

TechData is looking for **Clinical Data Managers, Biostatisticians, Statistical Programmer/Senior Statistical Programmer, Clinical Data Manager, sr. Manager, and Associate Director of Biostatistics** in PA, NJ, CA, IL and DE. Please see below requirements and send your resume to: recruiting@techdataservice.com or dan.chen@techdataservice.com. TechData offers very competitive pay rate and benefits.

Clinical Data Manager:

QUALIFICATIONS: BA/BS degree in associated functional discipline or RN required, Masters Degree preferred. CDM certification desirable. CRO overseeing experience and good SAS programming skills preferred. At least 5 years of hands-on experience in clinical trial data management at a pharmaceutical company or CRO. Solid understanding and technical expertise in data acquisition and cleaning. Knowledge of medical terminology, Clintrial or other database system, and GCP/ICH guidelines, Strong initiatives in identifying issues and proposing solutions with ongoing studies, a good investigative and meticulous approach to all activities and tasks.

Demonstrated ability to operate independently and to influence decision making processes within a matrix team environment Leadership ability and interpersonal, negotiation, and organizational skills.

Biostatisticians (Contract or Permanent):

Review protocol, write analysis plans and design data presentations. Must have MS or PhD in statistics and a minimum of 2 years experience in the pharmaceutical, CRO or biotech industry. Candidates must possess good working knowledge of SAS/Base, SAS/Macros, SAS Procedures and Report, SAS Graphics, SAS/Stat and SAS Version 8.2; Able to function in a team setting with good verbal and written skills. Experience with electronic FDA applications, NDA and experience with Items 10 and 11 of the FDA regulation for electronic submissions are big plus.

Statistical Programmer/Senior Statistical Programmer (Contract or Permanent, some contract positions can be telecommuting)

Duties: Responsible for statistical programming in support (analysis datasets, pooled datasets, listing and tables) of individual phase I-IV clinical trials and project level activities for drug project / indications. Maintain efficient interfaces with internal and external customers with support of SR management and the statisticians. Develop and comply with project/study

programming standards and specifications following internal guidelines. Make certain that study documents and specifications are consistent and comply with company standards by providing input into Study protocol, CRF and Data structures and outputs (listings, tables and figures) for phase I – IV clinical trials and submission activities.

Program according to specifications, analysis datasets, pooled datasets, listings, tables and figures for phase I-IV clinical trials and for SCS and SCE with high quality and within milestones.

Develop programming specifications for analysis datasets, pooled datasets and deliverables in consultation with the statistician. Support quality control and quality audit of deliverables.

Skills: Ability to coordinate programming work across a clinical study.

Experience in Oncology therapeutic area is a plus

Intermediate to expert knowledge of / experience with SAS software (including SAS macro language) Working knowledge of database design/structures

Good understanding of global clinical trial practices, procedures and methodologies.

Education: BA/BS or equivalent experience in mathematics, statistics, computer science, life sciences or related field, with at least 4 years of experience in a programming role supporting clinical trials in the pharmaceutical industry, or MS statistics/computer science with at least 2 years of similar experiences.

Clinical Data Manager (Contract)

Responsible for providing timely and professional ongoing quality management of clinical trial data by identifying errors/inconsistencies in CRF data and ensuring their resolutions in order that databases can be declared clean and locked according to strict performance standards. Review and contribute to the development of trial validation plan related documents and create/approve final CRF design, validation checks and reports necessary to assure high quality and consistent data. Review and contribute to the preparation of protocols, CRF's and prepare or review/contribute to operations manuals. Organize / chair data management meetings. Support and assist clinical data managers, clinical data assistants for allocated trials. Work very closely with Contract Research Organizations (CROs) contracted to perform data management functions. Travel when required. All other duties as assigned.

Associate Director (or Sr. Manager) of Biostatistics

Job Description Assume accountability for statistical support for clinical trials/clinical development plans within commercial operations, across multiple therapeutic areas including CNS, GI, Oncology and Institutional Care.

- Take an enterprise-wide perspective and influence the proper use of statistics throughout commercial operation; contribute to the development of Biometrics SOPs, standards and guidelines.
- Work with the clinical, marketing, project management, and data manager teams on strategic designs of studies; development, review and approval of clinical study protocols; review and approval of CRF, edit check specification, data management plan, and final database validation; author or review and approval of statistical analysis plans and final study report; performance of statistical analysis.
- Work with the internal / CRO statisticians and programmers to ensure the quality of CRO deliverables and on QA of data outputs.
- Work with regulatory and Medical Affairs clinicians on submission strategies and lead statistical activities on FDA submissions.
- Support publication and other marketing strategies.

**Job
Qualifications**

- Minimum of a Masters degree in Biostatistics (PhD highly preferred) or related discipline with at least 8 years of relevant experience in the pharmaceutical industry/CRO environment.
- Demonstrated excellence in statistical skills across multiple areas of pharmaceutical biostatistics, together with broad understanding and experience of the clinical development process.
- Experience with CRO overseeing and FDA submission highly desirable.
- Excellent technical writing and verbal communication skills.
- Strong teamwork ability/commitment and individual initiative.
- Strong organizational skills with ability to effectively manage multiple studies.