

Senior Global Program Clinical Head, Oncology

Job ID
393918BR

11月 07, 2024

USA

摘要

Onsite

Location: East Hanover, New Jersey

Job Description Summary

Onsite

Location: East Hanover, New Jersey

Hybrid

#LI-Hybrid

About the role:

As Global Program Clinical Head (GPCH), you are the clinical lead of a Oncology full development product and will lead the clinical assessment of internal Novartis Institute for Biomedical Research (NIBR) early clinical programs and external assets (Business Development & Licensing - BD&L) across Oncology (Solid Tumor) indications. As a key member of the Global Program Team, you will contribute to the overall strategy in collaboration with relevant other functions such as Regulatory Affairs, Market Access and others. You will develop and ensuring the implementation of the Clinical Development plan and leading a cross functional team of specialists such as Medical Directors, Trial

Directors, Safety Leaders, Biostatisticians and Regulatory Directors. In addition, you will lead the development and execution of the disease area strategy.

About the Role

Your Key Responsibilities:

- Responsible for clinical input to support Business Development & Licensing (BD&L) activities
- Serve as the Clinical Development Representative to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- Contribute to Integrated Development Plan (IDP) in line with the Target Product Profile (TPP) which is designed for successful global regulatory approval/market access for one or more treatment indications and/or multiple programs.
- Drive creation and implementation of Clinical Development to support decision analysis and optimal resource allocation in program(s).
- Lead a cross functional team through the creation of clinical components of key documents (e.g., Clinical Trial Protocols, Investigator 's Brochures, Clinical Study Reports, regulatory documents including maintenance of product licenses, registration dossiers, value dossiers, pharmaco-economic dossiers) with high quality and consistency.
- As the medical expert, lead interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards, patient advocacy groups), internal stakeholders (e.g., Research, Translational Medicine, Global Medical Affairs, Marketing, Health Economics & Outcomes Research), and internal decision boards.
- Together with Patient Safety, ensure continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance.
- Support registration, market access, commercialization, and maintenance of product licenses (e.g., Core Data Sheet, Periodic Safety Update Report, clinical benefit-risk assessment for license renewals) for the compound(s)
- Plan and implement publication and clinical communication strategy in coordination with Global Medical Affairs and Medical Writing and provide input into key external presentations.

The ideal location for this role is East Hanover, NJ, but remote work may be possible (there may be restrictions based on legal entity). Please note that this role would not provide relocation as a result. If the associate is remote, all home office expenses and travel/lodging to the East Hanover or corporate site for periodic live meetings will be at the employee 's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

Video Link

- <https://www.youtube.com/watch?v=ggbnzRY9z8w>

Role Requirements:

Essential Requirements:

- MD with 6+ years ' experience in clinical research or drug development in an industry environment spanning clinical activities in Phases I-III/IV, including submission dossiers.
- A passion for Oncology
- Advanced expertise in Oncology with ability to innovate in clinical development study designs, provide relevant evidence to decision-makers and to interpret, discuss and present clinical trial or section program level data
- Detailed knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Demonstrated leadership and management skills with a documented track record of delivering high quality projects/submissions/trials in a global/matrix environment (including remote) in pharmaceutical or biotech industry

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/careers/benefits-rewards>

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Accessibility and reasonable accommodations

The Novartis Group of Companies are 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 application process, or in order to perform the essential functions of a position, please send an e-mail to tas.nacomms@novartis.com call +1 (877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

<https://www.novartis.com/careers/careers-research/notice-all-applicants-us-job-openings>

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>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Innovative Medicines

地点
USA

站点
East Hanover

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

[Apply to Job](#)



Job ID
393918BR

Senior Global Program Clinical Head, Oncology

[Apply to Job](#)

Source URL:

<https://www.novartis.com/careers/career-search/job/details/393918br-senior-global-program-clinical-head-oncology>

List of links present in page

1. <https://www.youtube.com/watch?v=ggbnzRY9z8w>
2. <https://www.novartis.com/about/strategy/people-and-culture>
3. <https://www.novartis.com/careers/benefits-rewards>
4. <https://talentnetwork.novartis.com/network>
5. <https://www.novartis.com/careers/careers-research/notice-all-applicants-us-job-openings>
6. <https://www.novartis.com/about/strategy/people-and-culture>
7. <https://talentnetwork.novartis.com/network>
8. <https://www.novartis.com/careers/benefits-rewards>
9. <mailto:us.reasonableaccommodations@novartis.com>
10. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/East-Hanover/Senior->

Clinical-Development-Medical-Director--Oncology-Hematology393918BR

11. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/East-Hanover/Senior-Clinical-Development-Medical-Director--Oncology-Hematology393918BR>