Senior Principal Biostatistician

Job ID
REQ-10011232

Jun 02, 2025

United Kingdom

Summary

-Provide expert support and functional and technical knowledge to ensure the scientific integrity/validity for clinical development, early development, and/or research projects. Participate in the full lifecycle of producing key data and/or reports in support of data review reporting development including evaluation of requirements, design specifications, interface to programmers, report programming, coordinate validation and rollout activities along with providing quantitative analytical support. Provide statistical support for regulatory submissions including planning, analysis and reporting of clinical safety and efficacy summaries. May also provide statistical support to research or other R&D areas. -Responsible for advising/leading the planning, development & implementation of Industry (CDISC and regulatory) compliant, high quality, clinical data standards, infrastructure or automation technologies. Providing expert support and stellar customer focus to business users and teams on their use, including: -Data standard collection tools in EDC (CRFs, edits checks, derivations, core configurations) -Data transfer specifications -Analysis data/TFL standards/Define -Automation solutions / technologies -Business infrastructure, business rules and guidelines.

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 talent, 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:

The Senior Principal Biostatistician is responsible and accountable for all statistical work, scientific and operational, for one or more assigned clinical trials in collaboration with the clinical trial team/global clinical team (GCT). You will work independently at the clinical trial level and may lead indication-level or project- level statistical activities for a drug development project under limited supervision. You will propose and lead implementation of modern and innovative trial/experimental designs, statistical models, analysis and data exploration methodologies at the study or project level.

This role may be in Early Development, Full Development (Oncology, Immunology, Cardio-Renal Metabolic or Neuroscience) Global Medical Affairs .

Key requirements:

- Responsible for all statistical tasks on the assigned clinical trials and perform these tasks for mid- to high complexity trials independently with peer review/input as required. Responsible for protocol development in alignment with the clinical development plan, developing statistical analysis plan, study and indication-level reporting activities.

- Contribute to planning and execution of exploratory analyses, and/or PK, PK/PD analyses, exploratory biomarker and diagnostic analyses, and statistical consultation. Initiate, drive, and implement novel methods and innovative trial de-signs in alignment with the Lead Statistician.

- Explain statistical methodology and interpret analysis results. Provide statistical expertise to support submission activities and documents, significantly contributing to meetings with and responses to Health Authorities and other drug development activities, as required.

- Contribute to interactions with external review boards/ethics committees, ex-ternal consultants and other external parties with oversight as appropriate.

- Represent the Biostatistics & Pharmacometrics 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 for actions/decisions/statements, when required.

- Establish and maintain collaborative relationships and effective communications cross- functionally within the Clinical Trial Team and Biostatistics & Pharmacometrics team.

- Ensure all Biostatistics deliverables for assigned clinical trials related activities are delivered in a timely manner with the highest level of quality.

- Propose and implement innovative designs and methods to optimize dose finding and drug development. Contribute to planning, prioritization and tracking of program level biostatistics activities and effective partnership with vendors.

Your Experience:

- MS (in Statistics or equivalent) with 7+ years relevant work experience or PhD (in Statistics or equivalent) with 3+ years ' relevant work experience.

- Fluent in English with strong communication and presentation skills.

- Influences decisions that directly impact the trial/project and team ability to deliver objectives.
- Demonstrable experience in all tasks of a statistician at trial level with the ability to work independently.Demonstrable knowledge and expertise in statistics and its application to clinical trials; ability to explain statistical designs and concepts. 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.

- Proficiency in the use of statistical software packages (e.g. SAS, R).
- Good knowledge of drug development and Health Authority guidelines.
- Demonstrated efficiency working on a multidisciplinary team to achieve team objectives.

- Understanding of Franchise/Therapeutic Area and/r regulatory activities.

- Good project management and matrix leadership skills. Ability to collaborate well with non-statistical functions.
- This role offers a hybrid working environment, requiring 3 days per week or 12 days per month in our London Office.

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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部門
Development

部門
Innovative Medicines

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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