NOVARTIS

Associate Director Biostatistics Early Development

Job ID
REQ-10028542
Nov 05, 2024
United Kingdom

Summary

We are seeking a highly motivated Associate Director of Biostatistics in Early Development; you will be required in partnership with a pharmacometrician and other quantitative scientists to influence and drive the quantitative strategy and innovation through strong collaborations contributing to integrated drug development plan and design, execution and decision making for assigned trials/programs within early clinical development. Proven experience in supporting complex clinical trials and leading strategy through collaboration across the organization.

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:

Representing the Early Development Analytics function both internally and externally on decision boards, developing and mentoring other quantitative scientists, and providing solutions to the organization.

This role offers hybrid working, requiring 3 days per week or 12 days per month in our London Office.

Key requirements:

- Responsible for all statistical tasks on assigned 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, PK, PK/PD analyses, exploratory biomarker, and statistical consultation. Initiate, drive, and implement novel methods and innovative trial designs and dose-finding strategies.
- Experience in providing statistical expertise to support clinical pharmacology submission activities,

including documents, responses to Health Authorities, and 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 Early Development Analytics 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 sound working relationships and effective communication within the clinical trial team and with other Biostatistics & Pharmacometrics team members.
- Independent oversight of 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.

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, 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 early clinical development campaign.
- Strong understanding of early development. Expert scientific leadership skills demonstrated in facilitating and optimizing the early-clinical development strategy. Strong track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies. Familiarity with pharmacometric principles is a plus.
- Demonstrated strong skills in building partnerships and collaborations. Ability to mentor up to 8 junior associates.

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.

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

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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

Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
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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