# NESTcc Demonstration Projects Frequently Asked Questions (FAQ)

## What is NESTcc’s mission?

NESTcc’s mission is to catalyze the timely, reliable, and cost-effective development of real-world evidence to enhance regulatory and clinical decision-making within the medical device ecosystem.

## What are NESTcc Demonstration Projects?

NESTcc Demonstration Projects are studies that contribute to the field of real-world evidence within the medical device ecosystem. These projects can range in size and scope but should:

1. Develop, verify and operationalize methods of evidence generation and data use, and
2. Demonstrate scalability across healthcare systems, device types, and manufacturers

Additionally, NESTcc hopes to identify projects that can inform the organization’s strategy as it builds out critical functions and processes for a future sustainable organization.

## What is the goal for this call for Demonstration Projects?

This call for submissions is to identify an initial set of NESTcc Demonstration Projects. The call targets mature projects currently underway that have existing sources of funding for core activities. NESTcc is prioritizing 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.

## In what kinds of projects is NESTcc interested?

NESTcc is interested in projects that are moving the field towards high-quality, lower cost and near real time use of evidence. NESTcc is interested in a range of projects in various stages of the total product life cycle (TPLC), for example:

* 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

NESTcc is also interested in methods projects that demonstrate scalable state-of-the-art analytical or statistical methods for evidence generation for medical devices. It is also interested in infrastructure projects such as Unique Device Identifier (UDI) implementation or virtual coordinated registries.

## Can you give examples of the types of projects that NESTcc is interested in?

NESTcc is interested in a range of projects. Some examples of projects NESTcc is interested in include, but are not limited to:

* Piloting UDI implementation in health systems to generate safety or effectiveness evidence
* Benefit-risk or safety study linking company medical device registry with health system data
* Benefit-risk or safety study using patient generated or device generated data
* Use of tools for active surveillance, including patient- or device--generated data, and automated signal detection
* Studies that could improve Medical Device Reporting
* Models for embedded trials in registries or health systems for IDE studies

## What level of funding is available?

Limited funding is available to cover activities related to sharing processes and results through meetings and other mechanisms.

## What will I need to do if my project becomes a NESTcc Demonstration Project?

NESTcc designated projects will be expected to:

* Work closely with the NESTcc Governing Committee and Executive Director to further the goal of “moving the field towards high-quality, lower cost and near real time use of evidence.
* Contribute to generating sharable tools, resources, and methods that will be available on NESTcc’s future shared repository
* Contribute to further defining the overall functions and processes of NEST (e.g. data flows, data coordination, data-sharing and reporting with FDA, dissemination of results etc.)
* Contribute to developing critical standards and policies for a functional and sustainable national evaluation system (e.g. data sharing agreements, reporting standards etc.)

## How does my project benefit from being designated a NESTcc project?

NESTcc designation brings projects into the NESTcc network, which includes representatives from all parts of the health care ecosystem, including patients, providers, regulators, industry, payers, and academia.

When applicable, NESTcc may also be able to connect individuals or organizations from demonstration projects engaging in related work.

## When are submissions due?

The first submission deadline is July 31, 2017. Submissions will be accepted after July 31, 2017. All submissions will be reviewed on a rolling basis.