CSE Group Head

Job ID
REQ-10015345
Juli 11, 2024
Indien

Zusammenfassung

The CSE Group Head (CSE GH) supervises Clinical scientific experts (CSE I/ CSE II). Responsible for competency building of the team by coaching the Clinical Scientific Expert. The CSE GH facilitates their allocation across Development Programs/ Brands for planning and tracking all activities pertaining to one or more Development Programs/ Brands. Responsible for allocating/ balancing resources aligning with Clinical Development Functional Heads (CD-FH), Global Program Clinical Heads (GPCH), Therapeutic Areas Heads (TA Heads) and based on the Development Unit/portfolio needs. Responsible for driving the strategy, development and execution of Clinical Scientific Excellence in compliance with Novartis processes, ICH GCP and regulatory requirements. The Group Head reports to Head CSE and support Senior Leaders from the business and functions within Global Drug Development (GDD) to help to progress how Novartis innovates, engages and operates. The Development Units will be a key stakeholder and interactions will primarily focus on CSE support of Clinical Trials. Drives cultural change in the company, direct, oversee and coordinate all activities, deliverables and resources within CSE group and Development unit(s). The CSE role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The Group Head is expected to act as a leader on any cross-organizational governing body on clinical data review strategies through local and global level initiative.

About the Role

Major accountabilities:

Accountable for Leadership and Management of Clinical Scientific Experts (CSE I/II):

· Selects, recruits, develops, manages, motivates, coaches and appraises the performance of direct reports to ensure high quality performance and support career development through quality development plans across the CSE Team.

· Manages and coordinates the assignment of resources and workload within group or disease area, and ensures sharing of resources between groups in order to meet company objectives and priorities.

· Provides all necessary support to help address and resolve issues. Identifies solutions for remediation.

· Builds and establishes a strong team spirit and creates a team founded on clinical and scientific expertise, technical ability, excellence in performance and exhibiting the Novartis values and behaviors.

· Leads and supports special projects and initiatives/highlights the need for training programs and supports the establishment of these (technical and professional skills) for CSE group and ensure staff training is conducted and properly documented.

· May act as a Subject Matter Expert for key operational areas influencing Clinical Scientific Expert Group and wider area of Clinical Development

In collaboration with QA, manage audits and regulatory inspections and create an audit readiness working environment. Understands Health Authority requirements and is able to participate in Health Authority inspections as required.

Promoting cultural change

- Drive development and implementation of a change management concept in close collaboration with HR and closely aligned with the overall Novartis objectives to build a more data-centered mindset, including capability building, change agents, talent placement.
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Coach CSE I and CSE II to:

- Ensure high quality clinical trial data and Clinical Study Reports (CSRs)/outputs throughout the project life cycle, in compliance with Novartis processes, ICH GCP and regulatory requirements. This role applies the principles of clinical data review excellence and clinical data insights with a key core focus on trends analysis in terms of patient safety and data integrity. This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The CSE is a core member of the Clinical Trial Team (CTT). In addition, the CSE may support/lead program level documents or activities as assigned.

Minimum Requirements:
Work Experience:

- Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. Master's, PharmD, MPharm, PhD, MBBS, BDS, MD strongly preferred. Demonstrated ability to work effectively in a multi-national organization
- ≥3 years scientific, strategic and operational experience in planning, executing, reporting and publishing clinical studies in industry or Academia, or 5+ years in Clinical Operations/Clinical Scientific role.
- >5 years experience in team/ matrix management preferred. Intermediate to Advanced knowledge with hands-on experience in planning, executing, reporting and publishing global clinical studies in a pharmaceutical company or contract research organization or similar experience with an academic research institution
- Understanding of principles of well-designed clinical trials, including trial objectives, sample size rationale, defined trial population, methods for eliminating or minimizing bias, bio- statistical analysis methods, outcome measures, interpretation of results & ethics.
- Medical/scientific expertise with a good understanding of medical/scientific writing skills
- Prior experience of scientific partnership with investigators
- Strong scientific knowledge of assigned therapeutic area(s) is desired (e.g., understanding of basic mechanisms of diseases and associated symptoms, standard of care/treatment, scientific endpoints & clinical outcomes). Show capability to interpret, discuss and represent trial or program level data.
- In-depth knowledge of Good Clinical Practice, clinical trial design, statistics, regulatory processes, and clinical development process.
- Thorough knowledge of principles of clinical data collection and reporting; ability to use systems and tools (e.g., EDC systems, Excel, etc.) for data collection, analysis and reporting. Experience in Rave and/or OC-RDC is an advantage.

- Strong analytical/computational background; ability to detect data trends and escalate as appropriate
- Demonstrates knowledge and application of statistical analysis methodology and can identify trends and analyze/interpret/report data effectively
- Ability to collaborate across boundaries for shared success
- Profound people skills and leadership exposure (proven track record in leading teams is an advantage. This may include people management in a matrix environment.)
- Superior people management skills with demonstrated positive leadership, innovative, and collaborative behaviors.
- Advanced planning and tracking skills with attention to detail. Well-organized, excellent time management with respect to priorities and self-management.
- Experience in project management and managing projects driving performance improvements is desirable.
- Ability to mentor, coach associates, and to coordinate interactions with internal and external partners.
- Strong management, interpersonal, communication, and problem solving skills.

Why Novartis .

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Commitment to Diversity & Inclusion:

- *We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.*

  You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.
  https://www.novartis.com/careers/benefits-rewards

  Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

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

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Development
Business Unit
Innovative Medicines
Ort
Indien

Website
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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