Associate Director Biostatistics

Job ID
REQ-10011229
Ene 27, 2025
Reino Unido

Resumen

-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

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 areas 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 Role:

We are seeking a highly skilled and motivated individual to join our team as Associate Director of Biostatistics. You will be required to influence and drive the statistical strategy/innovation directly taking part in cross-functional collaboration and decision making for program(s) across (pre/early/full) clinical development and/or medical affairs. You will have proven experience in supporting complex clinical trials and leading strategy through collaborations with partners across the drug development organization.

This role may be in Early Development, Preclinical or Global Medical Affairs

Key responsibilities:

- Responsible for all statistical tasks on assigned clinical trials, with a high level of independence seeking peer input/review as required. Responsible for protocol development in alignment with the clinical development plan, developing statistical analysis plan, and leading study- and indication-level 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.
- 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 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 collaborative relationships and effective communications within the Clinical Trial Team and Biostatistics & Pharmacometrics team.
- Independent oversight of Biostatistics resources and deliverables for assigned trials.
- Ensure all Biostatistics deliverables for assigned clinical trials and/or non-clinical related activities are delivered in a timely manner with the highest level of quality.

Your Experience:

- MS Statistics with 10+ years' work experience or PhD (in Statistics or equivalent) with 6years + work experience
- Fluent in English with strong communication and presentation skills, with the ability to articulate complex concepts to diverse audiences.
- 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.

- Experience in providing statistical expertise to support submission activities, including documents, meetings with and responses to Health Authorities, pricing agencies and drug development activities, as required.
- Strong understanding of Franchise/Therapeutic Area and/or regulatory activities in at least one disease area.
- Expert scientific leadership skills demonstrated in facilitating and optimizing the clinical development strategy.
- Strong track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies.
- Demonstrated strong skills in building partnerships and collaborations. Ability to mentor for up to 8 associates.
- This role offers hybrid working, requiring 3 days per week or 12 days per month in our London Office.

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

Commitment to Diversity & Inclusion**:**

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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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

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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

División
Development
Business Unit
Innovative Medicines
Ubicación
Reino Unido
Sitio

London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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