Senior Principal Statistical Programmer

Job ID
REQ-10050491

May 28, 2025

Ireland

Summary

We are in search of a Senior Principal Statistical Programmer, with expertise in HTA and Pricing and Reimbursement activities. This role offers the chance to provide statistical programming solutions to HTA problems. The successful candidate will work closely with International Value & Access and HEOR teams to shape ways of working for Joint Clinical Assessment in Europe to ensure high-quality deliverables.

The Senior Principal Statistical Programmer will be responsible for all statistical programming aspects of several studies, a medium to large sized project or project-level activities. Acts as a key collaborator and strategic partner in ensuring that drug-development plans are executed efficiently with timely and high-quality deliverables. Complies with project / study standards and specifications following internal and regulatory guidelines. Oversees programming style, quality of statistical reporting & compliance with timelines.

About the Role

Key requirements

- Lead statistical programming activities for a medium to large sized project in phase I to IV clinical studies in Novartis Global Development Organization.
- Co-ordinate activities of programmers either internally or externally. Make statistical programming decisions and propose strategies at study or project level.
- May act as functional manager for local associates including providing supervision and advice to these programmers on functional expertise and processes.
- Key skills HTA, RWE, HE OR, R/R-Shiny, SAS, Statistics, Leadership
- Collaborate with cross-functional teams, discuss status of deliverables and critical programming aspects (timelines, scope, resource plan)
- Review eCRF, discuss data structures and review activities, ensure project-level standardization which allows pooling and efficient CRT production.
- Ensure timely and quality development and validation of datasets and outputs for CSRs, regulatory submissions/interactions, safety reports, publications, post-marketing activities or exploratory analyses (as required) in the assigned drug development studies/project.
- Responsible for quality control and audit readiness of all assigned statistical programming deliverables as well as accuracy and reliability of statistical analysis results.
- Act as subject matter expert or as assigned, lead process improvement/non-clinical project initiatives with a focus on programming and analysis reporting procedures.

This role will be hybrid, requiring 3 days per week in our Dublin office.

Your Experience

- Fluency in English with strong negotiation skills, ability to work well with others globally and influence. BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field

- Must have strong programming skills in R/R Shiny. Python is desirable (and SAS optional). Demonstrated knowledge of data visualization, exploratory analysis.
- Exposure to late phase studies & Real-World Evidence. (for strong candidates we can offer training)
- Ideally 7+ years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry. Experience in Health Technology Assessment /HEOR is preferable
- Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications
- Advanced knowledge of industry standards including CDISC data structures as well as a solid understanding of the development and use of standard programs
- Good understanding of regulatory requirements relevant to Statistical Programming (e.g. GCP, study procedures)
- Experience as Trial/Lead/Project Programmer for several studies or project-level activities, including coordination of team of internal or external programmers on a given study/project, ability to transfer own knowledge to others
- Please note that for this role we are unable to provide visa sponsorship.

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部門
Development

部門
Innovative Medicines

国
Ireland

勤務地
Dublin (NOCC)

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

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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