NOVARTIS

Clinical Development Director - Renal

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Сводка

The Clinical Development Director (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 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

Title: *Clinical Development Director

Office Location: London UK or Dublin Ireland

#LI-Hybrid Hybrid (12 days per month on-site)

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
- Proven experience working 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

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

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

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

Commitment to Diversity and Inclusion:

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

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Primary location salary range
£83,510.00 - £155,090.00
Дивизион
Development
Business Unit
Development
Место
Великобритания
Сайт
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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