

## Director of Evidence Generation, NESTcc



### COMPANY BACKGROUND

[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.

**Location:** Remote (15-20% travel)

### ROLE: DIRECTOR OF EVIDENCE GENERATION, NESTCC

The Director of Evidence Generation is a senior level position that will ensure robust and timely real-world data (RWD) analysis within the NEST platform. This member of the NESTcc Leadership Team will lead cross-functional project teams and exemplify change management to drive towards tangible outcomes. This role is for someone who enjoys both strategic visioning as well as day-to-day technical components of the architecture, information technology (IT), informatics, data science and

epidemiology required to build and utilize a health-tech focused RWD analysis platform and who thrives on building consensus with others to accomplish their goals. Day-to-day, this person will:

- 1) Engage across the medical device ecosystem to better understand stakeholder needs and build a pipeline of high-quality evidence generation;
- 2) Build and maintain relationships with data partners to ensure a collaborative data network that covers evidence generation needs across the medical device ecosystem;
- 3) Facilitate design and implementation of medical device studies to address the needs of stakeholders.

To succeed, this person will leverage experience with national leaders and key stakeholders in the health technology ecosystem including regulators, payers, industry, academia, health systems, clinicians, and patient advocacy groups to engender buy-in and championing of the NEST evidence generation efforts.

## KEY RESPONSIBILITIES

- Lead NEST evidence generation architecture and methodology efforts and demonstrate value of the NEST platform
- Work closely with and proactively anticipate the needs of collaborators to develop timely, meaningful, and robust evidence to support the understanding of medical device usage, benefits, risks, and value aligned with stakeholder needs and NEST Frameworks
- Maintain working knowledge of current and innovative analytical methodologies, tools and applications to ensure state-of-the-art evidence generation architecture, platforms, data, and analyses are fit-for-purpose
- Identify new ideas for RWD that are specific and measurable and promote an innovative mindset throughout the organization
- Foster learning with internal and external partners to advance proficiency and efficiency in understanding and using the data appropriately
- Implement and/or oversee the studies, including study protocol and statistical analysis plan development, analysis, interpretation, reporting, and dissemination
- Ensure compliance with applicable regulations and industry standards
- Maintain effective communication to internal and external stakeholders, as well as participate in external meetings and forums as a thought-leader
- Champion a culture of accountability and professionalism that is driven by milestones and timelines.

## KEY REQUIREMENTS

- At least 7+ years of professional experience in a technical position within an academic health-tech clinical data incubator or in the MedTech/Life Science industry
- Deep expertise of RWD to generate RWE that is scientifically rigorous and value-driven
- Strong understanding of medical device total product lifecycle and clinical studies

- Proven track record of leading and executing scientifically rigorous research projects, including design, analysis, and interpretation of studies using RWD such as claims (public & private), EHR, registries, biobanks, digital, and/or patient-generated sources
- Working knowledge of ISO 13485 and related regulations and developing processes for compliance
- Ability to lead and influence
- Travel up to 25% might be required

**Other Skills/Abilities:**

- Comfortable discussing complex surveillance and methodological matters with those who have little familiarity as well as those with deep expertise
- Natural ability to build relationships, lead and educate with excellent interpersonal and influence management skills
- Outstanding organizational and project management skills, ability to do complex multi-tasking, takes initiative
- Ability to work proactively in fast-paced environment, both independently and as part of a team
- Ability to represent Medical Device Innovation Consortium (MDIC) and NEST to senior industry leaders in a professional manner
- Building relationships with C-suite executives or senior leadership
- Self-directed, team-player with sense of humor
- 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 Senior Vice President, NESTcc
- Works closely with the NESTcc Leadership Team to support overall goals and objectives.

**EDUCATION**

Doctorate degree (PhD, ScD, PharmD) in epidemiology, health outcomes, biostatistics, population science, other medical product-focused clinical data evaluation is required; MD/PhD preferred

**COMPENSATION**

An attractive compensation package commensurate with this senior leadership role will be provided.

## HIRING EXECUTIVE PROFILE



**Simon Mason**  
*President, NESTcc*



**Richard Smith**  
*Vice President, NESTcc*

## KLEIN HERSH CONTACTS



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