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Sr. Scientist, Clinical Pharmacokinetics-REMOTE

Hiring organization
CarterMacKay

Employment Type
Full-time

Date posted
September 27, 2021

Description

The organization is responsible for defining the relationship between drug exposure (e.g., concentrations in blood) and efficacy measures (primary and/or secondary clinical outcomes or biomarkers) to select the optimal dose and dosing intervals. CPPM is also responsible for defining the relationship between drug exposure and safety measures (clinical outcomes or biomarkers (e.g., QTc)) to identify populations that may be at risk of increased toxicity or decreased tolerability.

CPPM performs the selection, design and interpretation of all Phase I studies including first in human, bioavailability/ bioequivalence/food effect, drug interaction, pilot/definitive cardiovascular (QTc), special population, pharmacogenetic and immunogenicity studies.

The organization provides critical support for conducting technical due diligence of new business opportunities (both in-licensing and out-licensing) by assessing probability of success for achieving Target Product Profile (TPP). CPPM contributes to responses to defend our intellectual properties and extension of patent protection, provides critical support for life-cycle management of marketed products, responds to questions from post-marketing safety, legal, pharmaceutical manufacturing and regulatory for marketed products world-wide, and publication of scientific information in patents and manuscripts. The Clinical Pharmacology and Pharmacometrics Organization (CPPM) leads the strategy, generation/analyses/interpretations/reporting of data and communications/agreements with global regulatory agencies in the areas of Clinical Pharmacology, Pharmacokinetics, Exposure-Response and Biopharmaceutics.

Responsibilities

Conceive and execute novel scientific research or development in Clinical Pharmacology that achieves projects and Clinical Pharmacology and Pharmacometrics (CPPM) goals. Generate new PK/PD

proposals and lead those efforts. Investigate, identify, develop, and optimize new methods and techniques in PK/PD field. Act as a lead PK scientist in his/her area of expertise and critically evaluate relevant Clinical

Pharmacology, PK/PD and regulatory advances and integrate this knowledge into research or development programs.

Responsibilities:

- Contribute to clinical development by supporting Phase 1-4 studies including study design, and clinical pharmacology strategy.

- Author regulatory documents including protocols, study reports, population PK reports, exposure-response analyses reports, relevant section of investigator brochures, common technical documents, white papers, and other similar documents.
- Conduct data analyses including non-compartmental analyses, modeling and simulation, literature data analyses.
- Participate and present at various departmental and cross functional teams such as study teams, clinical pharmacology and biopharmaceutics, clinical strategy team, CPPM leadership team, Journal club.
- Collaborate with scientific support from other CPPM functional groups to provide a unified clinical pharmacology position to clinical, CMC and regulatory teams.
- Author scientific publications and present at scientific conferences.

Contacts

For a more comprehensive list over over 25 total openings, please contact Brenda Roseberry directly

Brenda Roseberry
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