Establish a National Evaluation System for Medical Devices

To successfully harness real-world evidence ("evidence from clinical experience") in an efficient manner, the U.S. must develop the necessary infrastructure – a National Evaluation System for health Technology (NEST).

Supporting Actions

In 2016, CDRH took additional actions to achieve the goals established for this priority:

Establish the National Evaluation System for health Technology (NEST)

In Progress: A multi-stakeholder Planning Board and the Medical Device Registry Task Force issued a series of reports that outlined an organizational structure and infrastructure for the NEST Coordinating Center (February 2015, April 2016, September 2016, and August 2015). In 2016, FDA awarded $3 million to the Medical Device Innovation Consortium (MDIC) to establish the Coordinating Center, and $1 million to other organizations to continue projects that generate real-world evidence on device performance.

Develop a framework for the incorporation of real-world evidence into regulatory decision making.

In Progress: Issued draft guidance to describe how real-world evidence may be used to support pre- and postmarket regulatory decisions. Final guidance is planned for 2017.

Increase Access to Real-World Evidence to Support Regulatory Decision Making	
2016 Target	Results
25 Million By December 31, 2016, gain access to 25 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification.	**28.6 Million** Gained access to more than 28 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification using a variety of mechanisms, such as cooperative agreements and access through regulatory process.

Increase the Use of Real-World Evidence to Support Regulatory Decision Making	
2016 Target	Results
40% By December 31, 2016, increase by 40 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)	**85%** The number of premarket and postmarket regulatory decisions that used real-world evidence increased by 85 percent in 2016. (compared to FY2015 baseline)

Partner with Patients

We believe that if CDRH is to successfully achieve a mission and vision in the service of patients, we must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

Supporting Actions

In 2016, CDRH took several actions to achieve the goals established for this priority:

Patient Engagement Advisory Committee Convene the Patient Engagement Advisory Committee to discuss high priority topics regarding patient input in the total product lifecycle.

In Progress: CDRH chartered and began to recruit members for FDA's new Patient Engagement Advisory Committee (PEAC). PEAC members will be selected and announced in 2017.

Education and Training Develop education and training for CDRH staff and industry on the development and use of the science of measuring and communicating patient input throughout the total product lifecycle.

In Progress: CDRH trained more than 80 staff members on patient reported outcomes (PRO) and patient preference information (PPI), to advance staff understanding and CDRH review capacity in these areas.

Promote a Culture of Meaningful Patient Engagement by Facilitating CDRH Interaction with Patients

2016 Target	Results
10 Organizations By December 31, 2016, establish one or more new mechanisms for CDRH employees to obtain patient input on key pre- and postmarket issues facing CDRH and foster participation of 10 patient groups.	**34 Organizations** CDRH staff participated in 21 patient interaction opportunities, involving 34 patient organizations.
50% By December 31, 2016, 50 percent of CDRH employees will interact with patients as part of their job duties.	**68%** More than 68 percent of CDRH interacted with patients in 2016. When asked, 99 percent of staff who interacted with patients described their interaction as meaningful and 89 percent as relevant to their jobs.

Increase Use and Transparency of Patient Input as Evidence in Our Decision Making

2016 Target	Results
50% By September 30, 2016, 50 percent of PMA, de novo and HDE decisions will include a public summary of available and relevant patient perspective data considered.	**65%** In FY 2016, 65 percent of PMAs, *De Novo*, and HDEs included a public summary of available patient perspective data.
↑ By September 30, 2017*, increase the number of patient perspective studies (e.g., evaluating patient reported outcomes (PRO) or patient preferences (PPI)) used in support of premarket and postmarket regulatory decisions. (compared to FY 2015 baseline) **2017 Target*	**65%↑ PRO and 4↑ PPI** Increased by 65 percent the number of approved IDEs (pivotal studies only) with patient reported outcomes (PRO). Increased to four (from none) the number of patient perspective studies conducted by sponsors in support of pre- and postmarket regulatory decisions.

Promote a Culture of Quality and Organizational Excellence

A manufacturer's ability to design and make high-quality, safe and effective devices and CDRH's ability to provide the necessary oversight to assure devices on the market are high-quality, safe and effective will increase as manufacturers and CDRH embrace a culture of quality and excellence throughout our respective organizations.

Supporting Actions

In 2016, CDRH took several additional actions to achieve the goals established for this priority:

Quality Management Framework Resources permitting, continue to implement the CDRH Quality Management Framework.
In Progress: CDRH completed development of its document control system (DCS). DCS will ensure that current and approved quality program and key processes documentation—standard operating procedures, work instructions, forms, templates and process maps—is available to staff.

Education and Training Develop education and training for CDRH staff to facilitate adoption of practices characteristic of a culture of quality and organizational excellence.
In Progress: CDRH became an American Society for Quality (ASQ) enterprise member—enabling every employee at FDA to take advantage of ASQ's vast collection of learning resources. CDRH also offered on-site quality training to 150 staff. More than 90 percent of those who participated in the training earned ASQ quality certifications (Certified Quality Auditor and Certified Quality Improvement Associate).

Case for Quality As part of the Case for Quality, collaborate with members of the medical device ecosystem to identify, develop, and pilot metrics, successful practices, standards, and evaluation tools that will be specific to the medical device industry and focus on assuring product and manufacturing quality.
In Progress: In partnership with MDIC, CDRH collected input from stakeholders through six Case for Quality Forums; developed metrics and best practices designed to assess quality system performance using pre-production, production and post-production data; and led development of a product quality dashboard to assist hospital value analysis committees in identifying high quality devices.

Strengthen FDA's Culture of Quality within the Center for Devices and Radiological Health	
2016 Target	**Results**
10% By September 30, 2016, increase by 10 percent the number of CDRH staff with quality and process improvement credentials to improve organizational excellence. (compared to FY 2015 baseline)	**300%** In FY 2016, CDRH tripled the number of staff with quality credentials by providing on-site quality training and certification examinations.

Strengthen Product and Manufacturing Quality within the Medical Device Ecosystem	
2016 Target	**Results**
By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements.	Partnered with MDIC to develop metrics and best practices to assess quality system performance, and analytical tools to assess device quality by hospital value analysis committees.
By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.	Partnered with MDIC and Capability Maturity Model Integration (CMMI) Institute on a proof-of-concept and pilot with three device manufacturers, to evaluate use of the CMMI appraisal process as a foundation for a future third party program.

Voluntary Program Identify external partnerships and mechanisms to support a sustainable, voluntary third party program that will utilize quality metrics, practices, standards, and evaluation tools to assess and promote medical device product and manufacturing quality within industry beyond compliance with regulatory requirements.
In Progress: Continuing partnership with MDIC, CMMI Institute and other stakeholders, to expand application of maturity appraisal process; with the goal of developing the framework for a voluntary program in 2017.