NOVARTIS

Principal Biostatistician

Job ID
REQ-10054554

7月 25, 2025

India

摘要

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

Key Responsibilities

- Study Level-Responsible for all statistical tasks on the assigned trials, and perform these tasks for mid- to high- complexity trial 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, 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, 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 throughout the assigned 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 and effective communication within the Clinical Trial Team and Biostatistics & Pharmacometrics team. 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.
- **Project level-**May be a core member of an early project team for a low-complexity program and represents Biostatistics and Pharmacometrics as part of development plan with oversight. Collaborate with clinical, regulatory and other strategic functions to drive quantitative decision making in assigned indications/program with oversight. Collaborate cross-functionally (e.g. data management, programming, medical writing) to ensure timeliness and quality of statistical deliverables.
- 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. Significantly contributes to project team preparation for HA Advisory Committees and meetings.
- **Franchise or Global Line Function level:** Significantly contribute to initiatives at global line function level
- **Enterprise level-** Actively contribute to cross-functional organizational / process /scientific consulting improvement initiatives. Contribute to the review and implementation of health authority guidance. Identify, evaluate, and promote the use and the acceptance within and out-side the organization, of innovative methods, through scientific collaborations, publications in scientific peer reviewed journals, presentations and chairing sessions at professional meetings.
- **External level-** 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.

Role Requirements :

- MS (in Statistics or equivalent) with 7+ years relevant work experience or PhD (in Statistics or equivalent) with 3+ years relevant work experience
- Fluent English (oral and written) Good communication and presentation skills
- Influences decisions that directly impact the trial/project and team ability to deliver objectives. Experience in all tasks of a statistician at the trial/experiment level and demonstrated independence in the role.
- Proven knowledge and expertise in statistics and its application to clinical trials; able to explain statistical designs and concepts. 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). Good knowledge of drug development and Health Authority guidelines. Demonstrated effectiveness working on a multidisciplinary team to achieve team objectives.
- Good understanding of Franchise/Therapeutic Area and or regulatory activities.
- Good project management and matrix leadership skills. Ability to collaborate well with non-statistical functions. Good business ethics

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

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

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

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
India

站点
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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