



Pharmaceutical Lead

Summary

Are you a natural leader and self starter? This type of Statistician is keen to work more directly with Pharmaceutical clients, acting as an extension to their team. Lead and mentor younger Statisticians and help contribute innovative initiatives to Veramed.

Personality

- Independent
- Self Starter
- Enjoys guiding and mentoring teams
- Good communicator across multiple teams and levels

Responsibilities

- Act as the lead statistician on behalf of the client for one or more clinical studies within a clinical program or across multiple clinical programs.
- Understand the regulatory requirements related to design and analysis of studies.
- Participate in the protocol summary development. Give input into the study design, efficacy and safety parameters and the planned statistical analyses. Perform sample size calculations and study design simulations.
- Participate in protocol development, review and approval.
- Review data management related documents.
- Author/review the Statistical Analysis Plan (SAP).
- Work closely with the lead biostatistician at the assigned CRO to oversee the statistical deliverables for the client.
- Participate in data review/evaluation meetings and other study-related meetings and activities.
- Perform exploratory analyses.
- Review the clinical study report and provide input on interpretation of results.
- Review and input into regulatory documents and interactions.
- Contribute and review abstracts posters, presentations, and manuscripts for publication and ensure accuracy of all biostatistical aspects of such documents.
- Support and mentor more junior statisticians on the team.

Opportunities

- Presenting at conferences.
- Developing and executing innovative study design and/or efficiency optimisation ideas.
- Line management and peer mentoring.
- Contributing to business process improvements and authoring/presenting internal training.
- Contributing to initiatives that consider employees, the environment and our local communities as part of our B Corp accreditation.

Beneficial experience

- Understanding of clinical drug development process, relevant disease areas, endpoints and different study designs.
- Awareness of industry and project standards & ICH guidelines.
- Interpersonal/teamwork and communications skills for effective interactions.
- Proficiency in data handling using SAS or other statistical software (e.g. R).
- Self-management skills with a focus on results for timely and accurate completion of competing deliverables.
- Demonstrated problem solving ability and attention to detail.
- Ability to work independently and as part of a team.