The Director of Biostatistics is responsible for providing direct supervision for one or more therapeutic area leader(s). They will also provide direction on clinical development plans, protocols and analysis, reviews clinical study reports and regulatory submission materials, and ensures that standard procedures are followed within projects. The Director provides mentorship to biostatisticians in the department and is responsible for implementing consistent statistical conduct for the department in all locations. The individual also provides guidance to the department towards achieving departmental and corporate visions and goals. The Director maintains liaison with clinical research personnel in order to identify and meet their needs for statistical support. They will interact with the head of statistical programming and data management to synchronize prioritization of projects and in some cases, he/she represents Biostatistics in meetings with executive committee, commercial, regulatory agencies, and external development partners in the absence of the Senior Director of Biostatistics.

- Provides guidance and support for all biostatisticians in therapeutic areas under development; provides professional statistical support to clinical research (review protocols, analysis plans, and clinical study reports).
- Provides input into strategy, planning and contents of clinical components of regulatory submissions; strives to increase the operational efficiency of the biostatistics group by assisting in developing policies, procedures and strategies for Biostatistics.
- Represents the company when statistical issues are part of regulatory, legal or other challenges to the company’s products or processes.
- Responsible for directing overall statistical activities for the therapeutic areas assigned including implementing efficient, consistent, and practical processes for Biostatistics/Biometrics and develops, implements and monitors budgets for assigned therapeutic areas – including oversight of resource allocation and usage.
- Provides mentoring and guidance to biostatisticians towards achieving the vision and goals of Biostatistics, Biometrics and the company; develops staff through coaching and training.
- Leads inter-organizational projects or coordinates between organizations and may represent Biostatistics/Biometrics in the absence of Sr. Director, Statistics, and/or VP, Biometrics.

**Qualifications**

- MS with at least 12 or PhD with at least 10 years working on clinical trials.
- Past frequent interaction with FDA.
- BLA/NDA experience essential.
- Interaction with EMEA/CPMP and preparation of an MAA an advantage.
- Broad and thorough understanding of statistical principles and clinical trial methodology; able to practice and implement them.
- Ability to develop innovative/creative statistical/technical solutions to complex problems.
- Knowledge and experienced in meeting regulatory guidance, both FDA and international regulatory agencies.
- Broad knowledge of medical/biological terminology and clinical practice in relevant therapeutic areas.
- Attentive to detail.
- Able to write and present information effectively.
- Effective communicator: able to explain methodology and consequences of decisions in lay terms; able to understand requests for complex analyses, etc.
- Able to manage many projects simultaneously, to manage conflicting priorities, and to be flexible when priorities change.
- Able to manage staff.
- Demonstrates excellent leadership and communication skills.
- Demonstrates strong organizational skills, including the ability to prioritize.
Education

- MS or PhD in Biostatistics/Statistics or equivalent

Biogen (NASDAQ: BIIB) is a biotechnology leader that discovers, develops and delivers innovative therapies to improve the lives of patients with neurodegenerative diseases, hematologic conditions and autoimmune diseases. Patients worldwide benefit every day from our medicines for multiple sclerosis (MS) and hemophilia.

Founded in 1978, Biogen is the world’s oldest independent biotechnology company. Our development pipeline is focused on areas of high unmet medical need, as we pursue new therapies for patients suffering from diseases with few or no treatment options. These include programs for secondary progressive MS, Alzheimer’s Disease, spinal muscular atrophy, lupus and amyotrophic lateral sclerosis (ALS), amongst others.

With approximately 7,500 people worldwide, Biogen is truly a global organization. We are headquartered in Cambridge, Massachusetts, which is home to our research operations. Our international operations are based in Zug, Switzerland and we have world-class manufacturing facilities in North Carolina and Denmark. We offer therapies globally through direct affiliate presence in 30 countries and a network of distribution partners in over 50 additional countries.

All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability or protected veteran status.

http://www.statsjobs.com/jobs/director-biostatistics-biogen/