Job Title: Biostatistician

Department: Clinical Operations

Reporting to: VP, Biostatistics and Data Management

Location: Boston, MA

Rhythm seeks an experienced and highly motivated individual to join its team in Boston, Massachusetts. The Senior/Principal biostatistician is responsible for providing strategic input from Biostatistics perspective in a cross-functional project team environment and supports all the statistical aspects for assigned projects.

Principal Responsibilities

- Support the clinical development plans, propose innovative statistical design, sample size and power calculation, and responsible for statistical elements in protocol development, statistical analysis plans (SAPs) and TLFs, data analysis and statistical result interpretation.
- Prepare statistical related sections of protocol, clinical study reports, integrated summaries of safety/efficacy (ISS/ISE) etc. as needed.
- Oversee the vendors that conduct statistical work for Rhythm, validate and QC the statistical deliverables from vendors. Ensure the accuracy, consistency, and quality output.
- Work closely with statistical programmers in dry-runs, QC of key efficacy and safety data, identifying data issues etc.
- Support interim analysis plan, DSMB meetings, adhoc analysis etc.
- Help prepare the statistical components in regulatory submission packages (e.g., cCTD M2.5, M2.7 and M5 etc.).
- Support the clinical sections of INDs/NDAs/BLAs/MAAs to ensure proper presentation of statistical analyses and results
- Support regulatory documents such as briefing book, and regulatory meeting as needed
- Reviews CRFs, and work with data managers on DMPs, data edits check etc.
- Contribute to the development and revision of statistics SOPs

Qualifications and Experience

- MS with ~5 years or PhD with ~3 years clinical trials experience in Biopharma/CRO
- Excellent knowledge of drug/biologics development process
- Strong basis in statistical concepts and expertise in statistical methodologies in clinical trials
- Strong statistical programming skills with SAS and R, experience with sample size software such as EAST, nQuery etc.
- Familiar with CDISC requirements for SDTM and ADaM.
- IND/NDA/BLA/MAA experience desired but not required.
- Excellent communications, presentations and report writing skills, and the ability to explain complex statistical technical details in simple language.
- Ability to work on multiple projects simultaneously

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