Principal Biostatistician

Job ID
REQ-10040869

May 20, 2025

India

Summary

The Principal Biostatistician is responsible for all statistical work, scientific and operational, for one or more assigned trials in collaboration with the clinical trial team. May support project level deliverables for a development project with supervision.
Leads implementation of modern and innovative clinical trial/experimental designs, statistical models, analyses and data exploration at the study level.

About the Role

Major Accountabilities:-

1. Study level:
a. Responsible for all statistical tasks on assigned trials, and perform these tasks independently seeking peer input/review as required. Responsible for protocol development in alignment with the

development plan, developing statistical analysis plans, reporting activities. Contribute to planning and exe-cution of exploratory analyses, and/or PK, PK/PD analyses, exploratory bi-omarker and diagnostic analyses, and statistical consultation. Initiate, drive and implement novel methods and innovative trial designs in alignment with the Lead Statistician.
b. Explain statistical methodology and interpret analysis results. Provide statisti-cal expertise to support submission activities and documents, meetings with and responses to Health Authorities and other drug development activities, as required.
c. Contribute to interactions with external review boards/ethics committees, ex-ternal consultants and other external parties with oversight as appropriate. Represent Novartis in statistical discussions at external congresses, confer-ences, scientific meetings.
d. Represent the Biostatistics & Pharmacometrics Line Function on cross-functional teams for the assigned trials. Responsible for functional alignment and ensuring line function awareness of status and issues related to the as-signed trials.
e. Collaborate with other line functions. Explain statistical concepts in manner easily understood by non-statisticians and provide adequate statistical justifi-cations for actions/decisions/statements as required.
f. Establish and maintain sound working relationships and effective communica-tion within the Clinical Trial Team and Biostatistics & Pharmacometrics team.
g. Oversee all Biostatistics resources and deliverables for assigned trials. En-sure timeliness and adequate quality of all Biostatistics deliverables for the assigned trials and/or non-clinical related activities.

2. Project level:

a. Contribute to project level activities as needed.
b. Contributes to project team preparation for HA Advisory Committees and meetings.

3. Franchise or Global Line Function level:

Contribute to initiatives at global line function level

4. Enterprise level:

a. Participate in non-clinical project activities as needed
b. Contribute to the review and implementation of health authority guidance
c. Promote the use and the acceptance of innovative methods within the

organization, through scientific collaborations, publications in scientific peer re-viewed journals and presentations at professional meetings

5. External level:

a. Contribute to interactions with external review boards/ethics committees, ex-ternal consultants and other external parties with oversight as appropriate.
b. Represent Novartis in statistical discussions at external congresses, confer-ences, scientific meetings.

6. People Management:

Mentor new hires and/or junior Statisticians

Minimum Requirements:

1. Influences decisions that directly impact the assigned clinical trial and team ability to deliver objectives.
2. 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, diagnostic analyses, applied Bayesian statistics, or data exploration skills. Proficiency in use of statistical software packages (e.g. SAS, R). Knowledge of drug development and Health Authority guidelines. Able to work on and collaborate seamlessly with a multidisciplinary team to achieve team objectives.
3. Experience in Franchise/Therapeutic Area and/or regulatory activities desirable.

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Development

部門
Innovative Medicines

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India

勤務地
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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

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