

Associate Director Biostatistics

Job ID
REQ-10052506

8月 01, 2025

India

摘要

Provide highly advanced expert support & functional and technical leadership to ensure the scientific integrity/validity for clinical development, early development, and/or research projects. Develops and applies biostatistics and programming methods to ensure valid conclusions. 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. To meet challenges in data review, big data, analytics and reporting of clinical trial data may also Independently provide timely and professional leadership of special projects that focus on innovative tools and systems -Strategically and tactically supports Director Clinical Data Standards. Responsible for advising/leading the planning, development and implementation of Industry (CDISC and regulatory) compliant, high quality, clinical data standards, infrastructure or automation technologies. Providing expert support & 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. May lead global teams

About the Role

Key Responsibilities

- **Study Level-** Responsible for all statistical tasks on assigned clinical or non-clinical trials, and perform these tasks for high complexity trials with a high level of independence seeking peer input/review as required. Responsible for protocol development in alignment with the development plan, developing statistical analysis plan, and reporting activities. Contribute to planning and execution of exploratory analyses, innovative analyses related to publications and pricing & reimbursement submission and/or PK, PK/PD analyses, exploratory biomarker and diagnostic analyses, and statistical consultation. Initiate, drive and implement novel methods and innovative trial designs and dose-finding strategies in alignment with the Lead Statistician.
- Provide statistical expertise to support submission activities and documents, meetings with and responses to Health Authorities, pricing agencies and other drug development activities, as required. Independently lead 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.
- 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 and interpretation of analysis results for actions/decisions/statements, when required.
- Establish and maintain sound working relationships and effective communication within the clinical trial team and Biostatistics & Pharmacometrics team. Independent oversight of 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.
- **Project Level-** Responsible for strategic statistical input and influence into one or more projects (development plan, regulatory strategy, publication strategy, pricing & reimbursement strategy, statistical deliverables). May be a core member of one or more early project teams representing Bio-statistics and Pharmacometrics.
- Collaborate with clinical, regulatory and other strategic functions to drive quantitative decision making in drug development and enable successful impact on robust drug development plans. Collaborate cross-functionally (e.g., with data management, statistical programming, medical writing) to ensure timeliness and quality of statistical deliverables.
- Facilitate seamless transition of projects from early to late development. Effective partnership with other functions to ensure integrated quantitative input into project. Propose and implement innovative designs and methods to optimize drug development. Plan, prioritize and oversee project level statistical activities and ensure efficient resource management and effective partnership with vendors. Drive adherence to organizational standards and regulatory guidelines. Represent Biostatistics and Pharmacometrics at internal and external decision boards (e.g. regulators) Significantly contributes to project team preparation and may play a prominent role representing Biostatistics at HA meetings.
- **Disease Area / TA/Indication level:** As partner to clinical and scientific leadership, drive strategic statistical input and excellence to development programs within the assigned TA/DA/indications. **Franchise or Global Line Function level:** Lead or significantly contribute to

initiatives at global line function level, or cross-functional Franchise level, requiring coordination of diverse of team members. May contribute to line function review. Enterprise level: Actively contribute to cross-functional organizational / process /scientific consulting improvement initiatives. Represent Biostatistics in due-diligence teams for low- to mid-complexity in-licensing opportunities with supervision. Contribute to the review and implementation of health authority guidance.

- Identify, evaluate, and promote the use and the acceptance within and outside the organization, of innovative methods, through scientific collaborations, publications in scientific peer reviewed journals, presentations and chairing sessions at professional meetings. External: Represent Biostatistics and Pharmacometrics in interactions with external re-view boards/ethics committees, external consultants and other external parties with increasing independence. Chair sessions at professional meetings. People Management: Develop and mentor statisticians. As a local manager, responsible to recruit, retain and professionally develop up to 8 biostatisticians.

Role Requirements-

- MS (in Statistics or equivalent) with 10+ years relevant work experience or PhD (in Statistics or equivalent) with 6+ years relevant work experience
- Fluent English (oral and written) Strong interpersonal and communication skills bridging scientific and business needs.
- 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, diagnostic analyses, 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 interface to regulatory agencies/leading the early clinical development campaign.
- Strong understanding of Franchise/Therapeutic Area and or regulatory activities. Expert scientific leadership skills demonstrated in facilitating and optimizing the (pre/early/full-) clinical development strategy. Strong track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies.
- May have proven people leadership ability. Demonstrated strong skills in building partnerships and collaborations. Demonstrated skills in coaching and mentoring associates. Good business ethics

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>

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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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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

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>

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Hyderabad (Office)

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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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