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**Principal Programmer Analyst – CDISC SDTM Specialist using SAS at Thermo Fisher Scientific**

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Company: JobWebKenya

Location: Kenya

Category: life-physical-and-social-science

**Job Description**

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Thermo Fisher Scientific Inc. (NYSE: TMO) is the world leader in serving science, with revenues of more than $24 billion and approximately 70, employees globally. Our mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics, deliver medicines to market and increase laboratory productivity.

**About Job**

The Data Transformation and Submission(DTS) group within our Biostatistics & Programming department performs active global CDISC submission development for clients in our Biotech, Biopharma and FSP groups. There is also responsibility for Spotfire exploration, SDTM, DSUR reporting, eCRT (Define.xml) as well as cross functional development initiatives with various internal departments, including CDM, Early Dev Services, PVG, etc. The DTS group also works on many stand-alone studies that are led and driven fully within the group.

As a Principal Programmer within DTS, you will perform specification, development, quality validation and regulatory submission compliance for PPD developed CDISC SDTM and CDISC eCRT (Define.xml) programming deliverables, using Windows SAS Grid. You will deploy Spotfire dashboards, Safety notifications and reporting for Medical Monitor review and regulatory actions. As a DTS team member, you will be a key team player for internal

Biostatistics interactions and client engagement on CDISC submission topics, or internal contact for procedural and technical solutions.

Our Biostatistics & Programming (B&P) department are passionate about being data and technically agile and driving enhanced value for our clients and patients. Determined to improve patient health, we help PPD provide industry leading CDISC expertise and programming leadership through global delivery, consistent quality adherence and scientific insight.

**Your responsibilities will include (but are not limited to) the following:**
Act as programming lead on Phase II-IV group of studies.

As programming lead assume leadership responsibility as a contributing member of a global project team, communicating actively and frequently with other team members and ensuring adherence to working practice documents and SOPs.

Provides input into bidding process as requested.

May provide general infrastructure support to the Department, including representing the company at industry conferences, presenting/teaching at department meetings, assisting in establishing training materials etc.

Provides training, guidance, and project leadership to junior team members. – Develop instructional training and education materials for the wider B&P community.

Creation of specifications, development, validation, and delivery of CDISC SDTM and regulatory deliverables (eCRT Define.xml, SDTM aCRF)

Analysing and combining data from a variety of sources and structures including virtual trials, wearables, eCOA, etc.

Generating visualizations (Spotfire), Statistical safety reports (TLFs), safety event notifications and data alerts for study teams.

Provide consult, analysis, and support across various therapeutic area studies in their CDISC compliance and consistency in mapping.

**Requirements**

**To be considered for the role you should have the following qualifications and experience:**

Master's degree in computer science, statistics, biostatistics, mathematics, or related field and at least 4 years of experience that provides the knowledge, skills, and abilities to perform the job requirements,

OR

Bachelor's degree in computer science, statistics, biostatistics, mathematics or related field or equivalent formal academic / vocational qualification, and at least 6 years of experience that provides the knowledge, skills, and abilities to perform the job requirements.

**Knowledge/Skills:**

In-depth understanding of one or more programming languages

Strong attention to detail

Strong problem solving and innovative skills

Strong written and verbal communications skills to effectively interface with teams and clients, including proficiency in the English language

Capable of independently and effectively organizing and managing multiple assignments with challenging timelines

Capable of adapting and adjusting to changing priorities

Demonstrated positive attitude, enthusiasm toward work, and the ability to work well with others

Demonstrated leadership, initiative, and motivation

In-depth understanding of relational data base structure and complex data systems

Capable of training and mentoring others

Demonstrated leadership ability and ability to work on a multi-disciplinary project team

Solid project management skills to act as project lead across the most challenging and complex projects

Capable of effectively capturing biostatistical metrics

Capable of providing quality control review for statistical programming and identifying solutions and process improvements.

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