Clinical Scientific Expert I

Job ID
REQ-10046310

4月 28, 2025

United Kingdom

摘要

The Clinical Scientific Expert I (CSE I) provides clinical and scientific support through all phases of a clinical study under the guidance of the (A)CD(M)D in compliance with Novartis processes, ICH GCP and regulatory requirements. This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The CSE I is a core member of the Integrated Clinical Trial Team (iCTT) and may support program level activities as assigned.

About the Role

Your Responsibilities:

- Perform high quality clinical data review and identify clinical data insights through patient level review and trends analysis, supporting Interim Analysis, Database and Post Lock activities and facilitate resolution of clinical data issues. Collaborate with relevant line functions to

enhance the quality of clinical data review/insights with an emphasis on subject safety and eligibility, data integrity, trend identification, analysis and remediation, and identification of cases for medical review.
- Contributes to the development the Data Review/Quality Plan (DRP/DQP) and data review strategy, ensuring that protocol-level deviations, eligibility criteria, study assessments & other aspects of the protocol are implemented consistently across the study.
- In conjunction with the relevant line functions, may contribute to Case Report Form (CRF) development, and support the implementation of data capture tools.
- Contribute to and facilitate data review process improvements e.g. identification of delinquent/redundant reports and/or implementation of innovative data analysis processes and tools.
- May contribute (in collaboration with relevant line functions) to the development of study-level documents, including clinical sections of key regulatory documents, such as Investigator ' s Brochures, briefing books, safety updates and submission dossiers. In collaboration with relevant line functions, review/write clinical trial documents for study CSR activities, and publications.

What you ' ll bring to the role:

- Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. Master ' s, PharmD, MPharm, PhD, MBBS, BDS, MD strongly preferred.
- Scientific, strategic and operational experience in planning, executing, reporting and publishing clinical studies in industry or Academia, or experience in a Clinical Operations/Clinical Scientific role
- Intermediate knowledge of planning, executing, reporting and publishing global clinical studies in a pharmaceutical company or contract research organization or similar experience with an academic research institution
- Good knowledge of Good Clinical Practice and drug development processes
- Strong scientific knowledge in at least one therapeutic area (e.g., understanding of basic mechanisms of diseases and associated symptoms, standard of care/treatment, scientific endpoints & clinical outcomes)
- Knowledge of principles of clinical data collection and reporting; ability to use systems and tools (e.g., EDC systems, Excel, etc.) for data collection, analysis and reporting. Experience in Rave and/or OC-RDC is an advantage.
- Analytical / computational background; ability to detect data trends and escalate as appropriate
- Demonstrates knowledge and application of statistical analysis methodology
- Demonstrates good medical / scientific writing skills
- Ability to collaborate across boundaries for shared success
- Ability to resolve issues or understand when to escalate

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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.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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