

NEST Coordinating Center

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Posting Date: August 25, 2021 Due Date: September 27, 2021

Call for Experts for NESTcc Active Surveillance IT Cloud Working Group

Opportunity Snapshot

The National Evaluation System for health Technology Coordinating Center (NESTcc) was established in 2016 by the Medical Device Innovation Consortium. 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. In order to continue to achieve its mission, NESTcc is seeking experts to participate as members of the Active Surveillance IT Cloud Working Group.

The Active Surveillance IT Cloud Working Group will be a key contributor providing technical advisement to the ongoing build of the "NESTcc Cloud." The NESTcc Cloud will enable prospective, active surveillance of real-world data (RWD) for medical device safety signal refinement and detection. The architecture will deliver a primary NESTcc-managed cloud orchestrating federated learning across a data partner network of distributed, locally managed and firewalled systems containing patient-level records.

NESTcc seeks subject matter experts, scientists and engineers with experience in federated learning, federated analytics, cloud architecture and interoperability to join the Active Surveillance IT Cloud Working Group. Members are also being sought through a <u>separate call to join the Data Curation Working Group</u> to focus on data standardization and harmonization using a common data model (CDM), common vocabularies (e.g., LOINC, SNOMED) and distributed data quality checks for the Active Surveillance program.

The Active Surveillance IT Cloud 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 IT Cloud 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 participate in a federated Cloud Infrastructure platform which can accurately detect, and in the future, predict, safety signals. In Phase I of the Cloud Infrastructure build, NESTcc established an initial version of the IT Cloud Working Group with individuals from two partnering Network Collaborators, NESTcc's cloud services provider and industry members. For Phase II, NESTcc seeks to complement the expertise of the IT Cloud Working Group by including individuals with backgrounds in areas including, but not limited to: big data analytics, federated learning, cloud architecture and FHIR. In order to achieve this, NESTcc seeks to form a Working Group to inform and provide expert recommendations on the implementation of a secure, federated learning system based on the adoption and extension of a Common Data Model (CDM). The Working Group will also inform and provide expert recommendation on technical solutions regarding interoperability, machine learning and data pipelines, as well as cloud storage and architecture.

Membership

NESTcc anticipates that membership in this Working Group will represent different stakeholder groups, including cloud architects, data scientists (particularly those with experience in federated learning and big data architecture), cyber security and machine learning engineers.

NESTcc encourages applications from individuals who have participated in similar efforts which will help spur the development of NESTcc's Active Surveillance IT Cloud 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 IT Cloud Working Group is being launched.

Review and Selection Process

To apply for the Active Surveillance IT Cloud Working Group, submit the required <u>application form</u> by 5:00 p.m. ET on Monday, September 27, 2021 to <u>NESTcc@mdic.org</u>.

Applications will be reviewed by NESTcc staff to create a diverse Working Group which represents different stakeholder perspectives and 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	August 25, 2021
Applications Due	September 27, 2021
Applicants Notified	October 25, 2021

Submission Instructions

Submit the required application form by 5:00 p.m. ET on Monday September 27, 2021 to NESTcc@mdic.org.

Contact

Please contact NESTcc@mdic.org with any questions.