



1501 Wilson Blvd. Suite 910
Arlington, VA 22209
202-828-1600
www.mdic.org

Title: Research Scientist, NESTcc	Job Code: Full Time Exempt
Reports to: Director of Research, RWE	Location: Arlington, VA / Remote

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 data (RWD) to inform and empower patients, accelerate medical device innovation, and improve healthcare 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 Research Scientist will serve as the scientific lead for NESTcc in RWE studies spanning a wide range of technologies, methods, data sources, and regulatory objectives. The RS will provide the critical link between the study sponsors from industry and government, NESTcc's Network Collaborators—including provider systems, clinical research networks (CRNs), and other research and data providers—and regulatory entities, including FDA, CMS, EMA and others. S/he will collaborate with internal and external colleagues providing scientific and technical guidance on study design, real-world data selection, best practices in real-world data utilization, and adherence to NESTcc, industry and regulatory standards for research and reporting. S/he will assist Director of Research in advancing and shaping NEST's real-world data strategy. The role will promote best practice in RWD to generate RWE across multiple domains and/or stakeholder groups. This research position that will have exposure to national leaders and key stakeholders in the health technology ecosystem including regulators, payers, industry, academia, health systems, clinicians, and patients/patient advocacy. This is an individual contributor role that will bring a proven track record of delivering value through the leverage of



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routinely collected data from healthcare settings to provide health analytics and insights in a range of contexts including Medical Device/Pharmaceutical Research & Development, Commercial/Payer, and Public Health. This role is for someone who is a self-starter, loves working on complex and ambiguous topics and who thrives on engaging and leading broadly across the organization to drive towards tangible outcomes.

Objectives and Responsibilities for Research Excellence:

- Collaborate with external Research Network, Clients, and Collaborators to maximize the value derived from use of RWD to generate RWE for regulatory, coverage and clinical decision-making.
- Contribute to study design of relevant RWD studies to ensure compliance with Research Methods Framework and purpose of research
- Review analysis/results/outcomes from RWE generated using RWD to ensure compliance with Data Quality Framework and purpose of research
- Provide scientific guidance on the application of RWD to address client research needs
- Provide technical input, options and directions to strategic decisions made by study teams on study design, data partner selection and best practices in RWE data utilization
- Provide guidance and support to operations teams on project execution and delivery on timelines
- Engage actively with Research Network and support development of the Network in the US and other markets
- Assist in building a capability that becomes a source of sustained competitive advantage in identifying, acquiring, integrating, and mining diverse RWD from multiple geographic and healthcare system sources to support RWE generation
- Evaluate and assess strengths and weaknesses of external RWD sources, and potential partners for advancing data strategy across therapeutic areas
- Maintain a strong insight into the capabilities of potential external partners in RWE, especially for US and emerging markets.
- Champion a culture of accountability and professionalism that is driven by milestones and timelines

Requirements:

- Minimum requirement: Master's degree in public health, epidemiology, statistics, or related field. Doctorate (PhD, ScD, PharmD) is preferred.
- At least 3-5 years of professional experience in life sciences or related research institutions (health systems, payer organizations, research, and data consultants)
- Strong background in RWE, observational research, and analyzing large claims and EHR databases and registries
- Strong understanding of device and/or drug regulatory pathways, clinical research and evidence, clinical data standards, medical terminologies, coding, and healthcare delivery systems
- Understanding of modeling and simulation, propensity score analysis, Bayesian methods,



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machine learning, and other advanced methods

Other Skills/Abilities:

- Outstanding organizational skills, ability to do complex multi-tasking, takes initiative
- Ability to work proactively in fast-paced environment
- Experience managing activities involving national experts from diverse constituencies
- Ability to represent MDIC to senior industry leaders in a professional manner
- Knowledge of government regulatory and/or research funding agencies
- Natural ability to build relationships, lead and educate with excellent interpersonal and influence management skills
- Building relationships with C-suite executives or senior leadership
- Excellent verbal and written communication skills
- Strong skills in project management
- Ability to work independently and as part of a team
- Experience with Microsoft suite products and productivity technologies
- Self-directed, team-player with sense of humor

Reporting Relationships:

- The employee will report directly to the Director of Research, NESTcc
- Works closely with the NESTcc Leadership Team to support overall goals and objectives.

NOTE: This scope of services is not intended to be all-inclusive. The Research Scientist may perform other related duties as negotiated to meet the ongoing needs of the organization.

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

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.