

Senior Clinical Database Developer-1

Job ID
REQ-10059053

7月 30, 2025

India

摘要

Provide timely & professional ongoing Mgmt of Data Mgmt/Coding/CDDRA-Database Development/DAP deliverables and of clinical trial data with respect to cost, quality and timelines for all assigned trials within Clinical Data Mgmt. Ensure consistently high quality data available for analysis and reporting. Develop content and redefine training modules into engaging & interactive applications. Leverage technology to ensure process simplification and training delivery. Follows Good Clinical Practices (GCP), data-handling procedures and guidelines. Participates in the review of clinical research protocols, reports and statistical analysis plans. Drives participation and input within Data Operations (DO) in the delivery of quality data and programs, processes and documentation -Manage data Load, Transfer and conform of Clinical trial data to NCDS compliant standards. The position is a key contributor with Data Provisioning team in ensuring that pharmaceutical drug-development plans in Novartis Global Drug Development are executed efficiently with timely and high quality deliverables.

About the Role

Major Accountabilities

- 在指定的试用中提供 DM 领导权,并在需要时充当试用数据管理器
- 演示对复合型材的业务理解,以识别和协助成功应用 Mgmt 流程数据。
- 提供反馈,以确保良好的书面协议和修正案。
- 识别和解决可能影响数据库设计、数据验证和/或分析/报告且不能充分利用现有标准的协议问题
- 执行 DM 活动,以启动研究、数据处理计划、数据审查计划和执行用户接受测试 (UAT)
- 根据适用管理为临床数据库设置的本地实验室
- 在平台或流程中领导流程和培训交付成果。
- 负责职权范围内流程和培训的所有方面,以确保完全遵守所有适用的全球监管要求,并实现业务目标。
- 对所有质量相关方面负责
- 集中和调整 DO 进行审计和检查。
- 管理和衡量质量
- 协调例外请求、偏差和纠正/预防行动计划
- 在研究过程中执行 DM 手部活动
- 对临床研究生成的所有数据包括第三方和本地实验室数据以及适用的 SAE 对账进行持续审查
- 负责任和负责,以确保分配的试验与DM文档中程序级标准的一致性
- 已证明能够使用可用于生成数据审查列表的工具,并在必要时向研究团队提供这些列表。生成研究状态报告,供临床试验团队会议使用。
- 支持和协助初级工作人员进行分配的试验
- 为 DM 举措和创新提供有效投入,提高质量、效率,不断提高科学和运营卓越性
- 执行准确一致的编码,管理与编码相关的查询,解决编码问题,并确保及时完成分配的试用版的字典升级
- 在试用/程序级别领导/协调同义词审查活动和字典版本升级活动。
- 通过与研究团队和职能部门建立和保持牢固的工作关系,作为主要研究领导,确保及时和高质量的交付。根据需要担任技术顾问。
- 领导 DAP 活动,为诺华全球药物开发的第一至 IV 阶段临床研究分配/项目级别活动。
- 独立领导或参与改进计划和/或非Clin项目。
- 在收到诺华产品后24小时内报告与诺华产品相关的技术投诉/不良事件/特殊情况
- 营销样本的分发(如适用)

Key Performance Indicators

在数据管理活动和可交付成果中实现高水平的质量、及时性、成本效益和客户满意度。
由于数据管理,没有关键的审计发现
遵守诺华的政策和准则
客户/合作伙伴/项目反馈和满意度

Work Experience

项目管理
职能广度
跨文化经历

Skills

临床数据管理
数据治理
数据完整性

数据管理
数据质量
数据库
数据科学
项目管理

Language

英语

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>

部门
Development

Business Unit
Universal Hierarchy Node

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
正式

Shift Work
No

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