Position: Associate Director, Statistical Programming

Location: Waltham, MA

Position Summary:
The Associate Director, Statistical Programming is responsible for leading and directing the statistical programming strategy for multiple clinical projects across multiple therapeutic areas through own effort. Assist management in resource estimation and resource management.

Key Responsibilities Include:

- Demonstrated extensive understanding of SAS programming concepts and techniques appropriate to the pharmaceutical industry. Able to critically review programming techniques and strategy. Recognizes limitations in programming strategy and corrects flaws proactively.
- Effectively design/develop SAS programs and the programming specifications for producing and validating CDISC ADaM datasets to support the generation of tables, figures and listings for clinical study report and/or FDA submission in a timely fashion and high quality
- Work closely with clinical operations, data management and statisticians to ensure timely and quality support for analysis and reporting of clinical trials up to regulatory approval, and product launch
- Provide project management and technical guidance to ensure operational and technical excellence
- Liaise with vendors as needed to facilitate electronic data transfers and statistical programming
- Good project management skills, CRO oversight skills, professional attitude, self-improvement mentality with positive attitude
- Case report forms and database definitions: Provides strategic guidance on the development of CRFs and database designs. Provides strategic guidance on global standards related to CRF designs and database designs.
- Derivation Programming, Submission Data Sets and Programs: Demonstrated proficiency in interpreting statistical analysis plans and developing analysis data set specifications. Monitors and interprets industry/regulatory trends and regulatory guidance.
- Works collaboratively with multiple stakeholders to manage priorities and resources across therapeutic areas. Builds relationships with external partners and service organizations. Demonstrates an understanding of drug development principles. Anticipates potential problems within and across projects and develops appropriate contingency plans. Creates escalation plans to ensure resolution of all issues at the therapeutic and project levels.
- Effectively and persuasively presents statistical programming concepts, assessment of risks and impacts and logical arguments to other statistical programmers, statisticians, scientists and non-scientists. Effectively presents information through planning and execution of meetings and presentations.
- Establishes high expectations and goals to ensure organizational success. Creates an organization that executes efficiently and is committed to meeting goals. Encourages a culture of open, honest communication where all are encouraged to express their views.

Education, Registration & Certification:

- Minimum Master's degree with strong analytical skills

Experience:

- Experience 10+ years in a pharmaceutical/biotech, CRO setting

Skills, Knowledge & Abilities:

- Strong hands-on SAS programing skills for clinical trial reporting
- Excellent SAS programming and analytical skills using BASE/SAS, SAS/STAT, SAS/GRAPH and SAS MACROS
- Strong CDISC SDTM and ADaM experience
- Excellent working knowledge of SAS/BASE, SAS/STAT, SAS/GRAPH and SAS Macro language
- Strong knowledge and understanding of GCP/ICH Guidelines for conducting clinical trials
- Strong interpersonal, organizational, and multi-tasking skills
- Excellent attention to detail and problem solving skills
- Good project management skills, CRO oversight skills, professional attitude, self-improvement mentality with positive attitude
- Good written and oral presentation skills and ability to communicate effectively
- Ability to think creatively and independently, and to form sound opinions and make sensible decisions in a dynamic environment
- Pharmaceutical experience with clinical trials, including familiarity with expectations of regulatory agencies, especially FDA and EMEA. NDA/BLA or other regulatory filing experience, including ISS or ISE experience. Thorough understanding of ICH Guidelines and relevant regulatory requirements.

Apellis is…

A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

Visit **http://apellis.com/about.html** to learn more.

EEO Statement:

Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past,

current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.