Senior Principal Biostatistician Early Development

Job ID
REQ-10028570
Nov 05, 2024
United Kingdom

Summary

The Senior Principal Biostatistician in Early Development is responsible and accountable for all statistical work, scientific and operational, for one or more assigned trials in collaboration with the clinical trial team.

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:

Work independently at the trial level and may co-lead, with a pharmacometrician, indication or project level quantitative activities for a development project under limited supervision. Proposes and leads implementation of modern and innovative trial/experimental designs, statistical models, analysis and data exploration methodologies at the study or project level.

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

Key requirements:

- Responsible for all statistical tasks on the assigned 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 development plan, developing statistical analysis plan, reporting activities.
- Contribute to planning and execution of exploratory analyses, innovative analyses related to publications, PK, PK/PD analyses, exploratory biomarker, and statistical consultation. Initiate, drive, and implement novel methods and innovative trial designs in alignment with quantitative team.
- Explain statistical methodology and interpret analysis results. Provide statistical expertise to support clinical pharmacology submission activities and documents, responses to Health Authorities and drug development activities, as required.
- Contribute to interactions with external review boards/ethics committees, external consultants and other

external parties with oversight as appropriate.
- Represent the Early Development Analytics 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 sound working relationships cross functionally within the Clinical Trial Team and Biostatistics & Pharmacometrics team.
- 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 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, may require proven expertise in pharmacokinetics, exposure-response modelling, exploratory biomarker, 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 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 early clinical development campaign.
- Strong understanding of early development. Expert scientific leadership skills demonstrated in facilitating and optimizing the early-clinical development strategy. Strong track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies. Familiarity with pharmacometric principles is a plus.
- Demonstrated strong skills in building partnerships and collaborations. Ability to mentor up to 8 junior associates.

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 and experiment 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, may require proven expertise in pharmacokinetics, exposure-response modelling, exploratory biomarker, applied Bayesian statistics, or data exploration skills. Proficiency in 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.
- Strong understanding of early development. Familiarity with pharmacometric principles is a plus.
- Good project management and matrix leadership skills. Ability to collaborate well with non-statistical

functions.

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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Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
London (The Westworks)
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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