1501 Wilson Blvd. Suite 910
Arlington, VA 22209
952-314-1255
www.mdic.org & www.nestcc.org

Title: Medical Device Safety Surveillance Consultant	**Job Code**: Temporary Consultancy (up to 40 hours/week) – Ending December 31, 2019 with consideration to extend
Reports to: Data Network Director, NESTcc	**Revision Date**: June 2019

Organization Overview

The Medical Device Innovation Consortium (MDIC) is the first-ever 501(c)3 public-private partnership created with the sole objective of advancing medical device regulatory science for patient benefit. As a membership-based organization, MDIC brings together representatives of the Food and Drug Administration (FDA), National Institutes of Health (NIH), Centers for Medicare & Medicaid Services (CMS), industry, non-profits, and patient organizations to improve the processes for development, assessment, and review of new medical technologies. Our work is unique and complementary to trade associations such as the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association (MDMA). Members of MDIC share a vision of providing U.S. patients with timely access to high-quality, safe, and effective medical devices.

In September 2016, the FDA awarded a grant for the National Evaluation System for health Technology Coordinating Center (NESTcc) to MDIC. The mission of NESTcc is to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research. Stakeholders across the medical device ecosystem stand to benefit from improved use of RWE generated in the routine course of care. Beginning in 2018, the FDA awarded supplemental funding for NESTcc to develop active surveillance capabilities.

Position Overview

Under the direction of the NESTcc Data Network Director, the consultant will provide expert input into the development of NESTcc's medical device safety surveillance capabilities and help identify the regulatory, legal, and data requirements that will support such a capability. This position is temporary and will end on December 31, 2019, with an opportunity to extend. He/she will work closely with the NESTcc Active Surveillance Task Force, which launched in January 2019 and is developing a preliminary roadmap for the direction of NESTcc active surveillance activities. NESTcc's active surveillance system will be developed to utilize the NESTcc Data Network to address safety signal refinement and to detect safety signals. The active surveillance capabilities will be designed to support FDA initiated active surveillance questions and active surveillance questions submitted from other stakeholders.

Objectives and Responsibilities

- Develop alternative operational models for the lifecycle of active surveillance projects from initiation from various stakeholders through signal reporting.
- Determine the potential operating scenarios for conducting active surveillance through NESTcc, including outlining the appropriate roles for participating entities.
- Along with the development of the operating models, identify regulatory, legal, and data requirements for different key stakeholders in the medical device ecosystem, including MDIC and NESTcc, NESTcc Network Collaborators, the FDA, and medical device manufacturers.

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- Work collaboratively with the NESTcc team to develop the appropriate legal and regulatory frameworks surrounding each operating scenario.
- Develop strategies for mitigating risks and overcoming challenges including policy challenges (e.g. privacy, confidentiality, intellectual property, conflict of interest), technical challenges (e.g. data aspects including common data models, retention, and use limitations), and operational and regulatory challenges.
- Work with the Active Surveillance Task Force to ensure alignment and direction with the NESTcc active surveillance roadmap.

Requirements

- Advanced degree required (PhD, MD, or Masters degree) in related area such as informatics, clinical research, epidemiology, health policy, or law
- 8-15 years of related professional experience in federal, non-profit, health care, MedTech, or Life Science industry
- Experience with medical device safety surveillance
- Demonstrated leadership roles managing complex multi-stakeholder interactions
- Proven ability to think strategically and implement complex solutions within an aggressive timeframe
- Highly organized, detail-oriented and takes initiative
- Outstanding presentation and writing skills
- Exercise good judgment, and quickly identify and resolve problems
- Ability to be flexible and work collaboratively as a team within a dynamic, start-up work environment to include virtual teams
- Familiarity with applicable laws and regulations, including, but not limited to FDAAA, 21st Century Cures, FDARA, FOIA, FISMA, HIPAA, Common Rule

Reporting Relationships

- The consultant will report to the NESTcc Data Network Director

NOTE: This scope of services is not intended to be all-inclusive. Individual may be asked to perform other related duties as required to meet the ongoing needs of the organization.

To apply, please submit a resume and cover letter by email to: careers@mdic.org