

Biostatistician II

Job ID: 00411868

Job Function

Biometrics / Biostatistics

Schedule

Full-time

Location

United States-
United States

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Provide statistical and strategic support related to clinical development plans, study designs, planning and execution of exploratory biomarker analysis, and incorporation of biomarker objectives in clinical development plans.

Major Responsibilities and Accountabilities:

- As part of a clinical development team, collaborates in the preparation and review of protocol writing, CRF design and monitoring of ongoing clinical trials.
- Provides technical and strategic support into clinical development plans
- For assigned clinical development project(s), provides statistically sound clinical trials design, including clinical pharmacology trials and data analysis input to meet project objectives.
- Supports teams in the development and review of regulatory submissions such as clinical protocols, INDs and pre-meeting packages.
- Provides strategic and analytical support for exploratory project activities such as biomarkers and PK/PD analysis
- Develops statistical analysis plans, including biomarker analysis plans, prepares data displays and as necessary develops statistical programs to

- perform exploratory analyses.
- Authors the clinical study report; with help from senior statistical staff, leads team members to complete the report.
- Provides advice and training on the use of statistical methods and software packages to the biomarker scientists
- Collaborates with scientists in support of external publications.
- Keeps abreast of new developments in statistics, drug development, and regulatory guidance through literature review, workshop attendance, etc.

Participates in department and cross-functional initiatives aimed at optimizing drug development process

Who You Are

Qualifications:

- Ph.D. in statistics/biostatistics with at least 2 years of clinical trials experience or a Master's Degree in statistics/biostatistics with at least 5 years of clinical trials experience.
- Experience with statistical software packages such as R, S-Plus, SAS.
- Sound knowledge of theoretical and applied statistics.
- Ability to function effectively on interdisciplinary project teams
- Effective communication skills.
- Effective team contributor.
- Experience working as a statistical consultant

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