



## National Evaluation System for health Technology Coordinating Center (NESTcc)

# Call for Experts in Real-World Evidence (RWE) Studies for Medical Device Research for NESTcc Data Quality Subcommittee

### Opportunity Snapshot

The National Evaluation System for health Technology Coordinating Center (NESTcc) was established in 2016 by the Medical Device Innovation Consortium (MDIC). The NEST community is passionately committed to transforming the way medical device technologies are tested, approved and monitored. As NESTcc establishes its role as a coordinating center offering services to organizations seeking to sponsor medical device/technology research based on high-quality real-world data (RWD), it is seeking experts to participate on the NESTcc Data Quality Subcommittee who have RWD quality expertise in the following areas:

- *Medical Device Industry*
- *Coverage/reimbursement/payor*
- *Health Systems*
- *Medical Informatics*
- *Electronic Health Records (EHR) Vendor*
- *Digital/Health Technology*
- *Health Technology Assessment (HTA)*

The inaugural Data Quality Subcommittee was established in 2018. They were charged with devising a framework to be used by all stakeholders across the NESTcc medical device ecosystem for the purposes of capturing and using high-quality data for the total product lifecycle (TPLC) performance of medical devices. The initial version of the Data Quality Framework is grounded in the use of RWD gleaned from clinical care settings, focusing on electronic health records (EHRs) to inform the retrospective and prospective capture and use of clinical information to both support the generation of RWE and to provide guiding principles which can be used for decision-making. The first iteration of the Data Quality Framework was published in February 2020 and can be found along with the Research Methods Framework [here](#).

In Fall 2020, the Data Quality Subcommittee was tasked with the development of a tool, derived from the Data Quality Framework, for assessing data quality on an ongoing basis. The Data Quality Subcommittee created self-assessment tools for both EHR and claims data using the NESTcc Data Quality Maturity Model. Both assessment tools describe key concepts of data quality according to the stages of maturity listed in the Data Quality Framework. The foundational work for the development of the NESTcc Data Quality Maturity Model checklists was completed in Spring 2021.



## Data Quality Subcommittee Charge

NESTcc continues to [establish partnerships](#) with organizations which collect, curate and analyze data from EHRs, claims, pharmacies and other sources including registries (“NESTcc Network Collaborators”). It is critical that the quality of the data be assessed using transparent and agreed upon standards. There are several challenges related to evaluating data quality, which include but are limited to: availability of comprehensive sources of data, appropriateness of data linkages between different data sources, completeness of data collected, availability of longitudinal follow up, procedures for checking the internal validity of data collected, processes for auditing data quality, safeguarding patient data and more.

The Framework released in 2020 put forth data quality guiding principles to be used for decision-making. The Data Quality Subcommittee will be charged with updating that Framework to include development of operable standards which will ensure the reliability of the data used in RWE studies through the following activities:

- Consult with FDA, stakeholders and standards making bodies to create an appropriate outline and work plan for developing the set of data quality standards
- Explore more specific data quality checklists and discussions around multiple RWD sources (including EHRs, claims, registries, and patient-generated health data [PGHD])
- Elicit and incorporate feedback from Subcommittee members and external reviewers (including NESTcc feedback based on learnings) into the drafts
- Conduct searches for literature, policies and data sources
- Pressure-test the standards with appropriate user groups, to include those designing, executing, submitting and interpreting RWE studies (including feedback from the NEST Network Collaborators)
- Assist in developing a plan for alignment with the Research Methods Subcommittee, Active Surveillance Methodology Working Group and the associated work products
- Submit the draft standards for public comment
- Develop a response to any public comments received during the process
- Finalize and disseminate the standards and establish plans for promulgating the standards and training stakeholders in their use

## Membership

The new Data Quality Subcommittee is recruiting up to 12 members representing different stakeholder groups, including: industry, health systems, EHR vendors, payors, medical informatics, digital health technology and the FDA. Data Quality Subcommittee applicants should possess real-world data quality expertise within the stakeholder groups identified. Additional characteristics include:

- Clinical researchers, including health services researchers, epidemiologists and clinical trialists with expertise in using RWD sources. Expertise in the use of common data models to support distributed data analyses is also sought,



- Informaticians with expertise in the capture, exchange and reuse of standard core data elements and issues related to interoperability,
- Experts in various aspects of Unique Device Identifier (UDI) tracking and implementation,
- Experts in privacy and security issues related to health data, and
- Individuals familiar with the development of operable standards and standards setting of RWE.

It is anticipated that members will need to commit at least five hours per month to the Subcommittee. It is also expected that the Subcommittee may initially require a higher level of commitment in the earlier months while the work is being launched. Subcommittee participants do not receive remuneration for their time.

### Review and Selection Process

To apply for the Data Quality Subcommittee, submit the required application form **by 5:00 p.m. ET on Friday, November 19, 2021** to [nestccnominations@mdic.org](mailto:nestccnominations@mdic.org).

Applications will be reviewed by NESTcc staff and a slate of proposed Subcommittee members will be presented to the NESTcc Governing Committee for approval.

While it may not be possible for all interested applicants to participate on this Subcommittee at this time, there will be future opportunities for collaboration and NESTcc will be interested in remaining connected to a broader group of experts for future activities.

### Key Dates

Activity	Date
Opportunity Posted	October 20, 2021
Applications Due	November 19, 2021
Applicants Notified	December 20, 2021

### Submission Instructions

**Applications must include 1) the completed nomination application form and 2) the nominee's CV/resume.** These nomination materials must be submitted by email to [nestccnominations@mdic.org](mailto:nestccnominations@mdic.org) **by 5:00 p.m. ET on Friday, November 19, 2021.**

### Contact

Please contact [NESTcc@mdic.org](mailto:NESTcc@mdic.org) with any questions.