Associate Director Biostatistics

Job ID
REQ-10031517

May 07, 2025

United Kingdom

Summary

We are seeking a highly motivated Associate Director of Biostatistics; you will be required to influence and drive the statistical strategy and innovation through strong collaborations and decision making for assigned trials/programs within (early/full) clinical development and/or medical affairs. Proven experience in execution and analysis of complex clinical trials and leading strategy through collaborations with partners across the organization.

About the Role

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people ' s lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities - all to bring our medicines to patients even faster.

We are seeking key talents, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

The Role:

We are seeking a highly motivated Associate Director of Biostatistics; you will be required to influence and drive the statistical strategy and innovation through strong collaborations and decision making for assigned trials/programs within (early/full) clinical development and/or medical affairs. Proven experience in designing, and analyzing complex clinical trials and leading strategies through collaborations with partners across the organization and depending on the role, supporting regulatory submissions including planning, analysis and reporting of clinical safety and efficacy summaries as well as interacting with Health Authorities.

Representing the Advanced Quantitative Sciences function both internally and externally on decision boards, developing and mentoring other statisticians, and providing solutions to the organization.

This role offers a hybrid working environment, requiring 3 days per week or 12 days per month in our London Office.

Key requirements:

- Responsible for all statistical tasks on assigned clinical trials and perform these tasks for high complexity trials with a high level of independence seeking peer input/review as required. Responsible for protocol development in alignment with the development plan, developing statistical analysis plan, and reporting activities.
- Contribute to planning and execution of exploratory analyses, innovative analyses related to publications and pricing & reimbursement submission and/or PK, PK/PD analyses, exploratory biomarker and diagnostic analyses, and statistical consultation. Initiate, drive, and implement novel methods and innovative trial designs and dose-finding strategies in alignment with the Lead Statistician.
- Experience in providing statistical expertise to support submission activities, including documents, meetings with and responses to Health Authorities, pricing agencies and drug development activities, as required.
- Independently lead interactions with external review boards/ethics committees, external consultants, and other external parties with oversight as appropriate. Represent Novartis in statistical discussions at external congresses, conferences, scientific meetings.
- Represent the Advanced Quantitative Sciences Line Function on cross-functional teams for the assigned trials. Responsible for functional alignment and ensuring line function awareness throughout the trials.
- Collaborate with other line functions. Explain statistical concepts in an easily understandable way to non-statisticians and provide adequate statistical justifications and interpretation of analysis results for actions/decisions/statements, when required.
- Establish and maintain sound working relationships and effective communication within the clinical trial team and the Advanced Quantitative Sciences team.
- Independent oversight of Biostatistics resources and deliverables for assigned trials. Ensure

timeliness and adequate quality of all Biostatistics deliverables for the assigned trials and/or non-clinical related activities.

Your Experience:

- MS Statistics with 10+ years' work experience or PhD (in Statistics or equivalent) with 6years + work experience
- Fluent in English with strong communication and presentation skills, with the ability to articulate complex concepts to diverse audiences.
- Effective utilization of innovative statistics and quantitative analytics to influence assigned program team decisions and support department to deliver objectives.
- Proven knowledge and expertise in statistics and its application to clinical trials. Depending on the assignment, it may require proven expertise in pharmacokinetics, exposure-response modelling, exploratory biomarker, diagnostic analyses, applied Bayesian statistics, or data exploration skills. Demonstrated excellence in use of statistical software packages (e.g. SAS, R). Strong knowledge of drug development and Health Authority guidelines. Experience in independently leading a multidisciplinary team to achieve team objectives. Expert skills to facilitate and maximize the contribution of quantitative team. Hands-on experience in leading the interface to regulatory agencies/leading the early clinical development campaign.
- Strong understanding of Development Unit /Therapeutic Area and or regulatory activities(depending on the role: Oncology, Immunology and Cardio Renal Metabolic) and or regulatory activities. Expert scientific leadership skills demonstrated in facilitating and optimizing the (pre/early/full-) clinical development strategy. Strong track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies.
- Demonstrated strong skills in building partnerships and collaborations.

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

Commitment to Diversity & Inclusion**:**

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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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

部門
Development

部門
Universal Hierarchy Node

国
United Kingdom

勤務地
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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