Biostatistician III

Job Summary

Hologic is seeking a Biostatistician responsible for designing, monitoring, and analyzing clinical trials for obtaining FDA clearance or approval of in-vitro diagnostic medical devices. In addition, the Biostatistician will assist with solving statistical problems for R&D, QA, QC and Marketing and Manufacturing.

Essential Duties and Responsibilities

*The incumbent may be asked to perform other function-related activities in addition to the below mentioned responsibilities as reasonably required by business needs.*

* Provides biostatistical expertise to Clinical Affairs staff; determines appropriate statistical methods and procedures.
* Works with clinical investigators and scientists to determine protocol design.
* Works with other project team members in Clinical Affairs to ensure CRF and database design meets analysis needs.
* Writes and/or reviews Statistical Analysis Plans (SAPs) and develops and/or reviews table/listing/figure shells for statistical analyses and reports.
* Develops programs to perform statistical analysis and present results.
* Work with SAS programmers to ensure appropriate data analysis and presentation is performed.
* Writes and/or reviews the statistical and data analysis sections of regulatory submissions.
* Develops Biostatistical SOPs and work instructions.
* Provides input on Data Management SOPs and work instructions.
* Maintains expertise in state-of-the-art statistical analysis techniques.
* Acts as a statistical resource for other departments (e.g., R&D, QA, QC, Marketing, Manufacturing) regarding statistical issues including experimental design, sample size, statistical analysis, and interpretation of results.

Qualifications

Education

* BA/BS, MS or PhD
* MS or PhD preferred
* Degree in statistics or closely related field

Experience

* 5-8 years related experience (BA/BS)
* 3-5 years related experience (MS)
* 0-3 years related experience (PhD)

Skills

* Working knowledge of SAS
* Working knowledge of additional statistical software packages such R or JMP.
* Experience producing SAPs and TLFs for using in regulatory submissions to FDA
* Advanced knowledge of applied statistical methods for diagnostics clinical trials such as Passing-Bablok and Deming regression, ROC/AUC, PPV/NPV, and sample-size calculations for binary outcomes on matched-pair data
* Working knowledge of CRF and database development, including attribute assignment and logic checking.
* Knowledge of FDA regulatory requirements for IDE, BLA, PMA and 510K submissions.
* Knowledge of infectious disease, cancer, genomics, and common public health issues.
* Experience in technical writing.

Agency and Third-Party Recruiter Notice:

Agencies that submit a resume to Hologic must have a current executed Hologic Agency Agreement executed by a member of the Human Resource Department. In addition, Agencies may only submit candidates to positions for which they have been invited to do so by a Hologic Recruiter.  All resumes must be sent to the Hologic Recruiter under these terms or they will not be considered.

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