**Job Title:** Associate Program Director, Quantitative Medicine  
**Department:** Clinical Pharmacology and Quantitative Medicine  
**Reports to:** Director of Clinical Pharmacology and Quantitative Medicine  
**FLSA Status:** Full-time; Exempt  
**Location:** Tucson, AZ

**Job Purpose Summary:** This position represents the Quantitative Medicine expert who will primarily support the Huntington’s Disease Consortium. The position entails partnering with the consortium teams to integrate subject-level data in order to develop innovative drug development platforms for Huntington’s Disease.

The individual will work closely with clinicians, statisticians and other consortium scientists to create development plans that include assessments of endpoints, sources of variability and analysis approaches for the subject-level data, conducive to the development of quantitative drug development platforms. This individual has primary responsibility for the clinical pharmacology and modeling and simulation components of the development plan.

The individual is responsible to develop and execute the plans by using innovative analytical methods to integrate knowledge of pharmacokinetics, biopharmaceutics, pharmacodynamics, patient characteristics and disease states to create models to help optimize doses, dosage regimens and study designs, and to provide quantitative medicine, clinical pharmacology and modeling and simulation support and leadership in the preparation and defense of regulatory submissions.

The individual will routinely interact with internal governance bodies, consortia representatives, regulatory agencies and external opinion leaders, and is expected to influence the external environment by advancing their discipline through external presentations and publications.

**Essential Job Duties and Responsibilities:**
- Plans and directs clinical pharmacology and modeling and simulation components of programs.
- Works with multifunctional consortia teams to design, deliver and report the assigned clinical pharmacology and modeling and simulation tasks, and has scientific accountability for the designated analysis plans and developed quantitative drug development tools.
- Accountable for the development and implementation of modeling and simulation plans based on agreed upon best practices (i.e. model-based drug development).
- Responsible for use of quantitative methods to integrate knowledge of pharmacokinetics, pharmacodynamics, patient characteristics and disease states to inform optimization of doses, dosage regimens and study designs.
• Responsible for appropriate summarization and interpretation of results of data analyses with respect to their impact on development of quantitative drug development tools.
• During the planning stages, works with consortia teams to ensure that principles of model-based drug development have been applied.
• Prepares scientific summaries and reports which will be used for regulatory submissions and publications.
• Provides quantitative medicine, clinical pharmacology support and leadership in the preparation and defense of regulatory submissions.
• Coaches and develops other members of the consortia teams.
• Responsible for designing cost-efficient analysis plans.
• Responsible for recommending and/or working within budget allocated to the consortia and the Quantitative Medicine Team.
• Travel on occasion for out-of-town meetings (~ 15%).
• Other duties and responsibilities may be assigned.

Education and Training:
• PharmD, PhD, or equivalent training or experience in pharmacokinetics, pharmacometrics, clinical pharmacology, systems pharmacology, engineering or related discipline.
• Demonstrated experience with clinical pharmacology aspects of drug development.
• Proficiency or experience working in team settings.
• Proficiency or experience working with regulators is desired.

Knowledge/Skill/Abilities:
• Clinical Pharmacology: demonstrates thorough understanding of the following: 1) principles of PK, PK-PD and pharmacology relevant to quantitative drug development platforms; 2) knowledge of phase I-III studies including design and interpretation; and 3) other relevant scientific disciplines, including drug metabolism, drug transport, formulation sciences, biopharmaceutics, pathophysiology and therapeutics.
• Biostatistics: demonstrates thorough understanding of the following: 1) linear and non-linear mixed-effects models; 2) parametric survival analyses; 3) joint modeling for time-matched data; 4) model-based meta-analyses.
• Software: demonstrates thorough expertise in the use and coding for software platforms such as NONMEM, R and SAS.
• Communication: demonstrates ability to effectively present clinical pharmacology data, development plans and strategies to various audiences in both verbal and written form; demonstrates ability to write clinical pharmacology results, interpretations (including impact) and conclusions for reports and regulatory documents that are clear and concise.
• Scientific Excellence: demonstrates understanding of the complexities and recent developments in clinical pharmacology and the implications for drug development.
• Regulatory Knowledge: understanding of appropriate FDA, EMA and ICH guidelines in the design of analysis plans is desirable.
• Networking and Alliance Building: good interpersonal skills that ensure teamwork.
and productive interactions among diverse personalities/areas of expertise; ability to garner support and coordinate resources in support of consortia objectives.

- **Big Picture/Strategic Thinking:** ability to demonstrate a broad perspective on the overall consortium goals and how the Quantitative Medicine Team contributes; ability to understand all stakeholder needs.
- **Innovation:** constantly looking for new approaches and able to devise/apply new techniques in quantitative medicine, clinical pharmacology and modeling and simulation.
- **Courage with Decisiveness to Act:** bias towards action to achieve goals; excitement, enthusiasm and a sense of urgency with regard to the development of drug development tools.
- Practice highest level of integrity and core value system consistent with C-Path’s code of conduct.
- Ability to meet target deadlines and manage time effectively, balanced across multiple projects.

**Language Ability:** Excellent oral, written and virtual communication skills.

**Math Ability:** Commensurate with PharmD, PhD degree.

**Reasoning Ability:**
- Exercise sound business judgment when making decisions and adhere to external and internal policies and regulations.
- Strong critical thinking and analytical skills.
- Ability to successfully anticipate issues or challenges and proactively address without being specifically directed.
- Use sound judgment when working with critical or confidential information.

**Computer Skills:**
- Proficient use of Microsoft Office Suite: Word, Excel, PowerPoint, Outlook.
- NONMEM
- R
- SAS

**************************************************************************

**TO APPLY FOR THIS POSITION:** Please submit a resume/CV and cover letter to HR@c-path.org highlighting how your qualifications match the needs of the position. Indicate the position title for which you are applying in the subject line of your correspondence. Critical Path Institute is an equal opportunity employer. Visit our website at www.c-path.org

Please note: only those applicants authorized to work in the United States without corporate sponsorship need apply.