Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Biostatistician (Contract)

Position Summary:

This position is responsible for the development and conduct of biometrics for Stealth-sponsored clinical studies. Duties will include developing statistical analysis plans, running ad hoc analysis, designing studies with sample size calculations, helping to select appropriate and innovative statistical methods, analyses, assisting in interpretation and reporting of preliminary, interim and final study results, participation in EDC and CRF development, as needed. The ideal candidate is a self-starter, good communicator with high-energy and a hands-on, self-motivated forward thinker.

Responsibilities:

- Accountable for all statistical aspects of protocols and regulatory submissions for assigned clinical studies
- Work with Clinical, in preparation of Data Validation Manual (DVM), Edit Check Specs, UAT scripts, statistical documents (e.g. statistical analysis plans) and analyses (e.g. safety and efficacy analyses) to support study end points, Drug Safety Monitoring Board (DSMB), Development Safety Update Reports (DSURs), and Investigator Brochures (IB)
- Work with data management vendor and Clinical team in the preparation of CRF design and EDC data base that are of high quality and in user friendly format
- Work with medical writing personnel in preparation of clinical study reports and other regulatory documents, including relevant NDA modules
- Work with Medical Affairs and Clinical in the preparation of meeting abstracts/presentations and programmed analytical reports of preliminary data upon request from ongoing clinical studies
- Troubleshoots for solutions in data-related problem areas
- Guide Clinical in the design, sample size calculation and analysis of clinical studies using appropriate and innovative statistical methods
- Review draft presentations and training materials, including posters and slide decks, according to deadlines
- Ensures that we're using state of the art statistical methodologies in our clinical studies
- Considers and evaluates alternative methodologies for the analysis of data
- Assume responsibilities for the clinical database after the vendor fulfills contractual analysis responsibilities. Perform subsequent analyses to support medical affairs activities
- Provides subject matter expertise for all relevant departments

Competencies:

- Strong analytical skills; expert knowledge of SAS programming, with a wide range of analytic methods, statistical software
- Strong organizational and multitasking abilities, problem solving skills, and attention to detail

- Excellent oral and written skills; ability to effectively communicate statistical information to non-scientists, and a willingness to educate internal team
  - Sound judgement with the ability to work in a fast-paced environment and flexibly adapt to changing timelines
  - Ability to effectively collaborate with internal and external stakeholders

Requirements:

- MS/PhD. in Statistics or Applied Mathematics with a minimum of 8 years proven experience and subject matter expertise in clinical research and drug development
- Demonstrated ability to effectively contribute to the statistical aspects of clinical protocol design, data interpretation, review and reporting of results for multiple studies and projects
- Practical experience with application of advanced statistical methodologies to clinical trial design/analysis and with regulatory reporting/submissions
- Demonstrated core competency in successful IND/NDA/BLA submissions
- Demonstrated experience in gathering, interpreting and analyzing data in clinical research and drug development
- Experience in orphan and or ophthalmology indications is a plus