Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Position	**Associate Director, Biostatistics**
Location	**Cambridge, MA**
Reports to:	**Head Clinical Development**

POSITION SUMMARY:

The Associate Director Biostatistics will be primarily responsible for ensuring sound and innovative statistical thinking and methods are utilized in the analyses and reporting of longitudinal natural history data and biomarkers, which will be utilized in development, and planning of clinical trials. The incumbent may support other aspects of candidate drug products from early development (pre-IND) through late stage development (Phase 3 and NDA filings) using innovative approaches to improve the efficiency of drug development yet ensuring regulatory success.

Responsibilities

- Develop analytical strategies and analyses plans to maximize use of longitudinal data in support of data interpretation and rare disease filing strategy
- Play a leading role in the collaboration and/or acquisition of natural history data by thoughtful collaboration with consortia and/or academic centers
- Develop internal processes, in conjunction with data management, for the transfer and storage of external data and its associated meta-data and/or summary statistics
- Oversee/perform exploratory statistical analyses of novel endpoints and biomarkers from clinical trials
- Be able to conduct independent research and resolve statistical methodological issues with minimal supervision.
- Bring innovative statistical thinking and methods to exploratory biomarker analyses, with particular attention to predictive capabilities
- Provide planning and clear communication of statistical analyses, data presentations and scientific reports, exploratory and meta-analysis results, support for publication activities, scientific presentations and regulatory interactions
- Provide statistical support to clinical documents including clinical protocols, SAP, CSR etc
- Over time provide scientifically rigorous statistical input into study design, statistical analysis plans, interpretation of statistical results, being accountable for study level statistical deliverables
- Provide input as appropriate to project and regulatory documents (IND, IMPD, IB, NDA CTD) and defend package in interactions with Regulatory Agencies
- Ensure that all study and project level statistical activities are conducted in compliance with relevant regulatory requirements and internal standards/SOPs.
- Collaborate effectively with other statistical experts (e.g. consultants, vendors) to ensure cohesiveness in approaches
- Maintain knowledge of relevant scientific and regulatory practices, guidance and trends, and ensure that statistical aspects of development programs are contemporary.
- Oversee vendors as appropriate
- Develop and update SOPs as needed

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Person Specification

Skills, Knowledge, Qualifications and Experience:

- PhD in Statistics/Biostatistics and at least 5 years of experience (experience can be a combination of pharmaceutical and experience in application of statistical methods in research)
- Good knowledge of drug development regulations pertinent to statistical analysis
- Experience and broad knowledge of major statistical techniques, in particular linear and non-linear modeling, Bayesian statistics, exploratory methods, experimental design
- Proficiency in statistical software packages such as SAS, R or S-PLUS with experience of running simulations
- Aptitude for programming
- Demonstrated strong communication skills, both written and oral
- Must possess organizational skills and be able to manage multiple tasks concurrently
- Must have the ability to act independently and find solutions to ambiguous problems
- Experience with large datasets preferred
- Experience in rare diseases highly desired