NEST Coordinating Center
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Posting Date: November 15, 2023
Indication of Interest: December 15, 2023
Due Date: January 15, 2024
Invitation to Pitch: January 23, 2024
Pitch Days: February 5 thru 9, 2024

Request for Participation 23-MP1001

NESTcc Medical Device Real-World Evidence Marketplace

Background

NESTcc is a sustainable national resource, established in 2016 by a cooperative agreement between the FDA's CDRH and the Medical Device Innovation Consortium (MDIC). This Request for Participation is part of an ongoing collaboration between National Evaluation System for health Technologies (NEST) Coordinating Center (NESTcc) and the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) and in follow-up to NESTcc's Request for Information (RFI) 23-001.

NESTcc serves three roles in the medical device ecosystem:

- As a Coordinating Center offering unique approaches that catalyze real-world evidence (RWE) generation for medical device and health technology research sponsors.
- As a coordinator of a Collaborative Community comprised of representatives from across the medical device ecosystem working together to develop thought leadership and coalesce diverse stakeholders to advance innovation and understanding on initiatives of importance.
- As the implementor and manager of the first industry-wide active surveillance in medical device and health technology.

As part of the FDA efforts for Real World Evidence (RWE), user fee funding is distributed to the NESTcc to develop and implement processes that utilize RWE to deliver medical technology to patients. The Medical Device User Fee Amendment (MDUFA) V funding of NEST will (1) support the development of RWE resources to facilitate access for studies and (2) to convene experts and develop best practices to advance innovative methodologies with respect to RWE development and analysis. The NESTcc's direction and operations are informed by a diverse range of stakeholders including, patients, clinicians, device manufacturers, regulators, health systems, and payers.

NESTcc is creating and hosting a Marketplace of organizations engaging in various aspects of RWE generation for the support of medical devices. The NESTcc RWE Medical Device Marketplace (The NEST Marketplace) will be a network of institutional and commercial service partners (partners) to find better, faster, and less costly solutions to execute studies to support the evidentiary needs of the medical device manufactures (sponsors) and the regulatory needs of FDA.

Joining the NEST Marketplace provides an unparalleled opportunity for any partners involved in RWE support for the medical device industry. NEST is developing processes and approaches that support the goal of increased RWE use. One example is the NESTcc Mark for RWE. The NESTcc Mark provides confirmation that for the specific study question being asked, the resulting Real-World Evidence is deemed fit for purpose.
Using the NESTcc Mark process allows a commercial service provider partnering with NEST to work with their customer in a way that provides much higher visibility into the process and a clearer view to the submission.

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Overview

NESTcc set the foundational infrastructure and partnerships to propel the use of RWE in regulatory setting including: a) the establishment of a Research Methods and Data Quality Subcommittees that developed the NESTcc Research Methods and Data Quality Frameworks, designed processes for demonstrating conformance, and made recommendations for their implementation, and b) the creation of a NEST Research Network which under NEST's leadership executed of 21 Test Case Projects to accelerate its progress and provide proof of concept for generating high-quality RWE for medical devices across the total product life cycle.

In 2022 NESTcc established its first strategic partnerships to start building the NEST Marketplace. With this Request for Participation, NESTcc intends to grow the NEST Marketplace which will allow for wider participation of the RWE ecosystem in NESTcc RWE projects. Building on the NESTcc Research Network, the Marketplace will be made up of RWE partners that provide access to capabilities such as, but not limited to, data, data curation, data aggregation, data linkage, and data analysis. NESTcc will facilitate efficient study development and execution using a transparent process designed to comply with the regulatory needs of FDA, and other evidentiary needs.

NEST is now focused on generating fit for purpose RWE to support FDA premarket regulatory decisions. However, NEST also aspires to build the capability to generate RWE that is fit for purpose to fulfill FDA postmarket regulatory requirements, other national jurisdictions' pre- and post-market requirements (e.g., the EU MDR CER and PMCF requirements), enable collaborations in the TPLC Advisory Program (TAP), and generation of evidence to support CMS coverage decisions. By managing evidence generation needs across the diverse landscape of expertise and input necessitated by each project, NESTcc is reducing the timeframe, resources, and costs in conducting, high-quality RWD studies, increasing the reliability of study results. NESTcc's processes for generating RWE are designed to align with FDA's expectations. The goal is for RWE studies conducted via NESTcc Marketplace to use best practices that are agreed upon by FDA and can therefore be readily reviewed and accepted by FDA.

Objective

Expanding on previous work, the objective of this Request for Participation is to establish additional strategic partners to form the NEST Marketplace. The Marketplace and its partners will be able to efficiently curate, aggregate, and analyze health data, and will contribute to advancing the capabilities of the NEST Marketplace. This Request for Participation serves as a vehicle for NESTcc to select and qualify new strategic partners to serve in the Marketplace. It requests proposals describing what each respondent can do in five critical aspects of impactful RWE studies. Unlike a Request for Proposals, this Request for Participation does not request specific deliverables or their costs. These will be defined between NEST and selected Marketplace partners in a subsequent master services agreement (MSA) and/or statements of work (SOWs) via which specific deliverables and compensation for those deliverables will be defined and agreed upon. The Marketplace partners will work with NESTcc and with each other, as necessary, to optimize data access, quality, completeness, and analysis viable for generation and synthesis of fit for purpose RWE. The goal of

the Marketplace is to provide the broadest range of solutions and best value for all stakeholders.

Scope:

Strategic Capacity of the Marketplace Envisioned in this Request for Participation

The NESTcc Marketplace, once constituted, will support NESTcc by providing strategic capacity in following areas:

- Data platform: providing a foundation for data gathering and curation, especially platforms that put the patient in the driver's seat, to gather health data into one place and share with the device community
- Data sources: creating a national resource mirroring the experience of patient care in the United States and general experience of health throughout an individual's life
- Data connectors: deliver continuity of care and experience between disparate data sources (e.g., via aggregation/ linkage) while maintaining patient privacy and protections
- Data science and research methodology: design and analysis expertise and experience necessary to obtain the epidemiologic, informatic and statistical rigor inherent in fitfor-purpose RWD analysis
- Analytic cores: conducting analyses of ingested data and/or packaging analytics for data sources to conduct analyses, ensuring rapid, valid, and verified analyses suitable for RWD research.

Eligibility:

This opportunity to become a partner in the NEST Marketplace is open to private-sector, nonprofit, and for-profit organizations, especially those with experience in medical device evidence generation methodologies and supporting infrastructure (e.g., governance, IT and security, using interoperability standards [via FHIR or CDM] to enhance collaboration and automation).

Details and Requirements:

Each respondent is encouraged to frame the response in terms of how your organization can participate in the marketplace to further the NESTcc goals. The proposal should be submitted in the form of a presentation (e.g., PowerPoint, Prezi, Canva Google Slides), not to exceed 40 slides, and should include a plan for development and implementing the following.

General Information Requested:

- Provide organization name, address, and contact details for any follow-up information.
- Provide a description of your organization and research or RWE offering(s).
- Provide a listing of publications using your offering(s) in the past 5 years.
- Provide an overview of the plans to augment or modify your RWE-related offering(s) for the next 5 years.
- Describe your experience with medical device-related RWE (or, more generally, with medical product research).
- Describe protections and practices in place at your organization to assure patient privacy for data at rest and in transit.
- Describe your practices for HIPAA compliance and GDPR compliance.

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Specific Information Requested:

Applicants for inclusion as a partners in the Marketplace should demonstrate capacity in one or more of the following categories. All partners selected to be in the Marketplace should also demonstrate their ability to work with other partners to provide a seamless service and their experience working within the regulatory framework of the FDA.

1. **Data Platform:**
   - Provide information about data capture available on your platform (e.g., overall and by geographic region, sex at birth, race/ethnicity, and socio-economic status, longitudinal data for at least 5 years)
   - Describe the types of data your platform is capable of capturing (e.g., informed consent, patient reported outcomes, diagnostic test results, imaging etc.).
   - Provide information about the access to your data platform (e.g., traceability, extraction outside of your platform, analysis conducted within your data platform?
   - Provide examples of collaborations to conduct research using your data platform

2. **Data Sources:**
   - Describe the size of data source(s) (e.g., current number of individuals with data available, overall, and by geographic region, sex at birth, race/Ethnicity, and socio-economic etc.) and setting (hospital, specialist clinic, general practitioner, home etc.) and the number of patients with at least 5 years of data available.
   - Describe use of terminologies available in your data sources for diagnoses (e.g., International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM]), procedures (e.g., Current Procedural Terminology [CPT]), medications (e.g., National Drug Codes [NDC]), and labs/diagnostics (e.g., Logical Observation Identifier Names and Codes [LOINC]), medical devices identification (e.g., UDI, make and model)
   - Provide policies and procedures to ensure completeness, consistency, and accuracy of data collection and management.
   - Describe use of common data models leveraged for research purposes and capabilities for data extraction outside of your data source.
   - Describe data adjudication policies implemented in your data source(s)

3. **Data Connectors:**
   - Provide information about linkage methodology, assessment of accuracy of linkage and validations studies
   - Provide information about informed consent and patient privacy protection with linkages
   - Describe how your services have been used for aggregation/ linkage (e.g., whether services have been used to link RWD from health systems, registries, claim organizations, medical device manufacturers).

4. **Data Science and Research Methodology:**
   - Describe your capacity to refine study questions, develop protocols (including endpoints selection and

length of follow up) and analytic plans for device studies and produce reports
- Provide your expertise in statistical/epidemiologic methods (e.g., analysis, combining extant RWD with clinical studies)
- Provide information about your expertise in the natural language processing / machine learning / artificial intelligence (NLP/ML/AI) design and conduct (e.g., develop algorithm/model to define specific variable).
- Illustrate your expertise to design and conduct validation studies for RWD study outcomes, study populations and key covariates or other data elements an develop reports
- Describe your experience in your organization to develop code lists (e.g., ICD10-CM, CPT, NDC, LOINC) and develop, refine, and provide justification for operational definitions of data elements within RWD.

5. Analytic Cores:
- Describe your capacity for data adjudication, extraction, transformation, and loading accuracy into your system
- Describe your expertise for prespecified statistical modules available for analysis of RWD, data exploration, data analyses and auditing
- Provide information about ability for leverage novel data models for multiple studies
- Describe processes to build/deploy/house/monitor/QC data collection (e.g., for abstraction in data validation)
- Describe processes for data democratization/visualization for researchers outside of your organization to see the data
- Submission Components
- Organizations with expertise in one or more of the five areas defined above are invited to submit their proposals to join the NEST Marketplace by submitting their response via the following link - https://app.smartsheet.com/b/form/c5f86f67ff92414a9c62ef31ee8509ee

Applications must be submitted via Smartsheet through the required format by 5:00 p.m. EST on January 15, 2024. The application must include all required components listed below. To enable NESTcc to evaluate the submission, the responding proposal must include the following:

1. A plan to serve as NESTcc Marketplace partner. The plan must comply with the guidelines outlined above, be submitted in the form of a presentation (e.g., PowerPoint, Prezi, Canva Google Slides), and not exceed 40 slides.
2. A commitment to serve as a partner for a minimum of two years and ideally for five years.
3. Curriculum Vitae (CVs) of potential investigators and prior experience conducting similar engagements (experience with medical device evidence preferred)
4. Up to 3 Letters of Support from references demonstrating relevant capabilities required to perform the work outlined in this Request for Participation

Indication of Interest

As a preliminary step in the application submission process, please indicate your interest in submitting a proposal by contacting NESTcc@mdic.org no later than 5:00 p.m. EST on December 15, 2023. NESTcc will

provide interested parties with any additional supplemental material to prepare the proposals no later than December 22, 2023.

Review Process

Responses to this Request for Participation will be reviewed by NESTcc staff and FDA (Selection Team) using objective evaluation criteria. NESTcc is looking for multiple partners across the five areas described above and may select more than one Marketplace partner with expertise/capacity in each area. It is not required that all partners be proficient in all areas. After responses and presentations are considered by the Selection Team, the selected contractor(s) will be informed regarding their selection.

NESTcc staff reserve the right to contact applicants with additional questions during the review period. NESTcc staff reserve the right to consult external stakeholders to review applications. Any external reviews will be completed in accordance with the MDIC conflict of interest policy. Responses will be reviewed for completeness and appropriateness of the responses as they pertain to the required submission components. NESTcc will consider the programmatic aspects of the proposal, as well as the anticipated cost, with the programmatic elements of the proposal receiving greater weight.

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NESTcc understands that questions may arise during the application process. Please send questions to NESTcc@mdic.org using the subject line “RFP 23-MP1001”.

About MDIC

The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created with the sole objective of advancing medical device regulatory science throughout the total product life cycle. MDIC’s mission is to promote public health through science and technology and to enhance trust and confidence among stakeholders. We work in the pre-competitive space to facilitate development of methods, tools, and approaches that enhance understanding and improve evaluation of product safety, quality, and effectiveness. Our initiatives improve product safety and patient access to cutting-edge medical technology while reducing cost and time to market.

For more information visit: https://www.NESTcc.org/