# **Call for Initial NEST Demonstration Projects Summer 2017**

# *First Round of Submissions Due July 31, 2017*

# Context

The current fragmented health care ecosystem does not support the seamless, near real-time, cost-effective use of electronic health data to generate high-quality evidence for medical devices needed for regulatory decision-making both in the pre- and post-market space.

In 2016, the FDA awarded a grant to the Medical Device Innovation Consortium (MDIC) to establish the **National Evaluation System for health Technology Coordinating Center (NESTcc)**. NESTcc’s mission is to serve as a catalyst within the ecosystem to support the timely, reliable and cost-effective development of real-world evidence associated with medical devices both for pre- and post-market requirements. While still early in its planning and development, NESTcc is being conceived as a decentralized and federated organization. By maintaining a modular system, NESTcc will be more flexible and can evolve, eliminating the need to overhaul entire systems to reach efficiency. For more information regarding NESTcc please visit our website – <http://mdic.org/about-nestcc/>.

# NESTcc Demonstration Projects

The NEST Coordinating Center will begin identifying NESTcc Demonstration Projects in the Summer of 2017. These first NESTcc Demonstration Projects will serve to develop, verify and operationalize methods of evidence generation and data use, demonstrate scalability across healthcare systems and device types and manufacturers and build out critical functions and processes for a sustainable NESTcc.

This call for submissions is for an initial set of NESTcc Demonstration Projects and targets mature projects currently underway that have existing sources of funding for core activities. Preference is for projects with multiple partners including one or several medical device industry stakeholders. NESTcc may provide limited financial support for activities related to sharing processes and results through meetings and other mechanisms.

This will be one of several activities undertaken by the NESTcc over the coming months to begin establishing the critical partnerships needed to build NEST. Additional planned activities will likely include:

* A separate call for **targeted Demonstration Projects** in areas that have been identified as mission-critical for the development of a sustainable, efficient medical device evidence generation evaluation system. Funding from the NESTcc may be available for these projects.
* A **Request for Information** to identify third party collaborators from the academic, non-profit and private sectors with access to high quality data warehouses that can integrate such areas as cloud services, data aggregation, data storage, and data analytics to provide high quality, near real time and cost-effective solutions to the NESTcc to support the needs of medical device industry, the FDA and other key stakeholders in the ecosystem.

# Proposed Timeline for First Round Submissions for NEST Demonstration Projects:

*The proposed timeline is for first round submissions. Submissions after July 31, 2017 will also be considered. These applications will be reviewed on a rolling basis.*

July 31, 2017: Deadline for receiving the application form for first round of demonstration projects; Additional applications will be accepted on a rolling, monthly basis thereafter until November 2017.

August 2017: Applications will be reviewed by a NESTcc review committee; Applicants may be asked to submit further information on their project per request.

August 2017: Identification of at least the first two NEST demonstration projects; Additional Projects will continue to be identified on a rolling monthly basis thereafter until December 2017.

# I - Administrative Information

*Please complete the following fields:*

## Project Title:

## Principle Investigator/s:

Name:

Professional Title/Role:

Professional Affiliation:

Email Address:

Phone Number:

## Period of Performance:

Start Date (MM/YY):

End Date (MM/YY):

## Lead Organization:

## Collaborating Organizations (if any):

# II -Project Criteria

*Please confirm that you/your project can meet the following criteria. Mark all boxes that apply. Projects are not required to fulfill all criteria to be considered.*

## Significance:

|  |  |
| --- | --- |
|  | The Project addresses a critical gap for clinical research studies supporting regulatory submissions, infrastructure, or methods and either (select one):  Is intended to meet standards for regulatory decision-making across the Total Product Life Cycle for:   * + 510(K) clearance   + Premarket Approval (PMA)   + *De novo* requests   + Post-approval studies   + Section 522 studies   + Indication expansion and labeling changes   + Post-market reporting (including Medical Device Reporting (MDR) and malfunction reporting);   + Post-market surveillance such as signal detection   + Cost-effectiveness studies; or   Develops and uses scalable approaches to developing mission critical infrastructure such as Unique Device Identifier (UDI) implementation or virtual coordinated registries; or  Develops and uses scalable state-of-the art analytical or statistical methods for evidence generation for medical devices; or  Leverages mHealth for patients with medical devices. |
|  | The Project approach has a clear use case demonstrating scalability and generalizability to other devices and therapeutic areas, manufacturers or health providers or payers. |
|  | The Project is patient-centered[[1]](#footnote-1) and is willing to report final results back to participants. |

## Scientific Merit

|  |  |
| --- | --- |
|  | The Project meets high-quality robust, technical, methodological standards with respect to the quality of the data[[2]](#footnote-2) and the analytic methods applied. Where relevant, randomized and observational study designs are of interest, including prospective randomized clinical trials embedded in existing health data systems that do not require the creation of significant one-off, additional research infrastructure. |
|  | The Project makes use of data generated in the course of clinical care, or at home, by patients, providers, and/or payers. |
|  | The investigators have the appropriate qualifications and experience; the environment has the capacity (resources, facilities and equipment) to support the Project. |

## Potential for Collaboration with NESTcc

|  |  |
| --- | --- |
|  | The Project actively contributes to further defining the overall functions and processes of NEST (data flows, data coordination, data-sharing and reporting with FDA, dissemination of results etc.), and to developing critical standards and policies for a functional and sustainable national evaluation system (data sharing agreements, reporting standards etc.). Some funding will be available to participate in NESTcc activities. |
|  | The Project can contribute to developing NEST’s Open Science standards that will include reasonable standards for access to data for purposes of reproducibility, and standards around dissemination of results. |
|  | The Project leadership is committed to working closely with the NESTcc Governing Committee and Executive Director to further the goals of the NESTcc. |
|  | The Project contributes to generating sharable tools, resources, and methods that will be available on NESTcc’s future shared repository. |

## Funding Status

|  |  |
| --- | --- |
|  | The Project has clear funding sources independent of NESTcc. Preference will be given to studies that are collaborators with one or several medical device industry partners. |

## Feasibility and Timeliness

|  |  |
| --- | --- |
|  | The Project is expected to make impactful contributions in terms of processes and results in calendar year 2018. |
|  | Contract and Institutional Review Board (IRB) approval in place. |

# III - Project Abstract

*Please submit an abstract that highlight the elements captured below (350 words max):*

* Project Aims
* Methods Used
* Project Plan/Major Milestones
* Major Accomplishments To Date (including contracting and IRB status)
* Project Budget (this should not be a request for funds to NESTcc)
* Project Duration
* Funding Sources

# IV - Project Impact

*Please comment on how your project will advance the mission of NESTcc and the intended outcomes you anticipate from your study (350 word max):*

*When you have completed this form please save the document. To submit this document, please send an email to* [*NESTcc@mdic.org*](mailto:NESTcc@mdic.org) *and include the attached form. If you have any questions please contact our team at* [*NESTcc@mdic.org*](mailto:NESTcc@mdic.org)*.*

1. i.e. Pursues a question that is important to patients, measures outcomes that are noticeable and meaningful to them, and produces results that help them weigh the value of healthcare options given their personal circumstances, conditions, and preferences. [↑](#footnote-ref-1)
2. In the future, NESTcc will be reviewing existing standards to evaluate data quality and issuing guidance, in the meanwhile we recommend using the framework available in the [2016 draft FDA guidance “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices”](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf) to provide information on the quality of the data. [↑](#footnote-ref-2)