Clinical Bio-specimen Senior Scientist

Job ID
392618BR
Feb 21, 2024
USA

About the Role

Clinical Biospecimen Senior Scientist

Responsible for the implementation and end-to-end operational execution of each GCO clinical trial strategy as it relates to all biospecimens collected, including safety, pharmacokinetics, biomarkers for clinical trials of standard to medium complexity, in compliance with Novartis processes and regulatory and ethical requirements. May support specific aspects related to companion diagnostics.

Your Key Responsibilities:
1. With some oversight from the lead Clinical Biospecimen Scientist (CBS), contribute to all technical and operational biospecimen-related matters for assigned clinical studies of standard to medium complexity, in collaboration with internal partners and line function (LF) representatives.
• Provide input on clinical sample assessment sections in clinical trial-related documents (such as protocols and consents) in collaboration with the LF representatives.
• Create study-specific sample collection tables and ensure alignment with blood volumes needed versus allowed.
• Liaise with internal partners to provide input into the SSW's for all bio-specimen collection and testing needs.
• Responsible to set up and coordinate the technical aspects for all laboratories involved in kit building, sample management, and testing, including all related documentation such as lab manuals.
• Provide input and solutions on the ethical considerations for biospecimen collections and analyses for protocols and consents to ensure that all specific processes needed for approval in different countries are implemented.
• Responsible for sample management and logistics, with some oversight from the Lead CBS, throughout the biospecimen lifecycle; this includes ensuring timely analysis, proper consent, and oversight of samples, in collaboration with data management.
2. Risk management:
• Ensure proper escalation of any identified trial specific risks and issues related to biospecimen collection and analysis in conjunction with relevant line functions.
3. Resource management:
• In collaboration with vendor management and procurement, with some oversight from the Lead CBS, review all laboratory proposals and provide budget input for the trial forecast; review invoices.
• In collaboration with vendor management, manage relationships with labs.
4. Responsible for implementation of and compliance to standards (SOPs) and best practices within assigned clinical trial(s) and within clinical program(s), including sharing lessons learned.

Diversity & Inclusion / EEO

We are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Accessibility and Reasonable Accommodations: Individuals in need of a reasonable accommodation due to a medical condition or disability for any part of the application process, or to perform the essential functions of a position, please let us know the nature of your request, your contact information and the job requisition number in your message:

- Novartis: e-mail us.reasonableaccommodations@novartis.com or call +1 (877)395-2339
- Sandoz: e-mail reasonable.accommodations@sandoz.com or call: +1-609-422-4098

Role Requirements

• Advanced degree in life sciences strongly preferred, BS or BA in life sciences with relevant experience required
• Familiarity with standard sample testing methodologies, assay technologies, and molecular biology
• At least 2 years of experience handling diverse type of clinical samples
• Knowledge of GCP; intermediate knowledge of GLP and ICH
• Intermediate knowledge of clinical trial design and the overall drug development process
• Excellent organizational and communication skills
• Ability to manage multiple competing priorities and meet timelines

The company provides reasonable accommodations for otherwise qualified individuals with medical restrictions if an accommodation can be provided without eliminating the essential function of driving.
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
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

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $130,400 – $195,600/year; however, while salary ranges are effective from 1/1/23 through 12/31/23, 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.

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

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

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Business Unit
GCO GDD
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USA
Site
East Hanover, NJ
Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
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