

Associate Director Biostatistics

Job ID
REQ-10062884

10月 02, 2025

Switzerland

摘要

We are seeking a highly motivated Associate Director of Biostatistics; you will be required to influence and drive the statistical strategy and innovation through strong collaborations and decision making for assigned trials/programs within (early/full) clinical development and/or medical affairs. Proven experience in execution and analysis of complex clinical trials and leading strategy through collaborations with partners 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 talents, 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 motivated Associate Director of Biostatistics; you will be required to influence and drive the statistical strategy and innovation through strong collaborations and decision making for assigned trials/programs within (early/full) clinical development and/or medical affairs. Proven experience in designing, and analyzing complex clinical trials and leading strategies through collaborations with partners across the organization and depending on the role, supporting regulatory submissions including planning, analysis and reporting of clinical safety and efficacy summaries as well as interacting with Health Authorities.

Representing the Advanced Quantitative Sciences function both internally and externally on decision boards, developing and mentoring other statisticians, and providing solutions to the organization.

This role may be in Early Development, Full Development (Oncology, Immunology, Cardio-Renal Metabolic or Neuroscience) Global Medical Affairs

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 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.
- 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.
- 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 Advanced Quantitative Sciences 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 sound working relationships and effective communication within the clinical trial team and the Advanced Quantitative Sciences team.

- 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 work experience or PhD (in Statistics or equivalent) with 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, it 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 in 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 Development Unit /Therapeutic Area and or regulatory activities(depending on the role: Oncology, Immunology and Cardio Renal Metabolic) 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.
- Demonstrated strong skills in building partnerships and collaborations.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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部门

Development

Business Unit

Innovative Medicines

地点

Switzerland

站点

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Functional Area

Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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