Senior Pharmacometrician

Location: Richmond, Virginia (possibility to work remotely)

At Indivior, it is our mission to pioneer life transforming treatments for patients around the world suffering from the chronic disease of addiction. Indivior PLC (previously known as Reckitt Benckiser Pharmaceuticals) began in December 2014, however our history in the field of opioid dependence dates back to 1994. With multiple products in development, the Indivior team is growing and we are looking for leaders and entrepreneurs who share our passion for patient focus.

With headquarters located in the beautiful state capital, Richmond, VA, Indivior is able to provide a unique, entrepreneurial environment unlike any other. Our company offers competitive benefits, 401K, annual bonus potential and the opportunity to work for a world leader in addiction treatment.

Role Description

A qualified candidate will be a highly motivated individual who will be responsible for supporting quantitative clinical pharmacology activities on dedicated projects at all stages of drug development. He/she will focus on providing pharmacokinetics (PK)/ pharmacodynamics (PD) modeling and simulation expertise and oversight and will represent the quantitative clinical pharmacology discipline on multidisciplinary teams to support the design of an efficient clinical development program and robust registration package. He/she will report to the Head of Clinical Pharmacokinetics and Modeling and Simulation.

Primary Responsibilities

- Conduct or oversee the development of mathematical and statistical models to understand, characterize and predict disease progression, drug PK, dose-response relationships, and support dosing recommendations for special populations
- Conduct meta-analyses where appropriate to maximize the use of clinical data, and perform simulation studies to optimize the design and performance of future clinical trials
- Support overall translational research strategy by establishing IVIVC where needed, developing preclinical PK/PD models to help predicting human dose range, and by supporting the development of biomarkers
- Contribute to the design and interpretation of clinical pharmacology studies
- Present PK/PD modeling and simulation data to internal management and project teams, to inform drug development strategy and enhance decision making
- Write sections of clinical study protocols and reports, clinical investigator brochures and regulatory submission packages
- Present and defend quantitative clinical pharmacology plans and results to internal governance committees and regulatory agencies

- Provide oversight to PK/PD modeling CROs and consultants to ensure that high quality work is performed within the established timelines
- Innovate on mechanistic modeling, modeling and simulation techniques and methodology through effective collaboration with colleagues in other departments (statisticians, mathematicians, physicians, biologists) and external partners
- Learn and apply new modeling and simulation methodology to enhance efficiency in processes, model predictions and decision making
- Support publication in high-quality peer-reviewed journals and present at scientific conferences
- Ensure compliance with pertinent federal regulations and code of conduct

Education/Experience - Minimum Requirements

- M.D., PharmD or Ph.D. with advanced training in quantitative clinical pharmacology and population PK/PD analysis
- 5+ years of experience in quantitative clinical pharmacology with small or large molecules, with direct or indirect industry (Pharma/CRO) experience
- Working knowledge of common tools for quantitative clinical pharmacology such as NONMEM, R, SAS, MATLAB, WINNONLIN
- Experience in designing, analysing and reporting clinical studies, using a modeling and simulation-based approach where appropriate
- Clear and effective written (report writing) and verbal communication (presentation) skills are essential
- Ability to work independently as well as in a team environment and build effective working relationships inside and outside department
- Sound judgement, analytical mindset and skills in problem-solving

Additional Preferences:

- Familiarity with regulatory submission documents (e.g. INDs, NDAs, CTAs) and the utility of PK/PD (exposure-response) relationships in fulfilling regulatory requirements
- Experience in working with CROs and consultants
- Knowledge in CNS drug development
- Experience in quantitative system pharmacology models
- Experience in IVIVC modeling
- Prior experience working in an interdisciplinary team
- Matrix management / leadership experience

Contact: Celine Laffont - celine.laffont@indivior.com