

Company Overview

Esperion is a small company doing big things. Our innovative team of lipid management experts are committed to leveraging our understanding of cholesterol biosynthesis to develop innovative therapies for the treatment of patients with elevated low-density lipoprotein (LDL-C). At Esperion we are passionately committed to bringing complementary therapies to the hypercholesterolemia space that address unmet patient needs in a way that is “patient-friendly, physician-friendly and payer-friendly.”

Esperion’s corporate headquarters are located in Ann Arbor, MI. The Company offers a competitive salary including a performance-based bonus program and stock-based compensation, a comprehensive benefits package including a 401(k) matching plan and health insurance, and paid time off and holidays.

Position Title: Associate Director, Biostatistics

The Associate Director of Biostatistics will be responsible to ensure statistical integrity of study deliverables both by the CRO and internally. This role will assist with sponsor oversight to the CROs and contribute to study level tasks from a statistics perspective. Available as a remote position from a home-based office.

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Oversee study level tasks from a statistics perspective including: participate in study design and sample size determination, author/review statistics section of the protocol; author/review SAP and other biostatistics related study documents.
- Provide sponsor oversight to the CROs on the study level activities by providing guidance on statistical matters and ensure consistency across studies.
- Ensure statistical integrity of study deliverables (by CRO or internal); Review and sign off on the key documents, including SAP, mock shells, data derivation specification, CRF, CRF completion guidelines, etc.
- Coordinate with SAS programming staff to perform sponsor quality control of study level deliverables.
- Identify risks/gaps from study level activities and work within the biometric team and/or cross-functional teams to resolve or follow up.
- Be the statistical point of contact for Esperion for assigned project(s); participate in regular team meetings with the CROs; provide guidance to statistics related questions from cross-functional teams and facilitate sponsor internal discussion as needed.
- Project management of biometric activities, ensure biostatistics deliverables (from CRO or internal) meet product timelines.
- Independently conduct exploratory analyses as needed; propose appropriate methodological approaches to improve the efficiency of study results.
- Contribute in developing standards and biometrics SOPs within the company.
- Attend internal team meetings and provide updates for assigned project(s) as needed.

**additional duties and responsibilities not listed here may be required*

Qualifications (Education & Experience)

- PhD in Statistics or Biostatistics with a minimum of 8 years of experience in the clinical trials setting in the pharmaceutical industry required.
- Experience in phase 3 pivotal studies as a functional lead from a statistics perspective and including participation in strategy discussion in cross-functional settings.
- Experience in submission work involving ISS and ISE
- Experience working with CROs a plus.
- Experience with managing multiple studies and being able to prioritize.
- Experience with study level work including authoring and reviewing SAP and TFL specification.
- Solid understanding of mathematical and statistical principles.
- Excellent communication and interpersonal skills, with the ability to translate statistical concept to program/study strategies.
- Detail-oriented with organization, problem solving and prioritization skills.
- Demonstrated ability to prioritize and complete multiple tasks according company timelines.
- Familiar with SAS programming; preferably with knowledge in CDISC including SDTM, ADaM, and controlled terminologies.

Notice to Agency and Search Firm Representatives: *Esperion Therapeutics is not accepting unsolicited assistance from agencies and/or search firms for any job posted on this or a referring site. Please, no phone calls or emails. All resumes submitted by an agency and/or search firm to any employee at Esperion via email, the internet, or in any other form and/or method without a valid written agreement in place will be deemed the sole property of Esperion. No fees will be paid in the event that a candidate is hired by Esperion as a result of an unsolicited agency and/or search firm referral.*

All qualified applicants are requested to submit a cover letter and CV via email to hr@esperion.com.