



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

# Targeted Expansion: Call for Experts for NESTcc Methods Subcommittee

### Opportunity Snapshot

The National Evaluation System for health Technology Coordinating Center (NESTcc) was established in 2016 by the Medical Device Innovation Consortium (MDIC). NESTcc's mission is to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research. As NESTcc establishes its role 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, it is seeking additional experts to participate on the NESTcc Methods Subcommittee who have expertise in the following areas:

- *Artificial Intelligence and machine learning*
- *Biostatistics*
- *Coverage/reimbursement/HTA/HEOR*
- *Data engineering*
- *Data science*
- *Epidemiology*
- *Health Technology*
- *mHealth*
- *Mobile Applications*
- *Regulatory (U.S. and/or international (e.g., EU MDR, APAC))*
- *Software as a Service*

The inaugural Methods Subcommittee was established in 2018. Members were charged with devising a methodological framework or "living playbook," based on the constructs of study design and statistical methods, that could be used by all stakeholders across the medical device ecosystem for the purposes of designing, executing, and evaluating research studies based on Real-World Data (RWD). The Research Methods Framework was also intended to highlight device-specific considerations in benefit/risk studies based on both observational and experimental designs. Ultimately, the role of the Methods Subcommittee is to help ensure that NESTcc's projects can be interpreted based on the most efficient, appropriate, and rigorous methods of analysis. The first iteration of the Research Methods Framework was published in February 2020, and can be found along with the Data Quality framework on the NESTcc website: <https://nestcc.org/data-quality-and-methods>

### Methods Subcommittee Charge



RWD originates from a variety of disparate sources (EHRs, administrative claims, etc.) that will be combined, linked, and aggregated in order to support different types of evidence requirements from benefit/risk assessments. Attention to the appropriate statistical methods for the use of RWD, such as the use of distributed summaries, and specific issues related to medical devices, imaging, or diagnostic studies, will be critical for the quality of studies generated with NESTcc. Additionally, the development of innovative research methods where critical methodological gaps are identified may also be required.

## Membership

The Methods Subcommittee is currently composed of seven members representing different stakeholder groups, including academia, industry, and the U.S. Food and Drug Administration. NESTcc is seeking up to five individuals who represent one or more of the expertise areas above to serve on the Methods Subcommittee. Methods Subcommittee applicant expertise should include:

- Statistical and analytical methods for randomized and observational studies, as well as issues with choice of study design
- Knowledge of statistical and analytical issues, and study design issues, specifically related to medical devices, imaging, and diagnostics
- Knowledge of analytical and statistical issues related to use of RWD and RWE, as well as the use of distributed data networks

NESTcc encourages applications from individuals who have participated in similar efforts that will help spur the development of the Methods Subcommittee for NESTcc. Similar efforts include, but are not limited to, the PCORI Methodology Committee, PCORnet, MDEpiNet, the Medical Device Registry Task Force, Sentinel, the Clinical Trials Transformation Initiative, and the International Medical Device Regulators Forum.

It is anticipated that members will need to commit approximately five (5) hours per month to the Subcommittee. It is also expected that the Subcommittee may initially require a higher level of commitment in the initial months while the work is being launched.

## Review and Selection Process

To apply for the Methods Subcommittee, submit the required application form **by 5:00 p.m. ET on Friday, September 25**, to [nestcc@mdic.org](mailto:nestcc@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 applicants to participate on this Subcommittee at this time, NESTcc will be interested in remaining connected to a broader group of experts for future collaboration opportunities and activities.

### Key Dates

Activity	Date
Opportunity Posted	8/28/2020
Applications Due	9/25/2020
Applicants Notified	10/12/2020

### Submission Instructions

Applications must include 1) the completed nomination application form and 2) the nominee's CV. These nomination materials must be submitted by email to [NESTcc@mdic.org](mailto:NESTcc@mdic.org) by **5:00 p.m. ET on Friday, September 25.**

### Contact

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