

Statistical Scientist- Clinical Development and Personalized Healthcare

Job ID: 201903-107592

Job Function

Biometrics

LocationSouth San Francisco
California
United States of America**Schedule**

Full time

Job type

Regular

Company/Division

Pharmaceuticals

Job Level

Individual contributor

The Position

Genentech Biostatistics seeks talented and self-motivated statisticians to support clinical development activities and Personalized Health Care (PHC) projects in either early or late stage of clinical development. Our statisticians work as full members and key partners of multi-disciplinary teams to provide statistical and analytical leadership. We combine our expertise in applied statistics with our business knowledge to define and solve the right problems and to provide strategic input to maximize business impact. Teamwork and effective communication are essential. Candidates should be experienced in data analysis and expect to pursue projects involving statistical applications to molecular data for clinical development.

The statistician supporting late stage development will partner with senior scientists in biostatistics, clinical, safety, epidemiology, regulatory, research, and manufacturing on clinical development projects, research applications, development science applications, and/or product manufacturing applications. This typically includes partnering with senior scientists in the creation of strategies to address drug development needs and designing experiments, and evaluating and preparing study results for health authorities and the medical/research community. For clinical development programs, the Statistical Scientist typically is the lead Biostatistics representative on cross-development global clinical study teams.

The statistician supporting early development splits their time between molecule and non-molecule projects. For molecule projects, they will partner with senior scientists in biostatistics, clinical, safety, epidemiology, regulatory, research, and manufacturing on clinical development projects, research applications, development science applications, and/or product manufacturing applications. This typically includes partnering with senior scientists in the creation of strategies to address drug development needs and designing experiments, and evaluating and preparing study results for health authorities and the medical/research community. For early development programs, the Statistical Scientist typically is the lead Biostatistics representative on cross-functional development, clinical and

execution teams. For non-molecule projects, they are expected to have expertise and interest in a variety of data types including in genomics, imaging, and digital health data or related fields to support clinical development and personalized health care activities, including collaboration with research and biomarker scientists, computational biologists and computer scientists.

Job description (the statistician will either support early or late stage development):

Late Stage Clinical Development:

- Member of clinical team, collaborating in preparation of Clinical Development Plans and target product profiles; typically lead statistician on cross-functional study management teams or sole statistician on early development project teams
- Study Planning: Reviews study protocols, authors statistical sections of protocols, prepares the study randomization, develops the statistical and data analysis plans, develops independent data monitoring and endpoint committee charters
- Study Conduct: Reviews case report forms to ensure protocol objectives are met and project standards are maintained. Develops statistical programs as necessary to perform analyses, review and approve analyses produced by statistical programming.
- Analysis & Reporting: Authors the clinical study report, provides input into global health authority documents and regulatory response for health authority submissions. Contributes to study publications and presentations. Provides analytical and strategic leadership for exploratory activities such as personalized healthcare biomarker development and PK/PD modelling.
- Leads cross-functional teams in overseeing the generation of health authority submission datasets and associated documentation
- Participates in health authority meetings

Early Stage Clinical Development and Personalized Health Care (PHC):

- Serves as Biostatistics representative on clinical development teams, partners with cross-functional members and provides statistical and strategic input on clinical development plans.
- Looks beyond the statistical aspects, collaborating actively to promote rigor in the planning, conduct, analysis, interpretation and reporting of clinical and nonclinical experiments to meet project objectives, including clinical pharmacology trials and exploratory project activities such as biomarkers and PK/PD analysis.
- Provides strategic and analytic support for internal review and decision making.
- Collaborates with research, biomarker and computational scientists on personalized health care projects including in support of clinical development projects, disease areas and presentations/publications.
- Consults and provides statistical training to key stakeholders.

Functional Area:

- Understand and apply business requirements and processes. Participates in functional training.
- Keep abreast of new developments in statistics, drug development, and regulatory guidance through literature review, conference attendance, etc.
- Contributes to the biostatistics/scientific community by partnering with senior staff, mentoring junior colleagues, and participating in internal/external initiatives.

Job Qualifications: (Job level will be matched according to candidate's experiences.)

- Ph.D. or MSc in statistics or biostatistics or related fields

- Good knowledge of theoretical and applied statistics including methods in advanced analytics
- Very good knowledge and experience applying statistical methods to drug development
- Good understanding of regulatory guidelines in a pharmaceutical research setting
- Understands and applies business requirements and processes
- Understands and respects cultural differences when interacting with colleagues in the global work place
- Accomplishes responsibilities with little supervision
- Effective Communication and Collaboration Skills (including statistical consulting skills, interpersonal skills to contribute effectively in cross-functional team settings, ability to influence others without authority, ability to build strong collaborative relationships with scientific and non-scientific partners)
- Good Project management skills (including ability to manage scope and effectively delegate to other functions, staff, contractors and external vendors)
- Good Strategic Agility (including problem-solving and critical thinking skills, ability to drive drug development strategies, agility that extends beyond statistical aspects)
- Evident Drive for Results (Demonstrates interest and ability to learn new things, takes initiative, welcomes problems as challenges; finds solutions to technical problems)
- Effective mentoring other statisticians
- Experience with all data types including high dimensional data

#LI-PDBA1

Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our [Genentech Careers page](#).

THE FUTURE OF SCIENCE IS HERE

BIostatISTICS

Strategic Partners in Drug Development



At Genentech, Biostatistics is a strategic partner in drug development. We take leadership roles in many aspects of drug development, including the design, analysis and interpretation of clinical trials. We apply our statistical expertise and critical thinking to translate biologic concepts to measurable hypotheses and into vital drug development evidence.

Through our collaborations, we promote rigor in the planning and conduct of studies, and in the interpretation of results from diverse

data sources and analytical approaches. We advocate the principles of statistics to facilitate rigorous evidence generation and decision-making throughout the company.

Our contributions span from research applications through the lifecycle of our medicines, from nonclinical studies to first in human clinical trials, through regulatory approval and market access, as well as manufacturing.



PAUL MANSER
Statistical Scientist

“At Genentech, statisticians contribute to the development of novel therapies that have the potential to transform the lives of patients. Because of our broad and unique development pipeline, we work on a diverse array of scientifically interesting problems in many different disease areas. We have a culture that emphasizes collaboration, values intellectual curiosity, and promotes a fun, open work environment.”



YENNY WEBB-VARGAS
Statistical Scientist

“Work hard, play hard, give back. We strive to create amazing drugs for the health challenges ahead. We socialize as a company at least once a month. We help our community and the environment. And Genentech loves us back, empowering us in our careers and giving us tools to achieve work-life balance. As a nonclinical biostatistician, one grows into a drug developer; one that advises in manufacturing process development, bringing expertise in design of experiments, evaluation of assays, and interpretation of variability. The everyday epic.”



KWAME OKRAH
Statistical Scientist

“At Genentech, the use of high-throughput genomics data in drug development provides new and exciting opportunities for biostatisticians. As a clinical statistician who contributes to the development of biomarkers, I get to see how basic scientific research is translated into personalized therapies for patients. For the biostatistician at Genentech, no two days are ever the same.”



MAOXIA ZHENG
Associate Director

“Statisticians at Genentech go beyond what traditional statisticians do in a pharmaceutical company. We are not only leaders in quantitative science, but also strategic partners in drug development. We promote rigor in planning, conducting, and analysis of clinical trials. Many statisticians take leadership roles in various cross-functional teams and pursue leadership opportunities beyond the statistics department. The shared mission of helping patients, the strong promotion of strategic thinking, the flexibility in career opportunities, and the excellent colleagues make Genentech the place I am proud to work for.”

BIOSTATISTICS

Strategic Partners in Drug Development

WHO WE ARE

For more than 40 years, Genentech has been at the forefront of the biotechnology industry, using innovative science to discover, develop, manufacture and commercialize breakthrough medicines that improve the lives of people with serious or life-threatening diseases.

A member of the Roche Group since 2009, we are considered one of the founders of the biotech industry and continue to be an industry leader, with multiple drugs on the market and several more promising drugs in our pipeline.

How do we do it? We come to work every day with a sense of urgency, uncompromising ethics and passion for transforming lives. What's best for the patient drives our decisions, and our commitment to scientific rigor is second to none.

It's all so we can do now what patients need next.

CELEBRATING DIVERSITY AND INCLUSION

At Genentech, we believe diversity plays a critical role in our ability to discover life-saving drugs. We celebrate different approaches and new ideas—we welcome them. Those new and different ideas not only help create a vibrant, exciting place to work, but also push us to innovate, to make breakthroughs.

We are committed to continuing to increase our diversity. And we have several programs in place to help:

- *Gender Diversity Strategy:* We have implemented several strategies to help us bring more women into leadership positions at Genentech.
- *DNA Groups (Diversity Network Associations):* Today, more than 5,300 employees belong to one of our internal DNA Groups, which offer a chance for employees with similar interests or experiences to connect.
- *Veteran Recruitment:* We recognize and celebrate the contributions of our veterans and are working to build messaging pathways that let veterans know about the opportunities available at Genentech.
- *Disability Inclusion:* We are committed to ensuring accessibility and employee awareness for people of all abilities.

WE INTRODUCED THE FIRST:

- Biotech company and IPO
- Recombinant biotech medicine manufactured and marketed by a biotech company
- Therapeutic antibody approved for cancer in the United States
- Personalized medicine
- Anti-angiogenesis treatment for people with cancer
- Biologic for asthma
- Biologic for cystic fibrosis
- Treatment to improve vision in up to 40 percent of patients with wet AMD
- FDA-approved medicine for people with advanced forms of the most common skin cancer
- Medicine approved with the FDA's Breakthrough Therapy designation
- FDA-approved medicine for both relapsing and progressive forms of multiple sclerosis
- FDA-approved medicine for Erdheim-Chester Disease
- FDA-approved medicine in nearly 20 years for hemophilia A with inhibitors

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Genentech has been on Fortune's "100 Best Companies to Work For" 20 consecutive years.

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WHO WE'RE LOOKING FOR

Where do you come in? If you're passionate about your work, motivated to help others, and strategic and flexible in your thinking, we need to hear from you.

To look at opportunities within Biostatistics at Genentech, visit www.gene.com/careers. Genentech is an Equal Opportunity Employer.