



Call for Experts for NESTcc Active Surveillance Data Curation 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 of being passionately committed to transforming the way medical device technologies are tested, approved and monitored has led NEST to establish itself as the leading organization in the health technology and medical device ecosystem for conducting efficient and timely high-quality real-world evidence (RWE) studies throughout the total product life cycle (TPLC). In order to continue to achieve its mission, NESTcc is seeking experts to participate as members of the Active Surveillance Data Curation Working Group.

The Active Surveillance Data Curation Working Group will be a key contributor to the building of the NESTcc Active Surveillance System. 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 analysis of real-world data (RWD) for medical device safety signal detection and assessment. The system will support federated analytics to analyze partner data, undergo quality checks, run analytics and deliver results, compile and present metadata via dashboards and more.

The Active Surveillance Data Curation 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 Active Surveillance System development process, overseeing all Working Groups and reviewing and commenting on high level system and functional requirements for the Cloud Infrastructure build.

Active Surveillance Data Curation 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 seeks 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 is looking to form a Working Group to inform and provide expert recommendations on the adoption and extension of a Common Data Model (CDM) and the creation of a data curation pipeline for RWD used in general research and active surveillance on medical devices. NESTcc anticipates that the Data Curation Working Group will:

- Define interoperability and data standardization approach through the adoption and extension of a CDM soliciting the support of an established CDM community, including:
 - The selection of an established CDM,
 - Define appropriate modifications to the CDM, as needed to adequately characterize medical devices in datasets sourced from RWD, and
 - Establish and create a process for maintaining data dictionaries.
- Define approaches to standardize and automate data curation activities, including:
 - Defining a technical approach to execute data curation in an automated, repeatable manner across a distributed data network,
 - Establishing a quality control and data validation workflow for a distributed data network with centralized oversight, and
 - Refining metadata collection and logging so that these efforts produce useful supplemental information on the provenance and transformation of analytical input data.
- Define the stages of data curation and the key considerations for data quality in each stage, including:

- Consideration of the range of basic steps and transformations and how these might apply to different data sources (e.g., laboratory data, unstructured and structured clinical data, and claims data),
- Consideration of the biases that might be introduced as part of the data extraction and normalization process, and determine the steps that can be taken to mitigate these biases, and
- Documentation of data provenance at each stage for traceability and issues that might impact assessment of provenance (e.g., proprietary information).

Membership

The Active Surveillance Data Curation Working Group will be comprised of up to 15 members. NESTcc anticipates that membership in this Working Group will represent different stakeholder groups, including informatics subject matter experts (SMEs), data interoperability SMEs, clinicians, researchers/scientists with experience cleansing and curating RWD and regulatory/policy agencies such as the U.S. Food and Drug Administration, among others.

Active Surveillance Data Curation Working Group expertise will include:

- experts with knowledge of observational research and implementation of common data models,
- experts with knowledge of clinical informatics and healthcare interoperability standards, including FHIR,
- experts in cleansing and curating of real-world healthcare data.

NESTcc encourages applications from individuals who have participated in similar efforts which will help spur the development of NESTcc's Active Surveillance Data Curation 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).

NESTcc anticipates that members will need to commit approximately five hours per month to the Working Group. The Working Group may also require a higher level of commitment in the earlier months while the work for the Data Curation Working Group is being launched.

Review and Selection Process

To apply for the Active Surveillance Data Curation Working Group, submit the required application form by 5:00 p.m. ET on Friday August 20, 2021 to nestcc@mdic.org.

Applications will be reviewed by NESTcc staff to create a diverse Working Group which 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 NESTcc anticipates that this Working Group will be small, it intends to develop a broad range of expertise among the stakeholder community. Though 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	July 21, 2021
Applications Due	August 20, 2021

Applicants Notified	September 17, 2021
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Submission Instructions

Submit the required [application form](#) by 5:00 p.m. ET on August 20, 2021 to nestcc@mdic.org.

Contact

Please contact nestcc@mdic.org with any questions.