Associate Director Biostatistics

Job ID
REQ-10026158
Ott 28, 2024
India

Sommario

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.
Represents the Biostatistics and Pharmacometrics function at internal and external decision boards, develop and mentor other statisticians, and provide strategic, technical, operational and scientific leadership and solutions to the organization.

About the Role

Major accountabilities:

1. Study Level:
a. 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 inde-pendence seeking peer input/review as required. Responsible for protocol development in alignment with the development plan, developing statistical analysis plan, and reporting activities
b. 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.
c. Provide statistical expertise to support submission activities and documents, meetings with and responses to Health Authorities, pricing agencies and oth-er drug development activities, as required.
d. Independently lead interactions with external review boards/ethics commit-tees, external consultants and other external parties with oversight as appro-priate. Represent Novartis in statistical discussions at external congresses, conferences, scientific meetings.
e. 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.
f. Collaborate with other line functions. Explain statistical concepts in an easily understandable way to non-statisticians and provide adequate statistical justi-fications and interpretation of analysis results for ac-tions/decisions/statements, when required.
g. Establish and maintain sound working relationships and effective communica-tion within the clinical trial team and Biostatistics & Pharmacometrics team.
h. Independent oversight of all Biostatistics resources and deliverables for as-signed trials. Ensure timeliness

and adequate quality of all Biostatistics deliv-erables for the assigned trials and/or non-clinical related activities.

2. Project Level:

a. Responsible for strategic statistical input and influence into one or more pro-jects (development plan, regulatory strategy, publication strategy, pricing & reimbursement strategy, statistical deliverables).
b. May be a core member of one or more early project teams representing Bio-statistics and Pharmacometrics.
c. 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.
d. Collaborate cross-functionally (e.g., with data management, statistical pro-gramming, medical writing) to ensure timeliness and quality of statistical de-liverables.
e. Facilitate seamless transition of projects from early to late development.
f. Effective partnership with other functions to ensure integrated quantitative in-put into project.
g. Propose and implement innovative designs and methods to optimize drug development.
h. Plan, prioritize and oversee project level statistical activities and ensure effi-cient resource management and effective partnership with vendors.
i. Drive adherence to organizational standards and regulatory guidelines.
j. Represent Biostatistics and Pharmacometrics at internal and external deci-sion boards (e.g. regulators).
k. Significantly contributes to project team preparation and may play a promi-nent role representing Biostatistics at HA meetings.

3. Disease Area / TA/Indication level:

a. As partner to clinical and scientific leadership, drive strategic statistical input and excellence to development programs within the assigned TA/DA/indications.

4. Franchise or Global Line Function level:

a. Lead or significantly contribute to initiatives at global line function level, or cross-functional Franchise level, requiring coordination of diverse of team members.
b. May contribute to line function review.

5. Enterprise level:

a. Actively contribute to cross-functional organizational / process /scientific con-sulting improvement initiatives.
b. Represent Biostatistics in due-diligence teams for low- to mid-complexity in-licensing opportunities with supervision.
c. Contribute to the review and implementation of health authority guidance.
d. 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.

6. External:

a. Represent Biostatistics and Pharmacometrics in interactions with external re-view boards/ethics committees, external consultants and other external par-ties with increasing independence.
b. Chair sessions at professional meetings.

7. People Management:

a. Develop and mentor statisticians.
b. As a local manager, responsible to recruit, retain and professionally develop up to 8 biostatisticians.

Education & Qualification

1. MS (in Statistics or equivalent) with 10+ years relevant work experience or PhD (in Statistics or equivalent) with 6+ years relevant work experience,
Strong interpersonal and communication skills bridging scientific and business needs

1. Effective utilization of innovative statistics and quantitative analytics to influence assigned program team decisions and support department 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. 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.
3. 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.
4. May have proven people leadership ability. Demonstrated strong skills in building partnerships and collaborations. Demonstrated skills in coaching and mentoring associates.
5. Good business ethics

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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.

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