responsible for the scientific and medical strategy of assigned China-focused clinical trial(s), responsible for medical and scientific monitoring, and reporting of quality data. May take on the duties and responsibilities of the Global Assoc. CDMD role. A senior clinical leader responsible and accountable for quality medical strategy at China clinical programs level.

About the Role

Key Responsibilities

• As the Medical Lead for China-focused clinical trials, provides clinical leadership, medical and scientific strategic input, and contributes to the development of trial related documents (e.g., Clinical Trial Protocol, informed consent form, case report forms, data monitoring committee charters, data analysis plan, clinical study reports, publications) for assigned clinical trial(s) consistent with Integrated Development Plan (IDP); develops materials for trial-related advisory boards, data monitoring committees, investigators meetings, and protocol training meetings for local medical organization

• In collaboration with integrated Clinical Trial Team (iCTT) members: Ensures direct medical support of trials as needed and may act as medical monitor; Conducts ongoing medical and scientific review of clinical trial data; Manages patient safety and reports on trial data to safety and clinical boards (e.g., Safety Management Team (SMT), GCT, GPT); Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations

• Together with Patient Safety, ensures continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post- marketing surveillance

• Provides medical and scientific input and contributes to clinical sections of program level regulatory documents (e.g. Health Authority briefing books, safety updates, submission dossiers, and responses to Health Authorities)

• Supports Therapeutic Area Head (TAH) or GPCH with contributing to peer-review of IDPs, CTPs, and other clinical documents, as needed; Supports development of the disease area strategy for China, leads or serves on China work streams to improve clinical development process, acts as Subject Matter Experts for standard operating procedures or trainings, and/or contribute to other cross-functional or Clinical Development line function initiatives

• Responsible of medical/scientific training for relevant Novartis stakeholders on the disease area and compound/molecule

• Contributes to talent and career development of China CD associates through on- boarding, coaching, and/or mentoring support; and may contribute to the performance evaluation of China clinical trial team members; Contributes to China GDD initiatives (e.g. process improvement, training, local SOP development, other development unit line function initiatives)

• Takes on special task assigned by the line manage

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:

• Medical Degree is required and more than 5 years clinical experience is preferred

• Advanced disease knowledge is preferred with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level

• Strategic thinking by actively seeking information to develop optimal clinical development strategy for registration

• Demonstrated ability to establish effective working relationship with key investigators

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

• Strong interest/experience in coaching less- experienced associates and/or be able to function effectively as a medical leader in a cross functional team

• Strong learning agility; Strong interpersonal skills; Strong negotiation and conflict resolution skills; Proven ability to work independently in a cross functional team setting

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