

| Title: Project Manager              | Job Code: Full Time Exempt    |
|-------------------------------------|-------------------------------|
| Reports to: Deputy Director, NESTcc | Revision Date: September 2018 |

# **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 (NEST) Coordinating Center (NESTcc) to MDIC. The mission of NESTcc is the creation of structures for responsible sharing and efficient analysis of real-world evidence to inform and empower patients, accelerate medical device innovation, and improve health care outcomes. Stakeholders across the medical device ecosystem stand to benefit from improved use of real-world evidence (RWE) generated in the routine course of care.

# **Position Overview**

The Project Manager will be responsible for the day-to-day coordination of stakeholders, consultants, and staff working on the development and implementation of NESTcc's organization goals (<u>https://nestcc.org/about/nestcc-strategic-operational-plan/</u>) under the overall direction of the Executive Director. The Project Manager will report to the Deputy Director and provide overall project support for NESTcc activities to advance the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research.

While working collaboratively with the NESTcc team on overall program objectives, this Project Manager position will focus on supporting the establishment, implementation, and management of the NESTcc Data Network. The NESTcc Data Network launched in Spring 2018 with an initial set of Network Collaborators (<u>https://nestcc.org/about/network-collaborators/</u>). The establishment of the NESTcc Data Network is one of the key strategies for NESTcc as it establishes itself as the leading organization within the health technology and medical device ecosystem for conducting efficient and timely high-quality RWE studies throughout the total product life cycle (TPLC).



As a member of the MDIC team, the individual contributes to the general advancement of the MDIC mission and goals to advance medical device regulatory science through the work to establish NESTcc. **Objectives and Responsibilities** 

- Provides overall programmatic support to the Executive Director and Deputy Director to meet NESTcc objectives
- Manages the submission process and review of application submissions to NESTcc for openopportunities including for demonstration projects, test-cases, and Requests for Proposals (RFPs)
- Supports that management of the awarded NESTcc projects utilizing the NESTcc Data Network, including the test-cases
- Collaborate with project Principal Investigator(s) and site or project personnel on short and long-term project milestones and deliverables such as: memorandum of understanding (MOUs), conflict of interest (COIs), project timelines, communications activities, stakeholder convenings, and reporting requirements
- Creates and maintains comprehensive project documentation for the NESTcc workflows
- Plans and organizes data synthesis and analysis activities, including collecting and managing information about potential and existing NESTcc Network Collaborators, and engaging in outreach to potential and existing Network Collaborators
- Coordinates, executes, and facilitates meetings with external partners and stakeholders, including acting as a liaison with funding agencies
- Supports the advancement of the NESTcc communications strategy through communications collateral, social media, website development, and the development of conference sessions
- Represents NESTcc and MDIC conferences and other events and meetings
- Contributes to the overall development of the company, taking on responsibility or additional duties that may fall outside the general duties listed above

# Requirements

- Masters of Science/Arts candidate preferred
- Bachelor of Science/Arts degree in the health-related sector required
- 2-5 years of professional experience in health care, MedTech, Life Science industry, and/or clinical research as a project manager (private or non-profit sector)
- Use and maintain strict confidentially, discretion, and judgment in dealing with confidential, sensitive and controversial issues in all aspects of work
- Excellent verbal and written communication skills with the ability to write succinctly and quickly and comfort to interact both personally and professionally with staff and board members, stakeholders, and external executives
- Manage multiple, ongoing projects in a fast-paced environment
- Highly organized, detail-oriented and takes initiative



- 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 that includes virtual teams

# **Other Skills/Abilities**

- Knowledge of various Real-World Data (RWD) sources (electronic health data (EHR), Registries, patient-generated health data, Public and Private Claims, etc.) and study designs used for medical device products is advantageous
- Knowledge of government regulatory agencies
- Interest in the medical device industry and enterprise with a willingness to engage in continuous learning and professional and personal growth
- Interest in developing a distributed data network
- Natural ability to build relationships, lead and educate with excellent interpersonal and influence management skills
- Strong skills in project management, PMP certification a plus
- Excellent computer skills and experience with Microsoft suite products
- Experience with a variety of web-based tools including SalesForce, RingCentral, Box.com, WordPress, Adobe Design, Zoom and ability to adapt to new collaborative technologies as they become available
- Experience working with virtual teams is a plus
- Some travel required
- Self-directed, team-player with sense of humor

# **Reporting Relationships**

The employee will report to the NESTcc Deputy Director. This employee will work closely with the full NESTcc team, including other Project Managers.

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 <u>careers@mdic.org</u> MDIC provides equal employment opportunities (EEO) to all employees and applicants for employment without regard to race, color, religion, sex, national origin, age, disability or genetics. In addition to federal law requirements, MDIC complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation, and training.

MDIC is an Equal Opportunity Employer.