Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Associate Director, Clinical Pharmacology

Position Summary: In collaboration with the Sr. Director, Clinical Development, lead clinical pharmacology strategy across development portfolio from pre-IND to post-approval, including design and implementation of program specific clinical pharmacology studies, data analysis, internal decision points, and external regulatory interactions.

Responsibilities:

- Integrates clinical pharmacology knowledge with a broad understanding of, and collaboration with, related disciplines such as clinical, statistics, regulatory, nonclinical ADME, toxicology to support and impact development decisions
- Ensures appropriate PK, PD and PK/PD data analyses (including population PK, PK/PD modeling and simulation) are conducted for each study/program.
- Collaborates with internal and external stakeholders to design, analyze, interpret, and report preclinical PK and translational PK/PD studies to support candidate selection and IND filing, including human PK prediction to support starting dose and dose escalation schemes for first-in-human studies
- Serves as the clinical Pharmacology expert across study and program teams
- Contributes to program strategy, study design, protocol preparation, study execution, data review/analysis, study reports and regulatory document preparation
- Provides oversight to bioanalytical vendors, including method development and validation as well as sample analysis

Competencies:

- Excellent communication (verbal, written, presentation) and interpersonal skills; ability to effectively translate information and facilitate alignment with internal and external stakeholders
- Strong analytical skills with ability to understand and interpret complex clinical data, see the big picture, and drive operational execution
- Strong technical acumen, including proficiency in PK analysis (NCA and PopPK)
- Demonstrated ability in project management, objective setting, and plan execution; ability to work on multiple projects simultaneously and effectively prioritize workload
- Self-starter and innovative thinker with strong critical thinking and problem-solving skills; ability to identify realizable solutions and alleviate potential hurdles to help ensure success
- Ability to make data-based decisions in collaboration with cross functional colleagues
- Ability to nimbly “flex” between strategy and operational execution, and be open to learning new approaches

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Requirements:

- PhD, PharmD, or equivalent training in pharmacokinetics, pharmaceutical sciences, or related disciplines and a minimum of 5 years pharmaceutical or biotechnology experience in Clinical Pharmacology
- Direct clinical management of Phase I healthy volunteer studies is a plus