NOVARTIS

Preclinical Safety Data and Sample Management Expert

Job ID
REQ-10046269
Mar 31, 2025
USA

Summary

About the role:

#LI-Hybrid

This position is based in Cambridge, MA. The expectation of working hours will be defined by the hiring manager. 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). The ideal candidate will understand non-clinical safety data requirements for FDA submissions and will use this knowledge to advise during due diligences. The associate 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, this associate will ensure all non-clinical safety data and samples from mergers and/or acquisitions will be accounted for and properly archived. The ideal candidate should be knowledgeable about current SEND requirements for HA submissions and have strong communication skills which will be utilized to advise internal and external customers on same. Likewise, this expert will be expected to keep abreast of future changes to SEND requirements and ensure continual compliance. Ideally, this person will help to shape industry policy by participating in external consortia.

About the Role

Key Responsibilities:

- 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.
- Expertise in current and upcoming SEND regulations
- 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

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: $73,500.and $136,500 year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other

legally protected status.

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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Business Unit
Pharma Research
Location
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State
Massachusetts
Site
Cambridge (USA)
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Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Job ID
REQ-10046269

Preclinical Safety Data and Sample Management Expert

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