

Clinical Development Director

Job ID
REQ-10038915
Jan. 30, 2025
Ireland

Zusammenfassung

Our Immunology Development Unit has a pipeline with depth and breadth and is known to be a talent powerhouse. We are uniquely positioned to have a critical impact on bringing innovative medicines to patients across multiple disease areas. This includes developing Novartis' multi-blockbuster Cosentyx and several novel agents, with an extensive immuno-dermatologic footprint.

As our Clinical Development Director in Immunology you will be responsible for the scientific and clinical strategy of assigned clinical trials, scientific monitoring, and reporting of quality data. In addition, you may be responsible for the clinical and scientific strategy of assigned sections of a clinical development program, depending on the size and complexity.

About the Role

Your responsibilities include, but are not limited to:

- Provide clinical leadership, medical and scientific strategic input, and contribute to development of trial related documents (e.g., CTPs, informed consent form, case report forms, data monitoring committee charters, data analysis plan, reports, publications) for assigned clinical trial(s) consistent with Integrated Development Plan (IDP); develop materials for trial-related advisory boards, data monitoring committees, investigators meetings, and protocol training meetings for Novartis local medical organizations.
- Provide clinical and scientific input and contribute 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: Ensure clinical support of trials as needed; conduct ongoing medical and scientific review of clinical trial data with Clinical Scientific Expert(s) with appropriate oversight from Medical Lead; manage patient safety reports on trial data to safety and clinical boards (e.g., Safety Management Team (SMT), GCT, GPT) with appropriate oversight from Medical Lead; provide input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations.
- Support Therapeutic Area Head (TAH) with contributing to peer-review of IDPs, CTPs, and other clinical documents across various indications and programs, and support development of TA strategies, as needed.

- May contribute to the medical and scientific evaluation for Business Development & Licensing (BD&L) opportunities.
- Contribute to talent and career development of CD associates through on-boarding, coaching, and/or mentoring support; develop and foster CD culture; and may contribute to the performance evaluation of CTT members.
- Contribute to medical/scientific training of relevant Novartis stakeholders on the disease area and compound/molecule. May serve as speaker for franchise medical/scientific training.
- Contribute to global initiatives (e.g., process improvement, training, SOP development, other Clinical Development line function initiatives).

Minimum Requirements:

- Advanced degree in life sciences/ healthcare (or clinically relevant degree) is required.
- 5+ years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV; 2 or more 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.
- Proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level.
- Working knowledge of the disease area is desired with proven ability to interpret, discuss and present efficacy and safety data relating to clinical trial(s) or program level
- Working knowledge of GCP, clinical trial design, statistics, and regulatory and clinical development processes.

Desirable requirements:

- PharmD, or PhD strongly 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. <https://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>

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>

Abteilung

Development

Business Unit

Innovative Medicines

Ort

Irland

Website

Dublin (NOCC)

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Alternative Location 1

Barcelona Gran Vía, Spanien

Alternative Location 2

Basel (City), Schweiz

Alternative Location 3

London (The Westworks), Vereinigtes Königreich

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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