Associate Clinical Development Director (Oncology)

Job ID
REQ-10056881

7月 09, 2025

Ireland

摘要

LOCATION: Dublin. London, Basel or Barcelona
ROLE TYPE: Hybrid Working, #LI-Hybrid

The Associate Clinical Development Director (Oncology) (Assoc. CDD) provides input to development of protocols for assigned global clinical trials, scientific monitoring, and reporting of quality data. May be assigned to provide support to development of the clinical and scientific strategy of assigned sections of a clinical development program, depending on the size and complexity.

About the Role

Major accountabilities:

- Provides input to the development of clinical development strategy , and contributes to development of trial related documents (e.g., Clinical Trial Protocols (CTPs), informed

consent form, case report forms, data monitoring committee charters, data analysis plan, reports, publications) for assigned clinical trial(s) consistent with Clinical Development Plan (CDP); develops materials for trial-related advisory boards, data monitoring committees, investigator meetings, and protocol training meetings for Novartis local clinical development teams

- Provides clinical and scientific input and contributes to clinical sections of trial and program level regulatory documents (e.g., Investigator ' s Brochures, Health Authority briefing books, safety updates, submission dossiers, and responses to Health Authorities)
- In collaboration with appropriate Clinical Trial Team (CTT) members:

a) Ensures clinical development oversight and support of trials as needed

b) Conducts ongoing scientific review of clinical trial data with Clinical Scientific Expert(s) with appropriate oversight from Medical Lead (ML)/ Clinical Development Medical Director (CDMD)/ Clinical Science Liaison (CSL)

c) Manages patient safety reports on trial data to safety and clinical boards (e.g., Safety Management Team (SMT), Global Clinical Trials (GCT), Generative Pre-trained Transformer (GPT)) with appropriate oversight from ML/CDMD/CSL in collaboration with patient safety

d) Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations, with appropriate oversight from ML/CDMD/CSL

- Contributes to global initiatives (e.g., process improvement, training, Standard Operating Procedure (SOP) development, other Clinical Development line function initiatives)
- May be assigned to lead clinical trial(s) as Clinical Scientific Lead and provide leadership and guidance for all clinical aspects of a clinical trial in close collaboration with the assigned medical monitor and/or CDMD.

Key Performance Indicators:

Evidence of quality clinical and scientific strategic input as well as timely delivery of high-quality CTPs and other clinical deliverables

- Applies effective clinical research methodology, including trial design/analyses, efficacy endpoints, safety assessments, and risk management across disease area and development phases

- Supports TA through high quality contributions to CDP and protocol reviews

- Supports timely development of quality disease/program clinical standards, publications, and internal/external presentations

- Evidence of quality contributions to clinical sections of regulatory documents, Investigator ' s Brochures, briefing books, safety updates and submission dossiers

Work Experience:

- ≥ 3 years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV. ≥ 2 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
- Working knowledge of Oncology is desired with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level
- Demonstrated ability to establish effective working relationship with stakeholders
- Working knowledge of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Good Clinical Practice (GCP), clinical trial design and methodology, statistics, and regulatory and clinical development processes
- Strong communication skills, written and oral
- Strong interpersonal skills including strong negotiation and conflict resolution skills
- People management preferred

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 Handbook.

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

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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

部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Basel (City), Switzerland

Alternative Location 3
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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