Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Senior Clinical Scientist

Position Summary:

The Clinical Scientist will provide scientific support for clinical development activities in collaboration with internal and external stakeholders to ensure program integrity and success. Primary responsibilities include data review and analysis, authoring of trial-related documents, monitoring patient data and trial progress, and contributing to scientific communications.

Responsibilities:

- Supports the creation of the clinical development plan in partnership with cross-functional team members as well as KOLs and CROs
- Authors and reviews study materials for clinical trial utilization and health authority submissions
- Analyzes and interprets clinical trial data, collaborating with program lead to conduct data review
- Troubleshoots internal and external conflicts to ensure trial integrity and success
- Scientific author / contributor to internal and external communications, such as protocol training, posters, publications, and advisory board meeting presentations.
- Working with the statistician, lead the development of statistical analysis plans
- Engages with trial sites and CROs on an on-going basis to monitor subject data and data collection status, resolve queries, ensure adherence to protocol, and evaluate consistency of data
- Support protocol design and development strategy for clinical pharmacology trials
- Manage third-party CROs and consultants as necessary, including bioanalytical and biomarker laboratories, statisticians, pharmacokineticists, and data management teams
- Collaborate with the medical monitor to evaluate patient and program level safety data
- Maintains knowledge of the therapeutic area, current medical practice, and pharmaceutical regulations to help ensure best practices

Competencies:

- Ability to proactively predict issues, resolve problems, and make sound decisions
- Excellent oral and written skills; ability to effectively communicate complex information
- Ability to analyze and interpret clinical data
- Strong organizational abilities and attention to detail
- Ability to work independently and on a team
- Ability to effectively collaborate with internal and external stakeholders
- Strong understanding of the clinical research process through Phase I-III trials

Requirements:

- Bachelor's degree in science with 7+ years related experience or
  Master's degree and 5+ years related experience; Clinician preferred (RN, NP, PA, PharmD, or MD)
- Understands scientific & clinical research process
- Approximately 15% travel