Report to Congress

Device Pilot Projects
FY 2022

Submitted Pursuant to
Section 708 of the FDA Reauthorization Act of 2017

Executive Summary

Section 708 of the FDA Reauthorization Act of 2017 (FDARA) amended section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i). Section 708 of FDARA requires the Secretary of Health and Human Services to provide a report to the Committee on Energy and Commerce of the U.S. House of Representatives and to the Committee on Health, Education, Labor, and Pensions of the U.S. Senate; this report must contain a description of the pilot projects being conducted and the pilot projects being continued or expanded pursuant to that section. This is the fifth annual and final report by the U.S. Food and Drug Administration (FDA) to fulfill this requirement.

FDARA Section 708 (b) calls for, among other things, pilot projects to be designed to efficiently generate reliable and timely safety and active surveillance data for medical devices. For the pilot projects, *active surveillance* refers to actively and continuously generating information on the device's performance and on the clinical outcomes associated with the use of the device in routine clinical practice. Active surveillance of medical devices may be understood relative to FDA's traditional or "passive surveillance," which is an approach that relies on users notifying FDA of device-related events (e.g., through adverse event reporting). Active surveillance has the potential to empower stakeholders to make more timely evidence-based decisions.

The pilot projects that were initiated as required by section 708 of FDARA were designed and conducted in coordination with a comprehensive system for evaluating medical device technology. That system is the National Evaluation System for health Technology (NEST). The NEST Coordinating Center (NESTcc) operates under a governing board with an appropriate representation of stakeholders, including patient groups and device manufacturers, as set forth in the law. In coordination with FDA, the NESTcc promotes the use of electronic health data, including claims data, electronic health records (EHRs), patient survey data, registries, and other health information.

In general, the Center for Devices and Radiological Health at FDA has documented an increase in the use of real-world evidence (RWE) to support regulatory decision-making. The use of RWE in studies may be less burdensome for manufacturers because RWE is often less costly and can generate meaningful information about the safety and effectiveness of devices in a more timely manner than traditional studies.

FDARA specifies that this report should describe (1) how such pilot projects are being implemented through a contract, cooperative agreement, grant, or other appropriate agreement; (2) the number of manufacturers that have agreed to participate in such projects; (3) the data sources used to conduct such pilot projects; (4) the devices or device categories involved in the pilot projects; (5) the number of patients involved in such projects; and (6) the findings of each project in relation to the device's safety, including adverse events, malfunctions, and other safety information. This information is presented in the report and summarized in the Appendix.

This is the final report under section 708 of FDARA as all the projects that were being reported on in accordance with FDARA have now been completed. This report features two device pilot projects completed in fiscal year 2022 (i.e., October 1, 2021, to September 30, 2022). The data sources leveraged in those two projects were both national- and state-based, and they included EHRs, registries, and claims. The projects involved prostate ablation devices and ventral hernia mesh devices. A cumulative summary of all completed projects from previous reports is included in the Appendix.

Several of these pilot projects have produced RWE for device evaluation by various stakeholders, including FDA and industry. In addition, these projects have helped not only inform the development and practical application of active surveillance in real-world settings but also further develop the NEST and other RWE capabilities.

Table of Contents

Acronyms Used in This Report

ACHQC	Abdominal Core Health Quality Collaborative
CRN	Coordinated Registry Network
DELTA	Data Extraction and Longitudinal Trend Analysis
EHR	Electronic Health Record
EVAR	Endovascular Aneurysm Repair
FDA	U.S. Food and Drug Administration
FDARA	FDA Reauthorization Act of 2017
FY	Fiscal Year
HIVE	High-Performance Integrated Virtual Environment
ICD	Implantable Cardioverter Defibrillator
MDEpiNet	Medical Device Epidemiology Network
MDIC	Medical Device Innovation Consortium
NEST	National Evaluation System for health Technology
NESTcc	National Evaluation System for health Technology Coordinating Center
NLP	Natural Language Processing
OSHPD	Office of Statewide Health Planning and Development
PTX	Paclitaxel
RWD	Real-World Data
RWE	Real-World Evidence
SPARCS	Statewide Planning and Research Cooperative System
SPARED	Study of Prostate Ablation-Related Energy Devices
VISION	Vascular Implants Surveillance Intervention and Outcomes Network
VQI	Vascular Quality Initiative

I. Introduction

Section 708 of the FDA Reauthorization Act of 2017 (FDARA) amended section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i). Section 708 of FDARA requires the Secretary of Health and Human Services to provide a report to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor, and Pensions of the U.S. Senate that contains a description of the pilot projects being conducted and the pilot projects being continued or expanded pursuant to that section.

II. Background

Section 708 of FDARA calls for, among other things, the pilot projects to be designed to efficiently generate reliable and timely safety and active surveillance data for medical devices. For the pilot projects, active surveillance refers to actively and continuously generating information on the device's performance and the clinical outcomes associated with the use of the device in routine clinical practice. Active surveillance of medical devices may be understood relative to the U.S. Food and Drug Administration's (FDA's) traditional or "passive surveillance," which is an approach that relies on users notifying FDA of device-related events (e.g., through adverse event reporting). Active surveillance has the potential to empower stakeholders to make more timely evidence-based decisions.

Some of the ways in which FDA has used active surveillance strategies for monitoring medical device safety include the following:

- Conducting ongoing systematic monitoring of an existing high-quality granular data source with a system that provided regular feedback regarding safety alerts to the manufacturer and regulators.

- Collecting postmarket safety information as evidenced in real-world data (RWD) sources (typically electronic health records (EHRs) or registry data sources), extending to monitoring the overall performance of medical devices, including the effectiveness and durability of them.

- Using a pre-defined algorithm to detect potential safety signals instead of data mining or ad-hoc queries of existing data sources.

The pilot projects were designed and conducted in coordination with a comprehensive system for evaluating medical device technology, as specified by FDARA. That comprehensive system is the National Evaluation System for health Technology (NEST). The NEST Coordinating Center (NESTcc) operates under a governing board with appropriate representation of multiple stakeholders, including patient groups and device manufacturers. In coordination with FDA, the NESTcc promotes the use of real-world electronic health data, including claims data, patient survey data, EHRs, registry data, and other digital health information. The Medical Device Epidemiology Network (MDEpiNet) is one of the NEST data collaborators and is primarily involved in advancing the strategically Coordinated Registry Networks (CRNs) featured in the pilot studies.

Some of the device pilots included in this and previous reports pursuant to FDARA section 708 have contributed to and independent third-party evaluation of the strengths, limitations, and appropriate uses of evidence collected pursuant to the real-world

evidence. This independent evaluation, published in 2022, was funded by FDA, commissioned by Medical Device Innovation Consortium (MDIC) and conducted by the RAND Corporation[1]. It includes evaluation of FDA-funded test-cases of the Medical Device User Fee Amendments of 2017, authorized as part of FDARA. Complementary to the RAND report, FDA independent review of MDUFA-4 was conducted by Booz Allen Hamilton and published in 2021.[2]

The law calls for the voluntary participation by device manufacturers in these pilot projects. Accordingly, all the pilot projects reported here are voluntary. These pilots involve the use of multiple different RWD sources.

In general, the Center for Devices and Radiological Health at FDA has documented an increase in the use of RWE to support regulatory decision-making, as documented by a report released in March 2021 featuring 90 publicly available examples of different types of regulatory submissions supported by RWE. The use of RWE in studies may be less burdensome for manufacturers because RWE is often less costly and can generate meaningful information about the safety and effectiveness of devices in a more timely manner than traditional studies.

[1] https://nestcc.org/independent-assessment-of-the-nestcc-test-cases-rand-interim-report/

[2] https://www.fda.gov/media/152594/download

III. Selection of Pilot Projects

The selection of pilot projects described in this report was guided by the law's requirement that such projects inform the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for devices. The devices and device types in these pilot projects are widely used, and failure of any of these device types may be associated with significant health consequences. Therefore, the pilot projects involve devices and device types for which the collection and analysis of RWE regarding the devices' safety and effectiveness is likely to advance public health.

The pilot projects reported here have been completed. The data sources leveraged in these completed projects were both national- and state-based, and they included EHRs, registries, and claims. The projects involved prostate ablation devices and ventral hernia mesh devices.

Several of these projects have produced RWE for device evaluation (premarket and postmarket) by various stakeholders, including FDA and industry. In addition, these projects have (1) provided FDA and industry with tools and methods for the development of active surveillance and practical applications of active surveillance in real-world settings and (2) helped further develop the NEST and other RWE capabilities.

All pilot projects comply with the law’s requirements to have established security measures to maintain confidentiality and privacy of certain data.

The persons or organizations conducting these pilot projects have high levels of research, statistical, epidemiologic, data science, informatics, and/or clinical capability and expertise to conduct and complete the activities. As applicable, pilot projects are conducted under contracts, cooperative agreements, grants, or other appropriate agreements in compliance with all U.S. laws and regulations.

IV. Description of Pilot Projects

FDARA specifies that this report must describe (1) how such pilot projects are being implemented through a contract, cooperative agreement, grant, or other appropriate agreement; (2) the number of manufacturers that have agreed to participate in such projects; (3) the data sources used to conduct such pilot projects; (4) the devices or device categories involved in the pilot projects; (5) the number of patients involved in such projects; and (6) the findings of each project in relation to device safety, including adverse events, malfunctions, and other safety information. Each pilot project is described herein by providing the following information:

- Pilot project's name
- Description of the project and devices involved
- Party conducting the pilot project
- Agreement type (e.g., contract, cooperative agreement, grant)
- Specific aim(s) of the project
- Data source(s) involved
- Safety outcome(s) of interest
- Numbers and names of manufacturers involved
- Number of patients
- Findings of the project
- Status (as of October 2022)

The manufacturer's involvement in a project is defined broadly for this report. For example, some of the projects have a financial contribution from one or more device manufacturers while others do not. Additionally, some of the projects have industry representation on an oversight committee..

A narrative describing each pilot project is found in section V of this report. The narrative descriptions are followed by a short description of the status of each pilot project. The descriptions of the pilot projects are also summarized in the Appendix of this document. The Appendix also includes the cumulative list of all the projects previously reported.

These two studies were reported as ongoing in the FY 2021 Annual Report and were completed in FY 2022.

The status of these two studies, along with the study findings, is captured in section V of this report.

A note about CRNs, which are frequently mentioned in this report: Typically, CRNs are partnered, registry-based RWD sources that include registry data linked to other

sources, such as claims, EHRs, and patient-generated data to enable studies of long-term outcomes via longitudinal patient healthcare profiles.

V. Completed Pilot Projects

The findings from the two pilot projects completed in FY 2022 are presented below.

1. Project Name: Creating a National Surveillance Infrastructure for Devices Used in Hernia Repairs

a. Description and devices involved

The Abdominal Core Health CRN aims to address the long-term surveillance of the techniques and mesh devices commonly used in the care of abdominal core health, which includes improving the data infrastructure through a linkage of registry data with administrative and clinical data; this linkage may improve longitudinal and cross-facility follow-up rates as well as validations of complications and devices.

b. Party conducting the pilot project

The MDEpiNet Coordinating Center at Weill Cornell Medicine.

c. Agreement type (e.g., contract, cooperative agreement, grant)

A cooperative agreement with FDA.

d. Specific aim(s)

The primary aim of this pilot study is to link registry and state claims data to examine data completeness and to determine the feasibility of an effective linkage model in the abdominal core health space. The infrastructure achieved via these linkages is intended to be used in the future to) assess long-term follow-up rates, and determine long-term catastrophic complications following ventral hernia repair.

e. Data source(s)

The data sources for this pilot project include (1) the New York State Department of Health's Statewide Planning and Research Cooperative System (SPARCS) claims data; (2) the Abdominal Core Health Quality Collaborative (ACHQC) hernia patient registry data; and (3) Medicare data (covering 2016 to 2018).

f. Safety outcome(s) of interest

The primary outcomes to be identified in linked datasets include hernia recurrences, hospital readmissions, reoperations, surgical site infections, and mesh-related complications.

g. Numbers and names of manufacturers involved

None.

h. Number of patients involved

There were 737 registry patients identified in the ACHQC registry who had undergone hernia repair in New York State from 2015 to 2016.

i. Findings of project

A total of 737 New York State patients were originally identified from the ACHQC registry for linkage. SPARCS data were available through 2016, and therefore, 577 registry patients whose date of repair occurred in 2017 or later were excluded. Of the remaining 160 registry patients qualified for linkage, 88.1% (N=141) were successfully linked to SPARCS claims data using a sequential matching algorithm.

A total of 8457 patients, aged 65 or older or who had Medicare insurance, were identified from the ACHQC registry with abdominal wall repairs in years 2014 to 2018 (referred to as *eligible patients*). Five thousand nine hundred forty-three (or 70.3%) of the eligible patients were successfully linked to the Medicare database of the Centers for Medicare & Medicaid Services using the sequential matching algorithm.

j. Status

Completed.

2. Project Name: Active Surveillance of Medical Device Safety and Outcomes Using EHRs: Prostate Cancer Partial Gland Ablation Technologies

a. Description and devices involved

The primary objective of this project is to develop Natural Language Processing (NLP) methodologies using EHR data to perform an active surveillance of medical device safety and outcomes for prostate cancer therapies, including partial gland ablation. The project also aims to integrate the data into the Study of Prostate Ablation-Related Energy Devices (SPARED) CRN registry with the help of High-Performance Integrated Virtual Environment (HIVE) technologies at the MDEpiNet Coordinating Center at Weill Cornell Medicine.

b. Party conducting the pilot project

The MDEpiNet Coordinating Center at Weill Cornell Medicine.

c. Agreement type (e.g., contract, cooperative agreement, grant)

A cooperative agreement with FDA.

d. Specific aim(s)

The specific aims of this project are as follows: (1) collect data from EHRs with manual data extraction of cancer characteristics from pathology and radiology reports, (2) develop and validate NLP tools by developing sustainable and scalable strategies to supplement the existing NLP infrastructure to support active surveillance of partial gland ablation, and (3) develop and add active surveillance statistical methodology to the data ecosystem.

e. Data source(s)

The data sources for this project include the EHRs at Weill Cornell Medicine.

f. Safety outcome(s) of interest

The specific outcomes of interest are the data elements harvested from EHRs into the NLP and HIVE repository that are integrated into the SPARED registry.

g. Numbers and names of manufacturers involved

None.

h. Number of patients involved

A total of 111 patients participated.

i. Findings of project

During the first phase, NLP algorithms were utilized to conduct EHR queries and to extract findings from biomedical reports. Magnetic resonance imaging (MRI) reports and biopsy reports were processed to extract structured findings. During the second phase, the performance of the NLP was assessed in 111 MRI and biopsy reports by comparing NLP outputs to the gold standard, manually reviewed, and labeled MRI reports. The performance of NLP was assessed on the entity level. A total of 524 entities were compared between NLP output and manually labeled MRI reports. Overall, Positive Predictive Value was over 99% after two rounds of NLP process improvements. The NLP is considered adequate and reasonable for real-world studies, and it was implemented in HIVE. During the third phase, the automated extraction algorithm was developed and implemented in the HIVE.

j. Status

Completed.

VI. Progress on Ongoing Pilot Projects

Both pilot projects that were ongoing in FY 2021 have been completed and are detailed in section V of this report. No new pilot projects were initiated in FY 2022.

VII. Conclusion

A variety of active surveillance pilot projects were conducted that were able to produce RWE for device evaluation by various stakeholders, including FDA and industry. In addition, these projects have helped not only inform the development and practical application of active surveillance in real-world settings but also further develop the NEST and other RWE capabilities.

Appendix A: Summary Table of Device Pilot Projects Under Section 708 of the FDA Reauthorization Act of 2017

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
Pilot Projects for Current Reporting Period								
1	Creating a National Surveillance Infrastructure for Devices Used in Hernia Repairs	Mesh for ventral hernia repair	New York State's Department of Health's Statewide Planning and Research Cooperative System (SPARCS) and Abdominal Core Health Quality Collaborative And Medicare	Long-term catastrophic complications including hernia recurrences, hospital readmissions, reoperations, surgical site infections, and mesh-related complications	None	Completed	737 registry patients linked to SPARCS and 5943 registry patients linked to the Medicare database of the Centers for Medicare & Medicaid Services	A cooperative agreement with FDA.
2	Active Surveillance of Medical Device Safety and Outcomes Using electronic health records (EHRs): Prostate Cancer Partial Gland Ablation	Prostate Cancer Partial Gland Ablation Technologies	Electronic Health Records (EHRs) at Weill Cornell Medicine	Data elements harvested from EHRs into Natural Language Processing and High-Performance Integrated Virtual Environment repository that are integrated into Study of Prostate Ablation Related	None	Completed	111 patients	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	Technologies			Energy Devices (SPARED) registry				
Completed/Terminated/Discontinued Projects from Previous Reports								
	Signal Detection: Opioid Use and Risk of Joint Revision Surgery	Total knee and total hip	Kaiser Permanente's Total Joint Replacement Registry and EHRs	Risk of revision surgery	Johnson & Johnson, Smith & Nephew, and Zimmer Biomet	Completed	24,105 (knees) 12,895 (hips)	A cooperative agreement with FDA.
	Data Extraction and Longitudinal Trend Analysis (DELTA)-Implantable cardioverter defibrillator (ICD)leads	ICD Leads	ICD Registry in the National Cardiovascular Data Registry	Survival (freedom from failure)	None	Completed	374,132	A cooperative agreement with FDA.
	SPARED Robot-Assisted Cystectomy	Robotic devices	Surveillance, Epidemiology, and End Results - Medicare data	Benign ureter stricture and stricture diagnoses	None	Completed	1,781 patients	A cooperative agreement with FDA.
	Women's Health Technology (WHT)-Coordinated Registry Network	Mesh implants used in pelvic organ prolapse repairs	New York State's Department of Health's SPARCS	Reoperation risk	None	Completed	54,194 patients	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	(CRN) mesh for Pelvic Organ Prolapse repairs							
	WHT-CRN slight mesh for Stress Urinary Incontinence	Sling mesh implants for stress urinary incontinence	New York State's Department of Health's SPARCS	Reoperation and erosion	None	Completed	36,195 patients	A cooperative agreement with FDA.
	Outpatient Surgical Procedures for the Treatment of Benign Prostatic Enlargement in New York State and California	Transurethral prostatectomy and laser prostatectomy	New York State and California statewide databases	Reoperation rates	None	Completed	85,682 men	A cooperative agreement with FDA.
	Vascular Implants Surveillance Intervention and Outcomes Network (VISION)	Stents, stent-grafts, and other devices used in the treatment of diseases of the peripheral circulatory system	Vascular Quality Initiative (VQI)-Medicare data, New York State's Department of Health's SPARCS, device manufacturer clinical trial databases	Death, procedure-specific adverse events (stroke, rupture, and amputation), reinterventions, readmissions, surveillance, imaging, cost	Cook Medical, Endologic, W. L. Gore & Assoc., and Medtronic	Completed	>300,000 patients	A cooperative agreement with FDA.
	Orthopedics Coordinated	Joint replacements	Orthopedics Coordinated	Revision rates	Zimmer Biomet,	Completed	>600,000 patients	A cooperative agreement

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	Registry Network (formerly named *ICOR-USA*)		Registry Network members: Kaiser Permanente, American Joint Replacement Registry, Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement Registry, and Michigan Arthroplasty Registry Collaborative Quality Initiative		Smith & Nephew, and Johnson & Johnson			with FDA.
	VQI-DELTA Paclitaxel (PTX) Study	PTX Drug-Coated Balloons and PTX Drug-Eluting Stents	VQI data collected by the Society of Vascular Surgeons	Survival (i.e., freedom of death from any cause)	Medtronic, Bard, Philips, Cook, and Boston Scientific	Completed	7,814 patients	A cooperative agreement with FDA.
	Outpatient Surgical Procedures for the Treatment of	Transurethral prostatectomy and laser prostatectomy	New York State and California statewide	Reoperation rates	None	Completed	85,682 men	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	Benign Prostatic Enlargement in New York State and California		databases					
	Evidence-Based Objective Performance Criteria for the Evaluation of Hip and Knee Replacement Devices and Technologies	Total Hip Arthroplasty and Total Knee Arthroplasty devices	Literature, Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement Registry, Kaiser Permanente Registry, the New York State's Department of Health's SPARCS, and the California Office of Statewide Planning and Research Cooperative System (OSHPD)	Patient-Reported Outcome Measures and cumulative joint revision rates at 2 years	None	Completed	653,662 patients	A cooperative agreement with FDA.
	Endovascular Aneurysm Repair (EVAR)	Endovascular Treatment Devices	VQI-Medicare linked dataset for EVAR	In-hospital mortality, 30-day mortality, 1-year mortality, length of	None	Completed	15,937 EVAR patients	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	Conversion			Stay, Intensive Care Unit length of stay, hospital readmission within 30 days, and discharge destination				
	DELTA-Transcatheter Aortic Valve Replacement	Aortic and mitral valves	National Cardiovascular Data Registry Transcatheter Valve Therapy Registry	Survival (i.e., freedom from a composite of death, stroke, or repeat valve operations)	Medtronic, Abbott, and Edwards	Dis-continued	> 150,000 patients	A cooperative agreement with FDA.
	WHT-CRN Urogynecological Mesh and Risk of Cancer	Mesh	New York State's Department of Health's SPARCS	Cancer	None	Dis-continued	59,117 patients	A cooperative agreement with FDA.
	Examining Outcomes After Benign Prostatic Hyperplasia Minimally Invasive Surgical Procedures Using State All Payer Databases	Prostatic urethral lift, Trans Urethral Needle Ablation, and Trans Urethral Microwave Therapy, Devices (permanent implants, radiofrequency needles, and microwave-emitting	Data from the New York State's Department of Health's SPARCS and the California OSHPD	Rates of hospital readmission due to acute urinary retention, hematuria, and urinary tract infection at 30 and 90 days following the index Benign Prostrate Hyperplasia surgery. Risk of reoperation and developing urethral stricture at 1, 3, and 5 years following this index surgery.	None	Completed	2,694	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
		devices)						
	Long Term Evaluation of Type II Endoleak Using VQI and Linked Medicare Claims	Endovascular grafts	VQI-Medicare claims data via VISION	Mortality, reintervention, type II endoleak specific reintervention, and frequency of follow-up imaging at 1 and 2 years	None	Completed	6,079	A cooperative agreement with FDA.
	Association Between Devices and Long-Term Risks of Reintervention and Late Abdominal Aortic Aneurysm Rupture Among Patients Treated with Endovascular Aneurysm Repair	Endovascular grafts	VQI -Medicare data via VISION database	Reintervention and abdominal aortic aneurysm rupture after endovascular aneurysm repair	None	Completed	21,213 patients	A cooperative agreement with FDA.
	Two-Year Revision Rates in Total Ankle Replacements Versus Ankle Arthrodesis – A Population-Based Propensity	Ankle arthrodesis and total ankle replacement devices	Data from the New York State's Department of Health's SPARCS and the California OSHPD	Revision after the index total ankle replacement and ankle arthrodesis procedures, in-hospital complications, and below-knee amputations	None	Completed	1,477 total ankle replacements and 1,468 ankle arthrodesis	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	Score-Matched Comparison from New York and California							
	Changes in the Long-Term Risk of Adverse Outcomes in Patients Treated with Open and Endovascular Abdominal Aortic Aneurysm Repairs	Endovascular grafts	VQI-Medical data via VISION	Long-term mortality (at least 3 years) and reintervention	None	Completed	246,333 EVAR and 124,559 open aneurysm repairs	A cooperative agreement with FDA.
	Electrophysiology Predictable and Sustainable Implementation of National Registries	ICD leads and Cardiac Re-Synchronization Therapy device leads	Administrative claims, device remote monitoring data, manufacturer-device tracking, and complaint-handling databases	Cardiac tamponade and perforation, lead adverse events that require surgical intervention	Abbott, BIO-TRONIK, Boston Scientific, and Medtronic	Completed	64,777 patients	None
	Mortality After Paclitaxel (PTX)-Coated Balloon Angioplasty and Stenting of Superficial	PTX coated balloons and stents and non-PTX balloons and stents	VQI-Medicare data via VISION	Mortality	Most manu-facturers of PTX devices and non-	Completed	11,452 patients	A cooperative agreement with FDA.

#	Pilot Name	Device(s) Involved	Data Source(s) Involved	Safety Outcome(s) of Interest	Mfrs. Involved	Status	# of Patients	Agreement Type
	Femoral and Popliteal Artery in the VQI				PTX devices			

This report was prepared by FDA's Center for Devices and Radiological Health. For more information, please contact:

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This report is available on FDA's home page at https://www.fda.gov/.