Position Title: Director, Statistical Methods

Department: Clinical Operations

Location: King of Prussia, PA

Date: 4/9/18

☒ Exempt ☐ Non-Exempt

Summary of Position:

The Director of Statistics will provide industry-leading guidance and accountability for design and analytical support to Clinical Development and Medical Affairs. As an individual contributor, the candidate should have in-depth theoretical understanding of statistical methods and techniques, has demonstrated ability to conduct innovative methodology research and ability to perform simulations using various packages. This position will report to the Head of Biometrics and plays a key strategic role in a cross-functional, dynamic environment within the pharmaceutical industry.

Position Responsibilities:

- Provide statistical leadership with a track record of statistical accomplishments in clinical drug development, publications and medical affairs
- Act as a key statistical consultant to lead the collaborative process in refining research questions, selecting sample size and utilizing statistical methods that produce key results in all Phases of development, i.e. clinical trials, observational studies, meta-analyses and post-hoc analyses of existing databases
- Perform modeling, simulations and investigate design options and properties of analysis to provide statistical guidance and facilitate critical decision-making
- Plan, lead and implement statistical analyses to support publications, presentations and other Scientific/Medical Communications projects
- Lead statistical inputs for study concept, protocol, CRF and author SAP, ensuring the appropriateness of study design, sample size, data collection and proposed methodologies
- Perform/oversee statistical analyses using statistical programming/software, lead preparation of data presentations (tables, listings, figures) to communicate results of analyses effectively
- Experience and demonstrated success in defending statistical aspects of clinical development plans and studies, including influencing global regulatory agencies

Candidate Requirements:

- Ph.D. in Statistics/Biostatistics/Public Health (or related field) with a minimum of 10 years of related experience or MS/MA with a minimum of 15 years of experience is required
- Working expertise, as well as a proven track record, of successful application of Bayesian methods, which required prior elicitation, and Frequentist methods
- Comprehensive knowledge and superior understanding of advanced statistical concepts and techniques, demonstrated ability to put evidence into context and explain both standard and novel methods
- Exceptional interpersonal skills, with a focus on rapport-building, written and verbal communication, problem-solving and agile thinking
- Prior experience in infectious diseases drug development is highly desirable
- Working knowledge of FDA, EMA, and ICH guidance for drug development

- Understanding of real world evidence, epidemiologic research methods, health economic and outcomes research methods is preferred
- Proven ability to organize workload and competing priorities, and complete tasks on time with a high level of organization, attention to detail and accuracy
- Established ability to work independently or as part of a team in a dynamic environment with rapidly changing demands
- Enjoy working in a fast-paced, small company environment

Additional Information:

- Technology needs: Proficient in SAS and/or R programming; working knowledge of Microsoft Office (e.g., Excel, Word, PowerPoint)
- Travel requirements (%): <20%, as needed