Establish a National Evaluation System for Medical Devices

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

Goal: Increase Access to Real-World Evidence to Support Regulatory Decision Making	
2017 Target	**Results**
100 Million By December 31, 2017, gain access to 100 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification.	**103 Million** Gained access to more than 103 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.

Goal: Increase the Use of Real-World Evidence to Support Regulatory Decision Making	
2017 Target	**Results**
100% By December 31, 2017, increase by 100 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)	**193%** The number of premarket and postmarket regulatory decisions that used real-world evidence increased by 193 percent since 2016. (compared to FY2015 baseline)

Highlights

National Evaluation System for health Technology (NEST)

In 2016, FDA awarded $3 million to the Medical Device Innovation Consortium (MDIC) to establish the Coordinating Center. The NEST Coordinating Center (NESTcc) was established in 2016 and the Governing Committee and an Executive Director were selected in 2017. In December 2017, NESTcc issued its Strategic & Operational Planning: 2017 -2022. FDA continues to support projects that generate real-world-evidence through cooperative agreements with the NESTcc. In FY18 NESTcc, was awarded a five-year cooperative agreement with annual funding of $6 million from dedicated user fee funding in support of MDUFA IV real-world evidence commitments.

Framework for the incorporation of real-world evidence into regulatory decision making

In 2017, FDA issued final guidance to describe how real-world evidence may be used to support pre- and postmarket regulatory decision making and the factors the Agency and industry should use to determine whether or not real-world evidence is fit-for-purpose to support a particular pre- or postmarket decision.

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.

Goal: Promote a Culture of Meaningful Patient Engagement by Facilitating CDRH Interaction with Patients	
2017 Target	**Results**
20 Patient Groups By December 31, 2017, [establish…mechanisms…to obtain patient input on key pre- and postmarket issues…and] foster participation of 20 patient groups.	**48 Patient Groups** Since 2016, CDRH staff have participated in numerous patient interaction opportunities involving 48 patient groups/organizations.
90% By December 31, 2017, 90 percent of CDRH staff will interact with patients as part of their job duties.	**96%** Since 2016, 96.3 percent, have interacted with patients. When surveyed, over 90% of responders described their interaction as meaningful and relevant to their jobs.

Goal: Increase Use and Transparency of Patient Input as Evidence in Our Decision Making	
2017 Target*	**Results**
100% By September 30, 2017, 100 percent of PMA, *de novo* and HDE decisions will include a public summary of available and relevant patient perspective data considered.	**100%** All, 100 percent of PMA, *de novo*, and HDE pre-market decisions made by CDRH now include a public summary of available and relevant patient perspective data.
By September 30, 2017, increase the number of patient perspective studies (e.g., evaluating patient reported outcomes (PRO) or patient preference information (PPI)) used in support of premarket and postmarket regulatory decisions. (compared to FY 2015 baseline)	**75% PRO and 6 PPI** Increased by 75.4 percent the number of approved IDEs (pivotal studies only) with patient reported outcomes (PRO). Increased to six (from none) the number of patient perspective studies conducted by sponsors in support of pre- and postmarket regulatory decisions.

*An additional target addressed data development plans for the Expedited Access Pathways—this program changed significantly during the data collection period. Therefore, as a mid-course correction, FDA stopped data collection.

Highlights

Patient Engagement Advisory Committee

FDA established the Patient Engagement Advisory Committee (PEAC). PEAC held its inaugural meeting in October 2017. The Committee was convened to discuss patient-centered medical device clinical trials.

Patient Reported Outcome Measures (PROMs) and Patient Preference Information (PPI)

CDRH sees many examples of PRO measures used in clinical trials every year, but individual sponsors may not be aware of the utility of PROs in a particular device area. To assist, in 2017, CDRH issued a report on the Value and Use of Patient-Reported Outcomes (PROs) in Assessing Effects of Medical Devices, which includes a CDRH PRO Compendium which lists many, but not all, of the PROs that can be used and reported in medical device premarket clinical studies submitted to CDRH. In addition, CDRH partnered with multiple collaborators to host a Patient Preference workshop, designed to raise awareness regarding the state of science of patient preferences, discuss how to best incorporate PPI in medical product development and evaluation, and discuss how the capacity can be developed to further the field.

Patient and Care-partner Connection (P&CC)

In November 2016, CDRH announced the establishment of the P&CC program. This program provides CDRH staff with a formal process by which they can engage with patients and care-partners to obtain input on key issues. P&CC will broaden CDRH's exposure to patients' and care-partners' experiences regarding specific disease states and/or medical devices used for the patient's treatment, diagnosis, or assessment.

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.

Goal: Strengthen FDA's Culture of Quality within the Center for Devices and Radiological Health	
2017 Target	**Results**
ISO 9001 Certification By September 30, 2017, have system and procedures in place to be eligible for ISO 9001 certification.	**System and Procedures in Place** In 2017, CDRH completed a 3rd party internal assessment of its Quality Management (QM) Unit quality management system (QMS) and is implementing recommendations.
Baldrige Performance Excellence Criteria By December 31, 2017, submit to an Alliance for Performance Excellence member organization a formal application to assess our progress towards adopting the Baldrige Performance Excellence Criteria and achieving organizational excellence.	**Self-Assessment Submitted** CDRH partnered with the Virginia Senate Productivity Quality Award (VA SPQA) Discovery Program, submitted (March 2017) a Baldrige Self-assessment application and received the VA SPQA Feedback Report (September 2017). Report recommendations are being addressed as part of the ongoing continuous improvement efforts.
25% ↑ By September 30, 2017, increase by 25 percent the number of CDRH staff with quality and process improvement credentials to improve organizational excellence. (compared to FY 2015 baseline)	**670%** ↑ By the end of 2017, the number of CDRH staff with quality credentials (includes only staff who did not have any quality credentials prior to 2016) was about seven times the baseline number. About 10% of CDRH staff now hold at least one quality credential.

Goal: Strengthen Product and Manufacturing Quality within the Medical Device Ecosystem	
2017 Target	**Results**
Voluntary Program By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.	**CfQ Pilot Program** Announced in 2017, the voluntary Case for Quality (CfQ) Pilot Program. The pilot intends to explore the effectiveness of a quality maturity appraisal, the use of objective metrics, optimization of resources, and impact on quality culture and manufacturing quality.

Highlights

Quality Management

Since 2016, over 900 CDRH staff have enrolled in formal quality training and over 180 have attained quality and process improvement related certifications, including 46 new auditor certifications, 120 new quality associate certifications, and 18 new lean six sigma certifications. As of December 2017, over 740 staff were enrolled in the American Society for Quality (ASQ) Quality 101 class, which prepares them for the Certified Quality Improvement Associate (CQIA) certification exam.

Case for Quality Pilots

The Premarket Approval (PMA) Critical-to-Quality Pilot Program goal is to streamline the premarket approval process while assuring that a firm's quality system includes controls for features and characteristics considered critical to the safety and effectiveness of the device. Through this program, the FDA intends to forego conducting a preapproval inspection, which it would usually conduct, and instead conduct a post-approval inspection. Such post-approval inspections would focus on the design, manufacturing, and quality assurance practices identified by the applicant in its PMA. The Voluntary Medical Device Manufacturing and Product Quality Pilot Program (see CfQ above) uses third-party teams certified by the Capability Maturity Model Integration (CMMI) Institute to conduct quality system maturity appraisals using a maturity appraisal model developed by CMMI. The goal of these appraisals is to drive continuous improvement and organizational excellence among participating medical device manufacturing sites. Enrolled participants commit to engage early with CDRH and are required to submit baseline metrics before and during the appraisal to monitor their progress.