# **NESTcc: Request for Information: Data and Analytics Solutions for Medical Device Evidence Generation**

**July 14, 2017**

1. **Context**

Over the past decade, two societal trends have affected the way we think about clinical data for medical technology, and have driven the need for an organized strategy to collect and analyze data in near real-time to optimize patient health outcomes.

First, the notion that we can predict the performance and clinical outcomes of medical technologies in common clinical settings via inference derived from a historical pivotal clinical trial, or set of pivotal clinical trials, has been challenged. While the randomized controlled clinical trial is the bedrock method for understanding the isolated effect of a medical technology intervention on patients with pre-specified clinical conditions, necessary for regulatory approval and widespread use, the application of these results in common clinical practice may deviate widely from the clinical trial results. Variations in acute and downstream fragmented healthcare pathways and provider entities, variations in operator skills, and variations in patient behavior and compliance with necessary concomitant medical therapy, are just a few of the dynamics impacting the realization of the promised outcome of a medical technology. The remedies for navigating care across this fragmented system include increasing the measurement of clinical data and outcomes in near real-time across the care continuum so that necessary adjustments may be made, and learning can be available (i.e., the learning health care system). Moreover, this realization of increased evidentiary and safety monitoring requirements over the pathway from medical intervention to desired outcome has placed a greater demand on reliable product surveillance in the real world, which is not being satisfied by the present voluntary reporting system of unstructured and under-reported adverse events.

Second, is the extensive and widespread digitization of medical information in clinical practice. Since the high requirement for increased real-time data and healthcare evidence over the healthcare continuum cannot be realistically attained through use of expensive traditional methods of supplemental data collection systems (case report forms for clinical trials and registries), reliance on the growing availability of less expensive and already existing digital healthcare data, is inevitable. The major challenge of converting clinical practice digital data into useable information that can provide reliable outcome measures, covariate and intervention effects, as well as safety, performance, etc. for proper medical decision making, is the uniform lack of common data structures. In order to match the level of usefulness generally available from structured supplemental data methodologies (clinical trials and registries), the unstructured digital data sources need to address three common challenges: 1) poor ascertainment (missing data), 2) lack of standardized fields and outcomes, and 3) common lack of application of rigorous observational statistical analysis to reduce confounding.

1. **The National Evaluation System for health Technology Coordinating Center (NESTcc)**

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 and reliable development of real world evidence associated with medical devices for pre- and post-market needs. NESTcc has the potential to support a pre- post-market paradigm shift with the balance shifting to virtual registries of secondary use data enabling a real-world evidence base healthcare learning system. For more information regarding NESTcc please visit our website – <http://mdic.org/about-nestcc/>.

While still early in its planning and development, NEST is being conceived as a decentralized and federated structure. One model for improved evidence generation for medical devices includes establishing collaborations with a range of third party collaborators from the academic, non-profit and private sectors who will compete for business. Under this model the NESTcc would focus on developing: (1) standards and processes for data, (2) certification that data warehouses and data integrators are conforming to data model standards and using appropriate methods, (3) audit to establish that device manufacturers in the evidence generation system are using certified data systems and can reproduce any analysis, and (4) access to the data and reports for FDA and third parties. By maintaining a modular system, NEST will be more flexible and can evolve, eliminating the need to overhaul entire systems to reach efficiency.

1. **Opportunity**

We are looking to the wider ecosystem to provide possible solutions that employ state-of-the-art data and computer science technologies and data flow infrastructure that will deliver low cost, high-quality, longitudinal medical device information in near real-time. The reliance on data use agreements (DUAs), data licensing, data standards and data processes to enable data flow models from decentralized data warehouses has the potential to create a responsive ecosystem of innovative data integration and data warehousing services.

1. **Request for Information**

NESTcc is seeking to identify companies, organizations, collaborations and strategically coordinated registries from the private and non-profit sector that can offer third-party solutions to the problems described above. These solutions must develop, verify and operationalize methods of evidence generation and data use, that are of high quality, cost-effective, and in near real-time, as well as contribute to informing NESTcc as it builds out its critical functions and processes for sustainability. We are interested in identifying a range of collaborators from the academic, non-profit and private sectors with access to high quality data 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 the medical device industry, the FDA and other key stakeholders in the ecosystem.

1. **Deadline and RFI Submission**

**RFI Posted: July 14, 2017**

**Response Due: September 1, 2017**

*When you have completed the form below please save the document. To submit this document, please send an email to* *NESTcc@mdic.org* *and include the attached form. If you have any questions please contact our team at* *NESTcc@mdic.org**.* We may reach out to you for further information if needed.

# I - Administrative Information

*Please complete the following fields:*

## Solution or Project Title:

## Lead Contact:

Name:

Professional Title/Role:

Professional Affiliation:

Email Address:

Phone Number:

## Lead Organization:

## Collaborating Organizations (if any):

# II – Information about the Solution

*Please note that this section has a 8 page limit. You may delete the section prompts, i.e., the bullets under each section, but not section titles e.g., “Solution Description.”*

## Solution Description

* *Describe how the Solution can address a critical gap in evidence generation with particular interest in supporting submissions regulatory decision-making across the Total Product Life Cycle [[1]](#footnote-1) and/or in the uses of mobile health (mHealth) for patients with medical devices.*
* *Describe sources of data, data completeness (longitudinality), analytic and statistical methods.*
* *Describe collaborations in place that support the Solution*

## Data Quality and Methods Standards

* *Describe data sources and quality of the data*
* *Describe ability to identify brand-specific devices*
* *Describe approaches to obtaining complete longitudinal data*
* *Describe analytical and methodological standards used for analysis and apporoaches to conducting validation of results*

## Cost

* *Provide estimated cost per patient*

## Timeliness

* *Describe ability to analyze near real-time data*

## Validation

* *Describe approaches to validate results using gold-standard registries*

## Generalizability and Scalability

* *Describe scalability and generalizability to other devices, therapeutic areas and manufacturers*

## Leadership

* *Describe leadership’s team qualifications and experience*

## Collaborations with the NESTcc

* *Describe willingness to work closely with the NESTcc to further the goals of the NESTcc*
* *Describe willingness to contribute to informing the overall functions and processes of NEST (data flows, data coordination, data-sharing and reporting with FDA, dissemination of results etc.), and developing critical standards and policies for a functional and sustainable national evaluation system (data sharing agreements, reporting standards etc.)*
* *Describe ability to make impactful contributions in terms of processes and results in calendar year 2018*

## Prior Experience

* *Describe relevant prior studies and engagements. Experience with medical devices preferred but not required*
1. Including: 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. [↑](#footnote-ref-1)