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

Position	**Director / Senior Director, Biostatistics and Biometrics**
Location	**Cambridge, MA**

POSITION SUMMARY:

The successful candidate will be an experienced professional who will oversee all aspects of biostatistics and data management. She/He will have diverse experience enabling them to be equally comfortable with innovative methods/applications as well as regulatory-focused analyses and interactions. In all cases, she/he will be able to apply sound and innovative thinking to both biostatistics and data management to ensure quality and compliance in reporting deliverables. The candidate is expected to be hands-on and equally comfortable provide direct input to teams or working through others.

Responsibilities:

- Responsible for (either directly or via oversight) statistical aspects of all clinical trials, manuscripts and regulatory documents
- Responsible for data management oversight and deliverables with data management group
- Able to work effectively with vendors and collaborators to ensure timely, high quality deliverables and cohesiveness in approaches
- Drive statistical strategies in a collaborative way with relevant lines/team ensuring effective two-way communication with team members on statistical approaches being undertaken
- Work collaboratively with other quantitative disciplines (e.g. clinical pharmacology) to develop the best outcome for programs e.g. strategies around collaboration and/or acquisition of natural history data
- Ensure quality is “built-in” to all relevant methods and processes with sufficient rigor to support regulatory filings
- Represent company during regulatory interactions and/or provide appropriate coaching to others as required
- Bring innovative statistical thinking and methods to programs as appropriate, including exploratory biomarker analyses, natural history datasets and non-clinical data
- Provide leadership and development to current data management team, ensuring development of best practices allowing them to provide high quality data throughout the conduct of the trial (starting with the CRF), ensuring that clinical trial data structures are consistent across trials and ensuring compliance with SDTM data standards from data collection onwards
- Ensure that all statistical and data management activities are conducted in compliance with relevant regulatory requirements and internal standards/SOPs, contributing to SOP development as needed
- Maintain knowledge of relevant scientific and regulatory practices, guidance and trends, and ensure that statistical and biometrics aspects of development programs are contemporary
- Oversee evolution of biometrics as appropriate e.g. to support near real-time data visualization, develop bioinformatics support

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Candidate specification

- Ph.D. in Statistics or Biostatics or equivalent postgraduate statistical training, or commensurate degree depending on geography
- As a guide, at least 10 (Director) to 15 (Senior Director) years of experience in drug development, with a thorough understanding of the processes associated with clinical and regulatory operations with experience spanning from early clinical through to phase 3, and ideally filing activities.
- Strong evidence of creative thought-leadership, professional presence, and scholarship through publications and presentations.
- Effective verbal and written communication skills in relating to colleagues and associates both inside and outside the organization.
- Broad-based understanding of statistical theory and its application is required.
- Ability to interact with regulatory agencies on product-specific statistical issues and influence acceptance of novel statistical methods.
- Prior experience overseeing data management desired