Job Title:	**Clinical Data Scientist/Statistician**
Reports to:	VP, Clinical Affairs
Scope of Supervision:	None

BASIC JOB PURPOSE

The Clinical Data Scientist/Statistician will provide statistical support for clinical studies conducted by and for HemoSonics. This includes providing input to clinical development plans, writing statistical analysis plans and statistical sections of protocols, contributing to clinical study reports/publications, and analyzing data for clinical studies.

RESPONSIBILITIES

- Provide input on study protocols, develop data analysis and statistical analysis plans, and write data analysis sections of protocols
- Be accountable for selecting statistical methods for data analysis.
- Provide oversight of internal data management activities and activities outsourced to vendors, including the development of clinical databases.
- Proactively address potential data issues by leading data review within HemoSonics throughout the conduct of a study. Assess the overall quality of data and identify trends or patterns that may pose overall study compliance and/or data quality concerns.
- Analyze study data using statistical methods per statistical analysis plan.
- Conduct exploratory analyses of clinical and research data as needed.
- Be accountable for data analyses projects supported by third parties.
- Build relationships with teams in Research & Development, providing input on the design of nonclinical research studies, as needed.
- Present results to stakeholders including project teams and external collaborators.
- Author data sections of reports submitted to regulatory agencies, and manuscripts submitted to peer-reviewed journals.
- Ensure adherence to all Good Clinical Practice (GCP) global standards and department standard operating procedures for handling clinical data.

KNOWLEDGE & SKILLS

- Thorough understanding of statistical methods applied to the analysis of clinical and research data.
- Strong knowledge of core data management activities (e.g., Data Management Plans, data edit specifications, data quality assurance, database specs, electronic data transfers)
- Knowledge and experience with clinical databases.
- Ability to write summary reports and technical articles for publication in professional journals
- Self-sufficient and able to work with minimal oversight
- Detail-oriented and excellent problem-solving skills
- Excellent verbal/written communication/interpersonal skills
- Ability to prioritize and manage multiple tasks simultaneously
- Proficiency with statistical platforms (SAS, R, etc.)
- Experience working with clinical databases (EDC systems)

EDUCATION & EXPERIENCE

- Master's degree in Statistics or a relevant scientific discipline with 5+ years; OR PhD in health sciences field with 1+ year; OR Bachelor's Degree in Statistics or a relevant scientific discipline with 10+ years
- Experience working in IVD development a plus.

PHYSICAL REQUIREMENTS

- May involve domestic travel as needed