



## Call for Experts 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 experts to participate as members of the Active Surveillance Methodology Working Group.

The Active Surveillance Methodology Working Group will be a key contributor to the building of the NESTcc Active Surveillance Cloud Infrastructure. The Active Surveillance Infrastructure build is an initiative to construct a technical infrastructure to support research operations for Active Surveillance. An Active Surveillance Cloud Infrastructure platform will be designed and operated to 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 will conduct its work independently, but under the oversight of 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. These partner organizations collect, curate, and analyze data from electronic health records (EHRs), claims, payors, and other sources, including registries. NESTcc is looking to have its Network Collaborators contribute data to a Cloud Infrastructure platform which can accurately detect, and in the future predict, safety signals. In order to achieve this, NESTcc will create a report pertaining to the strengths and weaknesses of current safety signal detection methodology to then devise a Cloud Infrastructure platform that provides an analysis of potential safety signals and reports the results to appropriate stakeholders. It is anticipated that the Active Surveillance Working Group will:

- provide technical 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 technical expertise, 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.

### Membership

The Active Surveillance Methodology Working Group will be composed of six to eight members. It is anticipated that membership in this Working Group will represent different stakeholder groups, including academia, industry, and regulatory, among others.

## Active Surveillance Methodology Working Group expertise will include:

- 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 device surveillance.

NESTcc encourages applications from individuals who have participated in similar efforts that will help spur the development of NESTcc's Active Surveillance Methodology Working Group. Similar efforts 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. 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 July 2, 2020 to [nestcc@mdic.org](mailto: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 benefits from various experiences with similar initiatives. A slate of proposed Working Group members will be presented to the Active Surveillance Task Force for review. NESTcc will approve the final slate based on a recommendation from the Active Surveillance Task Force.

While it is anticipated that this Working Group will be small, 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 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 experts for future activities.

## Key Dates

| Activity            | Date          |
|---------------------|---------------|
| Opportunity Posted  | June 5, 2020  |
| Applications Due    | July 2, 2020  |
| Applicants Notified | July 20, 2020 |

## Submission Instructions

Submit the required application form by 5:00 p.m. ET on July 2, 2020 to [nestcc@mdic.org](mailto:nestcc@mdic.org).

## Contact

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