Clinical Development Director (Neuroscience)

Job ID
REQ-10048984

5月 01, 2025

United Kingdom

摘要

The Clinical Development Director (CDD) is the clinical/scientific and clinical development expert and provides leadership and support to clinical development deliverables and activities within a defined global clinical development program and/or global clinical trial (e.g. clinical development plan, clinical trial protocol), under the leadership of the GPCH.

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 and program specific standards, clinical components of regulatory documents/registration dossiers, and

publications
- Provides input into final analyses and interpretation including the development of the Clinical Study Report(s) (CSRs), publications and internal/external presentations.
- Leads development 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)
- Oversees/conducts ongoing clinical and scientific review of clinical trial data with medical monitor, Clinical Scientific Expert(s) with appropriate oversight from Medical Lead. Work in close collaboration with the data management and statistics teams to ensure proper data quality and analysis of clinical trial results.
- Inspection Readiness and interaction with QA - risk assessments, audit preparation, mock interviews, storyboard and presentation prep; Author and/or review abstracts, presentations and manuscripts for accuracy of clinical data and content
- May be the Program Manager of other associates (e.g., CSE)
- Provides support to Sr CDMD and/or GPCH in monitoring and safety data and signals the molecule for the assigned section of the clinical trial, may be a 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

This hybrid role can be based in London, Dublin, Basel or Barcelona.

Minimum Requirements:

Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. PharmD, or PhD preferred. Experience in Neuroscience, Cell & Gene, Rare or neuromuscular diseases, and/or Neuroinflammation (preferred).

Work Experience:

- ≥ 7 years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV. ≥ 3 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
- Advanced knowledge of assigned therapeutic area
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Thorough knowledge of GCP, clinical trial design and methodology, statistical analysis methodology, and regulatory/clinical development process
- >=1 year of People management experience preferred this may include management in a matrix environment. Global people management experience desirable

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#LI-hybrid

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部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点

London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Basel (City), Switzerland

Alternative Location 3
Dublin (NOCC), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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