**Overview**

**Lead clinical studies and provide statistical support for FDA interactions on product submissions for a Fortune 200 Company with some of the most iconic brands! Do you have a PhD or MSc in Statistics, Science or a Quantitative field with experience in the Bio-Tech, Medical Device or Pharmaceutical Industry? If so, we want to speak with you!**

We are currently seeking a **Principal Scientist, Biostatistics** to join our Regulatory Affairs team. This role can be **remote** or located in **Richmond, VA**. You will lead and support clinical studies and associated FDA interactions for tobacco product submissions. Working both independently and with scientists, engineers and other statisticians, to provide advanced statistical and analytical expertise in regulated environments. Part of your role will be to work face to face with the FDA, and communicate the statistical clinical study data, and demonstrate how they meet FDA objectives.

**How you will make an impact:**

• Provide subject matter expertise to clinical study designs, statistical analysis and data outputs for clinical trials. Lead collaboratively within a framework of study teams
• Lead the statistical design, sample size calculations, development of statistical analysis plans, data review, and query management for studies
• Lead SAS programmers and validation of STDM and ADAM datasets
• Optimize clinical systems and processes as they relate to clinical statistics
• Collaborate with CRO statisticians based on input from cross-functional study team
• Participate with Operations in the selection and management of statistics and data management suppliers (CROs) to include leading project timelines
• Collaborate with Regulatory Affairs and other health scientists to interact and communicate with FDA regarding regulatory submissions
• Apply innovative thinking in design and analysis of clinical studies by bringing creative ideas for problem solving. Interact with all levels of management
• Validated expertise in clinical study design and analysis, specialize in statistical methods used to support analytical and clinical validation of products for regulatory submissions
• Craft infrastructure to improve processes within department and ALCS; and Identify future technical talent needs and help assess/develop talent within department

**We want you to have:**

• Master’s degree required. Ph.D. or related specialized training in statistics or comparable quantitative sciences preferred
• Significant experience in Pharmaceutical, Bio-Tech or Medical Device industry with hands-on experience running the statistical aspects of clinical trials. 10+ years preferred
• Experience presenting the analysis of study data to the FDA as a sponsor subject matter expert
• Experience with leading and working with 3rd party vendors in clinical studies
• Strong knowledge of FDA regulations, ICH guidelines, GCP practices
• Knowledge of meta-analysis techniques
• Leadership experience in execution of all statistical aspects of clinical trials - from planning phase to completion phase
• Strong project planning and management skills
• Excellent writing skills and ability to optimally communicate with all partners and senior management

In addition to the opportunity to apply and develop your skills toward key business objectives, we offer an excellent compensation package including a competitive base salary, comprehensive health/vision/dental insurance, participation in our deferred profit sharing and incentive compensation programs as well as a relocation assistance package.

**Company Overview**

Altria Group is a FORTUNE 200 company that leads the premier tobacco companies in the United States. Headquartered in Richmond, Virginia, Altria Group holds diversified positions across tobacco, alcohol, and cannabis. Our tobacco companies include some of the most enduring names in American business: Philip Morris USA, U.S. Smokeless Tobacco Company, John Middleton, and Nat Sherman. We have 35 percent ownership of JUUL Labs, Inc., the nation’s leading e-vapor company. And we have an 80% interest in Helix Innovations, which manufactures and markets on!, an oral tobacco-derived nicotine pouch product. We complement our total tobacco business with our ownership of Ste. Michelle Wine Estates and our significant equity investment in Anheuser-Busch InBev, the world's largest brewer. Altria’s significant stake in Cronos Group, a leading global cannabinoid company, represents an exciting new global growth opportunity.

At Altria, we recognize that our people are the reason we achieve our business goals. It’s only through diverse perspectives and insights that we will be able to take on the important challenges we will face to dramatically transform our business – and our industry. The work opportunities and experiences, combined with training, development, and advancement programs, allow our employees to achieve their full potential and deliver superior business results. We have the opportunity to make more progress on harm reduction in the next 10 years than we have in the past 50 years. Join us as we work together to shape a better future for adult tobacco consumers, our employees, and our shareholders. Each Altria company is an equal opportunity employer.