Lead Research Associate, Sentinel

Tracking Code
291523-561

Job Description
Sentinel is an FDA-funded medical product surveillance system coordinated by the Therapeutics Research and Infectious Disease Epidemiology (TIDE) group that sits within the Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute. TIDE brings together the expertise of over 60 faculty, researchers, analysts, programmers, software developers, and staff who together support FDA’s regulatory mission. The Data Management and Quality Assurance Lead Research Associate works under the general direction of the Assistant Director for Scientific Solutions to define, manage and lead all activities relating to the compliance to the Sentinel Common Data Model (i.e., both quality assurance and characterization) of data held by data partner organizations within the Sentinel Distributed Database (SDD), and assure that the work is carried out in accordance with Sentinel stakeholder expectations and Sentinel Standard Operating Procedures (SOPs). The incumbent will also contribute to the strategic vision, planning, development, selection and scoping of specific data quality assurance projects as well as support decision-making activities relating to Sentinel Common Data Model revisions and other data expansion activities. Please see the public website for additional information about Sentinel: http://minisentinel.org/

Duties and Responsibilities:
- Define critical-need areas, business requirements, and use cases with respect to assessing and assuring the quality and characterization of data held across all data partner organizations that contribute data to the SDD, in partnership with key stakeholders, including but not limited to: Assistant/Associate Director for Scientific Solutions, as well as internal and external Sentinel stakeholders and collaborators
- With little to no supervision: plan, staff, track and progress-report a variety of data quality assurance and characterization activities, including but not limited to data management, technical project management, data quality assurance and characterization reviews, prioritization and investigation of data anomalies, communication and reporting of issues and findings, and effective resolution of issues and findings to the satisfaction of multiple stakeholder teams and in accordance with Sentinel SOPs
- In consult with each SDD data partner organization, establish and enforce a data update/refresh schedule; communicate the same to multiple stakeholder teams on a regular basis
- Design, maintain, document and manage the quality control of SAS programs that generate both routine and ad hoc reports relating to data quality assurance and characterization, in close consultation with investigators, statisticians and senior programmers and in accordance with internal standards and guidelines
- Develop and maintain a centralized resource to monitor, query and report aggregated data held in a distributed data environment
- Review, provide content for and enforce Sentinel SOPs with respect to all data quality assurance and characterization matters
- Contribute to or co-lead select data quality assurance and characterization projects, particularly those representative of new methods designed to streamline existing data quality assurance processes or to foster Sentinel CDM expansion activities
- Participate in the identification, selection and mentoring of new team members

Minimum Requirements:
- MA/MS in one or more of the following areas: data sciences, medical informatics, quantitative social sciences, public health and/or life sciences
- 7+ years of experience with database design and analysis, including demonstrated ability to identify, translate, document, and communicate meaningful data anomalies and trends
- Demonstrated experience with database and analytic applications, including but not limited to SAS, SQL, Microsoft Excel/Access and/or other statistical and database applications (e.g., i2b2, R)
- Prior project and/or staff management experience, including demonstrated ability to coach and develop colleagues to meet project needs, as well as manage the varied needs of multiple projects simultaneously
- Demonstrated ability to write and review data-related reports and other documents, for both technical and lay audiences
- Strong communication and relationship-building skills across all organizational levels, including the ability to quickly synthesize information and develop recommendations for senior leaders
- Experience with standard medical coding systems (e.g., NDC, ICD-9-CM/ICD-10-CM, HCPCS/CPT, SNOMED CT, LOINC), basic medical terminology and introductory epidemiological principles a plus

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We are an equal opportunity employer. We evaluate qualified applicants without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, veteran status, or any other protected characteristic. The EEO is the Law poster is available here.

**Job Location**
Boston, Massachusetts, United States

**Position Type**
Full-Time/Regular