Associate Director Biostatistics

Job ID
REQ-10011239
Aug 01, 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 Associate Director, Biostatistics influences and drives statistical strategy and innovation through cross-functional collaboration and decision making for assigned trials/programs within (pre/early/full) clinical development and/or medical affairs. Demonstrating high levels of independence in support of complex clinical trials or low to mid complexity programs they are responsible for leading quantitative strategy through collaborations with quantitative partners across the organization.

About the Role

Major Responsibilities include but not limited to:

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 justification 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 as-signed trials. Ensure timeliness and adequate quality of all Biostatistics deliverables for the assigned trials and/or non-clinical related activities. Responsible for strategic statistical input and influence into one or more pro-jects (development plan, regulatory strategy, publication strategy, pricing & reimbursement strategy, statistical deliverables).

May be a core member of one or more early project teams representing Biostatistics and Pharmacometrics. Collaborate with clinical, regulatory, and other strategic functions to drive quantitative decision making in drug development and enable successful im-pact 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 in-put 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. As partner to clinical and scientific leadership, drive strategic statistical input and excellence to development programs within the assigned TA/DA/indications. Lead or significantly contribute to initiatives at global line function level, or cross-functional Franchise level, requiring coordination of diverse of team members.

Minimum Requirements:

Education (desirable): MS (in Statistics or equivalent) with 10+ years relevant work experience or PhD (in Statistics or equivalent) with 6+ years relevant work experience

Experience/Professional Requirement:

- 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.

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

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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.

Division
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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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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.

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