

Medical Director of Hematology - Remote

Job ID
REQ-10064088

11月 14, 2025

USA

摘要

The Medical Director of Hematology develops and implements strategic and operational TAs Global Medical Affairs programs, with a focus on innovative evidence and/or launch readiness and/or post-market solutions, including medical affairs planning and execution of the medical/scientific engagement strategy addressing and delivering strategic pre-launch and launch medical activities needs for patient, clinical, access and value to health care systems. Provides expertise in the development and execution of the overarching strategies, providing inputs during design and along the end-to-end execution of programs. Develops and executes the Integrated Evidence Plan (IEP)/functional specific programs to maximize the value proposition for the prioritized launch portfolio and impact of our medicines.

- Serve as US Medical Director for multiple global clinical development trials and/or US Medical Affairs Trials (including phase I-IV, Expanded Access, Investigator Initiated, registries and Compassionate Use).
- Interface with the oncology therapeutic area Global and US Clinical Team Members, Clinical Operations, Scientific Operations, Regulatory Affairs, Drug Supply, Data Management, Finance, Quality, Compliance, and other relevant functional areas.
- Design and optimize clinical trial design and ensure clinical trials meet ethical and regulatory

standards including:

- o Write and review protocols that are in-line with the overall indication strategy.
- o Conduct medical review and interpretation of efficacy and safety data from clinical trials.
- Responsible for the quality, coordination, medical accuracy, and timeliness of clinical study reports, clinical sections of INDs, Investigator Brochures, CTAs, ISS ' s, ISE ' s, clinical expert reports, and label reviews.
- Review and provide US feedback to Global Protocols and Global Development Plans.
- Develop strategy for US Medical Affairs including exploratory indications and integrate US plan with overall Medical Affairs strategy. Oversee the review and approval of IIT concepts. Oversight during the conduct of trials including safety monitoring. Review of interim and final publication, manuscripts, or abstracts.
- Provide strategic input or develop strategy for US clinical trial programs. May also evaluate global strategy for the clinical trial programs.
- May supervise and manage individuals on the US disease team as appropriate. Lead the Clinical Team, including interactions with Safety, HEOR, Marketing, Regulatory, Research, and other functions.
- Work with Clinical Team and other functions to prepare abstracts, manuscripts and presentations for external meetings as well as author clinical sections of regulatory documents (i.e., IB, IND sections), for Company Sponsored project.
- Review and approve abstracts publications & manuscripts for Investigator Initiated Trials to ensure clinical accuracy and appropriate safety review.
- Present and discuss data and findings at relevant internal and external meetings.
- Ensure adherence to GCP/ICH and company Standard Operating Procedures (SOPs).

- Where applicable, may lead disease area teams to:
 - o Ensure delivery of US medical tactical plan and development activities across all of a compound ' s related to the disease area, cost, time and quality.
 - o Collaborate and work with other IMUS line functions for data gaps analysis, data generation activities, strategic congress management, strategic trial management, external stakeholder management and launch readiness plans.
- Support and participate in FDA meetings including presentations, briefing books, and responding to FDA inquiries as needed.
- Assist in the development and appropriate spending of clinical budget.
- Extensive interactions with academic thought leaders to optimize clinical trial strategies.
- Extensive interactions with other functional teams including HEOR, Medical Information, Scientific Communication, Commercial, Regulatory and others, to refine compound strategy and projects.
- Coach and train internal colleagues as requested

About the Role

Position Requirements

- MD, PhD Pharm D, or equivalent required. If MD, Board Certified or board eligible in either Hematology or Oncology, or relevant Medical Specialty.
- At least 3-10 years of experience in Hematology/Oncology clinical research in the pharmaceutical industry OR experience in clinical research or medical affairs is preferable or a combination of experience in academic medicine with clinical research and or clinical development experience in collaboration with the pharmaceutical industry.

- Scientific medical research experience in Oncology and or Hematology (or relevant specialty) with demonstrated record of scientific medical publications.
- Experience leading the design, conduct, analysis and reporting of clinical studies is strongly preferred.
- Superior leadership, networking, collaboration and communication skills.
- Successful interactions with Medical Experts and investigators.
- Demonstrated the capability for strategic planning along with operations skill and experience related to clinical research involving both single and multiple centers.
- Ability to work across multiple functions is essential.
- Effective oral and written communications skills and strong leadership are essential for success in the role.

Position will be filled at a level commensurate with experience.

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US

Business Unit
Marketing

地点
USA

状态
Remote, US

站点
Remote Position (USA)

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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