Associate Clinical Development Director (Neurology)

Job ID
REQ-10047569

4月 16, 2025

India

摘要

The Associate Clinical Development Director (Assoc. CDD) provides input to development of protocols for assigned global clinical trials, scientific monitoring, and reporting of quality data. May be assigned to provide support to development of the clinical and scientific strategy of assigned sections of a clinical development program, depending on the size and complexity
-Oversees all operational aspects of clinical trials end-to-end including the planning, execution, and interpretation of clinical trials research, data collection activities and clinical operations. -Complete oversight of budget and resource allocation within assigned trial. Drives operational excellence through process improvement and knowledge sharing across trials within program/franchise. Enables an empowered organization that can navigate in a matrix environment and adjust quickly to business needs. Point of escalation for resolution of trial management operational issues within assigned trial.

About the Role

Major accountabilities:

- 1)
  Provides input to the development of clinical development strategy , and contributes to development of trial related documents (e.g., CTPs, informed consent form, case report forms, data monitoring committee charters, data analysis plan, reports, publications) for assigned clinical trial(s) consistent with Clinical Development Plan (CDP); develops materials for trial-related advisory boards, data monitoring committees, investigator meetings, and protocol training meetings for Novartis local clinical development teams
  2)
  Provides clinical and scientific input and contributes to clinical sections of trial and program level regulatory documents (e.g., Investigator ' s Brochures, Health Authority briefing books, safety updates, submission dossiers, and responses to Health Authorities)
  3)
  In collaboration with appropriate Clinical Trial Team (CTT) members:
  a)
  Ensures clinical development oversight and support of trials as needed
  b)
  Conducts ongoing scientific review of clinical trial data with Clinical Scientific Expert(s) with appropriate oversight from Medical Lead/CDMD/CSL
  c)
  Manages patient safety reports on trial data to safety and clinical boards (e.g., Safety Management Team (SMT), GCT, GPT) with appropriate oversight from Medical Lead/CDMD/CSL in collaboration with patient safety
  d)
  Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations, with appropriate oversight from Medical Lead/CDMD/CSL
  4)
  Contributes to global initiatives (e.g., process improvement, training, SOP development, other Clinical Development line function initiatives)
  5)
  May be assigned to lead clinical trial(s) as Clinical Scientific Lead and provide leadership and guidance for all clinical aspects of a clinical trial in close collaboration with the assigned medical monitor and/or CDMD.
  - Responsible for the planning, executing and implementation of operational strategy of assigned clinical trial(s), -Develops materials for trial -related advisory boards, data monitoring committees, investigators meetings, and protocol training meetings for Novartis local medical organizations -Supports by contributing medical input into IDP and CTP reviews and contributing/driving development of disease clinical standards for new disease areas -Contributes to the global initiatives (e.g., process improvement, training, SOP development, other line function initiatives) -Contributes to talent and career development of associates through on -boarding, coaching, and/or mentoring support -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Evidence of quality clinical and scientific strategic input as well as timely delivery of high-quality CTPs and other clinical deliverables

Applies effective clinical research methodology, including trial design/analyses, efficacy endpoints, safety assessments, and risk management across disease area and development phases

Supports TA through high quality contributions to CDP and protocol reviews

Supports timely development of quality disease/program clinical standards, publications, and internal/external presentations

Evidence of quality contributions to clinical sections of regulatory documents, Investigator ' s Brochures, briefing books, safety updates and submission dossiers

- Excellence in execution and implementation of clinical operations strategy -Timely, efficient and quality execution of assigned trial and trial related activities within budget, and in compliance with quality standards.
- Proactive operational planning with effective contingency and risk mitigation plans.
- Cost effective management of budget and resources with limited unforeseen cost overruns.
- Applicable to Clinical Scientific Expert Group Head: -Strong leadership skills to be able to support management in team competency building, lead/contribute to local/global initiatives and best practice sharing across programs and/or departments -Efficient, quality-driven, timely delivery of quality documents to support Clinical Development activities by the team in compliance with international and local regulations and Novartis internal standards.
- Accountable for, review and updates resource needs for programs ensuring support to the portfolio.
- Timely delivery of program activities within the group to achieve critical milestones.
- Clearly anticipate and communicate risks.
- Cost effective management of budget and resource management within the CSE group.
- Clearly demonstrates Novartis Values and Behaviors (i.e. Innovation, Quality, Collaboration, Performance, Courage and Integrity.

Minimum Requirements:

- Neuroscience or similar experience preferred.
- Advanced degree in life sciences/ healthcare (or clinically relevant degree) is required. PharmD, or PhD strongly preferred.

Work Experience:

- ≥ 3 years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV. ≥ 2 years of contribution to and accomplishment in all aspects of conducting clinical trials (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry
- Working knowledge of the assigned disease area is desired with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level
- Demonstrated ability to establish effective working relationship with stakeholders
- Working knowledge of ICH, GCP, clinical trial design and methodology, statistics, and regulatory and clinical development processes
- Strong communication skills, written and oral
- Strong interpersonal skills
- Strong negotiation and conflict resolution skills
- People management preferred Organization Scope; Scale and Complexity.

- People Challenges.
- People Leadership.

Skills:

- Budget Management.
- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.
- Coaching.
- Cross-Functional Teams.
- Data Analysis.
- Learning Design.
- Lifesciences.
- Risk Management.
- Risk Monitoring.

Languages :

- 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

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

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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Development

Business Unit
Innovative Medicines

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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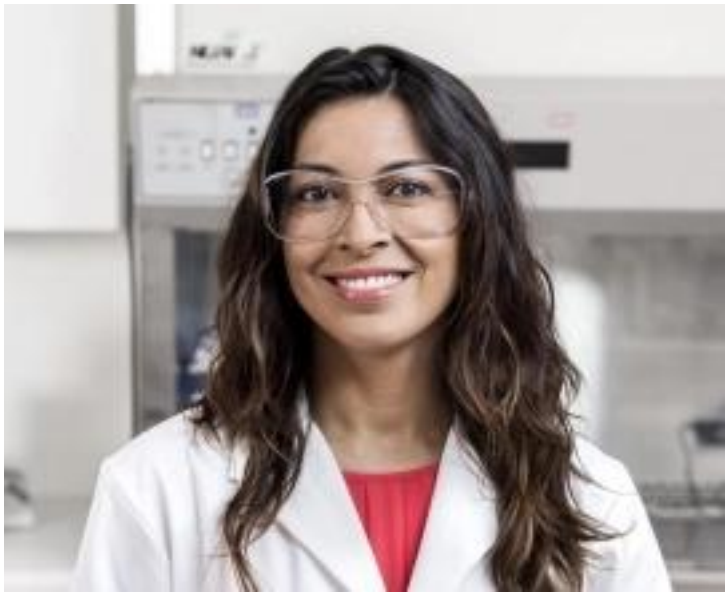
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



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