

Senior Principal Biostatistician

Job ID
REQ-10060669

9月 02, 2025

United Kingdom

摘要

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.

About the Role

The Role:

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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 extensive relevant work experience or PhD (in Statistics or equivalent) with 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.

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部门

Development

Business Unit

Innovative Medicines

地点

United Kingdom

站点

Home Worker

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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