

Principal Biostatistician

Job ID
REQ-10011238
Jul 10, 2024
India

Summary

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 area 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 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 Responsibilities include but are not limited to:

- 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 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 designs in alignment with the Lead Statistician.
- Explain statistical methodology and interpret analysis results. Provide statistical expertise to support submission activities and documents, 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 Novartis in statistical discussions at external congresses, conferences, scientific meetings.
- 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. Collaborate with other line functions. Explain statistical concepts in manner easily understood by non-statisticians and provide adequate statistical justifications for actions/decisions/statements as required.
- Establish and maintain sound working relationships and effective communication within the Clinical Trial Team and Biostatistics & Pharmacometrics team.
- Oversee all 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.
- Contribute to 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.

Minimum Requirements:

Education (desirable): MS (in Statistics or equivalent) with 4+ years relevant work experience or PhD (in Statistics or equivalent) with relevant work experience (including internship).

Experience / Professional Requirement:

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.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

Commitment to Diversity & Inclusion: We are committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

<https://www.novartis.com/careers/benefits-rewards>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

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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