Senior Principal Biostatistician

Job ID
REQ-10037813

2月 04, 2025

Ireland

摘要

Provide expert support and functional and technical knowledge to ensure the scientific integrity/validity for clinical development, early development, and/or research projects. Participate in the full lifecycle of producing key data and/or reports in support of data reporting, including evaluation of requirements, design specifications, interface to programmers, report programming, coordinating validation and rollout activities, along with providing quantitative analytical support. 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.

About the Role

Key Responsibilities:

- Responsible and accountable for the statistical activities and support on statistical solutions for trials/publications and conferences and support the tasks independently seeking peer inputs/ reviews as required. - Activities include: protocol development in alignment with the development plan; providing inputs on statistical scientific and operational aspects of the planning; design and reporting of mid- to high-complexity trials/experiments; production and delivery of statistical deliverables and exploratory analyses.
- Initiate, drive and implement novel methods and innovative trial designs in alignment with the Group Lead, Biostatistics.
- Propose and lead statistical/numerical/analytic research by providing advice and solutions on computational aspects of the problem. Explain statistical methodology and interpret analysis results.
- Guides the trial team/trial statistician to ensure that documents, specifications, programs/macros are consistent and comply with company standards by providing input into CRF and data structures tables, listings and figures for all studies.
- Maintain effective interfaces with internal and external stakeholders with advice from Principal Biostatistician and the Principal Statistical Programmers, CRO and CPOs as required.
- Assume responsibility and accountability for reporting and analysis execution for multiple studies. Responsibilities include, leading statistical deliverable meetings with necessary clinical trial team members and third parties, and exploratory analyses for ad-hoc analyses. Expected to provide support for publications for individual clinical studies and scientific analytical solutions.
- Provide guidance to trial statisticians and ensure compliance with project/study standards and specifications following internal guidelines.
- Ensure timeliness and adequate quality of all Biostatistics deliverables for the assigned studies and/or non-clinical related activities.
- Take lead role to collaborate with other line functions including the clinical trial team. Explain statistical concepts in a manner easily understood by non-statisticians, and provide adequate statistical justifications for actions/decisions/statements, when required.
- Support quality control and quality audit of deliverables.
- Provide input on process improvement initiatives and participate in non-clinical project activities with support from group head.
- Provide support, coaching and mentoring to new hires, senior and junior statisticians.
- Ensure to complete Trial level Process Adherence checklist and review CT.gov/EudraCT XML summaries.
- Manage the outsourcing of statistical activities from Biometrics to an approved vendor in accordance with Scientific Services vendor management procedures.
- Assist the Group Head in the assessment of applicants for statistician roles within Biometrics.
- Assist the Group Head in tracking the projects for resourcing and finance aspects.

What you will bring to the role:

- MS/ MSc (in Statistics or equivalent) with 11+ years relevant work experience or PhD (in Statistics or equivalent) with 8+ years of work experience
- Quality and timeliness of biostatistical contributions as assessed by the stakeholder POC, Clinical Trial Team and the Biostatistics Team Lead
- Effectiveness of the computational tools used and scientific input to clinical studies
- Contribution to exploratory analyses as and when required
- Experienced in influencing decisions that directly impact the assigned clinical trial and team ability to deliver objectives

- Strong understanding of drug development, regulatory requirements, ICH and HA guidelines
- Excellent knowledge of/experience with SAS/R, or any other business or research analytic software with expertise in at least one software
- Statistical and numerical knowledge and expertise in analytic aspects and applications in clinical trials; ability to explain statistical designs and concepts to non-experts.
- Document lifecycle management via DMS (experience of at least one platform desirable)
- Scientific writing
- Strong communication and presentation skills

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We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve

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部门
Operations

Business Unit

Universal Hierarchy Node

地点
Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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