NEST Coordinating Center
www.nestcc.org

Posting Date: March 9, 2018
Due Date: April 18, 2018

Call for Experts for NESTcc Data Quality and Methods Subcommittees

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 (TPLC), it is seeking experts to participate in two subcommittees to fulfill two mechanisms outlined in the NESTcc Charter:

1. Data Quality Subcommittee
2. Methods Subcommittee

As NESTcc establishes these mechanisms, the intention is to fully leverage efforts from leading groups including the PCORI Methodology Committee, PCORnet, MDEpiNet, Sentinel, the International Medical Device Regulators Forum (IMDRF), the Clinical Trials Transformation Initiative (CTTI), and other organizations that have initiated work in this space. Experts who have participated in these initiatives are highly encouraged to participate in these NESTcc subcommittees to increase the synergy between these various initiatives.

Data Quality Subcommittee Charge

NESTcc is establishing partnerships with organizations that collect, curate, and analyze data from electronic health records (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 a number of challenges related to evaluating data quality, which include: availability of comprehensive sources of data, appropriateness of data linkages between different data sources, comprehensiveness of data collected over time to provide longitudinal data, comprehensiveness of data elements collected, processes for checking the internal validity of data collected, processes for auditing data quality, policies in place to safeguard privacy, security of patient identified data, and more. NESTcc is establishing this subcommittee to address some of these issues particularly as they impact NESTcc's mission. It is anticipated that the Data Quality Subcommittee will be charged with:

- Developing NESTcc Data Quality Standards for NESTcc Network Collaborators by leveraging existing efforts in this area by organizations such as the U.S. Food and Drug Administration (FDA), the International Medical Device Regulators Forum (IMDRF), the Clinical Trials Transformation Initiative (CTTI), the PCORI Methodology Committee, and other peer-reviewed efforts to harmonize terminology and framework for data quality[i] (e.g. Kahn et al. EGEMS 2016),

- Designing a collaborative process by which NESTcc Network Collaborators can demonstrate their conformance with the NESTcc Data Quality Standards and providing recommendations on the implementation of this process, and
- Providing consultations on an *ad hoc* basis to NESTcc staff and the NESTcc Governing Committee to support NESTcc Network Collaborators abiding by robust standards of data quality.

Methods Subcommittee Charge

Real-World Data (RWD) will originate from a variety of disparate sources (EHRs, administrative claims, etc.) that will be combined and aggregated in order to support different types of evidence requirements from benefit/risk assessments to safety signal detection[ii]. Attention to appropriate statistical methods for the use of RWD, such as the use of distributed summaries, and specific issues related to medical device, 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.

It is anticipated that the Methods Subcommittee will be charged with:

- Developing a research agenda identifying critical issues in methods in device, imaging and diagnostic technologies studies across the TPLC,
- Developing a "living" methods playbook for NESTcc including device specific considerations in benefit/risk studies (both observational and interventional), and safety signal detection, and
- Providing consultations on an *ad hoc* basis to NESTcc staff and the Governing Committee to ensure that NESTcc activities are using the most appropriate and rigorous methods of analysis. This might include advice on specific study designs and analytical approaches.

Membership

Each subcommittee will be composed of up to seven members. It is anticipated that membership in each group will represent different stakeholder groups, including academia, industry, and government, and will include:

Data Quality Subcommittee **expertise will include:**	***Methods Subcommittee*** **expertise will 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, and • Experts in privacy and security issues related to health data.	• Methods experts in statistical and analytical methods for randomized and observational studies, as well as issues associated with choice of study design, • Methods experts with knowledge of statistical and analytical issues, and study design issues, specifically related to devices, imaging, and diagnostics, • Methods experts with knowledge of analytical and statistical issues related to use of RWD and RWE, as well as the use of distributed data networks, and • Methods experts in safety signal detection and surveillance.

NESTcc encourages applications from individuals who have participated in efforts that will help spur the development of these groups for NESTcc. These groups include, but are not limited to the PCORI Methodology Committee, PCORnet, MDEpiNet, the Medical Device Registry Task Force, Sentinel, CTTI, and IMDRF.

It is anticipated that members will need to commit at least five hours per month to the subcommittee. It is also expected that the subcommittees may initially require a higher level of commitment in the earlier months, while the work for these committees is being launched.

Review and Selection Process

To apply for the Data Quality or Methods Subcommittee, submit the required application form by 5p.m. EST on April 18, 2018 to nestcc@mdic.org.

Applications will be reviewed by NESTcc staff to create a diverse committee that represents different stakeholder perspectives, a broad range of expertise, and has various experience with similar initiatives. A slate of proposed subcommittee members will be presented to a Selection Team composed of a subset of the NESTcc Governing Committee. The NESTcc Governing Committee will approve the final slate based on a recommendation from the Selection Team.

While it is anticipated that these subcommittees will be small, nimble groups, NESTcc is looking to develop a broad range of expertise among the stakeholder community. While it may not be possible for all interested applicants to participate in these subcommittees 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	March 9, 2018
Applications Due	April 18, 2018
Applicants Notified	May 11, 2018

Submission Instructions

Submit the required application form by 5p.m. EST on April 18, 2018 to nestcc@mdic.org.

Contact

Please contact nestcc@mdic.org with any questions.

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i Kahn et al. A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data; EGEMS 2016, 4 (1): 1244 http://sumo.ly/59Z6.

ii Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research. A Report from the Medical Device Registry Task Force & the Medical Devices Epidemiology Network. August 2015. Available at https://goo.gl/AcVtoj. Accessed March 06, 2018.