## **Position:** Associate Director, Biostatistics

At Bristol Myers Squibb, we are inspired by a single vision – transforming patients' lives through science. In oncology, hematology, cell therapy, immunology and cardiovascular disease – and one of the most diverse and promising pipelines in the industry – each of our passionate colleagues contribute to innovations that drive meaningful change. We bring a human touch to every treatment we pioneer. Join us and make a difference.

### Position Summary

We are looking for a motivated statistician to join our growing cell therapy biometric group. The Associate Director of Biostatistics is a member of cross-functional Development teams and contributes to trial design, protocol development, analysis planning, interpretation of results, and preparation of regulatory submissions. With appropriate experience, the Associate Director of Biostatistics can have responsibilities for supporting a particular indication of an asset. These individuals develop collaborative relationships and work effectively with the Biostatistics indication/asset Lead, and other cross functional team members.

### Key Responsibilities

- Collaborates in design of innovative and efficient clinical trials, including the selection of study population/endpoints to address study objectives, and contributes to project development strategy
- Defends protocols and analysis plans at internal governance reviews and provides independent reviews of complex protocols.
- Independently authors and/or reviews protocol, statistical analysis plan, clinical study reports, associated publications, and other study level documents
- Presents summary data and analyses results, in a clear, concise, complete, and transparent manner
- Provides statistical support and leadership to address health authority request, publication, presentation, and other public release of information
- Manages multiple studies to ensure consistency and adherence to standards within an indication or therapeutic area
- Applies extensive knowledge of statistical / clinical trials methodology as it relates to clinical development
- Invests in developing knowledge outside of traditional statistical expertise in the clinical, regulatory and commercial environments with demonstrated application to study design.
- Effectively engages as a matrix team member on project teams, to act as a scientific and strategic partner in the drug development process
- Compliant with BMS processes and SOPs, adherence to global and project standards within an indication or therapeutic area and responsible for quality of deliverable
- Contributes to external and internal statistical community of practice
- Develops & advises team members

- Effectively communicates the GBDS Mission and Vision in a fashion that generates pride, excitement and commitment within GBDS.
- Enables a culture of inclusiveness, respect for diversity, compliance with process and allows for the questioning and challenging of others in a respectful and constructive manner.

Applicable to people managers

- Effectively engages as an employee advocate and management coach/mentor to team members - both internally and externally
- Provides leadership to empower and develop the team.
- Provides guidance to employee's development plans and carries out performance review and feedback. develops performance metrics for staff.

## Qualifications & Experience

- PhD (6+ years' experience) or MS (8+ years' experience) in statistics or biostatistics or related scientific field with clinical trials, drug development, pharmaceutical industry or healthcare experience
- Proficiency in scientific computing/programming (SAS, R or Python) and implementation of advanced statistical analysis, data manipulation, graphing & simulation.
- Great interpersonal, communication, writing and organizational skills
- Expertise in statistical/clinical trials methodology as it related to clinical development and ability to apply to relevant clinical development framework
- Good understanding of regulatory landscape and experience with participating in regulatory interactions
- Demonstrate collaboration, organizational/ leadership abilities, and interpersonal skills
- Demonstrate ability to plan, organize, and prioritize multiple work assignments, and strong project management skills
- People manager experience is preferred but not required

## Why You Should Apply

Around the world, we are passionate about making an impact on the lives of patients with serious diseases. Empowered to apply our individual talents and diverse perspectives in an inclusive culture, our shared values of passion, innovation, urgency, accountability, inclusion and integrity bring out the highest potential of each of our colleagues.

Bristol Myers Squibb recognizes the importance of balance and flexibility in our work environment. We offer a wide variety of competitive benefits, services and programs that provide our employees with the resources to pursue their goals, both at work and in their personal lives.

## Contact Information

Brian Marx
Brian.marx@bms.com

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## Contact Information

Brian Marx
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**Title: Associate Director, Data Science**

**Overview:**
You will join a new cutting-edge Data Science team to advance the global drug development process. We are looking for candidates with experience modeling complex clinical, real-world data (RWD) using the classical ML algorithms, latest NLP techniques/algorithms as well as Deep Learning. Also, there is opportunity to do Image Analysis, Operations Optimization, and Biosensor Data Processing Algorithms. We are looking for hands-on technical state of the art practitioners. This is a Remote By Design Role.

**What you'll do:**
- Work with stakeholder to develop, implement and apply state-of-the-art algorithms to address key business problems
- Develop novel ways of integrating, mining, and visualizing diverse, high dimensional and disparate data sets
- Drive the development and implementation of innovative statistical methods, novel trial designs, etc.
- Drive translation of digital health analytics; use of modern data processing learning capabilities including ML, AI, deep learning, and beyond.
- Formulate, implement, test, and validate predictive models and implement efficient automated processes for producing modeling results at scale.
- Responsible for collaborating with cross-functional teams, including but not limited to, clinicians, data scientists, translational medicine scientists, statisticians, and IT professionals.
- Manage and coordinate limited resources to produce quality deliverables within timelines for competing priorities.

**Key Requirements:**
- Ph.D. in a relevant quantitative field (i.e. Computational Biology, Computational Linguistics, Biostatistics, Statistics, Computer Science, etc.) and 10+ years of relevant experience
- 3+ years of experience as a professional Data Scientist after receiving a Ph.D.
- Mastery in data analysis with data generated from clinical trials, or electronic health records and modeling methods particularly in their application to pharma R&D Experience in the application of AI/ML, and proficient in SQL, Python, and R and cloud platforms
- Significant industry and track record of leading statistical innovation
- Experience developing statistical models and classical machine learning on high dimensional data for time to event data and longitudinal outcomes
- Perspective in leveraging innovative approaches to expedite drug development and address the complexities of emerging data
- Experience with NLP is highly preferred
- Experience with Survival Analysis is highly preferred
- Experience in working with different causal ML and explainable AI is highly preferred
- Experience in working with genomics, Flow Cytometry and immunobiology datasets is highly preferred

**Contact Information**

Brian Marx
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**Title: Sr. Manager, Biostatistics**

**Overview:**
BMS is developing novel cellular immunotherapies based on two distinct and complementary platforms – Chimeric Antigen Receptors (CARs) and T Cell Receptors (TCRs) technologies. Our goal is to revolutionize medicine by re-engaging the body's immune system to treat cancer.
The Cell Therapy CMC Biostatistics group supports the statistical and quantitative elements related to Cell Therapy Process and Analytical CMC activities - development, regulatory submissions, and post-approval commercial manufacture. The role of CMC Biostatistics is being increasingly recognized across the Pharma / Biotech / Medical Devices industry, both from a business as well as from a regulatory perspective, and so this role provides a wonderful opportunity for learning and growth within a rapidly expanding therapeutic area.

## Basic Qualifications:

- 2+ years of experience as a Non-clinical / CMC Statistician with an advanced degree in a quantitative discipline (Statistics, Chemical / Industrial Engineering, Applied Mathematics)
- Working knowledge of manufacturing processes and analytical methods in the biotech industries
- Communication and collaborative skills to work in a fast-paced, team environment
- Strong proficiency in at least one statistical software package (such as SAS, JMP, Minitab, R)

## Proficiency in at least two, as well as familiarity with most of the following:

- Statistical aspects of pharmaceutical regulations / guidance (some prior interaction with health authorities such FDA, EMA, PMDA, ICH, USP)
- Statistical design and analysis supporting the Biologics Manufacturing Process (Process Development (QbD principles, Process Characterization), Process Validation (CQA assessment, PPQ acceptance criteria), Process Monitoring (PAT, SPC, CPV))
- Statistical design and analysis supporting Analytical Methods (Analytical Method Development, Analytical Method Qualification and Validation, Analytical Method Comparability and Transfer, Analytical Method Performance Monitoring)
- Statistical data analysis for long-term / accelerated stability studies and shelf-life determination
- Statistical analysis supporting product specification

## Preferred / Additional Qualifications:

- An advanced degree in a quantitative discipline
- 4+ years of experience as a Non-clinical / CMC Statistician supporting commercialization in a Biologics / Biotech environment
- Prior experience with data-driven Root Cause Investigations (Data-mining / machine learning techniques, FMEA)
- Multivariate analysis of process and analytical data (using tools such as SIMCA, PLS_Toolbox)
- Data Visualization

## Contact Information:

Brian Marx
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**Title:** Sr. Manager, Statistical Programming

Project Responsibilities:

- Provides comprehensive programming leadership and support to clinical project teams and vendors, including deployment of programming strategies, standards, specifications and programmed analysis to comply with regulatory requirements, SOPs and work practices
- Independently develops, validates, troubleshoots, and maintains complex programs and utilities in accordance with predefined specifications and standards
- Leads / Supports the electronic submission preparation and review
- Develops unambiguous and robust programming specifications (e.g. ADaM specifications)
- Reviews key planning documents (e.g., statistical analysis plan, data presentation plan, data review plan) to align with project objectives and ensures clarity and completeness of programming assumptions and requirements; Assesses document robustness and impact on programming activities
- Communicates proactively and effectively around issues and risks and contributes to its remediation

Improvement Responsibilities:

- Identifies, leads, and supports opportunities to enhance processes and technology
- Communicates proactively and effectively around issues and risks and contributes to its remediation

Managerial Responsibilities (if applicable):

- Effectively recruits, manages, develops, evaluates, rewards, motivates, and retains up to 5 direct reports, resulting in an increasing level of capabilities within GBDS
- Conducts objective setting, performance check-ins, and year-end discussions in compliance with BMS policies; aligns objectives, feedback and performance evaluation with manager
- Meets regularly with direct reports, focusing on project updates, development needs, issue resolution, and provides real-time coaching and feedback; holds staff accountable for quality and timeliness of programming activities; ensures staff is compliant with training requirements
- Communicates with manager regarding promotions, performance concerns, and retention risks
- Builds and maintains a network with stakeholders and peers to ensure cross-functional strategies and objectives intertwine and build upon each other to achieve results

Minimum Requirements:

- Bachelor's degree in statistics, biostatistics, mathematics, computer science or life sciences required
- At least 7 years programming experience in industry including support of significant regulatory filings
- For US positions: US military experience will be considered towards industry experience
- Proficient knowledge of drug development process, clinical trial methodology, regulatory guidance, industry standards, statistical concepts, and medical terminology used in the analysis and submission of clinical data
- Broad expertise in statistical programming and in developing computing strategies
- In-depth understanding of clinical data structure (e.g. CDISC standards) and relational databases
- Demonstrated proficiency in using SAS to produce analysis datasets and TFLs and in using other software tools and applications (e.g. MS office, XML, Pinnacle 21)
- Demonstrated ability in processing of upstream data (e.g. multiple data forms, workflows, eDC, SDTM); Demonstrated ability in providing deliverables to meet downstream requirements, (e.g. ADaM, TFLs, e-submission components)
- Demonstrated ability to work in a team environment with clinical team members

Preferred Requirements:

- Management experience supervising technical professionals

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