Lead Project Programmer

Apply Now

Company: Argenx

Location: Ghent

Category: computer-and-mathematical

We are currently looking for a Lead Project Programmer.

The Lead Project Programmer supports biostatisticians and project teamswith cross-project planning ofdiverse statistical/programming tasks and resources, supporting the clinical development programswithin argenx.

Providing programming support towards other functional areas within argenx, such as data management, regulatory, global safety, medical.

Programming statistical analysis datasets, outputs and performing the QC thereof.

Ensuring CDISC compliance of ADaM datasets.

Designing, building and improving the statistical programming environment

Development of supporting tools

The role will report into the Head of Quantitative Sciences.

ROLES AND RESPONSIBILITIES

Manages timelines and in-house programming resources across projects, indications and studies or ad-hoc tasks

Participates in project team meetings.

Provides relevant input in the development of the CRF, statistical analysis plan andmock tables, listings and figures.

Supports outsourcing programming activities and oversees the QC of these activities

Develops programs to perform QC of statistical outputs.

Performs critical review of derived dataset specifications and derived datasets(ADaM).

Defines program specific standards for ADaM datasets. Checks compliance of CROdelivered ADaM datasets to CDISC standards.

Verifies define.xml (for ADaM's) and ADRG.

Develops, validates and documents programs for additional analyses.

Develops, reviews, documents and performs validation of generic SAS macros insupport of SAS programming environment.

Supports data submission activities according to regulatory guidelines (e.g. ISS, ISE).

SKILLS ANDCOMPETENCIES

Expertise with diverse statistical software packages such as SAS and ADaM.

Thorough knowledge of and experience with CDISC standards.

Knowledge of R is a plus.

Ability to plan and execute the statistical programming tasks for multiple clinical trials and integrated analyses (e.g., ISS, ISE).

Good communication skills and proficiency to work independently and as part of a team.

Knowledge of ICH-GCP and other applicable legislation, with good understanding ofclinical data and pharmaceutical development.

Experienced wit

EDUCATION, EXPERIENCE AND QUALIFICATIONS

Bachelors or higher degree in Science, Statistics, Information Technology or equivalent combination of education and related work experience.

Excellent knowledge of SAS and R.

Minimum of 10 years of professional experience.

Experience in Biotech, in managing CROs and vendors is a plus.

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