Request for Information: Active Surveillance Data Partners & Initial Use Cases

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1 DESCRIPTION

1.1 Request for Information

The National Evaluation System for health Technology Coordinating Center (NESTcc) is charged with executing an Active Surveillance program as part of the U.S. Food & Drug Administration's (FDA) 2018 Medical Device Safety Action Plan.[1] Active surveillance, of medical devices, is the practice of monitoring the safety of FDA regulated devices, post-market authorization, and the use of these devices in the general population via real-world data (RWD). NESTcc is seeking to identify organizations that have RWD systems (e.g., electronic health records [EHR], claims system, registry or other) and are interested in participating in a federated active surveillance system as a Data Partner.

Key priorities for the work include:

- Delivering a national system to advance safety signal detection (generation) and refinement
- Establishing procedures to ensure data quality and reliability
- Building technical services in secure, scalable and modular environments to accommodate the addition of future, innovative methodologies
- Developing applications beyond post-market safety while designing business practices and controls to encourage use by diverse constituents of the medical device ecosystem.

1.2 Examples of Potential, Initial Use Cases

NESTcc has convened an Active Surveillance Task Force and worked collaboratively with the Task Force and FDA to identify several use cases for the Active Surveillance program. Some potential medical device areas for initial use cases include:

1. Ventilators,
2. Robotic surgery systems,
3. Breast implants, and
4. Fully disposable duodenoscopes.

NESTcc is establishing the Active Surveillance system with a preliminary focus on surveilling for death, reintervention and/or device-related rehospitalization events. NESTcc recognizes that information about the medical device itself will vary by Data Partner, as may the common data model used, and we expect to work with teams to augment and standardize device characterization details. Note that with the federated architecture, these data are not required to be shared outside of a Data Partner's environment. Models/analyses will be run locally with only aggregate results shared back to NESTcc.

[1] Gottlieb, S., & Shuren, J. E. (2018, 11 20). *Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on FDA's updates to Medical Device Safety Action Plan to enhance post-market safety.* Retrieved from FDA.gov: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and-2

2 REQUESTED INFORMATION

In your response, please answer the following questions to provide a comprehensive understanding of your organization's interest and capabilities to participate in the NESTcc Data Partner Network.

2.1 Organization Profile

Please include the following information:

- Organization name and address
- Two points of contact (names, titles, phone numbers and email addresses)
- Organization designation: Health System/Hospital, Registry, Claims Payor, Other (please describe)

2.2 Description of Capability – Data Partner

Please describe your organization's capabilities related to participation as a NESTcc Active Surveillance **Data Partner**. As a reminder, our primary objective is to seek Data Partners with sources of RWD while including and accommodating a wide spectrum of data management and analytic capabilities across the available RWD.

- Describe the patient data your organization has.
    - What is the source(s) of the data? (e.g., EHR, commercial claims)
    - Describe the contents of the data: e.g., years spanned, number of distinct patients, specific clinical focus/specialty, geographical coverage, patient demographic summary statistics, level/granularity of device-related information available (e.g., UDI, manufacturer, brand name, version or model number, catalog number), median duration of individual patient follow-up in system (if available) and/or any unique characteristics of the data set
- Describe your organization's overall dataset, from a technical point of view.
    - What types of databases are used (e.g., MySQL, MongoDB) and for what purposes?
    - What statistical (e.g., SAS, SPSS), data science (e.g., Jupyter Notebooks for Python/R code, RShiny, DataBricks) and/or business intelligence/data visualization tools (e.g., Tableau, PowerBI), if any, do your research teams currently use? Currently have available for use? Prefer to use?
    - Describe any plans to add new data and analytics capabilities (applicable to active surveillance activities) in the next three (3) years
    - Describe any tools your teams currently use, research or otherwise, or plan to implement in the next 12 months that transform data into or between common data models (e.g., OMOPonFHIR, CAMP FHIR, IQVIA OMOP Converter), and include a description of the data, purpose and refresh frequency

    - Describe existing linkages to external data sources (e.g., National Death Index [NDI], Surveillance, Epidemiology and End Results [SEER]) and/or any current ability to perform such linkages
    - Describe your environment's use or plan to use FHIR standards including FHIR export services, entities or applications using FHIR including electronic health records, any use of Bulk FHIR or related capabilities
    - If possible, please attach your data dictionary or any documentation describing the contents and structure of your dataset
- Describe the number and areas of expertise of existing staff with data and analytics knowledge considering, but not limited to, the following areas:
    - Data management (extract, transform, load [ETL] capabilities, data pipeline software used, etc.), epidemiological and biostatistical analytics (indicate SAS, R, Python, etc. skillsets), experts who understand your data schema and contents, etc.
    - If these capabilities do not exist on your team, please indicate this as well
- Provide a brief description of up to three (3) examples of research in which your team used RWD (citations for publications, as applicable) and if you have not completed this type of research, please indicate this point

2.3 Comments

Please provide your comments or opinions pertaining to the difficulty and/or feasibility of the potential requirement along with any information regarding innovative ideas or concepts that you would like to highlight.

3 ADMINISTRATIVE INFORMATION

3.1 Eligibility

This opportunity is open to medical device, imaging and diagnostic technology manufacturers as well as hospitals and academic research institutions regardless of whether they are currently a NESTcc Network Collaborator.

3.2 Submission Instructions

Interested organizations are requested to submit a statement of interest on the organization's letterhead demonstrating qualifications to perform the defined work. Responses must be complete and sufficiently detailed to address the specific information requested above.

Responses are due via email (nestccnominations@mdic.org) on or before **Monday, January 10, 2022 at 5:00 p.m. Eastern Time** addressed to Jordan Hirsch and must include the information requested above. Late responses will not be accepted. Only emailed responses will be accepted.

Submissions will remain confidential and shared on a need-to-know basis with individuals supporting the Active Surveillance program and the associated development of the network of Data Partners, which may include NESTcc staff, contractors, Active Surveillance Task Force members and members of Active Surveillance Working Groups. Submissions will not be shared with the general public unless they are selected as a viable use case through the review and selection process.

3.3 Questions

Interested organizations may submit clarifying questions to Jordan Hirsch (jhirsch@mdic.org).

3.4 About MDIC and NESTcc

Founded in 2012, the Medical Device Innovation Consortium (MDIC) focuses on advancing medical device regulatory science throughout the total product life cycle. MDIC's mission is to leverage its unique position as the only public-private partnership of its kind to transform health care into human care. Collaborating with our partners to advance science, we enable medical technology to shape the world we want to live in and make that world possible by shortening the path from innovation to safety to access. For more information, visit https://mdic.org.

In September 2016, FDA awarded a grant for the NEST Coordinating Center (NESTcc) to the Medical Device Innovation Consortium (MDIC). The selection of a third-party entity was important given the need for NESTcc to establish relationships and agreements between partners in a neutral, objective manner and to solicit a balanced representation from stakeholders. The NEST community is passionately committed to transforming the way medical device technologies are tested, approved and monitored. For more information, visit https://NESTcc.org.