Senior Manager, Statistical Programming (Oncology)

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Company: SEC Life Sciences

Location: Belgium

Category: computer-and-mathematical

A leading pharmaceutical company is seeking a Senior Manager, Statistical Programming, to oversee all statistical programming deliverables, enhance programming efficiency, and establish standards for SDTM/ADaM datasets and TFLs. This role is critical in providing technical support to project teams and improving the company's programming efficiency. This position can be fulfilled remotely from anywhere within the EU. Applicants must have the right to work in the EU to be considered.

Your Role:

Serve as the statistical programming subject matter expert (SME) for outsourced projects, guiding internal programmers or directly performing programmatic reviews of SDTM and ADaM datasets as well as TLFs generated by statistical vendors.

Ensure compliance with CDISC and submission requirements, spearhead the strategic programming decision-making and planning, and facilitate the expedited preparation of regulatory submissions, particularly for Phase III oncology projects.

Develop programming submission strategies, support regulatory submissions with quick turnaround responses to regulatory agencies, and lead the development and implementation of standard templates on datasets and TLFs to improve efficiency and quality.

Lead the development and maintenance of programming macros or tools to support all programming needs and evaluate, assess, and enhance the computing environment system to support programming and analysis efficiency.

Experience and Qualifications:

A Bachelor's degree with 7-12 years of industry experience in pharmaceuticals or CROs, focusing on statistical analysis of clinical trials programming.

Must have lead experience at the Compound/Project-level with a strong background in Oncology Therapeutic Area (TA), including involvement in Phase III submissions.

Demonstrated ability to commit to US working hours, with availability for meetings at 6 or 7pm CET once or twice a week.

Previous experience in supporting SAS macro and/or system utility development, with advanced knowledge of SAS programming, CDISC SDTM, and ADaM.

Solid understanding of statistical concepts, advanced statistical methods using SAS and R, and knowledge in database structures and setup.

Candidates with the required expertise and a commitment to advancing the field of oncology through statistical programming are encouraged to apply. This role is an opportunity to contribute to significant projects within a leading company, offering the chance to make a tangible impact on the future of healthcare.

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