National Evaluation System for health Technology Coordinating Center (NESTcc)

Targeted Expansion: Call for Patients/Patient Representatives for NESTcc Active Surveillance Methodology Working Group

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 itself as the leading organization in the health technology and medical device ecosystem for conducting efficient and timely high-quality RWE studies throughout the total product life cycle (TPLC), it seeks patients/patient representatives to participate as members of the Active Surveillance Methodology Working Group.

The Active Surveillance Methodology Working Group is a key contributor to the building of the NESTcc Active Surveillance Cloud Infrastructure that will support research operations and facilitate collection and analysis of real-world data for medical device safety signal detection and assessment. The system will analyze de-identified data, undergo quality checks, run analytics and deliver results, compile and present metadata via dashboards, and more. It will also support federated analysis where applicable.

The Active Surveillance Methodology Working Group conducts its work independently, with oversight provided by the Active Surveillance Task Force. The Active Surveillance Task Force is a multi-stakeholder group charged by the NESTcc Governing Committee with providing input and guidance throughout the Cloud Infrastructure development process, overseeing all Working Groups and reviewing and commenting on high-level system and functional requirements for the Cloud Infrastructure build.

Active Surveillance Methodology Working Group Charge

NESTcc has established partnerships with Network Collaborators that collect, curate, and analyze data from electronic health records (EHRs), claims, payors, and other sources, including registries. NESTcc aims to have its Network Collaborators contribute data to a Cloud Infrastructure platform which can be used to accurately detect, and in the future, predict, safety signals. As a prerequisite to achieving these aims, NESTcc will create a report assessing the strengths and weaknesses of current safety signal detection methodologies and will devise the Cloud Infrastructure platform accordingly for analysis of potential safety signals and reporting of results to appropriate stakeholders. It is anticipated that the Active Surveillance Working Group will:

- provide direction on and review the results from a landscape analysis of the types of tools which have been developed and are currently used for active surveillance safety signal detection,
- create a list of priorities NESTcc should include in methodologies for implementation into the Cloud infrastructure, and
- provide input and review on the NESTcc-drafted report regarding the strengths and weaknesses of safety signal detection methodologies currently utilized in the medical device ecosystem.

Intent of Targeted Call for Nominations

Membership in this Working Group currently includes representatives from different stakeholder groups, including academia, industry, and regulatory/policy. However, the Task Force has identified Patients and/or Patient Representatives as a gap in Working Group membership. Therefore, NESTcc is seeking up to two (2) individuals who are patients or patient representatives to serve on the Active Surveillance Methodology Working Group.

Active Surveillance Methodology Working Group expertise will include:

- Patients or patient representatives who have knowledge of methods in statistical and analytical issues, and study design issues, specifically related to devices, imaging, and diagnostics,
- Patients or patient representatives who have knowledge of methods in analytical and statistical issues related to use of RWD and RWE, as well as the use of distributed data networks, and
- Patients or patient representatives who have knowledge of methodological safety signal detection and device surveillance.

NESTcc encourages applications from individuals who have participated in similar efforts which could include, but are not limited to, NESTcc Methods Subcommittee, the PCORI Methodology Committee, PCORnet, MDEpiNet, the Medical Device Registry Task Force, Sentinel, the International Medical Device Regulators Forum (IMDRF), the Clinical Trials Transformation Initiative (CTTI), and the Electrophysiology Predictable and Sustainable Implementation of National Registries (EP PASSION).

It is anticipated that members will need to commit at least five hours per month to the Working Group. This time will include 1-2 group calls per month with the remaining time for offline work including document review, research, and writing. It is also expected that the Working Group may require a higher level of commitment in the earlier months, while the work for the Active Surveillance initiative is being launched.

Review and Selection Process

To apply for the Active Surveillance Methodology Working Group, submit the required application form **by 5:00 p.m. ET on August 17, 2020** to nestcc@mdic.org.

Applications will be reviewed by NESTcc staff and presented to the Active Surveillance Task Force for review and approval.

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

Key Dates

Activity	Date
Opportunity Posted	July 27, 2020
Applications Due	August 17, 2020
Applicants Notified	August 24, 2020

Contact

Please contact nestcc@mdic.org with any questions.