

Senior Clinical Development Director - Renal

Job ID
REQ-10040259
fév 13, 2025
Etats-Unis

Résumé

The Senior/Clinical Development Director (Sr*CDD) is the clinical/scientific expert and if assigned the clinical development lead of a section of a global clinical program and/or trial. (e.g., an indication, a new formulation, or a specific development phase) or a large, complex trial, under the leadership of the GPCH. The Sr* CDD may be assigned to have a team leadership role for sections clinical programs and/or global clinical trials, depending on the size, nature and complexity

About the Role

Major accountabilities:

- Supports and if assigned leads delivery of all assigned clinical deliverables in the assigned section of a clinical program. Clinical deliverables may include the clinical development strategy for assigned program section(s), clinical sections of individual protocols consistent with the Integrated Development Plans (IDP), clinical data review program specific standards, clinical components of regulatory documents/registration dossiers, and publications
- Contributes and if assigned leads development and delivery of clinical sections of trial and program level regulatory documents (e.g., Investigator's Brochures, briefing books, safety updates, submission dossiers, and responses to Health Authorities)
- Drives execution of the section of the clinical program in partnership with global line functions, in particular clinical operations, trial leaders and data management/analysis, and regional/country clinical development associates
- Ensures ongoing clinical and scientific review of clinical trial data.
- Work in close collaboration with the data management and statistics teams to ensure proper data quality and analysis of clinical trial results.
- May be the Program or Function Manager of associates (e.g., CDD or associate CDD)
- Supports GPCH in assessing overall risk-benefit of the molecule for the assigned section of the clinical program, may be a (core) member of the Safety Management Team (SMT), and supports overall program safety reporting (e.g., Periodic Safety Update Reports (PSURs), Drug Safety Update Reports (DSURs), and other safety related documents) in collaboration with the medical monitor, CDMD and Patient Safety
- Member and if assigned may (co-)lead the Global Clinical Team (GCT), if there is a separate GCT for the assigned program section. Represents the section when assigned in Global Program Team (GPT) meetings, and as the section spokesperson in internal and external meetings/boards, as assigned
- Supports the Clinical Development Head (CDH) by providing clinical/scientific input into IDP/CDP and CTP reviews and contributing/driving development of disease clinical standards for new disease areas. May take on other TA responsibilities as directed by the CDH

Minimum Requirements:

Work Experience:

- Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. PharmD, or PhD strongly preferred
- ≥ 10 years of involvement in clinical research, global drug development in an academic or industry environment spanning clinical activities in Phases I through IV. ≥ 5 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. Experience in late phase clinical development strongly preferred
- Solid scientific writing skills
- Experience with regulatory submissions (IND, NDA/BLA, CTA/MAA) preferred
- Solid and advanced scientific acumen and ability to analyze and interpret scientific literature and data. Strong affinity with data, data quality and analysis.
- Preferred knowledge and/or experience of assigned therapeutic area
- Demonstrated ability to establish strong scientific partnership with key internal and external stakeholders
- ≥ 3 years people management experience required; this may include management in a matrix environment*

Final job title Senior Clinical Development Director, Level 6 / Clinical Development Director, Level 6 and associated responsibilities will be commensurate with the successful candidates' level of expertise.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: \$204,400 and \$379,600/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

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.

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Innovative Medicines

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Etats-Unis

État

New Jersey

Site

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Recherche & Développement

Job Type

Full time

Employment Type

Regular

Shift Work

No

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