

## Job Description - Sr. Biostatistician - Oncology

- **Location:** any i3 office location (Ann Arbor, MI, Austin, TX, Basking Ridge, NJ, Cary, NC, Eden Prairie, MN, Indianapolis, IN, Lexington, KY, San Diego, CA, West Chester, OH, Westerville, OH)
- Can also work home-based from any US home office
- **Status:** Permanent

**Manager's notes:** We are looking for a Senior Biostatistician who will be leader within our group. The candidate should have at least 8 years of experience overall and at least 4 years of experience in oncology. Main area of experience that we need is late phase oncology trials (i.e. phase 3). CRO and Pharma experience is preferred but experience in just one of these environments would be okay if they were strong overall. Good communication skills, collaboration across functional groups and solid clinical trial statistical experience will be key factors. I would like to hire someone quickly but willing to wait to find someone who will meet our needs.

### QUALIFICATIONS:

- Graduate degree in Statistics, Biostatistics, or equivalent.
- Minimum 3 years, preferably 5+, years experience performing clinical trial statistics.
- Excellent written and verbal English language skills.
- Understanding of regulatory (e.g., FDA, ICH) requirements.
- Ability to review and understand data from multiple sources.
- Ability to understand responsibilities of other functional areas (data management, medical writing, statistical programming, clinical) and work with their representatives.

### RESPONSIBILITIES:

Responsible for statistical methodology and statistical analysis plans for clinical studies as a member of the biostatistics team. Ensure that activities and processes performed are conducted according to company and sponsor requirements. This position works closely with the biostatistics and data management departments on various clinical projects.

- Act as lead Statistician on complex trials and across multiple studies.
- Act as a lead representative of the biostatistics department on project teams. Attend project team meetings as necessary.
- Meet with sponsors as requested during protocol development to ensure adequacy of proposed study designs with respect to statistical feasibility.
- Write statistical methodology sections of individual protocols. Write formal Statistical Analysis Plans to be carried out in the analysis of clinical studies.
- Perform statistical analyses of data and interpret results to ensure validity of conclusions. Meet with sponsor as requested throughout trial to discuss progress of clinical studies.
- Interact with data management personnel as necessary to ensure that datasets are in usable format; perform statistical diagnostics prior to database locking.
- Interact with SAS Programmers to ensure that appropriate programs are being developed for current clinical studies.
- Perform statistical quality assurance review and program validation for each project.
- Interact with medical writers in production of statistical and integrated clinical/statistical reports and other documents containing statistical information. Review statistical sections of draft documents.
- Interact with other departments, such as clinical operations and project management, to ensure a high level of client satisfaction through successful execution of projects.

## **Company Description**

At inVentiv Clinical Solutions (iCS), our mission is to be the alternative to traditional clinical outsourcing for the biopharmaceutical industry, allowing clients the greatest control and flexibility through unmatched access to the highest quality clinical resources. iCS provides clients with a variety of flexible options to meet their clinical trial objectives, including outsourcing of one or several functions associated with the clinical trial process, expert clinical staffing and recruitment, and creating strategically resourced work groups. Our solutions are designed to increase efficiency and accelerate results. iCS is headquartered in Houston, Texas, with offices throughout the globe.

## **Additional Information**

Posted: December 7, 2011

Type: Full-time

Experience: Mid-Senior level

Functions: Research

Industries: Biotechnology, Pharmaceuticals

Compensation: Salary, medical/dental benefits, PTO

## **Contact**

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