

Principal Statistical Programmer

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Company: ACL Digital

Location: India

Category: computer-and-mathematical

Principal Statistical Programmer (10 – 12 years of exp)

Location: Remote

The Principal Statistical Programmer of Statistical Programming is responsible for all statistical programming aspects of one or more clinical trials of drug development plans. The position ensures drug development plans are executed efficiently, with timely and high-quality deliverables. It is a blend of highly technical and leadership roles with a strong understanding of the drug development process and experience in regulatory activities.

Responsibilities:

The primary responsibilities will include:

- Implementation of statistical programming strategy related to innovation in technologies, automation, processes, and standards to maximize efficiency.

- Support the development and implementation of a programming ecosystem to enable successful project deliverables

- Review statistical analysis plans, mock-shells, database set-up specifications

- Validate or Review the Programming packages (includes the aCRFs, specifications and datasets, Define.XML and Reviewer's Guides (for both SDTM and ADaM)

- Develop department programming standards to meet business needs and regulatory

requirements, enabling efficient and seamless production of deliverables

Develop innovative solutions to standardize, automate and optimized efficiency and quality

Proactively addresses project uncertainties to minimize risk and alerts or escalates the issue to the appropriate person (project team member, lead biostatistician, or management), identifies, communicates, and overcomes technical and interpersonal obstacles

Development and maintenance of tracking systems, folder systems and archival of analysis

Contributes strategies that allow multi-tasking or efficient implementation to reduce execution time to meet deadlines in fast-paced environment

Build a team of programmers to support ongoing pipeline expansion

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