Preclinical Safety Data (SEND) and Sample Management Expert

Job ID
REQ-10057658

7月 17, 2025

USA

摘要

Internal Title: Senior Scientist II

#LI-Hybrid

This position is based in Cambridge, MA. This position will not require travel.

The Preclinical Safety Data and Sample Management Expert will play a critical role in managing all non-clinical study data and samples associated with our mergers and acquisitions (M&As). As the ideal candidate you will understand non-clinical safety data requirements for FDA submissions and will use this knowledge to advise during due diligences. In this role you will be required to the create and QC SEND packages, providing same for HA submissions, convert non-SEND data into SEND format, and integrate non-clinical data into internal warehouses. In addition, you will ensure all non-clinical safety data and samples from mergers and/or acquisitions will be accounted for and properly archived.

Use your knowledge about current SEND requirements for HA submissions and strong communication skills to advise internal and external customers on same. In this key role you will be

expected to keep abreast of future changes to SEND requirements and ensure continual compliance. Exciting opportunity to help shape industry policy by participating in external consortia.

About the Role

Major accountabilities:

- Advising before, during, and after M&As on the non-clinical data HA submission requirements
- Providing submission-ready SEND packages for FDA submissions
- Transfer of SEND data into Novartis' data warehouse and oversight of the complete life cycle of vendor samples and specimens to ensure all relevant PCS study information is retained in a designated archive
- Creating and assessing quality of SEND packages in collaboration with nonclinical CROs
- Engaging and collaborating with key internal and external customer partners
- Offering recommendations and challenging leadership by continuously analyzing, providing insights, and formulating strategies
- Fostering robust, cross-functional relationships to utilize Novartis ' expertise in identifying and addressing business objectives, while cultivating a comprehensive understanding of our key brands and their changing requirements
- Ensuring alignment to, compliance with, and ownership of all NPC policies, including the Code of Conduct and all applicable laws and regulations

• Essential Requirements:

- Bachelor ' s degree required, preferably in science-related discipline, advanced degree a plus.
- Minimum 2 years working as organizational expert with current and upcoming SEND regulations.
- Minimum 5 years overall pharmaceutical industry / CRO experience.
- Must have ability to create and assess quality of SEND packages in collaboration with nonclinical CROs
- Demonstrated experience with SEND and data in SEND format in pharmaceutical, biotech, or life sciences setting
- Experience with non-clinical safety data, sample and specimen retention policies in compliance with GLP regulations

- **Desirable Requirements:**
- Experience with Pristima/Savante, Pinnacle21 software, and SAS XPT and CSV file types
- Experience with sample tracking

The salary for this position is expected to range between $93,800 and $174,200 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the

published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

Company will not sponsor visas for this position.

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

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Biomedical Research

Business Unit
Universal Hierarchy Node

地点
USA

状态
Massachusetts

站点
Cambridge (USA)

Company / Legal Entity
U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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