

MDUFA V Independent Assessment

CONTRACT NO. 75F40124A00001
ORDER NO. 75F40125F19004

*Prepared exclusively for Food and
Drug Administration's (FDA's) Center
for Devices and Radiological Health
(CDRH)*

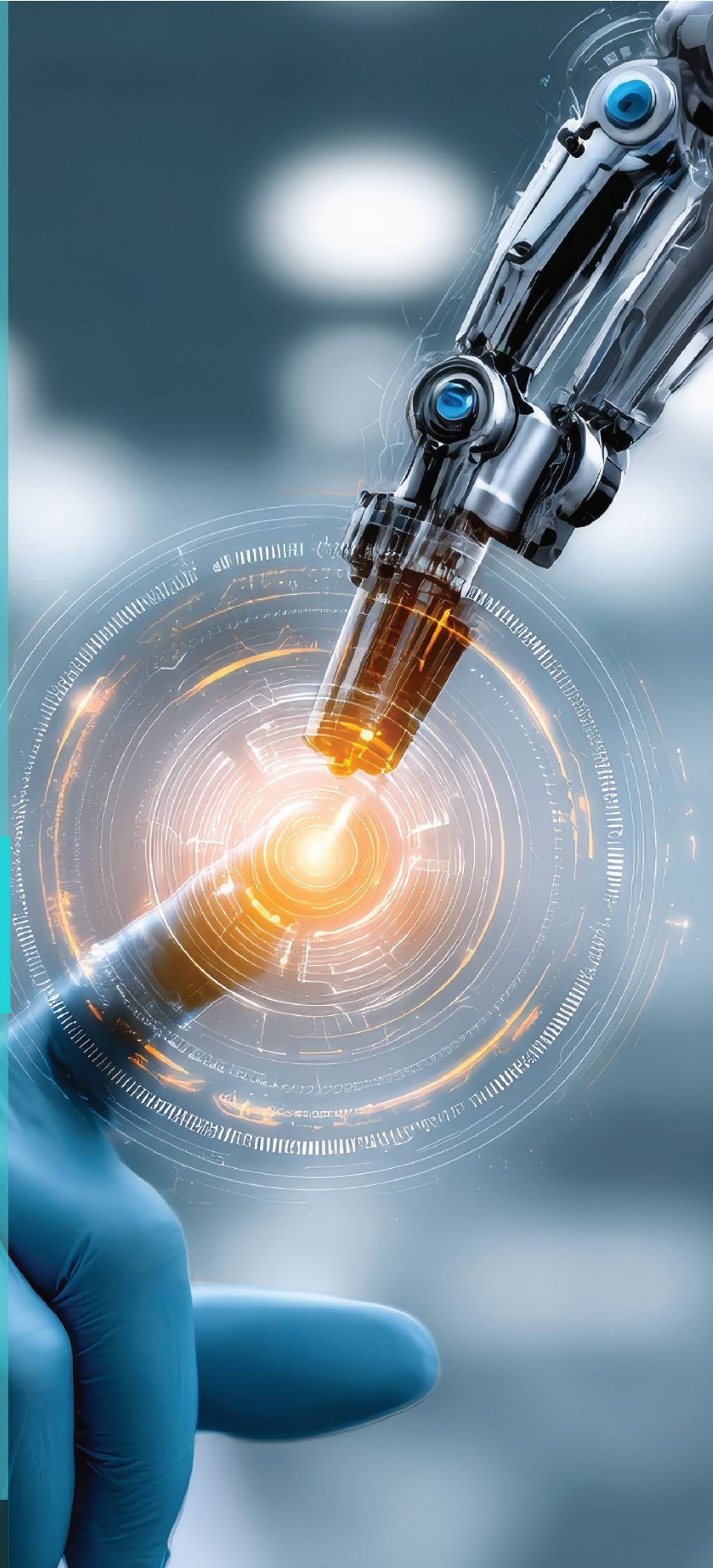


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1. Executive Summary

Pursuant to the Medical Device User Fee Amendments of 2022 (MDUFA V) Commitment Letter,¹ the Food and Drug Administration (FDA) committed to obtain an independent third party assessment of multiple programs intended to strengthen the review program and interactions between FDA and applicants. Federal law authorizes FDA to collect user fees to supplement the annual funding that Congress provides for the Agency. User fees help FDA fulfill its mission of protecting the public health and also facilitate timely availability of innovative FDA-regulated products without compromising the Agency's commitment to scientific integrity, public health, regulatory standards, patient safety, and transparency. The assessment focused on FDA's commitments to strengthen the efficiency and predictability of processes and programs across several assessment areas (Table 1-1).

Table 1-1: Objectives of Booz Allen's Independent Assessment for Each Assessment Area

Assessment Area	Objective Of Assessment
Premarket Review Efficiencies	Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V
Training and Alignment	Assess the alignment of resource needs with the training and expertise of hires
Best Practices across Offices of Health Technology (OHTs)	Identify and share best practices across OHTs in the Office of Product Evaluation and Quality (OPEQ)
Deficiencies Guidance	Assess the effectiveness of the implementation and impact of changes to the guidance "Developing and Responding to the Deficiencies in Accordance with the Least Burdensome Provisions"
Q-Submission Guidance	Assess the effectiveness of the implementation and impact of changes to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"
Third Party Review Program	Assess the effectiveness of the Third Party Review Program (continued reduction of routine re-review by FDA of Third Party reviews)
Digital Health Program	Assess the effectiveness of the Digital Health program
Patient Science and Engagement Program	Assess the effectiveness of the Patient Science and Engagement program
Real-World Evidence Program	Assess the effectiveness of the Real-World Evidence program
International Harmonization	Assess the effectiveness of international harmonization efforts

In addition, Booz Allen also assessed FDA's reporting on Total Time to Decision (TTD) and FDA and Industry's progress toward this outcome.

Overall, as of the publication date of this report, the assessment found that FDA met the relevant commitments for the program areas specified for the independent assessment as agreed upon in the MDUFA V Commitment Letter.² There are also a number of commitments with future or recurring deadlines. These have been noted throughout but are anticipated to be met by the close of the MDUFA V period. The full report details the findings and conclusions for each of the ten assessment areas.

¹ MDUFA V Commitment Letter (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2022-mdufa-v>).

² Ibid.

2. Background

Congress passed the standalone Medical Device User Fee and Modernization Act (MDUFMA)³ in 2002 to establish a user fee program and modernization provisions. It included the publication of a Commitment Letter that outlined a series of performance goals and initiatives to promote the efficiency, consistency, and transparency of the premarket review process for medical devices. Device user fees enable the Agency to improve the consistency and efficiency of premarket review through investments in a wide range of programs and processes. The subsequent reauthorizations occur every five years under MDUFA. The most recent authorization, MDUFA V, continued to commit to conduct an independent assessment of FDA's review process management. Federal law authorizes FDA to collect user fees in subsequent five-year reauthorization periods: 2007 (MDUFA II),⁴ 2012 (MDUFMA III),⁵ 2017 (MDUFA IV),⁶ and 2022 (MDUFA V)⁷ along with corresponding commitment letters.

3. Methodology

Booz Allen developed and used methodologies aligned with each assessment area's objectives, designed to evaluate whether FDA met the MDUFA V commitments identified in Section VI.B of the MDUFA V Commitment Letter.⁸ Booz Allen executed a three-part methodology – plan assessment, assess outcomes, and report findings – in parallel with ongoing stakeholder engagement, as outlined in Figure 3-1.

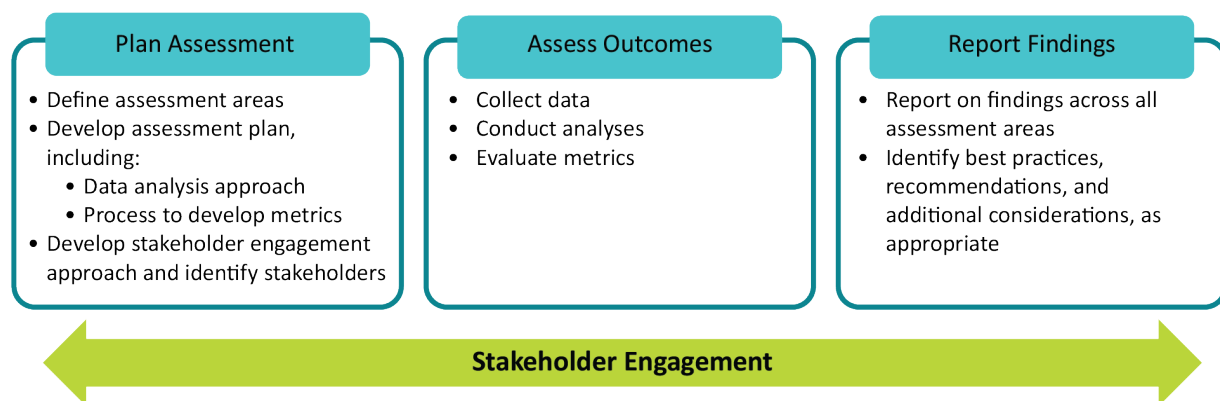


Figure 3-1: High-Level Overview of Booz Allen's Methodology

The first phase, **Plan Assessment**, involved developing and documenting an approach for each assessment area by defining the scope, determining potential quantitative and qualitative data sources, and identifying metrics (if appropriate); FDA points of contact (POCs) reviewed the assessment plan and provided feedback based on their expertise and contextual knowledge. The second phase, **Assess Outcomes**, included qualitative data collection and analysis (e.g., document review, thematic analysis) and quantitative data collection and analysis (e.g., descriptive analysis, trend analysis), as appropriate based on the assessment area. Table 3-1 summarizes the types of data sources used at this phase of the assessment and describes the intended purpose of each. In the third and final phase, **Report Findings**, Booz Allen reported on findings across all assessment areas and noted any relevant best

³ Medical Device User Fee and Modernization Act of 2002 (<https://www.congress.gov/bill/107th-congress/house-bill/5651>).

⁴ Food and Drug Administration Amendments Act of 2007 (<https://www.congress.gov/bill/110th-congress/house-bill/3580>).

⁵ Food and Drug Administration Safety and Innovation Act (<https://www.congress.gov/bill/112th-congress/senate-bill/3187>).

⁶ FDA Reauthorization Act of 2017 (<https://www.congress.gov/index.php/bill/115th-congress/senate-bill/934>).

⁷ Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (<https://www.congress.gov/bill/117th-congress/house-bill/6833>).

⁸ See footnote 1.

practices, recommendations, and additional considerations pertinent to the FDA’s alignment with the MDUFA V commitments. Across all phases, Booz Allen engaged regularly with FDA POCs, as well as with representatives of regulated industry organizations, including Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA), and American Clinical Laboratory Association (ACLA).

Table 3-1: Types of Data Sources Used in this Assessment

Source	Purpose
Public documents (e.g., guidance documents, strategic plans, MDUFA IV and V annual and quarterly reports)	- Understand FDA plans and activities related to the MDUFA V commitments - Determine whether FDA published guidance documents identified in the MDUFA V commitments
Internal FDA procedural documents (e.g., standard operating procedures [SOPs], work instructions [WIs])	Understand FDA’s internal processes and procedures and how they were updated to align with MDUFA V commitments
Communications data and examples (e.g., FDA.gov news and press releases, internal FDA SharePoint sites)	- Document FDA activities related to the MDUFA V commitments (e.g., meetings, staff communication) - Understand how FDA communicates regarding program updates, internally and externally
FDA audit data (e.g., audits conducted by the Quality Management and Organizational Excellence [QMOE] Program)	Evaluate FDA’s actions related to commitments for Deficiencies and Third Party Review
FDA survey and evaluation data (e.g., training survey data)	Understand FDA employee perspectives and response to programmatic changes in alignment with MDUFA V commitments

4. Assessment Findings

The findings in this section are organized and presented by the assessment areas defined for the independent assessment in the MDUFA V Commitment Letter. APPENDIX B: outlines the MDUFA V Commitment Letter assessment areas that align to the findings in each section.

4.1. Premarket Review Efficiencies

To achieve its mission of protecting and promoting public health, FDA’s premarket review program provides a pathway to perform comprehensive reviews of medical device submissions to ensure they are safe and effective before approving them for marketing in the United States. In MDUFA V, FDA committed to making improvements in areas impacting premarket review, ten of those areas were examined during this independent assessment. In addition, the Agency committed to exploring several other improvements related to electronic submissions and encouraging communication with applicants.

As part of the independent assessment, the external consulting firm, Booz Allen, was tasked with assessing and describing the improvements that FDA made to the premarket review process, as well as how these initiatives have promoted consistency and efficiency in device review. Booz Allen found that FDA initiated or expanded several major activities focused on improving the premarket review programs. These include developing various tools for both review staff and industry, as well as establishing programs designed to streamline internal processes and facilitate consistency and quality in device reviews.

The assessment findings are presented in two sections:

- 4.1.1 Effect of Programs and Policies on Premarket Review Efficiency
- 4.1.2 Impact of Tools and Process Improvements on Consistency

4.1.1. Effect of Programs and Policies on Premarket Review Efficiency

This section describes how FDA met the commitment shown in Table 4-1. The findings are described in the sub-sections:

- 4.1.1.1 Supporting Informal Communication During Interactive Review
- 4.1.1.2 Predetermined Change Control Plans
- 4.1.1.3 Enforcement Discretion Policies

4.1.1.1. Supporting Informal Communication During Interactive Review

FDA continued to use the interactive review process for 510(k), Premarket Approval (PMA) and De Novo submissions to encourage informal communication between FDA staff and applicants. Under MDUFA V, FDA developed resources for review staff to resolve issues and promote efficient review of the data necessary to make a final decision. Resources included process maps and step-by-step instructions that outline where informal communication between an applicant and FDA can be expected or may facilitate submission review. In addition, FDA developed a document outlining best practices, communication methods (e.g., telephone, emails, fax), and practical recommendations that are applicable to each stage of the review process.

Interactive review and substantive interaction (SI) reflect the dynamic processes FDA and sponsors engage in to resolve submission deficiencies and the efforts mentioned above are intended to improve this dynamic process. Historical trends indicate that the overall percentage of 510(k) submissions that received and met SI review performance goals increased from 87% in FY21 to 96% in FY24 (Figure 4-1A).^{9,10} PMA Originals and Panel-Track Supplements with SI increased from 79% in FY21 to 100% in FY24 (Figure 4-1B).^{9,10} These improvements in SI performance hint at an overall positive impact from internal FDA efforts meant to standardize and facilitate interactive review and informal communications.

Table 4-1: MDUFA V Commitment Letter
(Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants

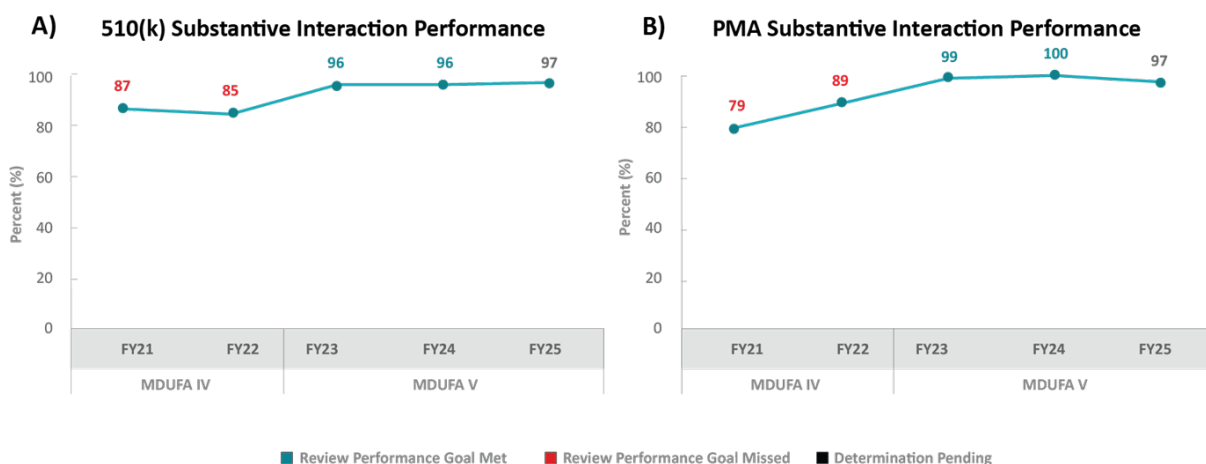


Figure 4-1: FY21-FY25 Substantive Interaction Performance for 510(k) and PMA Premarket Review Programs

⁹ FY 2023 MDUFA Performance Report (<https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-medical-device-user-fee-amendments-mdufa-performance-reports>).

¹⁰ FY 2025 MDUFA Performance Report (<https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-medical-device-user-fee-amendments-mdufa-performance-reports>).

4.1.1.2. Predetermined Change Control Plans

Predetermined Change Control Plans (PCCPs) are a regulatory framework that allows applicants to submit documentation on planned device modifications as part of a marketing submission. This framework can lower applicant burden and improve regulatory efficiency by allowing applicants to leverage PCCPs for certain device modifications to authorized devices rather than submitting a new premarket submission. The Food and Drug Omnibus Reform Act of 2022 (FDORA) has provisions for PCCPs for devices requiring PMA or 510(k).¹¹ FDA released multiple guidance documents and public-facing webinars to communicate the policies and guiding principles of PCCPs. Table 4-2 lists the relevant documents on the use of PCCPs and notes the documents that are further discussed in Digital Health (Section 4.7).

Table 4-2: Overview of PCCP Documents Released During MDUFA V

Document	Overview	Issue Date
"Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles"	These principles provide foundational considerations that highlight the characteristics of robust PCCPs and foster collaboration among stakeholders. (Additional details in Section 4.7 Digital Health)	October 2023
"Predetermined Change Control Plans for Medical Devices"	Draft guidance document proposing a policy for PCCPs for all medical devices, including the components that should make up PCCPs, the recommended content, and recommended types of modifications.	August 2024
"Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions"	This final guidance document provides policy recommendations for PCCPs tailored to artificial intelligence-enabled devices. (Additional details in Section 4.7 Digital Health)	December 2024, Updated August 2025

FDA developed resources for review staff to enable effective and consistent review of PCCPs as part of device marketing submissions and established a working group to develop internal infrastructure such as a centralized inbox to provide policy consults and additional resources including internal presentations and internal procedural documentation. In Fall 2025, the Center for Radiological Devices and Health (CDRH) launched the PCCP Representatives Program with leadership-identified staff assigned responsibilities for PCCP review and trained in best practices. These representatives serve as internal SMEs within their respective OHTs, supporting staff with PCCP-related questions and reviews. Figure 4-2A, highlights the yearly number of authorized PCCPs for devices under the 510(k), PMA, and the De Novo pathways, with a total of 118 authorized PCCPs for devices across all programs between FY23 to FY25.^{12,13,14} PCCP authorization rates improved across all three pathways between FY23 and FY25, with 510(k) rates rising steadily from 60.0% to 66.7%, PMA rates increasing from 0% to 88.6%, and De Novo rates climbing from 0% to 100% over the same period (Figure 4-2B). Further, historical MDUFA workload data indicate that, by the end of FY 2025, authorized PCCPs for devices represented approximately 1.3%, 34%, and 1.4% of total submission workloads for the 510(k), PMA, and De Novo pathways, respectively (Figure 4-2C).^{12,13,14,15} Although most authorized PCCPs applied to submissions under the cardiovascular, microbiology, and radiology medical specialties, there are several other specialties with authorized PCCPs, including neurology, pathology, clinical chemistry, orthopedic, and anesthesiology (Figure 4-2D).

¹¹ Food and Drug Amendments of 2022 (<https://www.congress.gov/bill/117th-congress/house-bill/7667>).

¹² 510(k) Premarket Notification Database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>).

¹³ Premarket Approval (PMA) Database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>).

¹⁴ Device Classification Under Section 513(f)(2)(De Novo) Database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm>).

¹⁵ See footnote 10.

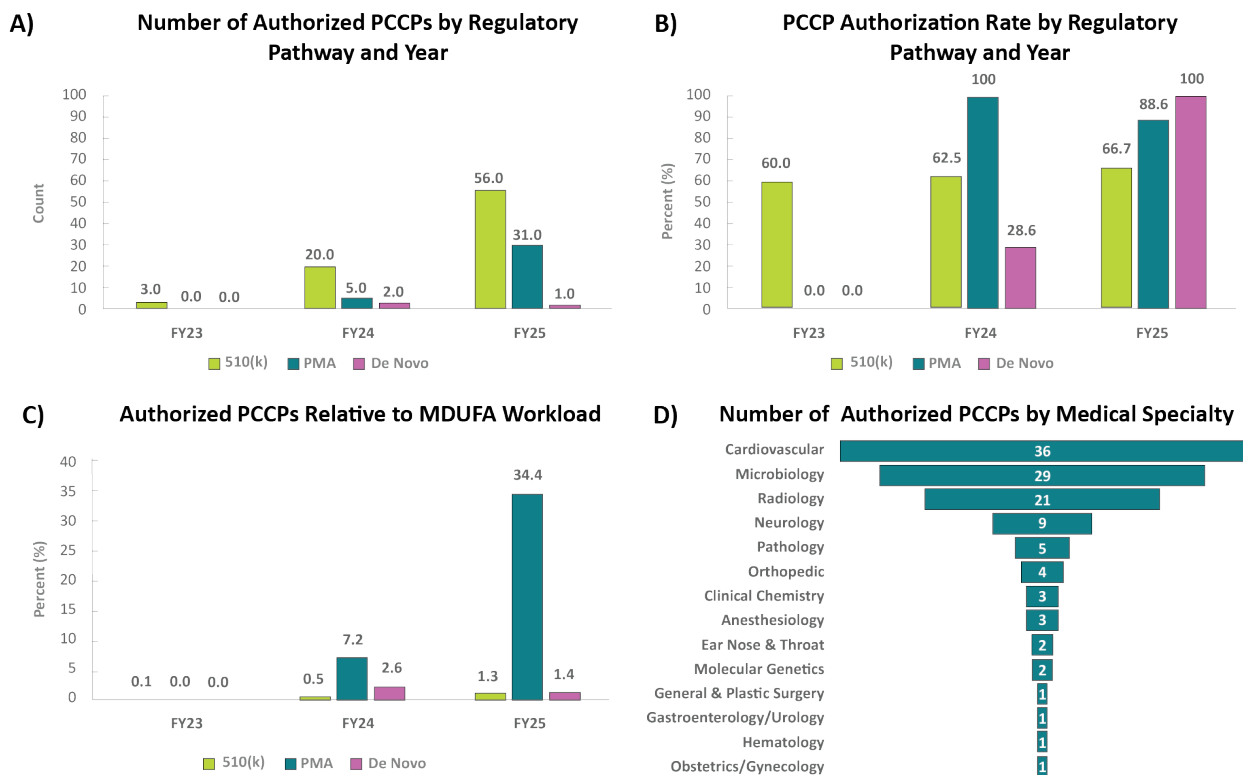


Figure 4-2: PCCPs Authorized Between FY23 and FY25

4.1.1.3. Enforcement Discretion Policies

The Secretary of Health and Human Services declared a public health emergency (PHE) on January 31, 2020, under Section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to the 2019 Coronavirus Disease (COVID-19). The Federal COVID-19 PHE declaration ended on May 11, 2023. However, during MDUFA V, FDA extended the use of COVID-19 enforcement discretion policies enacted during the PHE, releasing two superseding final guidance documents.^{16,17} The first guidance document, titled *Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions* provides FDA's policies and regulatory review expectations for certain limited modifications to devices required to have an approved PMA or HDE to help address manufacturing limitations or supply chain disruptions. The second guidance document, titled *Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring* describes an enforcement policy where FDA does not intend to object to limited modifications to the indications, functionality, or hardware or software of certain non-invasive remote monitoring devices that are used to support patient monitoring without prior submission of a 510(k). Moreover, FDA released an additional superseding final guidance document titled *Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements* which identifies certain unclassified medical devices that the Agency believes meet the standards for exemption from premarket notification. These guidance documents are not all encompassing of the deregulatory actions taken by CDRH but represent ones applicable to the premarket review process.

¹⁶ Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-supplements-approved-premarket-approval-pma-or-humanitarian-device>).

¹⁷ Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring>).

4.1.2. Impact of Tools and Process Improvements on Consistency

This section describes how FDA met the commitments in Table 4-3. The findings are described in the sub-sections:

- 4.1.2.1 Electronic Submissions
- 4.1.2.2 Safety and Performance Based Pathway Guidances and Regulatory Science Tools

4.1.2.1. Electronic Submissions

Electronic Submission Template and Resource (eSTAR)

eSTAR is a dynamic PDF template designed to interactively guide applicants through the construction of an electronic submission.¹⁸ eSTAR is intended to enhance the quality of submissions and facilitate more efficient premarket reviews through such capabilities and features as standardized submission format that mirrors FDA's Submission Memo and Review Templates (SMART) and automates submission verification, eliminating the need for a separate Refuse to Accept (RTA) review for certain submission types. During MDUFA V, FDA transitioned from voluntary to mandatory eSTAR usage for 510(k) submissions and De Novo requests, unless exempted, in October 2023 and 2025, respectively.^{19,20} Additionally, FDA expanded the use of eSTAR, making it available for voluntary use for Premarket Approval (PMA) Applications, Investigational Device Exemptions (IDE), Pre-Submissions, and 513(g) Requests for Information.

FDA reviewers perform Technical Screening (TS) for eSTAR submissions. In 2024, FDA solicited feedback from review staff on challenges and opportunities for improvement of this process. FDA created a working group to synthesize feedback and implement changes to the TS process. Changes included updating internal procedural documentation to clarify eSTAR TS criteria, providing reviewers with additional direction for navigating eSTAR submissions and giving OHT Division Directors final concurrence on TS decisions. FDA provided reviewers with training on the updated TS process.

eSTAR improvements are intended to streamline the administrative requirements for high-quality premarket submissions for sponsors and reviewers alike. MDUFA Quarterly Reports document the total number of submissions within a fiscal year that are accepted during the first review cycle (i.e., applications that received an RTA accept decision or passed TS in the first review cycle), which can be used to calculate the percentage of submissions that meet the administrative standards for full review consideration during the first review cycle.^{21,22} Although the quarterly reports provide a snapshot of performance, they can be used to extract historical data and bring attention to notable trends in submission quality between MDUFA IV and MDUFA V. Between FY21 (MDUFA IV) and FY24 (MDUFA V), first cycle acceptance for 510(k) (Figure 4-3A) and De Novo submissions increased meaningfully (Figure 4-3B), while PMA first cycle acceptance remained above 90% since FY22 (Figure 4-3C). These trends may, in part, reflect that the effective use of submission templates is allowing submissions to pass the administrative quality check FDA staff performs upon receipt. Thus, the continued improvement to submission templates may be having a net positive impact on premarket review.

Table 4-3: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V
- Continue to develop electronic submission templates that will serve as guided submission preparation tools for industry
- Maintain and improve on the Customer Collaboration Portal

¹⁸ eSTAR Program (<https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>).

¹⁹ Electronic Submission Template for Medical Device 510(k) Submissions (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions>).

²⁰ Electronic Submission Template for Medical Device De Novo Requests Guidance (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-de-novo-requests>).

²¹ November 16, 2023 MDUFA IV Performance Report (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/mdufa-reports>).

²² November 20, 2025 MDUFA V Performance Report (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/mdufa-reports>).

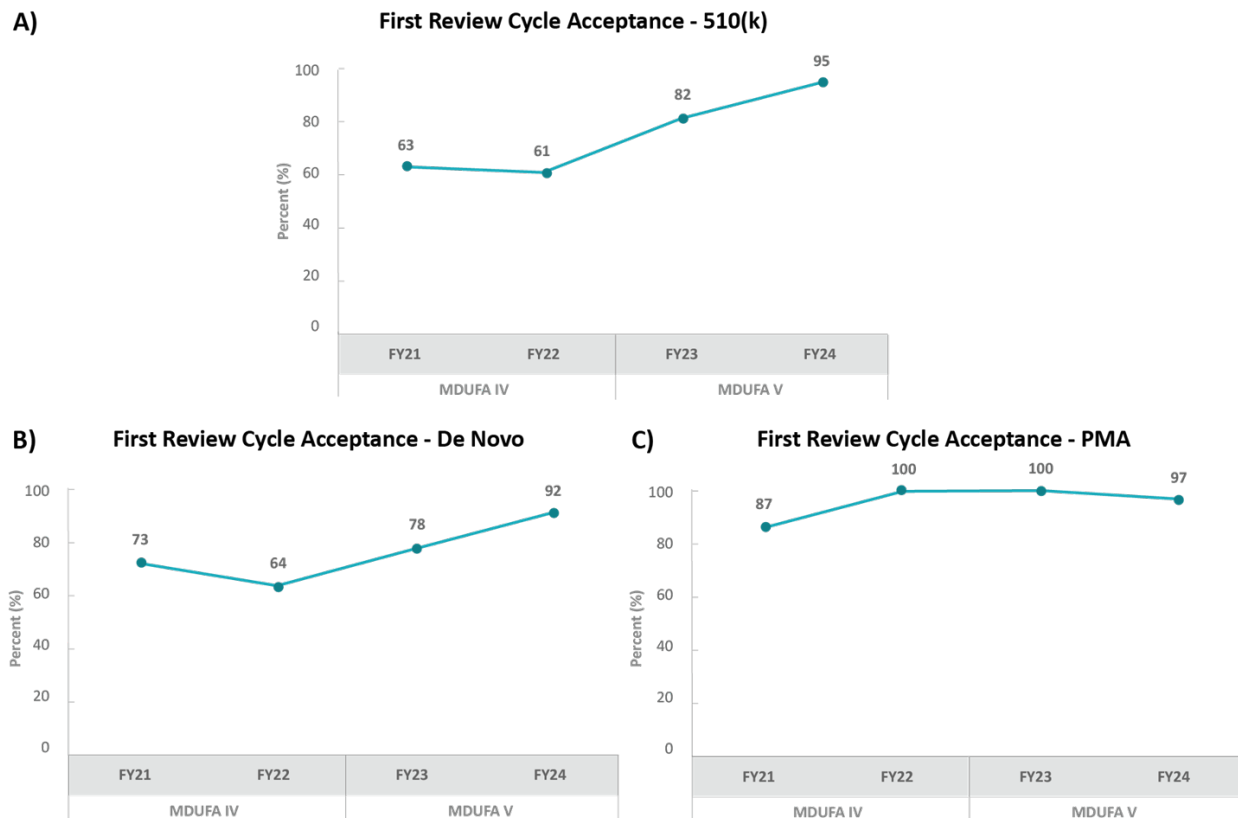


Figure 4-3: First Review Cycle Acceptance for Major Premarket Review Programs

Customer Collaboration Portal

FDA improved the Customer Collaboration Portal (CCP), a web-based platform that provides electronic submission capabilities and near real-time progress tracking for CDRH premarket submissions. Under MDUFA V, FDA incorporated progress tracking of additional submission types and added features, such as:

- Progress tracking for submission types noted in Table 4-4: CCP Submission Types Supported by Portal Tracking (i.e., most submission types except for Humanitarian Device Exemption [HDE] and 510(k) Third Party Review submissions)
- Submission of Small Business Determination Requests with support and communications functionality²³
- Enhanced progress tracker features such as the ability to share submission progress tracking, new search filters, dashboard customization options, and default hiding of inactive reviews
- Enhanced security features such as Zero Trust password requirements
- User support features such as a “What’s new” and “Common questions” sections with over 8,000 views recorded for the 15 most viewed questions

In December 2025, FDA updated the eCopy guidance to clarify the intersection of the eCopy Program with the eSTAR Program and the availability of the CCP to send eCopy submissions.²⁴ Internal documentation reviewed as part of this assessment, the details of which are not available for public disclosure, highlighted that expansion of the CCP

²³ Reduced or Waived Medical Device User Fees: Small Business Determination (SBD) Program (<https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-or-waived-medical-device-user-fees-small-business-determination-sbd-program>).

²⁴ eCopy Program for Medical Device Submissions (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>).

features and submission support coincided with a sustained growth in the estimated number of users, total document uploads, and Pre-Submissions between 2022 and 2025. In 2023, FDA held a webinar, *CDRH Portal Overview and Feature Walkthrough*, to provide industry sponsors with foundational information about the CCP including the support features that can help streamline the premarket submission process.²⁵

Table 4-4: CCP Submission Types Supported by Portal Tracking

Submission Type	Implementation Date
Traditional 510(k)	August 2021
Special and Abbreviated 510(k)	February 2022
Pre-Submissions	May 2023
De Novo	December 2023
PMA Original and Panel-Track Supplements	September 2024
IDE	August 2025

Additionally, FDA expanded internal IT capabilities by integrating artificial intelligence (AI), adding new tools for data validation and analytics tools, workload and communication tracking systems, and data monitoring dashboards. These technological capabilities and tools are intended to improve and automate internal workflows, promote consistency, and reduce submission review times and administrative burden for review staff.

4.1.2.2. Safety and Performance Based Pathway Guidances and Regulatory Science Tools

Safety and Performance Based (S&P) Pathway

The S&P Pathway is an expansion of the abbreviated 510(k) program that enables applicants to demonstrate substantial equivalence using FDA-recognized consensus standards and/or special controls and without direct predicate comparison testing.^{26,27,28} FDA expanded the number of S&P Pathway guidance documents to further facilitate effective and consistent review practices for conducting the review of S&P Pathway submissions. Between 2023 and 2025, the Agency published six new guidance documents outlining the specific performance criteria and recommended testing methods needed to support the finding of substantial equivalence for several devices (Table 4-5). The Agency also published an update to one of the already existing guidances.²⁹

Table 4-5: Safety and Performance Guidance Documents Published During MDUFA V

Guidance	Published
“Soft (Hydrophilic) Daily Wear Contact Lenses - Performance Criteria for Safety and Performance Based Pathway”	March 2023

²⁵ CDRH Portal Overview and Feature Walkthrough (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>).

²⁶ The Abbreviated 510(k) program enables applicants to use guidance documents, special controls, and FDA-recognized consensus standards to establish substantial equivalence in a way that is less burdensome yet still requires comparison between a proposed device and a predicate device. “Abbreviated 510(k) Program (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>).

²⁷ Safety and Performance Based Pathway (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway>).

²⁸ To establish substantial equivalence, FDA must request the minimum information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time, in accordance with the least burdensome provisions – The Least Burdensome Provisions: Concept and Principles (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles>).

²⁹ Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance>).

Guidance	Published
“Air Powered Dental Handpieces and Air Motors - Performance Criteria for Safety and Performance Based Pathway”	September 2024
“Dental Cements - Performance Criteria for Safety and Performance Based Pathway”	September 2024
“Dental Ceramics - Performance Criteria for Safety and Performance Based Pathway”	September 2024
“Dental Impression Materials - Performance Criteria for Safety and Performance Based Pathway”	September 2024
“Endosseous Dental Implants and Endosseous Dental Implant Abutments - Performance Criteria for Safety and Performance Based Pathway”	October 2024

Regulatory Science Tools Catalog

FDA developed the Regulatory Science Tools Catalog to provide industry with an assembly of regulatory science tools which may be used when consensus standards and qualified Medical Device Development Tools (MDDTs) are not available.³⁰ The catalog houses over 100 tools across five primary categories that include lab methods, computer models, datasets, phantoms (e.g., simulations), and clinical outcome assessments. The goal of this resource is to provide innovators with methods that enable early benchmarking and de-risking of product development cycles.

4.2. Training and Alignment

The professional development of new and existing reviewers is vital to FDA’s mission. FDA established collaborative training programs to respond to reviewers’ individual learning needs and expertise levels. The Reviewer Certification Program (RCP)

provides foundational knowledge and skills for new premarket reviewers, while the Experiential Learning Program (ELP) provides CDRH review staff with hands-on training experiences with industry exposure. The Focal Point Program (FPP) builds specialized expertise in cross-cutting technical areas. The MDUFA V commitments for training are focused on improving training for new and existing reviewers and coordinating with the QMOE Program to provide more targeted and personalized training to staff.

Table 4-6: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
FDA will continue to evaluate and improve training for new and existing reviewers under this agreement.

The following sections describe how FDA met the commitment shown in Table 4-6:

- 4.2.1. Evaluate and Improve Training for New and Existing Reviewers
- 4.2.2. Quality Management and Operational Excellence Program Supporting Efforts

4.2.1. Evaluate and Improve Training for New and Existing Reviewers

Improved Reviewer Certification Program Training

RCP provides foundational knowledge and skills for new premarket reviewers through 22 online modules, 14 instructor-led courses, activities, and assessments. RCP is a mandatory training delivered in eight-week cohorts offered six times per year. RCP is designed for new device reviewers and medical officers with extensive knowledge in their fields (medicine, engineering, biocompatibility) but need to learn regulatory requirements, processes, and tools to review medical device submissions. The program consists of an eight-week RCP Core sequence and RCP Advanced modules. Reviewers have one year after completing the foundational curriculum to complete the advanced modules.

³⁰ Regulatory Science Tools Catalog (<https://cdrh-rst.fda.gov/>).

During MDUFA V, FDA used a multi-faceted approach to evaluate RCP training. FDA conducts Kirkpatrick Level 1 evaluations after each RCP course to determine participant satisfaction and administers pre- and post-tests for each course to collect Level 2 evaluation data. The clinical and capstone portions of the program provide additional Kirkpatrick evaluation data for skills developed throughout the course. In addition, FDA compiles frequently asked questions from trainings to assess program effectiveness. Periodically, FDA conducts focus groups with new and experienced reviewers to obtain feedback on how well the trainings prepared them for their role. In 2023, FDA conducted a task analysis to identify steps and specific knowledge needed to review different submission types.

The evaluations identified opportunities to offer scalable, consistent trainings adapted to reviewer needs. RCP training shifted from a heavily subject matter expert (SME)-led format to a self-directed, modular, and role-based curriculum. Content was stratified by level with a gradual ramp-down in support as reviewers gained competency in their roles, with role-based training pathways. Additional updates include a centralized knowledge repository and reusable learning objects such as videos and interactive modules.

FDA updated content and created new internal trainings to support final guidances (e.g., “Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions”) and MDUFA V readiness. FDA developed MDUFA V Introduction Training for the CDRH community, as well as targeted training for OPEQ Leadership and managers, on goals and commitments. By March 2023, over 2,500 FDA staff completed these trainings. FDA held live Q&A sessions to assist the CDRH community in the first few months under MDUFA V. FDA replaced MDUFA IV training modules covering Pre-Submissions, 510(k), PMA, De Novo, and Deficiency letters with content aligned to MDUFA V. The Agency updated Pre-Submissions training to incorporate guidance updates from the final Q-Submission guidance, with sessions offered in May 2023 and June 2025. FDA revised the Four-Part Harmony training module to address MDUFA V commitments and removed the outdated “Master Four-Part Harmony” course from Advanced RCP.

Improved Experiential Learning Program Training

Launched in FY13, ELP³¹ provides staff with immersive training experiences around medical device development, testing, and manufacturing that help close knowledge gaps between emerging and innovative technology and the premarket review of the resulting medical device. ELP provides CDRH staff with opportunities for virtual and on-site visits to manufacturing facilities, surgical centers, clinical sites, and other production sites.

FDA uses standardized surveys, administered after staff complete their site visit, to conduct Kirkpatrick Level 1 and Level 2 evaluations of the program. A learning management system maintains registration and training completion data. Although on-site visits paused in FY22 due to COVID-19, the program continued by implementing virtual visits. Based on feedback, virtual visits were incorporated into the program after in-person activities resumed to provide flexibility in including covered topics and selecting staff for site visits. In FY23, FDA conducted nine site visits for 162 attendees, and in FY24, FDA conducted 36 site visits for 814 attendees. In FY25, CDRH conducted two site visits for 62 attendees. While virtual visits are offered, industry has indicated/noted a strong preference for in-person site visits. In FY26, FDA issued a data call for ELP proposals, to develop new topic content to help review staff better understand medical product development, industry challenges, and current manufacturing practices outside the formal regulatory review.

Training content is systematically organized through Focus Areas, with specific training needs identified bi-annually by Senior Champions serving as SMEs. ELP participants are encouraged to share the knowledge gained from the site visits with colleagues in their Focus Area, expanding the program’s reach. The program maintains broad engagement with external stakeholders by actively soliciting proposals from companies, academia, clinical facilities, medical device incubators and accelerators, health insurers, and health technology assessment groups. Senior Champions review proposals and make selections based on their applicability to current areas of interest, available resources, and logistical considerations to ensure site visits address the most critical training needs and help close knowledge gaps between emerging technologies and premarket review processes. Under MDUFA V, and in alignment with

³¹ CDRH's Experiential Learning Program (ELP) (<https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/cdrhs-experiential-learning-program-elp>).

current industry trends and regulatory challenges, the program’s areas of interest expanded to include innovation, DH, biocompatibility, reprocessing, and sterilization.

Improved Focal Point Program Training

FPP trainings are intended to provide baseline knowledge for all review staff for topic areas (TA) that affect review programs across offices. Focal Points, or specialized reviewers for a TA, complete additional training for advanced instruction on moderate to high-complexity topics and subspecialties to ensure they have the necessary expertise to serve as effective resources within their office. Focal Points can either provide the reviewer with resources, conduct the review, or connect the reviewer to a subspecialist if the review requires highly specific expertise. The program has expanded from approximately four to five TA during MDUFA IV to 11 TA under MDUFA V, with over 180 designated Focal Points across the Center as of FY26.

The FPP Committee periodically requests proposals from CDRH staff for new TAs and prioritizes them based on available resources and potential regulatory impact (i.e., cross-cutting over multiple OHTs). Under MDUFA V, the Committee selected six new TAs: sterility and reprocessing, quality and compliance, patient science, real-world evidence, robotics, and electrical and battery safety, as shown in Table 4-7.

Table 4-7: MDUFA V FPP Examples

Topic Area	Topic Description
Sterility and Reprocessing	Evaluation of sterility and reprocessing documentation in a submission
Quality and Compliance	Assessment of compliance related submissions (e.g., manufacturing, Establishment Inspection Reports (EIR), recalls) and communications to manufacturers
Robotics	Identification and assessment of robotic medical devices
Patient Science	Evaluation of patient preference information (PPI) and clinical outcome assessments (COA) in regulatory submissions (See Section 4.8 Patient Science and Engagement for additional details)
Real-World Evidence	Assessment of real-world data sources and evidence to support regulatory decision-making for medical devices (Section 4.9 Real World Evidence for additional details)
Electrical Safety and Battery Safety	Evaluation of electrical safety and battery safety documentation in a submission

4.2.2. Quality Management and Operations Excellence Program Supporting Efforts

The quality program facilitates continuous improvement while supporting quality and consistency. The program maintains the CDRH Quality Management System (QMS). The quality program uses the QMS and its feedback mechanisms to determine quality-related training topics and routinely delivers quality and QMS-related lunch and learn events. The quality program develops tools to facilitate the assessment of reviewer training needs, collects feedback about the review process and tools, supports improvement and assessment of review programs and activities, and delivers results to experts who determine actions, including training, to improve premarket review. The program also collaborates across offices to provide work-related resources and learning aids that are accessible to all staff and support their development (e.g., delivering audit results that can be used to determine individual and collective training needs, and making self-aid tools like procedures, job aids, and micro learning accessible to staff).

4.2.3. Conclusion

FDA met its MDUFA V commitments by enhancing training for new and existing reviewers and providing targeted and personalized training to staff. FDA added new training content to RCP, ELP and FPP; this included self-directed, modular, and role-based curriculum based on reviewer feedback, provided targeted instruction, and used QMS to assess and identify cross-Center resources and development needs targeted to review staff.

While the Commitment Letter focuses on evaluation and improvement of training rather than demonstrated effectiveness outcomes, the assessment reveals important considerations for understanding the scope and impact

of FDA's efforts. The distinction between implementing evaluation and improvement activities versus achieving demonstrable training effectiveness is important for contextualizing FDA's progress. FDA has fulfilled the procedural aspects of the commitment through systematic training evaluation activities and responsive coordination with QMOE.

4.3. Best Practices Across OHTs

Table 4-8: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Identify and share best practices across OHTs

In 2019, FDA announced a new organizational structure across offices to enhance agility and resilience to improve its ability to adapt to change. CDRH established multiple OHTs where each OHT focuses on a therapeutic or product category. In alignment with CDRH's adoption of the Total Product Lifecycle (TPLC) approach, this reorganization allows each OHT to manage a device type from development to post-market surveillance.

As part of the independent assessment, Booz Allen, was tasked with assessing the methods of identifying and sharing best practices across OHTs (Table 4-8). Booz Allen was not able to identify additional practices that rose to the level of a best practice appropriate for broader application across OHTs, beyond those already identified by FDA. Booz Allen identified that CDRH has its own mechanisms for continuous identification and sharing of best practices: the Audit Program shares audit results and best practices on premarket processes, and the Team Management Model (TMM) shares managerial best practices from OHTs. Additionally, OPEQ implemented processes and communication mechanisms to support consistency across the OHTs. Details are provided in the sections:

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- 4.3.1 Proactive identification of best practices
- 4.3.2 Supporting Consistency across OHTs

4.3.1. Proactive Identification of Best Practices

OHTs engage in self-identification of management best practices through the use of the TMM. Not specific to MDUFA, TMM launched in 2020 and offers a dedicated platform for the identification of managerial best practices. It aims to increase agility and collaboration, promote shared accountability, and expedite decision-making, all of which indirectly facilitate more effective implementation of MDUFA programs. Best practices for TMM were communicated during OPEQ Rounds in June 2023. Staff can submit best practices across three areas of interest – resource management, organizational learning, and professional development. Suggested best practices are reviewed and then made available via a TMM Database. The TMM Database contains 80 descriptive submissions of best practices, with roughly half related to resource management (e.g., more efficient communication between reviewers and managers, staff expertise tracking), and the remainder split approximately evenly between organizational learning (e.g., review consistency across divisions) and professional development (e.g., providing training and mentoring to staff). Submissions were representative of nearly all review areas, demonstrating broad engagement and knowledge-sharing with this approach, encouraging the spread of management best practices across OHTs and promoting cross-collaboration and collective ownership to improve review consistency across all regulated device types. Best practices are informed by internal documentation reviewed as part of this assessment, the details of which are not available for public disclosure.

4.3.2. Processes to Support Consistency Across OHTs

Promotion of Continuous Improvement

FDA promotes a culture of continuous improvement through the use of various audit and advisory groups and participation in cross-CDRH groups relevant to the implementation of MDUFA V. The MDUFA V Council is composed of relevant FDA offices and participants and designed to promote continuous improvement in medical device program activities through collaborative problem-solving, accountability, and transparency in progress towards MDUFA V goals. Within CDRH, an internal MDUFA V Advisory Group aids in the implementation of the MDUFA commitments by providing updates and soliciting input from staff. To provide ongoing support following implementation of new programs or modification to existing programs, the CDRH Audit Program conducts regular audits of the premarket review program, designed to encourage continuous improvements and identify potential

areas for modification; findings are discussed internally and shared during the MDUFA performance updates (e.g., quarterly, annually).

Alignment on Key Scientific and Regulatory Topics

FDA facilitates alignment on key scientific and regulatory topics across CDRH through Communities of Practice (CoP) and Rounds programs, promoting consistency in the regulatory approach across all regulated device types. CoPs are collaborative forums for “sharing information, experiences, and best practices” on a specific discipline, typically one that cuts across multiple device types in the MDUFA review program. Rounds are presentation forums, some of which are broader and others of which are focused on a specific scientific topic or regulatory program of interest. OPEQ Rounds is a recurring presentation series focused on initiatives, projects, or updates that impact MDUFA review programs (e.g., regulatory history of real-world evidence [RWE] and the RWE FPP). Sessions are open to all staff with materials made available internally following the session for future reference. TPLC Rounds is another recurring presentation series specific to the TPLC Program, an approach that enables FDA oversight over the full lifecycle of a device, from premarket review to post-market compliance monitoring.³² TPLC Rounds address cross-cutting issues such as innovative device technologies and challenging regulatory issues (e.g., Data Integrity). The Benefit Risk Rounds is a recurring presentation series focused on challenging benefit-risk case studies, allowing for learning opportunities for staff.

Alignment on Current or Future Processes and Procedures

CDRH uses working groups and other internal programs to align staff across OHTs on current or future processes and procedures and promote internal consistency. The Deficiency Letter Working Group supports efforts to improve the deficiency writing process, a key MDUFA V commitment, by identifying strong deficiency examples and communicating those via representatives from each OHT to promote alignment across various device types and expand the reference examples available to reviewers. CDRH also uses the Quality Management Program to facilitate the development, improvement and assessment of Center-wide review processes. The Premarket Redesign Working Group, a quality-related process improvement effort, identified premarket review program best practices and piloted those practices across other OHTs. Lastly, the CDRH Audit Program examines the impact of internal efforts to promote consistency.

Communication of Changes or Critical Information

To support clear communication of changes or critical information with impacts across multiple OHTs, CDRH leverages recurring meetings with managers and leadership to disseminate information. Manager meetings are used to discuss changes or critical information relevant to managers, providing managers with an overview of their role in facilitating enhancements, and supporting their role in providing oversight across implementation of MDUFA programs by providing transparent updates on key program information (e.g., year-to-date metrics reviews).

4.3.3. Conclusion

As part of the independent assessment, Booz Allen was tasked with assessing the methods of identifying and sharing best practices across OHTs. Booz Allen was not able to find additional practices beyond what FDA identified within an OHT that rose to the level of a best practice appropriate for broader application. CDRH already has its own mechanisms for the continuous identification and sharing of best practices and has implemented processes and communication mechanisms to support consistency in regulatory approach across all regulated device types and enhance organizational agility, resilience, and adaptability.

4.4. Deficiencies

FDA uses the Four-Part Harmony (4PH) framework to help FDA staff develop, and applicants respond to Deficiency letters. The MDUFA V commitments for deficiencies are focused on updating Part 3 of the 4PH, the statement of basis for the deficiency, and supervisory review responsibilities to promote clarity and consistency in the Deficiency guidance and to provide a statement of basis in an increasing percentage of marketing submission deficiencies.

³² Total Product Life Cycle for Medical Devices (<https://www.fda.gov/about-fda/cdrh-transparency/total-product-life-cycle-medical-devices>).

Booz Allen’s assessment of the effectiveness of the implementation and impact of changes to “Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions” (the Deficiency guidance) to meet MDUFA V commitments is presented in the sections:

- 4.4.1 Deficiency Guidance
- 4.4.2 Performance Goals

4.4.1. Deficiency Guidance

This section describes how FDA met the commitments shown in Table 4-9. The findings are described in the following sub-sections:

- 4.4.1.1 Updated Deficiency Guidance
- 4.4.1.2 Implemented Deficiency Guidance

4.4.1.1. Updated Deficiency Guidance

Statement of Basis and Supervisory Review Guidance Updates

FDA updated the Deficiency guidance to provide reviewers with clearer instructions for writing an effective statement of basis using the 4PH framework. The update aims to improve communication between FDA review staff and the industry sponsor by reducing miscommunication and providing industry with greater clarity regarding the premarket review process and potential application deficiencies. Additionally, FDA updated the Deficiency guidance to clarify the language for two of the four parts of the 4PH framework (i.e., Parts 2 and 3). Figure 4-4 reflects the language for the 4PH framework.³³

Table 4-9: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- By January 1, 2023, update the 2017 guidance “Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions; Guidance for Industry and FDA Staff” to clarify what constitutes a statement of the basis for the deficiency and continue alignment with the following:
 - Deficiency letters should include a statement of the basis for the deficiencies (e.g., a specific reference to applicable section of a rule, final guidance, recognized standard unless the entire or most of document is applicable). In the instance when the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, FDA will cite the specific scientific issue and the information to support its position.
 - Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cites are relevant to a marketing authorization decision (e.g., 510(k) clearance, PMA approval, and de novo classification).
- Train staff and managers on the updated guidance and work to make improvements (including incorporating best practices), to address findings from audits and consistent with the guidance.

³³ Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions: Guidance for Industry and Food and Drug Administration Staff (2022) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions>).

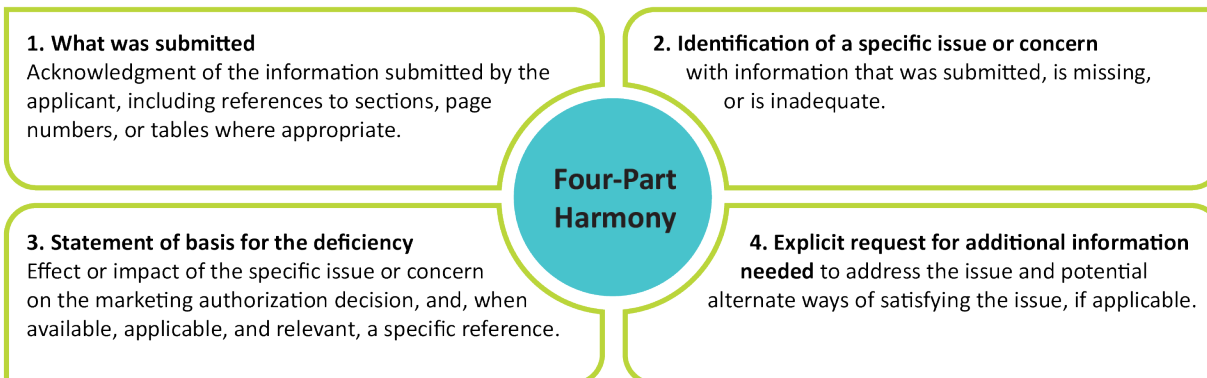


Figure 4-4: Four-Part Harmony Framework

FDA also updated the 2022 Deficiency guidance language, adding two footnotes clarifying the statement of basis criteria. The footnotes include language from the Deficiency guidance on how FDA defines the statement of basis and specific references. These changes further clarify how the statement of basis is written and referenced in Deficiency letters. In addition, FDA streamlined and clarified existing Appendix A examples (“Deficiency and applicant response examples”) in the guidance to improve consistent understanding of the 4PH criteria.³⁴

FDA aligned the Deficiency guidance with existing supervisory review principles, including specificity for references in Deficiency letters. Supervisory review of deficiency letters provides a quality control mechanism within CDRH's premarket review process, promoting consistency and regulatory compliance across all device evaluations. When a Lead Reviewer (LR) completes a review and develops a Deficiency letter, the supervisory reviewer conducts a secondary review to verify all identified deficiencies are appropriate, relevant, ordered by significance, and follow the 4PH framework. Although supervisory review previously existed in the premarket review process, CDRH clarified supervisory responsibilities around “specific references” in the 2022 Deficiency guidance.^{35, 36}

Additional Guidance Updates

Beyond the MDUFA V commitments described above, FDA made additional updates to the Deficiency guidance to better align with other relevant guidances issued since the last Deficiency guidance update in 2017. For example, the 2022 Deficiency guidance incorporates language and concepts from FDA’s Benefit-Risk guidances (issued in 2018 and 2019)^{37,38} and Uncertainty guidance (issued in 2019).³⁹ The updated guidance language summarizes why reviewers consider a device’s benefit, risk, and uncertainty profile to assess its safety and effectiveness during the review process.

³⁴ See footnote 33.

³⁵ Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions (2017) (<https://collections.nlm.nih.gov/catalog/nlm:nlmuid-101719811-pdf>).

³⁶ See footnote 33.

³⁷ Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-factors-consider-when-determining-substantial-equivalence-premarket-notifications-510k>).

³⁸ Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de>).

³⁹ Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de>).

4.4.1.2. Implemented Deficiency Guidance

Internal Procedural Documentation

CDRH updated internal procedural documents to guide reviewers and managers on writing deficiencies aligned with 4PH, the Deficiency guidance, and Least Burdensome Provisions, and communicated those changes to impacted staff (e.g., via email for minor updates and via OPEQ Rounds for major updates). For example, CDRH updated internal procedural documents used since MDUFA IV, to specifically reflect the Deficiency guidance updates described in Section 4.4.1.1 above (namely, the updated 4PH description and updates to support supervisory review). CDRH also updated internal procedure documents to address findings from the audit. For example, after reviewing audit results from FY23, CDRH updated internal procedure documents and training in FY24 to clarify that general statements in a Deficiency letter such as “does not function as intended” would not satisfy Part 3 criteria and would warrant detail specific to the device, resulting in increased clarity for the product sponsor while also maintaining Least Burdensome Provisions.

Deficiency Writing Tools

CDRH leverages SMART to reinforce deficiency writing principles by providing integrated references to regulations and guidances, example language, and access to relevant resources within the review workflow. For example, the deficiencies subsection pop-up message provides an overview of 4PH and links to internal procedural documents. To promote consistency across Deficiency letters, each SMART also contains multiple FPP Review Guides, containing specific guidance-based questions that, when answered as deficient, automatically ask the reviewer if they would like to add (into their SMART memo) the relevant FPP drafted Deficiency from the repository that applies to that specific question. Reviewers also use Correspondence Generator (CorGen), a tool that automatically generates Deficiency letters in the standard format. Deficiencies can be pulled directly from SMART memos into the standard format letter CorGen generates to minimize errors from copying deficiencies into the final letter. Using SMART in tandem with CorGen minimizes burden on review staff, promotes correct formatting of deficiencies in 4PH, and includes standardized, template language for every Deficiency letter issued.

Additionally, CDRH maintains a repository of over 300 new or updated example deficiencies across multiple cross-cutting TAs. This repository includes all the FPP drafted deficiencies referenced above (which reviewers can access via the FPP Review Guides in SMART), as well as other example deficiencies in other topics (not accessible in SMART). Reviewers can reference and customize the examples, promoting compliance with 4PH elements, encouraging consistency, reducing reviewer burden, and enhancing communication with sponsors. Focal Points, specialized reviewers with advanced training, develop example deficiencies and update them as needed to reflect evolving recommendations, including policy changes, reviewer feedback, audit results, new or revised guidance documents, and consensus standard revisions (e.g., ISO standards). CDRH convened cross-office working groups to develop new staff resources that meet to discuss how to effectively communicate concerns and focus on 4PH specific improvements in key example deficiency areas such as Biocompatibility, Sterility, Software, Cybersecurity, Electromagnetic Compatibility (EMC), Wireless, Chemistry/Toxicology, MR Safety, Labeling and Statistics. Newly developed example deficiencies undergo analysis prior to their release as a quality control mechanism and CDRH provides training when it updates deficiencies (e.g., new example deficiency, revisions based on reviewer feedback). CDRH attributes the increase in statement of basis performance (Section 4.4.2.1) to updated example deficiencies delivered from the cross-office working groups, particularly for biocompatibility and EMC, and wireless deficiencies.

Staff Training and Communication

The 4PH Team, comprised of lead reviewers and policy staff, developed a training on the updated 2022 Deficiency guidance titled “MDUFA V Deficiency Guidance Update: Clarifying Four-Part Harmony.” The training identified three objectives: (1) enable review staff to describe all elements of 4PH based on the guidance updates; (2) guide reviewers with identifying 4PH components subject to MDUFA performance goals (i.e., the statement of basis); and (3) teach review staff to recognize the two components of the statement of basis through clear instructions and examples. The training included updates to internal documents (e.g., SOPs, SMART; see Section 4.4.1.2). Training was mandatory for all review staff and management across CDRH. Training was administered to approximately 1,500 CDRH and CBER staff between November 1-December 14, 2022. CDRH reviewed questions from all sessions and provided in-depth responses to all review staff. CDRH has subsequently updated and delivered this training multiple

times (e.g., February 2023, March 2023, May 2023, January 2024) to incorporate changes to internal processes, findings from the annual audits, and lessons learned from reviewer experiences.

CDRH communicates updates to guidance, corresponding internal resources (e.g., procedural documents), upcoming and available trainings, and FAQs to reviewers via a weekly email sent to staff. CDRH incorporated deficiencies training into established training modalities. Training opportunities are described in Section 0. Table 4-10 lists the training opportunity and describes the deficiency-related content.

Table 4-10: Training Opportunities with Deficiencies-Related Content

Training Opportunity	Content
RCP	Deficiency-related trainings, e.g., Four-Part Harmony – The Basics, were updated to reflect the October 2022 guidance updates
OPEQ Rounds	Dissemination of information related to substantial guidance updates, available resources (e.g., Four-Part Harmony SOP) and tools (e.g., SMART)
Internal Webinars, Workshops, Presentations	(4PH team-hosted webinars and workshops) Opportunities to share deficiency examples and best practices specific to divisions, devices and teams and identify examples that can be integrated into OPEQ-wide resources

4.4.2. Performance Goals

This section describes how FDA met the commitments shown in Table 4-11. The findings are described in the sub-sections:

- 4.4.2.1 Statement of Basis Audits
- 4.4.2.2 Process Improvements

4.4.2.1. Statement of Basis Audits

Audit Methodology

To conduct the MDUFA V audits, auditors employ an independent parallel approach developed with input from the review program. Sample sizes for Deficiency letters audited each FY are determined in accordance with ISO 2859-1:1999, *Sampling procedures for inspection by attributes*. For each audited letter, auditors independently assess whether deficiencies cited in Original PMAs, Panel-Track Supplements, 510(k)s, and De Novo requests include a statement of basis for the deficiency that describes the effect or impact of the specific issue or concern on the regulatory decision. In instances where the auditors' independent assessments differ, a group of auditors convenes to review the deficiency in question and render a collective determination. The audit process includes a structured feedback cycle that enables SMEs and staff to request auditors' rationale for their determinations, and conversely, allows auditors to seek clarification from SMEs as needed. Audit results and associated audited letters are provided to the review program on a weekly basis to support ongoing process improvements.

Audit Results

FDA consistently met performance goals for the inclusion of a statement of basis in Deficiency letters from FY23 to FY25, with results improving each fiscal year, and surpassing the performance goal each year (Table 4-12). CDRH shared these results with industry no later than the first quarterly meeting of the following FY.

Table 4-11: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
• FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in Deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 2859-1:1999 ("Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection"). FDA will review each fiscal year's audit results with industry no later than the first quarterly meeting of the following fiscal year.

Table 4-12: Deficiency Letter Audits Overview

Audited PMA, Panel-Track Supplement, De Novo, 510(K)S Requests	FY23 AUDIT	FY24 AUDIT	FY25 AUDIT
MDUFA V Performance Goal (%)	75%	80%	85%
Audit Result: Percent of Deficiencies with a Statement of Basis (%)	78%	87%	90%
Number of Audited Letters	133	416	416
Number of Audited Deficiencies	610	1854	1824

4.4.2.2. Process Improvements

Supporting Activities Undertaken to Meet Performance Goals

From FY23 to FY25, CDRH implemented and maintained six core process improvement activities informed by audit data. Table 4-13 summarizes the status of each activity across this period, noting when it was implemented, updated, or maintained without major change.

Table 4-13: Overview of Supporting Activity Status Through MDUFA V

Activity	FY23	FY24	FY25
Audit Result Sharing	Implemented	Updated	Maintained
Audits for Improvement	Implemented	Maintained	Maintained
Collaboration and Communication	Implemented	Maintained	Maintained
Division Feedback	-	-	Implemented
Enhanced Resources	Implemented	Updated	Updated
Office Liaisons	Implemented	Maintained	Maintained
Training and Staff Development	Implemented	Updated	Maintained

FDA noted the combination of these process improvement activities as a driver for meeting performance goals during a MDUFA V quarterly meeting with industry on audit results:

- **Audit Result Sharing:** Since FY23, the audit team implemented reporting of results to the review program on a weekly basis. In FY24, auditors continued sharing weekly audit results with the review program through an internal tool, which tracks audits for number of letters, number of deficiencies, and the percentages of deficiencies including a statement of basis. CDRH made the tool accessible to all staff in July 2024, enabling individual staff members to access current performance results.
- **Audits for Improvement:** Auditors conducted additional assessments to support the review program's implementation of the MDUFA V Deficiency letters performance commitment. As part of the audits for improvement activities, auditors also review deficiencies included as part of the SMART Template. Significantly increasing the amount of information from audited letters, improvement audits provided additional granularity, facilitated earlier identification of best practices and areas of focus, and were used to validate implemented changes. In FY23, 78 FY22 MDUFA IV letters (426 deficiencies) and 317 additional MDUFA V letters (1348 deficiencies) were audited to support early implementation of the MDUFA V commitment. FDA found that 59% of the MDUFA IV deficiencies contained a statement of basis, setting a baseline for the MDUFA V audits.⁴⁰ Auditors continued the effort in FY24, auditing 799 additional letters (3,632 deficiencies) and

⁴⁰ November 20, 2025 (FY25 Q4) MDUFA V Performance Report (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/mdufa-reports>).

observed 87% of the examined deficiencies had a complete statement of basis.⁴¹ In FY25, FDA audited 849 additional letters (3,795 deficiencies). In total, the MDUFA V annual audit and the additional sample for FY25 totaled 1,265 letters (5,619 deficiencies) with 89% observed to have a complete statement of basis.⁴²

- *Collaboration and Communication:* In FY23, cross-office teams and SMEs started meeting regularly to discuss best practices for deficiency writing, while staff shared best practices within individual offices, divisions, and teams. In FY23, CDRH began regularly sharing information with review staff and managers via email announcements, including examples of audited deficiencies, explanations of the audit procedure, current deficiency performance, and encouragement to review and use key resources. Through FY25, cross-office working groups maintained regular meetings to share best practices on deficiency writing. These meetings resulted in the development and improvement of about 90 example deficiencies.
- *Division Feedback:* In FY25, CDRH conducted a survey of OHT divisions on high-priority areas for improvement related to internal resources and training. The survey received responses from 60% of divisions and the results were used to guide improvements to internal resources and training.
- *Enhanced Resources:* In FY23, CDRH increased the number of example deficiencies. The review program continued adding examples throughout FY24, focusing on TAs needing improvement (e.g., biocompatibility examples). CDRH expanded the 4PH office liaisons to include representatives in all OPEQ review divisions and continued monthly liaison meetings. Cross-office review teams and SMEs met regularly to discuss deficiency writing best practices, while staff shared best practices within individual offices, divisions, and teams. The review program updated training for new reviewers and provided targeted training to divisions and teams based on audit results. Throughout FY25, CDRH continued to improve internal resources as the foundation for success in meeting deficiency commitments (e.g., improvements to example deficiencies for biocompatibility and MR safety).
- *Office Liaisons:* In FY23, CDRH created 4PH office liaisons to serve as first-line resources for review staff. Selected liaisons were experienced deficiency writers who assisted their respective office staff with office-specific challenges and questions related to 4PH and deficiency writing. Through FY25, 4PH office liaisons continued to assist review staff with deficiency writing on an as-needed basis, offering feedback on whether deficiencies capture and address all 4PH components. Review staff are encouraged to contact 4PH office liaisons to assist in developing deficiencies, locating resources, and updating resources.
- *Training and Staff Development:* In FY23, CDRH provided additional training sessions (e.g., OPEQ Rounds, outreach training) to support staff following initial updated guidance training. In response to FY23 audit results indicating that deficiencies required additional clarification, CDRH updated training and internal procedures in January 2024. CDRH trained over 1,000 review staff and auditors to advance the shared goal of clear and least burdensome communication. While auditors used a similar audit methodology as FY23, they received updated training and began incorporating updated statement of basis criteria (Section 4.4.1.1) starting in March 2024. Additionally, in FY23, the 4PH Team began meeting with managers and staff individually as needed to help improve deficiency writing for teams and divisions.

Additional Metrics and Performance Tracking

Quality audits include additional metrics to support internal efforts, including performance by office, division, and team, and by deficiency category (e.g., biocompatibility). Auditors complete MDUFA V audits and audits for improvement, and report results on a weekly basis to the review program through an internal tool. The review program makes performance results available to all review staff and managers. Since FY23, auditors have assessed over 3,000 letters or 13,000 deficiencies, providing valuable data critical to process improvements efforts. Review staff also access audited letters to understand how auditors made determinations on specific deficiencies. The

⁴¹ November 22, 2024 (FY25 Q4) MDUFA V Performance Report (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/mdufa-reports>).

⁴² Ibid.

internal tool enables managers and staff to identify trends, track performance metrics, and identify areas for improvement and targeted feedback.

4.4.3. Conclusion

FDA met its MDUFA V deficiency-related commitments by updating the Deficiency guidance to incorporate streamlined and clarified language around statement of basis criteria and supervisory review responsibilities. To support implementation of the updated Deficiency guidance, CDRH systematically revised internal procedural documentation, and implemented mandatory staff training to provide updated support to reviewers as they write deficiencies. FDA committed to providing a statement of basis for deficiencies identified in Deficiency letters for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions, targeting 75% of deficiencies in FY23 and increasing by five percent annually to 95% by FY27. CDRH met its annual statement of basis performance targets each year from FY23 through FY25, supported by a structured audit process in which audit results and performance data were shared with review staff and managers on a weekly basis. The annual audit results and updates on supporting process improvement activities were presented to industry by the first quarterly meeting of the following FY (e.g., CDRH presented FY23 audit results in Q1 FY24).

4.5. Q-Submission Guidance

The Q-Submission Program provides mechanisms for submitters through which they can request interactions with FDA related to medical device submissions. MDUFA V commitments focus on updating the guidance “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” (Q-Submission guidance) to help applicants and review staff identify circumstances where informal communication is more appropriate than a

Pre-Submission, directing simple questions to informal channels while reserving formal Pre-Submissions for complex issues requiring documented feedback.⁴³

Booz Allen’s assessment of the effectiveness of the implementation and impact of changes to the Q-Submission guidance to meet MDUFA commitments (Table 4-14) is presented in this section:

- 4.5.1 Q-Submission Guidance Changes, Implementation and Impact

4.5.1. Q-Submission Guidance Changes, Implementation and Impact

Guidance Changes and Implementation

Q-Submissions encompass various types of submissions, including Pre-Submissions (Pre-Subs), Submission Issue Requests (SIRs), Study Risk Determinations, Informational Meetings, PMA Day 100 Meetings, etc. The bulk of Q-Submissions has historically been Pre-Submissions. Indeed, Pre-Submission volume has grown steadily across the MDUFA V period, rising from 3,843 submissions received in FY 2023 to 4,140 in FY 2024 and 4,429 in FY 2025. Despite this increasing workload, FDA has consistently met its Pre-Submission written feedback goals, achieving performance rates of 98.84%, 98.66%, and 97.44% in FY 2023, FY 2024, and FY 2025, respectively, against a 90% goal each year.⁴⁴

Table 4-14: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
• Pre-Submissions will be accepted in accordance with the Pre-Submission acceptance checklist described in FDA’s guidance “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” • By March 31, 2024, the Agency will issue draft guidance to update the guidance on “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant’s question is most appropriate for informal communication instead of a Pre-Submission. FDA will provide an opportunity for the public to comment on the updated guidance

⁴³ Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>).

⁴⁴ August 26, 2026 MDUFA V Performance Report (<https://www.fda.gov/media/194465/download?attachment>).

Pre-Submissions are accepted via the Pre-Submission acceptance checklist, which supports consistent evaluation of Pre-Submissions by establishing basic information needed when assessing if a submission qualifies as a Pre-Sub before entering formal review. In May 2025, FDA updated the acceptance checklist in the final Q-Submission guidance, under Appendix 1. Specifically, FDA updated the acceptance checklist by adding the word "focused" to Question 3 and adding "Accessory Classification Request" to Question 4.

For informal communications, the updated Q-Submissions guidance added Section II.H to help applicants and review staff identify when to use informal communications instead of submitting a Pre-Submission. This section lists examples of situations appropriate for informal interactions and identifies the communication channels available to applicants, including Division of Industry and Consumer Education (DICE), OPEQ Submission Support, the Device Advice website, and direct contact with reviewers. The guidance also recommends that Pre-Submissions include at most 7-10 questions and focus on 3-4 substantial topics to help facilitate more productive interactions and lead to more effective conversations and feedback. The updated Q-Submission guidance also expanded on the meaning of substantial topics to help clarify this term and improve broader Q-Submission Program understanding. While Pre-Submissions may include both complex and simpler questions, the guidance encourages sponsors to reserve the formal process for submissions that include substantial topics requesting documented feedback. Additionally, FDA updated Appendix 2, which is a list of example Pre-Sub questions, by adding a new category for Computational Modeling and Simulation questions and improving existing sample questions with examples of questions that FDA believes lead to more productive Pre-Sub interactions. To support these changes, the Agency updated internal processes to incorporate the new informal communication criteria and examples.

FDA published the draft Q-Submissions guidance on March 15, 2024, and provided a public comment period from March through May 2024. The Agency finalized the guidance on May 29, 2025, within 18 months of the comment period close, meeting all timelines. In support of the final guidance, FDA conducted staff training at OPEQ Rounds on June 9, 2025, covering the guidance updates and best practices for helping applicants determine the appropriate pathway for their request, i.e., a Q-Submission versus an informal interaction, and confirmed that review staff completed this training. FDA communicated that the Agency works with industry stakeholders on a case-by-case basis to help them determine the appropriate submission pathway.

Impact of Guidance Changes

To measure Pre-Submission alignment to the guidance, Booz Allen conducted a content analysis of 86, FDA-provided Pre-Submissions to determine whether submissions received after the guidance fell within scope of the guidance recommendations with regards to the number of questions and topics in submissions, if the questions were specific, in scope, or broad, and if the submissions included only questions better suited for informal communication. The analysis indicated appropriate alignment to the recommendations in the guidance. The reviewed submissions were well-scoped and focused, suggesting applicants understood and applied the criteria for determining the suitability of a formal Pre-Submission compared to an informal interaction with FDA.

As for informal communications, CDRH has various means to encourage informal communication between FDA and applicants. CDRH operates 15 specialized mailboxes, listed in Table 4-15, to allow the review programs to respond to sponsor inquiries across several TA related to medical device regulation. Across these mailboxes, CDRH responds to approximately 55,000 requests per year.

Table 4-15: Specialized Mailboxes that Facilitate Informal Communications

Mailbox	Focus Area for Inquiries and Requests
ccp@fda.hhs.gov	CCP (CDRH) Portal
cdrh-ecopyinfo@fda.hhs.gov	eCopy information and common eCopy issues
cdrhocimport@fda.hhs.gov	Import of medical devices
CDRH_PatientEngagement@fda.hhs.gov	Internal and external patient engagement
devicedetermination@fda.hhs.gov	Medical product determination and classification
Device.reg@fda.hhs.gov	Policy, registration and listing requirements and compliance

Mailbox	Focus Area for Inquiries and Requests
DICE@fda.hhs.gov	Medical devices and radiation-emitting products
digitalhealth@fda.hhs.gov	Digital health policy, regulatory status of digital health products, and digital health initiatives
exportcert@fda.hhs.gov	Export of medical devices
eSubPilot@fda.hhs.gov	eSTAR information
OPEQSubmissionSupport@fda.hhs.gov	Medical device submissions
reglist@cdhrh.fda.gov	Registration, listing, and use of FURLS/DRLM
RST_CDRH@fda.hhs.gov	CDRH Regulatory Science Tools (RSTs)
GUDIDSupport@fda.hhs.gov	Unique Device Identification Program
udi@fda.hhs.gov	Policies related to the Unique Device Identification Program

4.5.2. Conclusion

FDA has met both of its Q-Submissions guidance commitments. FDA continues to implement the Pre-Submission Program as described in the Q-Submission guidance and accept Pre-Submissions in accordance with the acceptance checklist. FDA also met the timeline for updating the guidance, to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission. Booz Allen's review suggests that Pre-Submissions received after guidance publication aligned with the guidance, as the provided submissions were appropriately scoped and focused, indicating that applicants understood and effectively applied the new criteria for determining when a formal Pre-Submission is appropriate. While FDA does not track informal communications, making direct analysis of their usage difficult, the content analysis supports that applicants are appropriately utilizing informal communication channels, as Pre-Submissions reviewed were well-aligned with the formal submission criteria outlined in the guidance. The full long-term impact of the guidance on resource utilization and applicant behavior will become clearer with continued monitoring over subsequent fiscal years.

4.6. Third Party Review Program

The Third Party Review Program allows accredited organizations (Third Parties) to conduct reviews of eligible 510(k) submissions. FDA recognizes qualified Third Parties to conduct reviews of low-to-moderate risk devices and make recommendations regarding substantial equivalence, with FDA retaining final decision-making authority. MDUFA V commitments for the Third Party Review Program focus on maintaining and refining training, communication, and performance transparency mechanisms to reduce routine re-review while upholding FDA standards.

Booz Allen's assessment of the effectiveness of the implementation and impact of changes to meet MDUFA commitments is presented in the following sections:

- Training for Third Parties
- Transparency and Communication
- Third Party Performance

4.6.1. Training for Third Parties

This section describes how FDA met the commitments shown in Table 4-16. The findings are described in the sub-sections:

- 4.6.1.1 Continue to Provide Training
- 4.6.1.2 Provide Tailored Retraining After Audit

Table 4-16: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
• Provide training for Third Parties seeking accreditation by FDA and provide them with access to redacted review memos • Audit and provide tailored re-training to accredited Third Parties based on the results of audits.

4.6.1.1. Continue to Provide Training

During MDUFA V, CDRH continued to deliver a training program that improved Third Party Review quality and efficiency. The program provides foundational training for organizations seeking accreditation and addresses performance gaps identified in the MDUFA IV business process improvement (BPI) analysis of 38 re-reviewed submissions. The curriculum covers foundational regulatory knowledge, device-specific modules (e.g., X-ray systems, dental devices, diagnostic ultrasound systems), specialized areas (e.g., radiological imaging analysis, labeling, cybersecurity management, human factors engineering), and access to redacted review memos. CDRH delivers training through multiple methods, preparing Third Parties to conduct FDA-equivalent reviews.

Training Content Development

Over MDUFA IV and V, CDRH developed materials, including 25 training videos, addressing basic device regulation principles to advanced technical specializations. SMEs, review divisions, program leadership, and DICE collaborated on content creation. Multiple interested parties review content at each stage to verify content meets program needs. This structured approach enables CDRH to develop targeted training that addresses gaps in technical expertise and review quality.

Training Delivery and Access

The training is designed to prepare all Third Parties for accreditation and to conduct 510(k) reviews.⁴⁵ The training consists of approximately 24 hours of modules that cover fundamental 510(k) review principles, FDA regulatory requirements, and device evaluation procedures. CDRH delivers these modules via live, instructor-led sessions and CDRH Learn self-paced sessions. Table 4-17 summarizes the key training requirements for Third Parties.⁴⁶

Table 4-17: Key Training Requirements

Requirement	Details
Personnel Certification	3P510k Review Organizations (ROs) must certify that designated personnel will attend FDA's training for recognition and re-recognition
Pre-Review Completion	The organization's most responsible person or designee(s) must complete FDA training prior to performing any reviews
Acceptance	FDA will not accept reviews and recommendations from 3P510k ROs that have failed to have at least one designated person attend an FDA training session for recognition
Ongoing Training	FDA addresses training needs on quarterly grading to meet statutory requirements

FDA also offers supplementary training to Third Parties, including device-specific training modules based on eligible product codes. FDA offers these as virtual or in-person training opportunities. During MDUFA V, FDA hosted the Third Party 510(k) Program Workshop at the White Oak Campus (May 2023). The workshop covered product code training for specific device categories, emerging technologies such as AI/ML, and regulatory process updates. FDA also provides live Q&A sessions via Zoom on an as-needed basis (per Third Party request), where expert panels address questions from Third Parties, and offers call-in numbers to accommodate international participants outside the U.S. Training materials remain available once posted and are updated as needed when policy changes occur, giving Third Parties continuous access to current information needed to perform FDA-comparable reviews.

Since 2019 and continuing under MDUFA V, FDA provides Third Parties with access to redacted review memos, recognizing that insight into historical review practices provides important information that helps Third Parties conduct FDA-equivalent reviews. FDA created a publicly accessible library focused on devices that tend to have a

⁴⁵ 510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review (2024 Guidance) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review>).

⁴⁶ 510(k) Third Party Review Program (for Third Party Review Organizations) (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>).

high volume of Third Party Review (e.g., surgical masks, vinyl patient examination gloves).⁴⁷ For additional redacted memos beyond those publicly available, Third Parties can request access through the Freedom of Information Act (FOIA) process. Outlined in the core training, this dual approach offers Third Parties access to common review examples and a formal process for requesting specific historical precedents, when needed to assist with completing review.

4.6.1.2. Provide Tailored Retraining After Audit

FDA conducts audits to assess Third Party submissions and compliance of Third Parties in the 510(k) review program. Via a partnership between multiple CDRH offices—ORP, OCEA, and Office of Inspections and Investigations—these audits evaluate organizational infrastructure, review processes, staff qualifications, and adherence to regulatory requirements through facility inspections and performance assessments. The audit framework establishes standardized procedures for conducting systematic evaluations, including grading Third Party submissions to assess quality and consistency, documentation requirements, and post-audit follow-up activities. The result is a routine monitoring mechanism that allows direct communication (e.g., review of quality grades, direct email/phone feedback from CDRH with suggestions).

On-site Audits of Third Party Facilities

The Office of Inspections and Investigations conducts inspections of Third Party facilities or their records on a periodic or for-cause basis between accreditation and reaccreditation. These audits assess conformance to the statute, regulations, and guidance to meet standards according to Section 523(b)(2)(C) of the Federal Food, Drug, and Cosmetic (FD&C) Act. The re-recognition process considers review performance, results from audits, documented procedures, and adherence to applicable statutes, regulations, and guidance. Auditors evaluate Quality Management Systems (e.g., complaint handling procedures, corrective action systems for identifying and preventing quality problems, and processes to monitor performance, including incorporation of CDRH feedback). These assessments provide insight that support a Third Party's ability to conduct FDA-equivalent reviews. As of FY25, no Third Parties have failed an on-site audit.

Audit of Third Party Submissions

CDRH's audit of Third Party Review submissions evaluates whether Third Parties perform FDA-comparable reviews. The four-part audit process – intake, triage, review, action – is a systematic performance monitoring and feedback process. This includes 1) data gathering from completed Third Party submissions; 2) collection of grading and additional feedback from CDRH reviewers; 3) analysis of performance trends across multiple submissions; and 4) communication of results to individual organizations through phone calls and follow-up emails. CDRH assesses submissions using a supervisory review memo, which provides consistent review of Third Party submissions determining if a submission is FDA-comparable requiring no re-review, or not FDA-comparable, requiring re-review.

Audit Results

Third Parties provided a Substantially Equivalent (SE) recommendation to 77 submissions in FY23 and 67 submissions in FY24. CDRH evaluates whether these reviews are comparable to FDA reviews, assigning grades based on the supervisory review memo. In both FY23 and FY24, most Third Party submissions were determined FDA-comparable (63.6% and 58.8%, respectively), while a smaller proportion were not (23.4% and 20.6%, respectively). However, some submissions could not be assessed during the reporting period, which reflects submissions that do not have a final MDUFA decision. These quality assessments should be considered alongside the publicly reported performance indicators (Section 4.6.3), including declining hold rates and improved review timeframes during MDUFA V. Together, these metrics suggest that while individual submission quality assessments may vary, the overall Third Party Review Program is achieving its performance objectives.

Tailored Retraining

⁴⁷ Review Memos for Third Party 510(k) Reviewers (<https://www.fda.gov/medical-devices/510k-third-party-review-program/review-memos-third-party-510k-reviewers>).

CDRH established document management procedures that track audit results, performance reports, and training records, allowing CDRH to identify Third Parties, as appropriate, with specific retraining needs. During the Action phase (the fourth and final step of the audit process), CDRH communicates reviewer grades and overall premarket review performance to Third Parties through phone calls and follow-up emails, including specific feedback on areas where Third Parties can improve review quality. When Third Party submissions are classified as "Not FDA-Comparable," CDRH provides targeted communication from CDRH review teams informing Third Parties of areas of the submission that warranted improvement or revisions, directing Third Parties to relevant training materials and resources to assist their future reviews (Sections 4.6.2.1 and 4.6.2.2). CDRH encourages Third Parties to engage proactively on the review process (e.g., by asking if they would benefit from additional interactions or retraining).

4.6.2. Transparency and Communication

This section describes how FDA met the commitments shown in Table 4-18. The findings are described in the sub-sections:

- 4.6.2.1 Conveyance of Device Type Expectations
- 4.6.2.2 Continued Use of Guidance for Third Party Eligibility

Table 4-18: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
• FDA will maintain a process to convey changes in expectations for a particular device type to the Third Parties and to industry • FDA will consider the factors described in the guidance, "510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review," in determining device type eligibility for the Third Party Review Program

4.6.2.1. Conveyance of Device Type Expectations

CDRH uses multiple communication channels and formal processes to keep Third Parties informed when expectations change, including newsletters, Early Interaction mechanisms, and formal meetings.

Newsletters

CDRH communicates with Third Parties through newsletters, providing updates on program developments, regulatory changes, and operational guidance. Recent newsletters offer a breadth of information, including announcements of new guidance documents (e.g., the 2024 guidance, guidance documents on topics such as cybersecurity and biocompatibility), mandatory implementation updates for eSTAR and CDRH Portal requirements, DI alerts and warning letters to testing laboratories, program personnel changes, re-recognition process updates and deadlines, submission formatting and organization instructions, clarifications on different types of 3P510(k) submissions (i.e., Traditional, Abbreviated, Special), and reminders about Early Interaction procedures with contact information. When FDA's expectations change (e.g., change in product code eligibility) newsletters direct Third Parties to relevant sources (e.g., updated guidance documents, product code classification databases, regulatory announcements). CDRH has established detailed procedures for determining these eligibility changes, applying the criteria described in Section 4.6.2.2.

Early Interaction Mechanisms and Formal Meetings

The Early Interaction (EI) mechanism allows Third Parties to communicate with CDRH through a dedicated email inbox during their review of a 510(k) submission. Third Party engagement with this pathway has increased over recent fiscal years. Before contacting FDA, however, CDRH expects Third Parties to conduct a review of available resources, including relevant guidance documents (both device- and topic-specific, such as biocompatibility, software, sterility), regulatory requirements for Class I and II devices, post-market databases for recalls and adverse events, premarket review information about predicate devices, and FDA-recognized consensus standards.⁴⁸ CDRH responds within seven calendar days through a structured process involving documenting incoming requests in FDA's Center Tracking System (CTS). CDRH has demonstrated improved performance in meeting its 7-day response timeline over the past three fiscal years. The Agency monitors its overall response timeline to keep communication

⁴⁸ Interacting Early with the FDA During a 510(k) Review (<https://www.fda.gov/medical-devices/510k-third-party-review-program/interacting-early-fda-during-510k-review>).

with Third Parties timely and effective. Beyond these EI opportunities, CDRH maintains additional formal communication channels with Third Parties and industry. CDRH holds regular meetings with Third Parties and industry upon request, and the Agency provides *ad hoc* interactions (e.g., meetings, emails, other communications) when needed.

4.6.2.2. Continued Use of Guidance for Third Party Eligibility

CDRH's approach to managing device type eligibility evolved during MDUFA V with the release of updated guidance that clarifies eligibility factors and expands program scope. This guidance identifies the criteria used to evaluate Third Party appropriate device types but also introduces new program elements and operational improvements.

Guidance Factors and Eligibility Criteria

During MDUFA V, FDA published the November 2024 final guidance titled, "510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review" which superseded the 2020 Program guidance.⁴⁹ The guidance describes expectations for the Third Party EUA Review program alongside the existing 3P510(k) Review Program, reflecting lessons learned from the COVID-19 pandemic and new legislative authority under the Prepare for and Respond to Existing Virus, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) of 2022. The 2024 guidance lists the factors that determine device type eligibility in the 3P510(k) Review Program, including device risk, life sustaining/supporting characteristics, extent of device understanding and available information, review complexity, and whether the device is the subject of a safety signal. Specific to device types that rely on clinical data, the 2024 guidance states, "if a device type contains simple clinical data such as sample clinical images or tests using banked specimens, it may be eligible for 3P510(k) review," and that "most *in vitro* diagnostic products are eligible for 3P510k review." CDRH periodically reviews new device types using factors described in the 2024 guidance and then updates the product code classification database and list of devices eligible for Third Party Review accordingly. Examples of device types that rely on clinical data that are eligible for Third Party Review include those listed under product codes LLZ (radiological image processing), DQD (electronic stethoscope), and DXN (blood pressure measurement system). The 2024 guidance also introduced formal EI response timelines detailed in Section 4.6.2.1, reinforced the expected use of eSTAR for 510(k) submissions, and simplified processes by utilizing the CDRH Portal.

4.6.3. Third Party Performance

CDRH publishes performance metrics of accredited Third Parties with at least five complete submissions on FDA's website. The purpose is to increase transparency in the premarket review program and provide insight into the overall effectiveness of the program. This section describes (1) publishing performance of Third Parties with at least five completed submissions and (2) publishing performance metrics and trends (Table 4-19).

Table 4-19: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
Publish performance of individual accredited Third Parties with at least five completed submissions on FDA's website

Publishing Performance of Third Parties with at Least Five Completed Submissions

CDRH publishes aggregate metrics, and metrics for Third Parties that completed five or more submissions. There were nine active Third Parties in FY23, and seven in FY24 and FY25. For FY23-FY25, FDA published performance data for two organizations that performed between 94-97% of all Third Party reviews. In addition, CDRH publishes performance indicators quarterly for organizations meeting the five-submission threshold, including rates of Not Substantially Equivalent (NSE) decisions, rates of SE decisions, average time to SE decisions and additional metrics such as total review times and decision timelines. Table 4-20 describes these in more detail.

⁴⁹ See footnote 45.

Table 4-20: Selected Third Party Performance Metrics

Metric	Definition
Initial Third Party Review Time	Elapsed time in days for a Third Party to review the 510(k) Submitter's file and determine its decision recommendation (SE or NSE).
Third Party Hold Time	Elapsed time in days for the Third Party to respond to a request for additional information from FDA.
Total Third Party Review Time	Elapsed time in days for a Third Party to review a file from a 510(k) Submitter, including hold time.
Total FDA Review Time	Elapsed time in days for FDA to provide a final MDUFA V decision (30 days by statute). The time does not include the number of days that a submission is on hold waiting for additional information from the Third Party.
TTD from FDA Receipt	Elapsed time in days between FDA's receipt of a Third Party submission and FDA's final MDUFA V decision including hold time.
TTD from Third Party Receipt	Elapsed time in days for FDA and a Third Party to provide a final MDUFA V decision (SE or NSE), which spans the entire lifecycle of a Third Party submission.

Publishing Performance Metrics and Trends

As of December 9, 2025 the Third Party Review Program improved "Average Initial Third Party Review Time," "Average Third Party Hold Time," "Average Total Third Party Review Time," "Average Total Time to Decision from Third Party Receipt," and "Average Total Third Party Review Time" (158 days FY23, 149 days FY24, 113 days FY25). "Average Total FDA Review Time" decreased from 31 (FY23) to 27 days (FY25).⁵⁰ See Figure 4-5 for Initial and Total Third Party Review Time and TTD trends.



Figure 4-5: TTD from FDA Receipt (left) and Initial and Total Third Party Review Time (right)

*Cohort for FY25 is not closed and therefore data is subject to change, as of 12/9/25, 50/67 submissions had a final decision

⁵⁰ 510(k) Third Party Performance Metrics and Accreditation Status (<https://www.fda.gov/about-fda/cdrh-transparency/510k-third-party-performance-metrics-and-accreditation-status>).

Training Effectiveness and Outcomes

Third Party performance improved during MDUFA V, with gains across three key metrics: 30-FDA Day review goal, re-review rates, and hold rates.⁵¹ By statute, FDA has 30 days to concur with the decision, reverse it, or place the submission on hold. The 30-day goal is calculated as the percentage of Third Party submissions that receive final decisions (SE or NSE) within 30 FDA days, divided by the number of submissions with MDUFA final decisions, excluding withdrawn, deleted, or other non-MDUFA decisions and pending submissions. FDA met the review goal for 85% of Third Party reviews under MDUFA IV (FY18-22, weighted average of 394 total submissions with final decisions). Under MDUFA V, performance remained consistent: 87% in FY23 (68 submissions), 84% in FY24 (61 submissions), and 85% in FY25 (46 submissions) (Table 4-21).

A decision reversal occurs when CDRH's supervisory review process identifies issues requiring additional scrutiny of the Third Party's SE recommendation. The decision reversal rate is calculated as the number of non-SE outcomes (NSE decisions plus withdrawn, deleted, or other administrative outcomes) divided by the total number of Third Party SE recommendations with final decisions. Decision reversal rates averaged 12.18% under MDUFA IV (FY18-22, weighted average based on 394 submissions). Under MDUFA V, decision reversal rates averaged 16.88% in FY23 (13 out of 77 submissions), 10.45% in FY24 (7 out of 67 submissions), and 8.00% in FY25 (4 out of 50 submissions), demonstrating improvement in re-review rates during MDUFA V. A hold occurs when FDA pauses the 30-day review clock to request additional information from Third Parties before completing their review. Hold rates improved during MDUFA V, declining from a MDUFA IV weighted average of 0.41 holds per submission to 0.25 in FY23, increasing slightly to 0.28 in FY24, and declining to 0.20 in FY25 (Table 4-21).

Table 4-21: Third Party Review Performance Metrics

Metric	FY18-FY22 MDUFA IV Avg	FY23	FY24	FY25*
Meeting 30 FDA Day Goal	85%	87%	84%	85%
Decision Reversals	12.18%	16.88%	10.45%	8.00%
Holds per Submission	0.41	0.25	0.28	0.2

* Subject to change as data is presented up to 9/30/2025 which is not a complete cohort.

4.6.4. Conclusion

FDA met all five MDUFA V commitments for the Third Party Review Program. FDA developed and delivered a training program with access to 25 training videos, as well as access to redacted review memos through a publicly accessible library and the FOIA process. FDA conducted systematic audits using a four-part process and provided tailored retraining based on audit results, with most Third Party submissions determined FDA-comparable in FY23 and FY24. FDA maintained multiple communication channels including quarterly newsletters and EI mechanisms with seven-day response timelines to convey changes in device type expectations to Third Parties and industry. FDA also released the November 2024 final guidance, "510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review," superseding the 2020 guidance. FDA published quarterly performance reports for individual Third Parties with at least five completed submissions, tracking key metrics that demonstrated program improvements during MDUFA V, including average total Third Party Review time falling from 158 days to 113 days. Together, these performance measures demonstrate that the Third Party Review Program is achieving its objectives and advancing the goal of eliminating routine re-review while maintaining FDA standards for quality and consistency.

4.7. Digital Health Program

Under MDUFA IV, FDA established the Digital Health Center of Excellence (DHCoE) to foster responsible and high-quality DH innovation. DHCoE supports efforts to bring safe and effective technologies to market in the rapidly evolving DH technology landscape by 1) building partnerships with internal and external stakeholders to accelerate

⁵¹ See footnote 50.

DH advancements and advance international harmonization; 2) sharing knowledge through guidance documents, training opportunities, and other shared resources to increase understanding and promote best practices; and 3) streamlining and aligning regulatory processes by innovating new approaches, such as developing novel frameworks tailored for digital health technologies. The MDUFA V commitments focus on building and sustaining technical expertise in software and emerging DH technologies while strengthening staff training and consistency, advancing international harmonization, publishing and finalizing key guidance documents and engaging a broad range of stakeholders.

Booz Allen’s assessment of the effectiveness of the implementation and impact of changes to meet MDUFA V commitments is presented in the following sections:

- 4.7.1 Continued Development of Digital Health Expertise to Support Review
- 4.7.2 Continue to Support Review of Digital Health Premarket Submissions
- 4.7.3 Engagement to Explore Regulatory Approaches to Digital Health

4.7.1. Continued Development of Digital Health Expertise to Support Review

This section describes how FDA met the commitments (Table 4-22) to maintain and develop DH expertise supporting consistent evaluation of DH submissions and staff understanding of DH topics.

Provide Training to FDA Staff

CDRH incorporated DH training into established training modalities, described in Section 4.2. Table 4-23 also lists DH-related content.

Table 4-22: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section	
•	Continue to develop software and digital health technical expertise to provide assistance for premarket submissions that include software, interoperable devices, or otherwise incorporate digital health technologies, such as artificial intelligence or machine learning (AI/ML), Virtual, Mixed, and Augmented Reality (VR/MR/AR) and wearables
•	Strengthen efforts to expand staff understanding of digital health topics and enhance consistent evaluation in submissions through training and internal infrastructure (e.g., Focal Point Program)

Table 4-23: Training Opportunities with Digital Health-Related Content

Training Opportunity	Content
FPP	• Software Review, DH guidances (Device Software Functions, Mobile Medical Apps, AI PCCP), AI Review (including Advanced Training)
ELP	• Data: Building real-world data ecosystems with AI; managing data, validating, and deploying research models • Development: platform architecture, design controls, and risk management for medical device software • Patient experience: Connected Health at home; patient and caregiver experiences of home use digital health technologies, how to design devices for usability, and the application of AI to build scalable solutions • Devices: surgical robotic devices
OPEQ Rounds	• AI/ML PCCPs • Review of January 2026 updates to “General Wellness: Policy for Low Risk Devices” and “Clinical Decision Support Software” guidances.
Internal Webinars, Workshops, Presentations	• AI Seminar Series; Policy Learning Sessions (e.g., Good Machine Learning Practice (GMLP), AI/ML Development Lifecycle, Red-Teaming for GenAI); AI/ML, AR/VR, and Interoperability working groups; guidance and policy roundtables; AI/ML Reviewer Help Hours; DH Glossary

Engagement with External Experts

DHCoE continues to maintain the Network of Digital Health Experts (NoDEX), comprised of over 80 vetted external experts from partner organizations.⁵² These experts possess recognized expertise and leadership in DH subfields, including AI, physiologic sensors and wearables, digital therapeutics, software engineering, RWE, mobile networks and wireless communication, cybersecurity, and digital biomarkers. The Network shares knowledge and experience on DH issues with FDA staff on an as-needed basis. To ensure impartiality, FDA requires these experts to file conflict of interest forms.

4.7.2. Continue to Support Review of Digital Health Premarket Submissions

This section describes how FDA met the commitments in Table 4-24. The findings are described in the sub-sections:

- 4.7.2.1 Consults
- 4.7.2.2 Guidances
- 4.7.2.3 International Harmonization
- 4.7.2.4 Tools to Support Digital Health Submissions

4.7.2.1. Consults

DHCoE provides consult services across three areas: Software, DH Policy, and AI/ML (including PCCPs), and maintains a database of all premarket submission consults, tagged by topic and device function. To ensure consistency, DHCoE employs several processes, including peer review and leadership concurrence on consults and weekly DH Consult office hours, where consults under review or recently completed are discussed. DH consults increased more than tenfold from FY18 to FY25. This growth reflects the expanding role of DH expertise supporting more than 5,000 medical device submissions with DH considerations received by FDA since FY18. Further, submissions with PCCPs reviewed by DH consultants increased 114% in FY24 compared to FY23 and 193% in FY25 compared to FY24.

FDA captures lessons learned and feedback from consults to assess training effectiveness and inform programs. Mechanisms for this include weekly DH Consult office hours, analysis of deficiencies for AI-enabled device reviews, and Digital Health Focal Point meetings that examine recent reviews. Recurring questions from reviewers in consult requests drive training initiatives.

4.7.2.2. Guidances

Content of Premarket Submissions for Device Software Functions

On June 14, 2023, FDA met its commitment by issuing the final guidance, "Content of Premarket Submissions for Device Software Functions."⁵³ The guidance introduced a risk-based approach (i.e., "Documentation Level" framework), with two documentation levels, Basic and Enhanced. It identifies the recommended software documentation elements, acknowledges modern development practices by allowing additional forms of software requirements (e.g., use cases and textual descriptions), and harmonizes terminology with international consensus standards. The guidance recommends an option for sponsors to provide a Declaration of Conformity to specific clauses of the FDA-recognized version of ANSI/AAMI/IEC 62304 in lieu of additional documents for certain elements.

Table 4-24: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Continue to develop software and digital health technical expertise to provide assistance for premarket submissions that include software, interoperable devices, or otherwise incorporate digital health technologies, such as artificial intelligence or machine learning (AI/ML), Virtual Mixed, and Augmented Reality (VR/MR/AR) and wearables
- Finalize the draft guidance, "Content of Premarket Submissions for Device Software Functions," by 18 months from close of the comment period
- Publish draft guidance describing a process to evaluate a predetermined change control plan for digital health devices
- Continue to participate in international harmonization efforts related to digital health, including work on developing software and other digital health convergence efforts

⁵² Network of Digital Health Experts (<https://www.fda.gov/medical-devices/digital-health-center-excellence/network-digital-health-experts>).

⁵³ Content of Premarket Submissions for Device Software Functions (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions>).

To support interested parties, FDA hosted a webinar on July 20, 2023, to explain how FDA incorporated feedback on public comments that requested more clarity, flexibility, and examples. In response to comments, the Agency simplified documentation level considerations, increased the number of examples from 5 to 27, revised recommendations for combination products, and provided new architecture diagram examples. To facilitate a smooth transition, FDA utilized a 60-day transition period and provided updated eSTAR versions and educational materials on CDRH Learn.

Predetermined Change Control Plans for Digital Health Devices

FDA's work on PCCPs involved multiple publications. The Agency published a draft guidance on April 3, 2023 (i.e., "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions"),⁵⁴ incorporating relevant feedback from the 2019 discussion paper and 2021 AI/ML Action Plan. FDA finalized the guidance in December 2024 and updated it in August 2025. The guidance incorporated stakeholder feedback (e.g., marketing submission types, device labeling, types of modifications). It identifies three recommended types of modifications: improvements to quantitative performance specifications, changes to device inputs and compatibility, and modifications to device use and performance. FDA hosted a webinar January 2025 on the final guidance to support implementation. The webinar materials were made available on CDRH Learn and the FDA YouTube channel, encouraging manufacturers to engage early through the Pre-Submission process.⁵⁵

4.7.2.3. International Harmonization

International Medical Devices Regulators Forum

As a member of the International Medical Devices Regulators Forum (IMDRF), FDA co-chairs the Software as a Medical Device and the AI/ML-enabled Medical Devices working groups (WGs). IMDRF established the Software as a Medical Device WG in 2022 to enhance existing technical documents. It established the AI/ML WG in 2023 to develop harmonized GMLP principles. The Software as a Medical Device WG developed the technical document "Characterization Considerations for Medical Device Software and Software-Specific Risk."⁵⁶ Following a public consultation period that began in May 2024, FDA published the final document in January 2025. The document provides a harmonized framework for the risk characterization of medical device software, establishing common vocabulary and a consistent approach to promote transparency and safety across the TPLC. The WG also developed the draft technical document "Essential Principles and Content of Predetermined Change Control Plans," which was posted for public consultation in October 2025 and was published in final form in August 2026.^{57,58}

The AI/ML WG, which FDA co-chairs with the UK's Medicine and Healthcare Products Regulatory Agency (MHRA), developed the "Good machine learning practice for medical device development: Guiding principles"⁵⁹ document. After public consultation in July 2024, IMDRF published the final form in January 2025 and identified ten guiding principles for the development of AI/ML-enabled devices.⁶⁰ These principles serve as a call to action for international

⁵⁴ Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence>).

⁵⁵ Webinar - Final Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (<https://www.fda.gov/medical-devices/cdrh-new-news-and-updates/webinar-final-guidance-marketing-submission-recommendations-predetermined-change-control-plan>).

⁵⁶ Characterization Considerations for Medical Device Software and Software-Specific Risk (<https://www.imdrf.org/documents/characterization-considerations-medical-device-software-and-software-specific-risk>).

⁵⁷ Essential Principles and Content of Predetermined Change Control Plans (<https://www.imdrf.org/documents/essential-principles-and-content-predetermined-change-control-plans>).

⁵⁸ Consultation - Essential Principles and Content of Predetermined Change Control Plans (<https://www.imdrf.org/consultations/essential-principles-and-content-predetermined-change-control-plans>).

⁵⁹ Draft – Good Machine Learning Practice for Medical Device Development: Guiding Principles (Government of Canada <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/good-machine-learning-practice-medical-device-development.html>).

⁶⁰ Good Machine Learning Practice for Medical Device Development: Guiding Principles (<https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles>).

standards organizations, regulators, and collaborative bodies to advance GMLP through research, educational resources, international harmonization, and consensus standards development. The WG also developed the draft technical document "Technical Framework for Artificial Intelligence Life Cycle Management," and released it for public consultation in April 2026.⁶¹

Other Collaborations

Through trilateral collaboration with the UK's MHRA and Health Canada, the agencies published guiding principles for PCCPs in October 2023 titled, "Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles" to address regulatory challenges of rapid AI/ML development, and "Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles" building on GMLP principles and promoting transparency and human-centered design in June 2024.^{62,63}

FDA also engaged in other collaborative efforts to advance the use of AI in healthcare. For example, for the May 2023 Veterans Cardiac Health and AI Model Predictions (V-CHAMPS) Challenge, DHCoE collaborated with the Veterans Health Administration and the UK MHRA to solicit public development of AI/ML models for predicting cardiovascular outcomes.⁶⁴ Additionally, FDA is involved in the GMLP Work Team of the AI Global Healthcare Initiative, an alliance of industry, providers, and regulatory agencies.⁶⁵ FDA also co-organized the February 2024 AI Regulatory & International Symposium (AIRIS) with the Ministry of Food and Drug Safety of the Republic of Korea to develop collaborative AI regulatory frameworks and examine case studies of AI implementation.⁶⁶

4.7.2.4. Tools to Support Digital Health Submissions

Digital Health Policy Navigator

In September 2022, FDA created the DH Policy Navigator to help product developers understand whether a software function falls under the Agency's regulatory oversight as a device.⁶⁷ The interactive tool provides an overview of DH policies, accounting for changes from the 21st Century Cures Act, as well as current final guidance documents, and guides users through seven steps with questions about their product's software functions. Based on the user's answers, the Navigator provides one of three possible outcomes for a given software function: 1) likely not a device, 2) likely that FDA intends to exercise enforcement discretion, or 3) likely the focus of FDA's regulatory oversight. The tool helps users identify relevant laws and policies but does not provide a formal FDA device determination.

Regulatory Accelerator

In July 2025, DHCoE launched the Regulatory Accelerator,⁶⁸ a resource designed to help innovators navigate the regulatory process, with the goal of facilitating more complete submissions, efficient reviews, and timely patient access to safe and effective devices. The accelerator includes two resources: 1) the Resource Index for DH Device Innovators, a visual guide to FDA tools, engagement opportunities, and guidance documents organized by the stages of the product development lifecycle; and 2) the Medical Device Software Guidance Navigator, helping innovators identify relevant FDA guidance for their submissions by mapping to relevant sections of the eSTAR template and embedding applicable resources such as specialty programs and FAQs. In addition, FDA offers Orientation Meetings, an interactive review mechanism for sponsors to provide an overview and demonstration of their device early in the

⁶¹ Technical Framework for Artificial Intelligence Life Cycle Management (<https://www.imdrf.org/consultations/technical-framework-artificial-intelligence-life-cycle-management>).

⁶² Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles (<https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles>).

⁶³ Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles (<https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles>).

⁶⁴ The Veterans Cardiac Health and AI Model Predictions (V-CHAMPS) Challenge (<https://precision.fda.gov/challenges/31/intro>).

⁶⁵ AI Global Healthcare Initiative – Healthcare Products Collaborative (<https://healthcareproducts.org/ai/aighi/>).

⁶⁶ AIRIS.

(https://www.mfds.go.kr/eng/brd/m_61/view.do?seq=162&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=9).

⁶⁷ Digital Health Policy Navigator (<https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator>).

⁶⁸ Regulatory Accelerator (<https://www.fda.gov/medical-devices/digital-health-center-excellence/regulatory-accelerator>).

review process. These meetings give sponsors a dedicated forum to present innovative software functions that are difficult to convey in writing, while helping the FDA review team develop a thorough understanding of the technology under review. To guide sponsors in preparing for these meetings, FDA published a "Best Practices"⁶⁹ webpage.

Enhanced Digital Health Page

DHCoE continued to maintain FDA's public-facing DH website, which serves as a central resource hub, publishing infographics with questions for healthcare professionals and patients to consider when deciding whether to use medical extended reality technology.⁷⁰ For example, FDA created two infographics on medical extended reality (XR), one for patients and one for healthcare professionals. These resources provide questions to consider when deciding whether to use the technology and encourage review of device labeling to understand the benefits and risks as these technologies evolve. In addition, FDA developed a cybersecurity infographic highlighting the medical device cybersecurity team's 10-year contributions to patient safety, including 17 safety alerts, 479 vulnerabilities, 13 cybersecurity incidents, 31 cybersecurity resources, and 68 cybersecurity-related recalls.

Authorized Medical Device Lists

FDA continued to maintain and expand publicly available lists of medical devices, which have been authorized by FDA. FDA released the AR/VR Medical Devices List in December 2022 and the sensor-based DH technology (sDHT) Medical Devices List July 2025.⁷¹ FDA provides periodic updates to the lists (i.e., most recently June 2026). As of June 2026, FDA's list includes 1,524 AI-enabled, 115 AR/VR, and 269 sDHT medical devices.

Digital Health Inbox

FDA maintains the DH Inbox⁷², where experts answer questions from industry, patients, providers, and stakeholders. This provides informal, non-binding feedback on regulatory considerations related to DH policy. Stakeholders use resources like the DH Policy Navigator as a starting point before contacting FDA for additional clarification.

CDRH Learn

FDA maintains CDRH Learn,⁷³ a platform for industry, healthcare professionals, and the public. Interactive modules cover device and radiation-emitting product regulations, guidances, and policies across the total product life cycle. CDRH Learn includes training modules on digital health topics such as clinical decision support software, content of premarket submissions for device software functions, cybersecurity, design considerations for interoperable medical devices, marketing submission recommendations for PCCPs for AI-enabled devices, and the Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot.⁷⁴

4.7.3. Engagement to Explore Regulatory Approaches to Digital Health

This section describes how FDA met the commitments in (Table 4-25).

Table 4-25: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Engage with stakeholders, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approaches to digital health technologies

Partnership Collaborations

DHCoE forms partnerships with external stakeholders to advance healthcare through knowledge-sharing and alignment of

⁶⁹ Best Practices (<https://www.fda.gov/medical-devices/regulatory-accelerator/best-practices-early-orientation-meetings-marketing-submissions-medical-device-software>).

⁷⁰ Augmented Reality and Virtual Reality Medical Devices: Questions to Consider (<https://www.fda.gov/medical-devices/digital-health-center-excellence/augmented-reality-and-virtual-reality-medical-devices-questions-consider>).

⁷¹ AR/VR Medical Devices List (<https://www.fda.gov/medical-devices/digital-health-center-excellence/augmented-reality-and-virtual-reality-medical-devices>).

⁷² Digital Health Inbox (<https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-frequently-asked-questions-faqs>).

⁷³ CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>).

⁷⁴ TEMPO for Digital Health Devices Pilot (<https://www.fda.gov/medical-devices/digital-health-center-excellence/tempo-digital-health-devices-pilot>).

regulatory approaches (Table 4-26).⁷⁵ Collaborations are facilitated through mechanisms such as the Centers of Excellence in Regulatory Science and Innovation (CERSIs), bringing together FDA and academic partners to advance regulatory science through research. FDA also participates in Collaborative Communities such as the Digital Health Measurement Collaborative Community (DATAcc), the Connected Health Collaborative Community (CHcc), and the Pathology Innovation Collaborative Community (PIcc) to support collaboration across public and private sectors. Table 4-26 lists examples of FDA’s collaborative research efforts.

Table 4-26: Examples of FDA Collaborations

Collaborator	Collaboration
Johns Hopkins CERSI	Assessing the Robustness of Clinical Machine Learning Models to Changes in Context of Use
UCSF/Stanford CERSI	Developing Data Science Methods for Post-marketing Surveillance of AI Diagnostic Tools and Algorithm-Based Therapeutics
Yale/Mayo CERSI	Informing labels of AI/ML-Based Software to Enable Transparency and Trust for Cardiac Monitoring and Diagnostics
Research Triangle CERSI	Assessing how Digital Health Technologies Can Be Used as Digital Biomarkers to Measure Aspects of Opioid Use Disorder
Research Triangle Institute	Evaluating Benefit Risk Preferences for the Use of AI and Machine Learning in Imaging Diagnostics
American Academy of Ophthalmology	Studying AI/ML-Based Diabetic Retinopathy Screening Devices Real World Performance
DATAcc	Developing Core Digital Measures in Disease Areas such as Mental Health and Pediatric Rare Disease

Digital Health Advisory Committee (DHAC)

FDA established DHAC in October 2023 to foster collaboration with patient groups, industry, and academia on digital health technologies. DHAC consists of voting members who are qualified experts in various DH fields and hosted its first in-person meeting November 2024, centered on TPLC considerations for Generative AI-enabled devices. During the November 2024 meeting, FDA discussed AI regulatory approaches and oversight, challenges and evidence-based needs. FDA also sought input on premarket performance evaluation, risk management, and post-market performance monitoring.⁷⁶ A subsequent virtual meeting on November 6, 2025, focused on Generative AI-Enabled Digital Mental Health Devices, where the Committee discussed benefits, risks, and premarket and post-market monitoring considerations.⁷⁷ The DHAC meetings serve as a space where various stakeholder perspectives converge to provide advice and recommendations on the development, evaluation, risks, barriers, and innovation of DHTs.

Publications

FDA publishes stakeholder-related findings and strategies related to AI/ML development (e.g., “Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together”) to outline its cross-agency strategy to foster collaboration with patient groups, industry, and academia on AI/ML products. The Agency published findings from an October 2021 workshop on the transparency of artificial intelligence/machine learning-enabled medical devices in a 2024 *npj Digital Medicine* article synthesizing perspectives on transparency for AI/ML-enabled

⁷⁵ Digital Health Research and Partnerships (<https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-research-and-partnerships>).

⁷⁶ November 20-21, 2024: Digital Health Advisory Committee Meeting Announcement (<https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-20-21-2024-digital-health-advisory-committee-meeting-announcement-11202024>).

⁷⁷ November 6, 2025: Digital Health Advisory Committee Meeting Announcement (<https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-2025-digital-health-advisory-committee-meeting-announcement-11062025>).

devices.^{78,79} The Agency published a discussion paper to obtain public feedback on premarket and post-market assessment of Generative AI-enabled devices.⁸⁰ The Agency also published a document outlining key considerations related to development and use of digitally derived measures (DDMs) in clinical investigations.⁸¹

4.7.4. Conclusion

FDA successfully met its MDUFA V commitments, strengthening consistent and efficient regulatory oversight, developing internal expertise, maintaining DH tools, and expanding stakeholder and international engagement. FDA implemented training programs, including FPP and ELP to enhance staff understanding and consistent evaluation of DH submissions. FDA finalized guidances on Device Software Functions and PCCPs and launched programs (e.g., Regulatory Accelerator) and advanced stakeholder engagement by establishing the DHAC and other public forums. Concurrently, FDA fulfilled its international harmonization commitment by co-chairing key IMDRF WGs and collaborating with global partners to align regulatory approaches.

4.8. Patient Science and Engagement Program

Under MDUFA IV, CDRH established the Patient Science and Engagement (PSE) Program with the mission to engage with patients, understand their perspective, and proactively integrate their perspectives into the TPLC of medical devices. MDUFA V commitments focus on expanding patient science expertise, supporting the integration of patient perspectives into medical device development and promoting research and innovation.

The assessment findings are presented in three sections:

- 4.8.1 Patient Science Expertise and Support
- 4.8.2 Supporting the Integration of Patient Perspectives into Medical Device Development and
- 4.8.3 Promoting Research and Innovation

⁷⁸ Artificial Intelligence and Medical Products (<https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-medical-products>).

⁷⁹ Transparency of artificial intelligence/machine learning-enabled medical devices (<https://www.nature.com/articles/s41746-023-00992-8>).

⁸⁰ Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper and Request for Feedback (<https://www.fda.gov/medical-devices/digital-health-center-excellence/considerations-regulation-generative-ai-enabled-medical-devices-discussion-paper-and-request>).

⁸¹ Key Considerations for the Development and Use of Digitally Derived Measures for Clinical Investigations, FDA Paper (<https://www.fda.gov/medical-devices/digital-health-center-excellence/key-considerations-development-and-use-digitally-derived-measures-clinical-investigations-fda-paper>).

4.8.1. Patient Science Expertise and Support

This section describes how FDA met the commitments in Table 4-27 with findings presented in sub-sections:

- 4.8.1.1 Develop Guidance
- 4.8.1.2 Expand and Provide Support for FDA Staff
- 4.8.1.3 Expand Support for Industry

4.8.1.1. Develop Guidance

FDA issued a draft and final guidance in the Patient-Focused Drug Development (PFDD) series, providing FDA's viewpoint on selecting, modifying, developing, and validating COAs in clinical research and their use as endpoints.^{82,83} FDA also issued a final guidance on the use of RWE to support medical device submissions, and a final guidance on PPI across the TPLC, analytical methods for quantitative preference data, the role of qualitative methods in PPI studies, fit-for-purpose PPI studies, and attribute selection.^{84,85}

Table 4-27: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Issue a draft guidance providing best practices on incorporating into premarket studies COAs including their use as primary or co-primary endpoints
- Update FDA's existing guidance, "Patient Preference Information Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling"
- Expand clinical, statistical, and other scientific expertise and staff capacity to respond to submissions containing applicant-proposed use of voluntary patient preference information (PPI), voluntary patient reported outcomes (PROs), and/or patient-generated health data (PGHD). These staff will provide submission review and early consultation/advice to industry during study planning
- Strengthen efforts to expand staff understanding of Patient Science and Engagement (PSE) topics, and consistent evaluation in submissions through training curriculum and internal infrastructure to improve consistency
- Facilitate industry efforts to collaborate with patients in key areas by generating patient-friendly educational modules
- Use the existing dispute resolution process in the event of disagreement between the applicant and the Agency on the need for PPI, PRO and/or other tools to capture PGHD

⁸² Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory>).

⁸³ Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessment (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome>).

⁸⁴ Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices>).

⁸⁵ Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle>).

Table 4-28 outlines the PSE-related guidances issued during MDUFA V. FDA presented these updates and others at a webinar (recording and transcript publicly available).⁸⁶

Table 4-27: PSE-Related Guidance Documents Issued During MDUFA V

Title	Issue Date
“Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision-Making” – Draft guidance	April 2023
“Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments” – Final guidance	October 2025
“Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices” – Final guidance	December 2025
“Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle” – Final guidance	March 2026

4.8.1.2. Expand and Provide Support for FDA Staff

New Staff

In 2024, CDRH reorganized the Patient Science Program into the Division of Patient-Centered Development (DPCD), structured around three pillars to encompass MDUFA V commitments: (1) foster consistency in regulatory review, (2) build a culture of patient engagement, and (3) optimize the PSE research roadmap.⁸⁷ The Division expanded staff capacity to review data and consult industry. DPCD provides expertise in COAs, PROs, PGHD, PPI, qualitative patient input, statistics, and patient engagement.

Training

In 2024, DPCD established the Patient Science FPP and began offering FPP trainings for reviewers, aiming to increase their understanding of patient science topics to facilitate consistent review of submissions containing patient experience data. In collaboration with OHTs, DPCD hosted three CDRH Patient Engagement Town Halls. These internal CDRH events are open to all employees and are intended to improve employee knowledge and facilitate discussions on patient relevant topics such as at home use of medical technologies and involvement in medical device clinical studies. In addition, CDRH incorporated patient science training into established training modalities. Training opportunities are described in Section 4.2. Table 4-29 lists the patient science-related content training.

Table 4-28: Patient Science-Related Training

Training Opportunity	Content
FPP	• Patient Reported Outcome Measures (PROMs) and their use in submissions • PPI methods • PRO and PPI guidances • Inclusion of patient perspectives in Summaries of Safety and Effectiveness Data (SSEDs) • Advanced training on PROs, including OHT-specific fit-for-purpose PROs, context of use, and validity evidence
ELP	• Patient Engagement in Device Development
Cross-Center Rounds	• PPI methods and use cases

⁸⁶ Webinar - Draft Guidance: Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle - 10/15/2024 (<https://www.fda.gov/medical-devices/medical-devices-news-and-events/webinar-draft-guidance-incorporating-voluntary-patient-preference-information-over-total-product>).

⁸⁷ Division of Patient-Centered Development (<https://www.fda.gov/about-fda/center-devices-and-radiological-health/division-patient-centered-development>).

Provide Internal Consult Support

DPCD provides consults on submissions with PGHD. DPCD developed internal procedural documentation for the review of submissions containing patient input data, as well as instructions outlining when and how review staff should request an internal consult to determine if a COA instrument (e.g., a PROM) is fit-for-purpose. For example, DPCD developed work instructions for a product where submissions include COA data. This document contains specific instructions for reviewing patient input data in submissions for this product for reviewers to support their review and enable DPCD consults to be focused on more complex reviews.

4.8.1.3. Expand Support for Industry

Patient-friendly Educational Modules

To support industry efforts to collaborate with patients, DPCD conducted an external landscape analysis to assess patient engagement educational tools and learning management systems (LMS) during FY22-FY23. Subsequently, DPCD contracted support to develop patient-facing course modules on patients as advisors in clinical studies, the basics of device development, and real-world data and PGHD. Designed for patients, these modules include *Patients as Advisors in Medical Device Clinical Studies*, released in 2026, with the remaining modules targeted for completion by end of FY27.⁸⁸

Early Industry Consults

DPCD continues to provide early consultation to industry on inclusion of PROs, PPI, and PGHD through Q-Submissions and the IDE process. DPCD conducted a preliminary analysis to assess the impact of early consultation on substantive reviews (i.e., lower number of PRO-related deficiencies during substantive review) across review programs (i.e., 510(k), PMA, and De Novo). The analysis reviewed as part of this assessment, the details of which are not available for public disclosure, focused on submissions with PRO data and revealed that a review history that included early DPCD consult received fewer PRO-related deficiencies during substantive review compared to marketing submissions that did not receive DPCD consult. The preliminary results of this analysis are consistent with the desired impact of this initiative. DPCD anticipates an increase in consult volume in response to release of final guidances related to the collection and use of patient experience data and the Division will continue monitoring the effectiveness of early consultation. There are several instances where Division staff advised sponsors on the inclusion of patient input measures in study design to collect PPI. DPCD intends to add PPI and PRO examples to the Division webpage as they are identified.

MDDT Program

COAs are publicly available in the MDDT program, through which FDA qualifies tools that medical device sponsors can choose to use in the development and evaluation of medical devices.⁸⁹ Medical device sponsors can use these COAs within the same COU, limiting the need to reconfirm the COA's suitability and utility. The current list of qualified tools includes eight COA instruments, including two PRO instruments qualified during MDUFA V period: WOUND-Q and Assessment of Intraocular Lens Implant Symptoms (AIOLIS).

Dispute Resolution

Under MDUFA V, FDA committed to use the existing dispute resolution process in the event of disagreement between the applicant and the Agency on the need for PPI, PRO and/or other tools to capture PGHD. CDRH reports that as of February 2026, there were no disputes related to these topics during the MDUFA V assessment period. In

⁸⁸ CDRH Patient Education Program Course Video: Patients as Advisors in Medical Device Clinical Studies (https://www.fda.gov/about-fda/division-patient-centered-development/cdrh-patient-education-program-course-video-patients-advisors-medical-device-clinical-studies?utm_medium=email&utm_source=govdelivery).

⁸⁹ Medical Device Development Tools (MDDT) (<https://www.fda.gov/medical-devices/medical-device-development-tools-mddt>).

the event of a future dispute, CDRH reaffirmed that it would follow the dispute resolution process outlined under the guidance document, CDRH Appeals Processes, issued March 2022.⁹⁰

4.8.2. Supporting the Integration of Patient Perspectives into Medical Device Development and Regulatory Decision-Making

This section describes how FDA met the commitments in Table 4-30. The findings are described in the sub-sections:

- 4.8.2.1 Promoting Use of Patient Experience Data in Medical Device Development
- 4.8.2.2 Incorporating Patient Perspectives into Regulatory Decision-Making

4.8.2.1. Promoting Use of Patient Experience Data in Medical Device Development

CDRH facilitated and participated in public workshops and conferences to discuss how COAs, PPI, and PGHD may be included in device development. FDA co-hosted with the Digital Medicine Society (DiMe), a public meeting exploring the use of PGHD to advance remote clinical trial data collection. The workshop titled *Using Patient Generated Health Data in Medical Device Development: Case Examples of Implementation Throughout the Total Product Lifecycle* (Table 4-31), explored implementation of PGHD during medical device development and clinical studies, including its potential to advance remote clinical trial data collection and facilitate high-quality COAs.^{91,92} Attendees discussed how to implement PGHD, reviewed case examples that informed medical device development, and participated in case-based sessions on the use of PGHD for medical device developers, scientists, and patients. CDRH reported approximately 2,000 registrants for the workshop, and at least 12 FDA presenters.

Providing Insight into the Use and Review of Patient Experience Data in Medical Device Submissions

CDRH participated in public meetings, webinars, workshops, and other events with industry, academia, patient organizations, patients, and patient caretakers, to discuss how to implement patient experience data throughout medical device development and clinical trials, as well as FDA’s approach to reviewing submissions with patient experience data. These sessions enabled CDRH to disseminate feedback on strategies to encourage patient engagement throughout the product development process. Table 4-31 provides an overview of these events.

Table 4-30: Overview of External Events on the Use and Review of Patient Experience Data

Event	Date
<i>Expediting Innovation of Vision Restoration Bioelectronic Implants – Co-Sponsored Public Workshop with the University of Pittsburgh</i>	October 2022
<i>Maximizing the Impact of Ophthalmic Imaging and AI on Population Health: Health Equity, Reimbursement, and Interoperability</i>	January 2023
<i>Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee Meeting</i>	February 2024
<i>Dry AMD PFDD Meeting</i>	March 2024

⁹⁰ Center for Devices and Radiological Health (CDRH) Appeals Processes (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes>).

⁹¹ Vision 2030: A strategic roadmap for implementing the patient voice into medical devices (<https://dimesociety.org/vision-2030-a-strategic-roadmap-for-implementing-the-patient-voice-into-medical-devices/>).

⁹² Using Patient Generated Health Data in Medical Device Development: Case Examples of Implementation Throughout the Total Product Lifecycle (<https://dimesociety.org/webinar/public-workshop-using-patient-generated-health-data-in-medical-device-development-case-examples-of-implementation-throughout-the-total-product-lifecycle/>).

Event	Date
<i>FDA Rare Disease Day 2024</i>	March 2024
<i>American Brain Coalition Educational Webinar 2024: Collaborating Partnership Opportunities with the FDA</i>	May 2024
<i>NORD Corporate Council Meeting</i>	May 2024
<i>2024 MDIC Annual Patient Summit</i>	May 2024
<i>Using Patient Generated Health Data in Medical Device Development: Case Examples of Implementation Throughout the Total Product Lifecycle</i>	June 2024
<i>FDA/NIH Joint Workshop: Developing Implanted Brain Computer Interface Clinical Outcome Assessments to Demonstrate Benefit</i>	September 2024
<i>Oregon Bioscience Association (OBA) Biotech Summit</i>	October 2024
<i>Understanding Medical Device Users Through PPI: Webinar</i>	November 2024
<i>15th International Conference on Health Policy Statistics: Statistical Innovation to Improve Health Equity</i>	January 2025
<i>FDA Rare Disease Day 2026</i>	February 2026

4.8.2.2. Incorporating Patient Perspectives into Regulatory Decision-Making

CDRH coordinates programs that provide an interface between patients and reviewers. This includes the Patient and Caregiver Connection (PCC) program, a partnership between CDRH and patient and caregiver organizations which allows CDRH staff to receive patient and caregiver input.⁹³ Coordinated by DPCD, the program includes 20 partner organizations, including umbrella organizations representing multiple diseases and conditions (e.g., American Brain Coalition). Patients and caregivers can share their experiences with medical devices in general or aspects of living with a disease or condition with FDA through these PCC partner organizations. Some PCC organizations also support TPLC Advisory Program (TAP) innovator inquiries.

4.8.3. Promoting Research and Innovation

This section describes how FDA met the commitments in Table 4-32.

Improving Patient Science and Engagement Tools

DPCD created a research agenda, reviewed as part of this assessment and not available for public disclosure, that outlines objectives for advancing the understanding and development of patient science and patient engagement tools across the TPLC. DPCD identified three goals for tool development: advancing new methods of capturing patient input; addressing diseases and health conditions where there are unmet patient science needs; and resolving novel regulatory questions that arise due to device innovation. DPCD regularly engages with reviewers to align research objectives with areas of importance identified by reviewers. Accordingly, much of the research funded by DPCD comes from high-impact areas identified in conjunction with reviewers and patients.

Table 4-31: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
• Develop case examples of modified or adapted PRO instruments to make efficient use of existing validated PRO instruments • Explore opportunities to improve patient science tools for medical devices and incorporate data and perspectives from different patient populations • Support the use of innovative technologies to capture patient input and reduce patient burden to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention

⁹³ CDRH Patient and Caregiver Connection (<https://www.fda.gov/about-fda/division-patient-centered-development/cdrh-patient-and-caregiver-connection>).

Funding Support to Develop New Tools

CDRH funds PSE research, including novel and adapted PROMs and the integration of patient perspectives. To guide funding decisions and its research agenda, DPCD works with others in CDRH to identify areas of high impact, identified for regulatory relevance, device innovation, and/or public health importance. Table 4-33 outlines funded projects expected to result in novel or modified/adapted PROMs. Results from these studies are intended to be made publicly available through published research literature and planned updates to FDA’s website by FY27. DPCD also intends to update useful information for understanding commonly used PROs in medical device regulatory decisions and related contexts of use.

Table 4-32: Ongoing Research Aiming to Produce Novel and Modified/Adapted PROMs

Novel or Modified/Adapted	Condition	Description
Modified/Adapted	Heart failure	Adapting a PROM for symptoms of heart failure for use among pediatric populations
Novel	Profound vision loss	Creating a novel PROM for ocular bioelectronic implants
Novel	Temporomandibular joint disorders	Creating a novel PROM and manual for assessing symptoms of temporomandibular joint disorders
Modified/Adapted	Tricuspid valve disease	Adapting the Kansas City Cardiomyopathy Questionnaire (KCCQ) for assessing symptoms of tricuspid valve disease and for different patient demographics
Modified/Adapted	CKM	Adapting an existing PROM for CKM
Novel or Modified/Adapted	Overactive Bladder	Developing a minimum meaningful change scale for the items of the LURN Symptom Index-10 (LURN SI-10) given treatment-related risks
Novel or Modified/Adapted	Genitourinary symptoms of menopause	Adapting an existing PROM, or developing a novel PROM, for genitourinary symptoms of menopause

DPCD funded research projects on the integration of patient perspectives, primarily focused on methods and tool development for PRO/PPI. In addition, DPCD funded additional research into methods that can expand access to clinical trials, focusing on topics including clinical site readiness, representativeness in clinical trial participation, and technologies to support decentralized clinical trials. Together, these research projects represent a robust research portfolio developed to meet the MDUFA V commitments related to patient science tool development and innovation.

4.8.4. Conclusion

FDA met or is on track to meet, all MDUFA V commitments for PSE. CDRH expanded support by growing internal expertise across COAs, PROs, PPI, PGHD, qualitative patient input, statistics, and patient engagement, centralizing the program into DPCD, and developing specialized internal training and support infrastructure. FDA released one draft and three final guidances to provide practical information on PPI, real-world data (RWD), and the development, incorporation, evaluation, and validation of COAs. To advance the development of modified and adapted PROs, the incorporation of different patient perspectives, and use of innovative technologies that capture patient input and reduce patient burden, CDRH led the PCC program, coordinated meetings, and funded regulatory science to support a comprehensive research portfolio with planned updates to FDA’s website by FY27. CDRH supported industry efforts in patient science by providing submission review and consultation services, supporting industry’s use of patient input measures, developing publicly available patient-friendly educational modules (anticipated by end of FY27), and co-hosting a public meeting on the use of PGHD. Lastly, although FDA did not report any disputes with industry, the Agency reaffirmed its commitment to use the existing dispute resolution process in the event of disagreement between applicants and the Agency on the need for PPI, PRO and/or other tools to capture PGHD.

4.9. Real-World Evidence Program

The RWE Program advances the use of RWD (i.e., data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources) to generate RWE (i.e., clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD) to support regulatory decision-making. In the last decade, FDA developed the RWE Program, notably through publication of CDRH's first RWE guidance in 2017 and the establishment of the National Evaluation System for health Technology (NEST) as one of CDRH's 2016-2017 strategic priorities.^{94,95} RWE has remained a priority for FDA and the MDUFA V commitments focus on the continued development of the RWE Program and program transparency.

Booz Allen's assessment of the RWE Program to meet the MDUFA V commitments is presented in the sections:

- Continue to Develop the RWE Program

4.9.1. Continue to Develop the RWE Program

This section describes how FDA met each of the commitments in Table 4-34. The findings are presented in the sub-sections:

- 4.9.1.1 Clarify Reporting Requirements
- 4.9.1.2 Updated RWE Guidance
- 4.9.1.3 Provide Real-World Evidence Training

4.9.1.1. Clarify Reporting Requirements

FDA updated the "Exemptions, Variance and Alternative Forms of AE [Adverse Events] Reporting for Medical Devices" webpage with information on reporting exemptions for RWD sources.⁹⁶ Many sources of RWD (e.g., electronic health records, medical device registries, medical claims) continuously capture a large amount of real-world, post-market clinical data, and typically have to comply with the MDR requirements in 21 CFR Part 803. However, the use of large RWD sources for reporting of AE presents unique challenges, which FDA addressed with updated information on the "Exemptions, Variance and Alternative Forms of AE Reporting for Medical Devices" webpage. The new section, "Exemptions Granted for Adverse Events Identified in Certain Medical Device Real-World Data Sources," describes exemptions to certain AE reporting requirements for large RWD sources, which FDA grants on a case-by-case basis. This new information encourages use of RWD by reducing burden on manufacturers. Despite the potential for exemption, FDA maintains transparency through publicly posting the summary medical device reports on FDA's Manufacturer and User Facility Device Experience (MAUDE) database.

Table 4-33: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section	
	• Use user fee revenue for the continued development of RWD and RWE methods and policies to advance regulatory acceptance for premarket submissions, including expanded indications for use and new clearance/approval of new devices, and clarify related reporting requirements
	• Update the 2017 guidance document Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices to provide more clarity on: • Least burdensome general expectations on what is needed to demonstrate Fit-for-Purpose • More information, including examples, on previously used and accepted methodologies • Best practices for RWE review • Continue to advance CDRHs RWD/RWE Training program for FDA review teams including the medical review staff. Topics will include best practices for RWE review and when to engage with CDRH RWE SMEs

⁹⁴ Real-World Evidence: Advancing Regulatory Decision-Making for Medical Devices (<https://www.fda.gov/news-events/fda-voices/real-world-evidence-advancing-regulatory-decision-making-medical-devices>).

⁹⁵ 2016-2017 Strategic Priorities, Center for Devices and Radiological Health (<https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-strategic-priorities-and-updates>).

⁹⁶ Exemptions, Variances, and Alternative Forms of Adverse Event Reporting for Medical Devices (<https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/exemptions-variances-and-alternative-forms-adverse-event-reporting-medical-devices#exemptions>).

4.9.1.2. Updated RWE Guidance

Guidance

FDA updated the “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices” guidance (RWE guidance) document via publication of the draft guidance in December 2023, and the final guidance in December 2025.⁹⁷

Clarifying Least Burdensome General Expectations Updates

As part of updates to the RWE guidance, FDA clarified the general expectations on the Least Burdensome Provisions⁹⁸ for use of RWD throughout the document, but particularly in two sections titled “Assessing Data Relevance and Reliability” and “Considerations for Methodologies for Collection and Analysis of RWD to Generate RWE.” The Agency recommends that applicants include an assessment of key relevance and reliability factors (e.g., data availability and timeliness, data quality and integrity, generalizability of data) for the study using RWD that can be used to generate RWE. Additionally, FDA recommends that sponsors provide contextual information (e.g., how RWE fits into the rest of the submitted clinical evidence, unique considerations) since the assessment of RWE to support a regulatory decision is considered in the context of the totality of evidence available for review.

Providing Generalized Examples and Additional Information on Previously Used and Accepted Methodologies

FDA updated the RWE guidance to include “Appendix A: Recommended Relevance and Reliability Elements for Documentation and FDA Review” and “Appendix B: Examples where RWE is Used.” “Appendix A” outlines generalized examples of recommended elements to assist in determining relevance and reliability of the RWD for use in the regulatory review setting (Table 4-35). “Appendix B” outlines how RWE has generally supported prior regulatory decision-making (e.g., new or expanded indications for use, 522 submissions, EUA devices).

Table 4-34: Partial List of Recommended Elements for Document and FDA Review (Excerpts from 2025 RWE Guidance, Appendix A)

Recommended Element	Details
RWD Relevance	• Determine if the RWD contains sufficient detail to capture data elements and address the study question • Assess longitudinality of data source • Assess continuity of care in data source • Ensure reasonable time between data collection and release for research
RWD Reliability	• Provide information and descriptors about data source(s) • If applicable, describe defined processes around data monitoring and programs for quality audit and ongoing training of data collection • Document routine migration of data from various sources over time • Describe sources and technical methods used for data element capture

Outlining Best Practices for RWE Review

The RWE guidance updates emphasized the importance of the relevance and reliability assessment, which should evaluate factors such as data availability, timeliness, integrity, and generalizability of data. Prior to analyzing RWD, the RWE guidance recommends developing a study protocol and analysis plan with clear definitions of the study population, device exposure, outcomes, and covariates. Using appropriate study designs and analytical methods to determine the relationships between variables and identify potential confounders, especially since RWD is often collected outside of a controlled setting, sponsors should consider additional precautions. To visualize the relationships, the RWE guidance includes causality diagrams (e.g., directed acyclic graphs). The RWE guidance recommends other best practices (e.g., providing thorough documentation on RWD sources) to ensure adequate

⁹⁷ Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices – Final Guidance (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices>).

⁹⁸ See footnote 25.

protections for privacy and data confidentiality. The RWE guidance urges sponsors to demonstrate that RWD is relevant and reliable for addressing specific regulatory questions, encouraging sponsors to engage with FDA early to discuss planned RWE use.

4.9.1.3. Provide Real-World Evidence Training

FDA committed to advancing CDRH's RWD/RWE Training program for FDA review teams, including the medical review staff, and included best practices for RWE review and when to engage with CDRH RWE SMEs. The RWE training commitment was met by building out training initiatives into existing training programs, including OPEQ Rounds, FPP, ELP, and RCP, as well as conducting several OHT-specific trainings. Table 4-36 lists training opportunities and describes the RWE-related content.

Table 4-35: Examples of Training Opportunities with RWE-Related Content

Training Opportunity	Content
OPEQ Rounds	Summary of RWE guidance and use of RWE for medical devices
FPP	- Baseline training: identifying RWD/RWE in submissions; introduction to relevance and reliability review; requesting support and consultation from RWD/RWE SMEs - Advanced training: types of health care data in RWE; conducting relevance and reliability review
OHT-Specific Training	RWE review considerations; case example(s) exploring relevance and reliability considerations
ELP	Leveraging data from RWE; RWD study design; using RWE evidence in evidence generation plans and product portfolio planning; RWE for medical device regulatory applications using RWD sources
RCP	Agency-wide definitions; high-level RWE review considerations; RWE resources

4.9.2. Enabling Real-World Evidence Transparency

This section describes how FDA met each of the commitments in Table 4-37. The findings are presented in the sub-sections:

- 4.9.2.1 Providing RWE Transparency
- 4.9.2.2 Providing NEST Transparency

4.9.2.1. Providing RWE Transparency

Updating Stakeholders and Providing User Fee Transparency

FDA committed to providing transparent updates pertaining to the RWE Program. FDA committed to hosting two or more open public meetings to update stakeholders on program activities over the course of MDUFA V. CDRH presented RWE updates at the Duke Margolis Institute for Health Policy Regulatory Submissions with Real-World Evidence Public Meeting and at the 2025 Medical Device Innovation Consortium (MDIC) Real-World Evidence Summit, held on 09/23/2025 and 11/04/2025, respectively. Additionally, FDA committed to track the hiring of internal

Table 4-36: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section
Provide transparent program development updates and financial accounting of User Fee revenue specifically intended for the activities in this section. - Update stakeholders on the RWE Program activities at two or more open public meetings - Hiring of internal experts to support the review of RWD/RWE-related submissions will be tracked - If any portion of the user fee funding is distributed to NEST, the funding should be used to transparently: - Support the development of RWD resources to facilitate appropriate access for research studies - Convene experts to develop best practices and advance innovative methodology approaches - Include, on the organization's governing board, no fewer than four representatives of the trade associations that participated in the MDUFA V negotiations - By the end of FY 2023, publish a document requesting public comment on how FDA should use any portion of the user fee funding that may be distributed to any external organization(s) other than NEST - If any portion of the user fee funding is distributed to an external organization(s) other than NEST, the funding will be accounted for in FDA's quarterly MDUFA report

experts to support the review of RWD/RWE-submissions; no internal RWE experts have been hired with MDUFA V user fee funds. Lastly, FDA committed to transparency if funding external organizations other than NEST, information it agreed to share in FDA's quarterly MDUFA report. At this time, no user fee funding has been allocated to external organizations other than NEST.

Requesting Public Comment

On January 18, 2023, FDA published a request for public comment on how medical device user fee funding distribution should occur to external organization(s) outside of NEST. Per MDUFA V Commitment Letter language, FDA added the question, *How should the FDA use device user fee funding that may be distributed to an external organization other than NEST?*, for comment on public docket FDA-2023-N-0156, which remained open through March 20, 2023, to receive comments.⁹⁹ Nine stakeholders responded to the request for public comment. Comments came from industry representatives (e.g., AdvaMed, MDMA, Medical Imaging & Technology Alliance [MITA]), health providers, organizations, and associations.

4.9.2.2. Providing NEST Transparency

Support the Development of RWD Resources

Since NEST's establishment along with CDRH's 2016-2017 strategic priorities, FDA has aligned MDUFA V priorities to develop RWD resources, distributing roughly six million dollars per year to NEST from user fees to support initiatives (e.g., NEST Marketplace, NEST Mark). The Marketplace connects medical device manufacturers and RWD and research partners, supporting RWE for medical devices.¹⁰⁰ In 2023, NEST released a Request for Information and a Request for Participation to solicit interest from organizations interested in generating RWD solutions and expertise.^{101,102} NEST has accepted new partners through an interest form, while NEST develops NEST Mark, a process that structures the assessment and use of RWD for premarket regulatory submissions for medical devices.¹⁰³ This collaborative effort, involving CDRH and industry, applies clear, consistent methodologies to support RWD studies in meeting high standards of data quality and study design, aligned with FDA guidance documents and NEST frameworks. FDA continues to assist in promoting the development of these RWE projects.

Convene RWE Experts

FDA committed to NEST's plan to convene experts to develop best practices and advance innovative approaches to RWE development and analysis, reinforced by staff supporting day-to-day operations.¹⁰⁴ NEST is supported by an Executive Committee, established by the MDIC Board of Directors, and a Governance Committee, each of which is comprised of stakeholders, including FDA, CMS, and industry.¹⁰⁵ The NESTcc Research Methods Subcommittee and Data Quality Subcommittee—working groups comprised of experts from health systems, academia, industry, and FDA – support NEST's studies. During the 2025 MDIC RWE Summit, the Research Methods and Data Quality Subcommittees presented the finalized NESTcc Research Methods Framework and Data Quality Framework, respectively.¹⁰⁶ These frameworks provide direction for stakeholders interested in collaborating with NESTcc. Beyond the Subcommittees, NEST has contracted individual consultants and organizations to provide expertise in support of RWD source assessment, NEST Mark and Marketplace, and in developing the aforementioned frameworks.

⁹⁹ FDA Seeks Public Comment: Advancing Real-World Data and Real-World Evidence with User Fee Funding (MDUFA V) (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/fda-seeks-public-comment-advancing-real-world-data-and-real-world-evidence-user-fee-funding-mdufa-v>).

¹⁰⁰ NEST Marketplace (<https://nestcc.org/nest-medical-device-rwe-marketplace/>).

¹⁰¹ NEST Marketplace Request for Information (<https://nestcc.org/wp-content/uploads/NEST-Marketplace-Request-for-Information-RFI-23-001.pdf>).

¹⁰² NEST Marketplace Request for Participation (<https://mdic.org/wp-content/uploads/2023/11/RFP-23MP1001-v2.pdf>).

¹⁰³ NEST MARK (<https://nestcc.org/nest-mark/>).

¹⁰⁴ NEST Team (<https://nestcc.org/about/nestcc-team/>).

¹⁰⁵ NEST Governance (<https://nestcc.org/about/governance/>).

¹⁰⁶ Research Methods and Data Quality (<https://nestcc.org/data-quality-and-methods-2/>).

NEST's Governing Board Representation

FDA committed to certain industry representation on NEST's governing board, the NEST Executive Committee, comprised of stakeholders across the medical device ecosystem. The MDUFA V Commitment Letter (CL) specifies that each of the four trade associations that participated in the MDUFA V negotiations (i.e., AdvaMed, MDMA, MITA, and ACLA) serve on the board, with additional stipulations for vacant positions. Industry representatives will make up at least 25% (minimum) of the governing board membership. Of the 13 members currently on the Executive Committee, four are industry representees, including AdvaMed, MDMA, ACLA, and an independent imaging representative. This accounts for roughly 30% industry representation, exceeding the minimum in the CL. The MDUFA V CL details that if one of the four trade associations elects not to participate, the remaining trade associations can decide how to fill the vacant industry position. As MITA did not nominate a representative for the Committee, a second AdvaMed representative filled the MITA position.

4.9.3. Conclusion

FDA met all its commitments for the RWE Program. To meet the reporting commitment, FDA updated the "Exemptions, Variance and Alternative Forms of AE Reporting for Medical Devices" webpage with new information on reporting exemptions for RWD sources. In 2025, FDA published the final guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" which addressed least burdensome general expectations to demonstrate RWD relevance and reliability for a particular regulatory decision and included generalized examples on methodologies and overall best practices for RWE. As for RWE training, FDA fulfilled this commitment by building out RWE training initiatives into existing training programs, including the FPP, ELP, OPEQ Rounds and RCP.

FDA met its RWE Program transparency commitments by participating in two public meetings in FY25-26 to update stakeholders on RWE Program activities. FDA published a document requesting public comment on how medical device user fee funding should be distributed to external organization(s) outside of NEST. For NEST, user fee funding supported the development of RWD resources, in the form of initiatives such as NEST Marketplace and NEST Mark.

4.10. International Harmonization

To support its mission of streamlining global regulatory pathways, FDA participates in international harmonization efforts to build a global network and make the regulatory process more efficient and consistent for all stakeholders through aligned standards, practices, and review processes for decision-making. MDUFA V commitments for International Harmonization focus on promoting global engagement and outreach through various approaches to reduce duplicative efforts and promote timely patient access to safe and effective medical devices.

Booz Allen’s assessment is presented in the sections:

- 4.10.1 Expanding Engagement and Outreach
- 4.10.2 Reporting on International Harmonization Efforts

4.10.1. Expanding Engagement and Outreach

This section describes how FDA met the commitments in Table 4-38. The findings are described in the sub-sections:

- 4.10.1.1 Bilateral Partnerships
- 4.10.1.2 Multilateral Partnerships
- 4.10.1.3 Regulatory Partner Engagement
- 4.10.1.4 Industry and Regulatory Authority Engagement

4.10.1.1. Bilateral Partnerships

FDA collaborates with Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) through the Harmonization by Doing (HBD) bilateral partnership. HBD aims to align clinical and regulatory approaches for medical devices through specialized proof of concept projects, scientific sessions, and HBD think tank meetings.¹⁰⁷ HBD stakeholders include government, academia, and industry in both the U.S. and Japan with the goal of promoting regulatory convergence and addressing “barriers that may delay patients in both countries from getting timely access to safe and effective medical devices.”¹⁰⁸ In September 2025, CDRH participated in the HBD East 2025 Think Tank meeting and presented an overview of the U.S. regulatory landscape for DHTs and ongoing initiatives to accelerate medical device access. The goal of this presentation was to identify how the U.S. and Japan can deepen collaborations on device development and review to reduce duplicative regulatory efforts.¹⁰⁹ Topics of this meeting focused on 1) marketing approval pathways to advance regulatory convergence; 2) real-world clinical evidence to leverage multi-regional clinical data; 3) DH technologies to promote innovation; 4) pediatric and orphan device development to promote innovation; and 5) strategies for global collaboration and access to encourage sustainable global device development ecosystems.

Table 4-37: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.
- Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies, and practices, as needed and consistent with applicable disclosure law and policy.
- Support the creation of a forum to engage with relevant stakeholders, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another’s approach to decision-making.
- Participate in outreach activities to other regulatory authorities that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.

¹⁰⁷ Japan-US Harmonization by Doing, Harmonization of clinical and regulatory approaches in the US and Japan (<https://www.pmda.go.jp/english/int-activities/int-harmony/0028.html>).

¹⁰⁸ FDA US-Japan Regulatory Collaboration (<https://www.fda.gov/medical-devices/cdrh-international-affairs/us-japan-regulatory-collaboration>).

¹⁰⁹ CDRH International Harmonization Annual Assessment: Fiscal Year 2025 (<https://www.fda.gov/medical-devices/cdrh-international-affairs#assessment2024>).

Health Canada and the U.S. utilized the bilateral Regulatory Cooperation Council (RCC) relationship for efforts that include pre- and post-market regulatory convergence. In FY22, FDA and Health Canada simultaneously reviewed two submissions, and Health Canada has piloted eSTAR as developed by FDA. During MDUFA V FDA discussed the benefits of eSTAR utilization with other regulatory authorities to facilitate multi-regional submission and review of premarket applications. Following the pilot, the U.S. and Canada conducted surveys on eSTAR and received “generally positive” feedback.¹¹⁰ In August 2025, Health Canada announced their second pilot utilizing FDA’s eSTAR focused on IVD devices.

4.10.1.2. Multilateral Partnerships

IMDRF

CDRH continued to participate in and strengthen collaboration with other regulatory authorities through IMDRF. In 2024, the Good Regulatory Review Practices (GRRP) working group of the IMDRF, chaired by the United States and Singapore, organized a two-part training to help authorities understand real-world applications of the "IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices" technical document. This workshop covered an introductory overview of future topics IMDRF training sessions may expand on, including how to use the Essential Principles as a foundation for medical device regulatory frameworks.¹¹¹ During 2024, FDA concluded their chairmanship of IMDRF and transitioned responsibilities to Japan, participated in the March and September meetings of IMDRF, and supported publication of one new technical document¹¹² and updates to ten technical documents (Section 4.10.2.1).

As of August 2026, CDRH participated in all eight active IMDRF WGs and co-chaired several (e.g., Adverse Event Terminology, Artificial Intelligence/Machine Learning-enabled devices, GRRP, Software as a Medical Device, Foundational Documents). In 2025, CDRH directly contributed to new IMDRF documents in areas such as good machine learning practices (Section 4.7.2.3). The GRRP WG released The Playbook for Medical Device Regulatory Reliance Programs was released in February 2026 to promote strategies for establishing reliance programs to promote efficient and aligned regulatory decision-making across jurisdictions.¹¹³ The reliance principles included in the Playbook can be applied to a medical device in any stage of the product lifecycle and references global resources such as guidances, technical documents, and standards.¹¹⁴ The Playbook provides real-world examples, practices, and types of decisions regulatory authorities may want to leverage from other jurisdictions. FDA, through the IMDRF, also helped facilitate discussions with the medical device industry to identify appropriate opportunities for industry to provide feedback on IMDRF activities.¹¹⁵ The IMDRF Industry Group provides feedback on potential future areas of collaboration, such as standards and product changes. For example, during the September 2025 IMDRF meeting in Japan, industry provided feedback on standards, product changes, and Universal Device Identifier (UDI) experiences.¹¹⁶

Medical Device Single Audit Program (MDSAP)

Originally developed by the IMDRF WG, MDSAP evolved into a recognized auditing organization "to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory

¹¹⁰ The eSTAR pilot: Notice to industry (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/estar-pilot-notice-industry.html>).

¹¹¹ IMDRF Good Regulatory Review Practices Working Group (<https://www.imdrf.org/working-groups/good-regulatory-review-practices>).

¹¹² Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators (<https://www.imdrf.org/documents/common-data-set-adverse-event-data-exchange-between-imdrf-regulators>).

¹¹³ Playbook for Medical Device Regulatory Reliance Programs (<https://www.imdrf.org/documents/playbook-medical-device-regulatory-reliance-programs>).

¹¹⁴ Ibid.

¹¹⁵ CDRH International Harmonization Annual Assessment: Fiscal Year 2024 (<https://www.fda.gov/medical-devices/cdrh-international-affairs#assessment2024>).

¹¹⁶ IMDRF 28th MC Meeting Sapporo, Japan September 2025 - Outcome Statement (<https://www.imdrf.org/documents/imdrf-28th-mc-meeting-sapporo-japan-september-2025-outcome-statement>).

authorities participating in the program."¹¹⁷ During MDUFA V, MDSAP Regulatory Authority Council (RAC) members include the United States, Australia, Brazil, Canada, and Japan. However, additional countries are involved as Official Observers or Affiliate Members. FDA works toward MDSAP goals of leveraging resources to manage an efficient, effective, and sustainable audit program focused on the oversight of device manufacturer's Quality Management Systems. In 2023, FDA attended the MDSAP forum in Brazil.¹¹⁸ In 2024, three countries joined MDSAP as Affiliate Members (i.e., Kenya, Mexico, Taiwan). FDA was involved in the planning of the annual MDSAP forum in Germany (June 2024) to increase engagement with European parties.¹¹⁹ In 2025, FDA attended the annual forum in the Netherlands, and expanded membership to include Singapore and Malaysia. As of September 2025, MDSAP auditing organizations completed audits at about 7,500 manufacturing sites. Internally, CDRH continues to enhance MDSAP knowledge and participation through training for the audit process and additional resources and assistance from the MDSAP SMEs. From 2026 to 2027, FDA will serve as the chair of MDSAP.

Asia-Pacific Economic Cooperation (APEC)

FDA contributed to the relaunch of the Regulatory Harmonization Steering Committee (RHSC) Key Performance Indicators (KPIs) initiative, with Phase 1 completed in 2025 and Phase 2 scheduled for 2026. The goal of the initiative is to continue measuring progress towards convergence with the goals of protecting population safety, attracting investment, making products available, preventing corruption, saving public resources, and improving global standing to strengthen the global community. FDA is one of the regulatory leads for the Medical Device Priority Work Area coordinating and approving trainings delivered by aligning with the IMDRF and former Global Harmonization Task Force foundational documents.¹²⁰

4.10.1.3. Regulatory Partner Engagement

FDA met its commitment to support regulatory convergence by exchanging publicly available and non-public information under confidentiality commitments to enable regulatory authorities to leverage resources, data, and information to inform regulatory policies and decisions. This exchange of information occurs on a routine or ad hoc basis.¹²¹ FDA relies on existing confidentiality commitments with regulators that include, but are not limited to, the European Commission, Australia, UK, Argentina, South Africa, Canada, Sweden, Singapore, France, and Switzerland.¹²² Under MDUFA V, FDA formed confidentiality commitments with Israel and Kenya.

The Multilateral Brain-Computer Interface (MBCI) Devices WG represents an example of a forum intended to share topics of interest for brain-computer interface (BCI) devices. This WG includes representatives from six regulatory authorities, including FDA. It meets two to three times per year under confidentiality commitments and details were not made available to Booz Allen for this assessment. In FY25, the BCI Think Tank virtually met twice to share regulatory intelligence and harmonize approaches to device review. The discussion focused on regional updates, approaches to clinical trials, COAs, and potential development of BCI device standards. Best practices encouraged include building relationships, encouraging joint support on policies, and promoting harmonization through this multilateral venue.

4.10.1.4. Industry and Regulatory Authority Engagement

Forum Collaboration

In 2023 CDRH convened several industry representatives to outline the overall vision for a forum where representatives from global regulatory bodies and industry could identify opportunities that support international harmonization and convergence. FDA and industry representatives met throughout 2024 to discuss in-scope topics

¹¹⁷ FDA Medical Device Single Audit Program (MDSAP) (<https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap>).

¹¹⁸ Anvisa hosts the MDSAP Annual Forum in Brasilia (<https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2023/anvisa-sedia-o-forum-anual-do-mdsap-em-brasilia>).

¹¹⁹ See footnote 115.

¹²⁰ See footnote 109.

¹²¹ CDRH International Affairs (<https://www.fda.gov/medical-devices/cdrh-international-affairs>).

¹²² FDA Confidentiality Commitments (<https://www.fda.gov/international-programs/cooperative-arrangements/confidentiality-commitments>).

of interest.¹²³ In addition, the Center extended its support to help establish the operational structure of the forum, which currently employs a tiered approach to identify priorities, formulate strategies, share intelligence, develop projects, and facilitate multi-stakeholder collaboration. This tiered approach enables the forum, involving AdvaMed and other industry stakeholders,¹²⁴ to hold a consistent meeting cadence and streamline administrative and logistical processes. As of 2025, the forum identified several priorities aligned with MDUFA V commitments including regulatory reliance, opportunities for regional training, and collaborative projects.¹²⁵ Further, although the Center originally only committed to supporting the creation of this forum, it has remained an active participant, attending three forum meetings between August 2025 and January 2026 to provide insights that support the forum's mission.

Conference, Seminar, and Meeting Participation

Globally, CDRH delivered presentations either virtually or in-person at conferences, trainings, roundtables, and meetings to promote the importance of regulatory alignment and FDA's review practices and international priorities to other regulatory authorities and industry stakeholders. Examples of conferences FDA participated in were the Association of British HealthTech Industries (ABHI) and MedCon. In November 2023, FDA engaged with 22 nations at the African Medical Devices Forum (AMDF) meeting in Kenya. Training provided included an overview of FDA regulations, reliance and regulatory best practices, internationally recognized standards, and IMDRF's work. Following the meeting, six countries joined IMDRF as Affiliate Members.¹²⁶

In February 2024, FDA co-hosted the AI and International Symposium (AIRIS) with South Korea's Ministry of Food and Drug Safety (MFDS) to discuss challenges of AI and how to prepare for these challenges¹²⁷. CDRH participated in two international workshops of the Digital Mental Health Project led by the United Kingdom's MHRA to discuss device technologies with potential to improve outcomes for mental health conditions. These workshops built on conversations from 2023 where representatives from 14 regulatory authorities explored approaches, opportunities, and challenges to mental health technologies.¹²⁸ Additionally, in 2024, FDA participated in the UK Digital Therapeutics workshop funded by Wellcome Trust. In April 2024, FDA attended an in-person meeting in India to describe the FDA premarket submission process and the latest policies for DH, software as a medical device, and AI-enabled devices to industry. Following this meeting, India's Central Drugs Standard Organization (CDSCO) joined IMDRF as an Affiliate Member.¹²⁹

CDRH conducted outreach and maintained their bilateral relationships with other regulatory authorities. For example, CDRH engaged in multiple discussions with South Africa regarding the development and implementation of medical device regulations. CDRH also participated in two sessions on U.S.-Japanese clinical and regulatory convergence at cardiovascular conferences. To increase outreach activities in Europe, CDRH developed and delivered several trainings for two regulatory authorities on U.S. premarket pathways.¹³⁰ CDRH engages in activities with regulatory authorities in Europe who are considering reliance on FDA decisions. For example, CDRH conducted training on the 510(k) process to inform regulatory determinations that rely on FDA marketing authorizations.

¹²³ See footnote 115 CDRH.

¹²⁴ Ibid.

¹²⁵ Ibid.

¹²⁶ Ibid.

¹²⁷ Ibid.

¹²⁸ Ibid.

¹²⁹ Ibid.

¹³⁰ Ibid.

4.10.2. Reporting on International Harmonization Efforts

This section describes how FDA met the commitments in Table 4-39. Findings are described in the sub-sections:

- 4.10.2.1 Creation of IMDRF Implementation Reports
- 4.10.2.2 Creation of Draft Strategic Plan and Assessments

4.10.2.1. Creation of IMDRF Implementation Reports

A key objective of IMDRF is creation of technical documents of common interest to global regulatory bodies.¹³¹ IMDRF WGs develop these documents to facilitate convergence of regulatory practices across TAs.¹³² Once published, there are four levels of implementation (i.e., implemented, partly implemented, not implemented, not applicable) with technical implementation left to the discretion of individual regulatory bodies.¹³³ IMDRF released two implementation reports in 2024 and 2025.^{134,135} In 2024, CDRH reported implementation of 14 out of 31 IMDRF technical documents (17 partially implemented).¹³⁶ IMDRF published three additional technical documents in 2025. Of the 34 documents, the Center implemented 22 and partly implemented 12.¹³⁷

4.10.2.2. Creation of Draft Strategic Plan and Assessments

Draft Strategic Plan Development

CDRH issued a draft strategic plan in September 2023 outlining the Center’s vision for implementing all MDUFA V international harmonization goals.¹³⁸ This report outlines CDRH’s plan of implementing inward-looking practices that contextualize Center regulatory processes within the scope of globally harmonized practices, as well as outward-looking activities intended to promote the advancement of globally harmonized best practices to external stakeholders. Table 4-40 highlights inward and outward-looking activities structured around five interdependent strategies CDRH will use through FY27, and that align with international harmonization commitments under MDUFA V.¹³⁹ The draft strategic report was open for public comment through a public docket posted on November 7, 2023.¹⁴⁰

Table 4-38: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- Commencing in FY 2023, assess the extent of CDRH implementation of International Medical Device Regulators Forum (IMDRF) technical documents and make this information publicly available to enhance clarity and transparency.
- By the end of FY 2023, issue for public comment a draft strategic plan with additional details and timelines associated with achieving the international harmonization objectives described in Table 4-40.
- Commencing with FY 2024, publish an annual assessment of the international harmonization activities described in the strategic plan above, including the progress assessment described above.

Table 4-39: CDRH Strategies for Medical Device International Harmonization and Convergence

#	Strategy	Commitment
1	Increase engagements in international harmonization, convergence, and reliance efforts	Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and

¹³¹ IMDRF Terms of Reference (<https://www.imdrf.org/documents/imdrf-terms-reference>).

¹³² Ibid.

¹³³ IMDRF Standard Operating Procedures (<https://www.imdrf.org/documents/imdrf-standard-operating-procedures>).

¹³⁴ IMDRF Document Implementation Report (2024) (<https://www.imdrf.org/documents/imdrf-document-implementation-report-0>).

¹³⁵ IMDRF Document Implementation Report (2025) (<https://www.imdrf.org/documents/imdrf-document-implementation-report-0>).

¹³⁶ See footnote 134.

¹³⁷ See footnote 135.

¹³⁸ CDRH Announces International Harmonization Strategic Plan (<https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-international-harmonization-strategic-plan>).

¹³⁹ Ibid.

¹⁴⁰ FDA-2023-N-4897 (<https://www.regulations.gov/docket/FDA-2023-N-4897>).

		internationally developed policies, including exploring the development of harmonized premarket review processes.
2	Create mechanism for CDRH to share best practices with trusted partners	Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies and practices, as needed and consistent with applicable disclosure law and policy.
3	Assess the extent of CDRH implementation of IMDRF technical documents	Commencing in FY 2023, assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available to enhance clarity and transparency.
4	Support creation of a forum to engage with stakeholders to identify opportunities for regulators to leverage one another's approach to decision-making	Support the creation of a forum to engage with relevant stakeholders, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision-making.
5	Participate in outreach activities to encourage harmonization, convergence, and reliance	Participate in outreach activities to other regulatory authorities that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.

Draft Strategic Plan Assessments

Despite a delay in the expected publication timeline in 2025, CDRH released the FY24 and FY25 annual assessments reporting on progress towards its medical device international harmonization goals.¹⁴¹ Each report delineates the Center's initiatives and achievements that are directly advancing the five strategies outlined in the 2023 draft strategic plan.^{142,143} In addition, the Center also highlighted the progress of key international harmonization initiatives as part of the CDRH annual report for FY24 and FY25.^{144, 145} Table 4-41 provides an overview of the activities completed by CDRH and are mapped to the strategy in the 2023 draft strategic plan.

Table 4-40: Activities Advancing CDRH International Harmonization and Convergence Strategic Priorities

Strategy #	Activity	FY
1	Serve as IMDRF Chair and Secretariat	2024
1	Chair/Co-chair IMDRF working groups	2024
1	Expansion of MDSAP program	2024
1	Modernization of APEC's RHSC CoE training protocols	2024
1	Contributions to new IMDRF technical documents	2025
1	Expansion of MDSAP program	2025
1	RHSC's Phase 1 KPIs initiative	2025
2	Participate in the MBCI forum	2024 -2025

¹⁴¹ International Harmonization Annual Assessments (<https://www.fda.gov/medical-devices/cdrh-international-affairs#assessment2024>).

¹⁴² See footnote 109.

¹⁴³ See footnote 115.

¹⁴⁴ CDRH Annual Report Fiscal Year 2024 (<https://www.fda.gov/about-fda/cdrh-reports/cdrh-annual-reports>).

¹⁴⁵ CDRH Annual Report Fiscal Year 2025 (<https://www.fda.gov/about-fda/cdrh-reports/cdrh-annual-reports>).

Strategy #	Activity	FY
3	IMDRF Document Implementation Report	2024 -2025
4	Support creation of a forum for representatives from companies, trade associations, and regulatory jurisdictions to share intelligence and discuss topics of interest	2024 -2025
5	Develop and conduct individualized training for two European regulatory authorities	2024
5	Co-host AIRIS with South Korea's MFDS	2024
5	In-person workshop in Delhi, India to educate industry on FDA's premarket submission process, AI-enabled devices, SaMD, and DH policies	2024
5	Interact with European regulatory authorities	2025

4.10.3. Conclusion

FDA met its international harmonization-related commitments by expanding bilateral partnerships (i.e., Japan, Canada) and multilateral engagement (i.e., participation in IMDRF, MDSAP, APEC), and conducting targeted outreach activities (e.g., forums, conferences, seminars, meetings, WGs) to advance a collaborative regulatory framework through sharing regulatory expertise, promoting reliance on FDA decisions, and fostering relationships with regulatory authorities and industry stakeholders worldwide. FDA continued informing and aligning regulatory strategy by maintaining confidentiality commitments, establishing new confidentiality commitments, and forming the MBCI WG. FDA committed to documenting measurable progress towards international harmonization commitments through publication of numerous documents including reports on CDRH's implementation of IMDRF technical documents, a draft strategic plan, and two international harmonization annual assessments. CDRH will release two more annual assessments reflecting international harmonization progress in FY26 and FY27.

4.11. Progress Toward Achieving Shared Objective of Reducing Average Total Time to Decision

The MDUFA V CL includes a shared vision between FDA and industry that the process improvements outlined in the agreement, when implemented by all parties as intended, should reduce the average TTD for PMA and 510(k) submissions. Success of this program will rely

Table 4-41: MDUFA V Commitment Letter (Excerpt)

MDUFA V Commitment Letter Addressed in This Section

- FDA will be reporting Total Time to Decision performance.
- FDA and industry will participate in the independent assessment of progress toward this outcome.

on the cooperation and dedicated efforts of both FDA and applicants to reduce their respective portions of TTD. Consistent with this shared vision, the CL states that "FDA and industry will participate in the independent assessment of progress toward this outcome," and this section fulfills that commitment.

Booz Allen examined Annual and Quarterly MDUFA V report data to assess performance trends in the average FDA and industry days to MDUFA decision, and whether the available data illuminate any methodological or structural factors that may affect the feasibility of meeting the shared outcome TTD goals.

4.11.1. Reporting on and Progress Toward TTD Performance Goals

Reporting on Total Time to Decision Performance

FDA reported their TTD performance in the FY 2025 MDUFA Performance Report and included data up to September 30, 2025. FDA reported that the TTD goal for FY23 510(k) TTD was met while TTD goals for FY24 510(k) TTD and FY23 PMA TTD were not met. At the time of writing, the FY24 PMA TTD cohort was not yet closed and therefore, not reported.

Trends in FDA and Industry Days

To assess performance, Booz Allen reviewed historical quarterly performance data to capture trends in the average number of “FDA Days” and “Industry Days” which reflect the average number of days submissions are either under FDA review or sponsor review, respectively, and contribute to the calculation of TTD.^{146,147} These historical data indicate that, overall, the average number of FDA days and industry days to MDUFA decision seems to be lower in MDUFA V than MDUFA IV, though some variability across fiscal years is observed (Figure 4-6). In addition, the average FDA Days to MDUFA V decision fell within the performance review goal margins outlined in the MDUFA V CL for 510(k) and PMA (i.e., a MDUFA decision within 90 and 180 FDA Days, respectively).

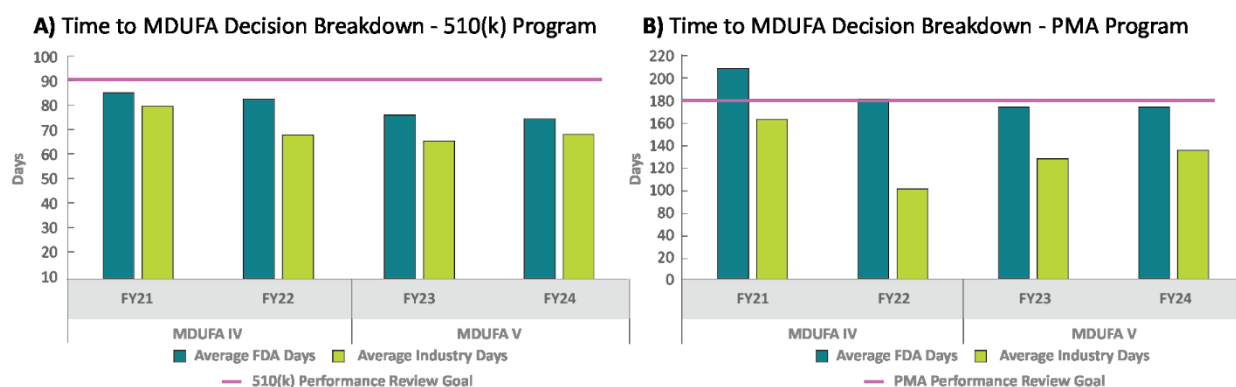


Figure 4-6: Historical Average FDA and Industry Days for 510(k) and PMA Review Programs

Factors Affecting TTD Performance

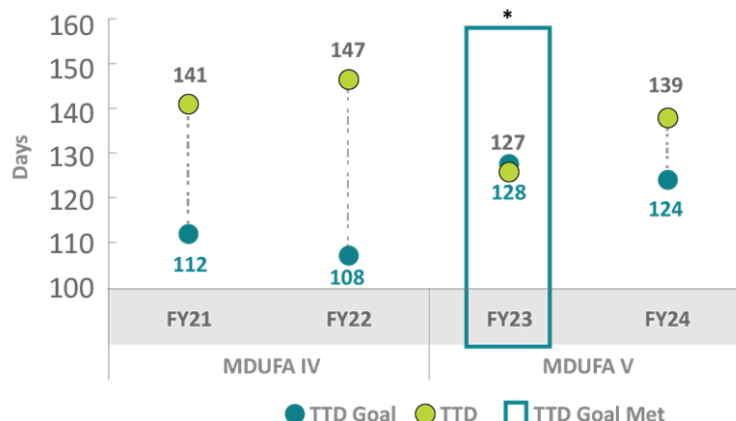
A change in methodological approach to the calculation of TTD may, in part, account for why FDA and industry met the 510(k) TTD goal in FY23 but missed it in FY24, as well as the preceding MDUFA IV years. Specifically, the MDUFA V CL stipulates that for FY23, 510(k) submissions with holds greater than 180 days, as well as those with the highest 5% TTD of the remaining cohort, are excluded from the calculation, whereas for FY24-27 (and previously, throughout MDUFA IV), submissions with the highest and lowest 2% TTD are excluded from the calculation.¹⁴⁸ This methodological approach translates into a more robust trim of excessively long submissions during FY23, which is reflected by a meaningful decrease in annual TTD performance for FY23 (Figure 4-7). Reverting in FY24 to the distributional trim employed during MDUFA IV re-introduces submissions with excessively high hold times that negatively impact review time and increase the annual average TTD for FY24, similar to what is seen in the annual performance for FY21 and FY22 (Figure 4-7).

¹⁴⁶ See footnote 21.

¹⁴⁷ See footnote 22.

¹⁴⁸ MDUFA IV Commitment Letter (<https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2017-mdufa-iv>).

TTD Goal v TTD Performance - 510(k)



* Alterations to TTD methodological approach may, in part, account for why FDA and industry met the 510(k) TTD goal in FY23.

Figure 4-7: MDUFA IV and V TTD Performance for 510(k) Submissions

Though not subject to a change in methodological approach, the missed PMA TTD goals may be, at least in part, due to disruptions faced during the COVID-19 pandemic. The PMA TTD is calculated as a three-year rolling average, meaning that the FY21-23 data may partially reflect the Agency's prioritization of EUAs and other PHE actions, which contributed to longer review times across premarket review programs including PMA.

Historical data can provide insights into plausible premarket review efficiencies realized between MDUFA funding periods, and this assessment found evidence that both FDA days and Industry days to MDUFA decision appeared generally lower during the MDUFA V period compared to the MDUFA IV period. However, as this assessment relied on data extracted from MDUFA Quarterly and Annual reports, the types of data and metrics available to inform its findings were inherently limited. In this context, there are variables beyond the methodology dictating how TTD is calculated that may help further contextualize why TTD goals for 510(k) and PMA submissions were missed during the MDUFA V period, despite improvements in both FDA and industry performance.

4.11.2. Conclusion

FDA met its commitments to report on TTD and participate in an independent assessment of progress towards TTD Performance Goals. Based on closed reporting cohorts, FDA reported meeting the 510(k) FY23 goal and missing the 510(k) FY24 goal and PMA FY23 goal. These outcomes may be attributable in part to methodological factors specific to how TTD is calculated under MDUFA V, and in part to the lasting effects of COVID-19 pandemic disruptions on PMA review timelines, as described above.

5. Summary

Overall, as of the publication date of this report, Booz Allen's assessment found that FDA met the relevant commitments for the program areas specified for the independent assessment as agreed upon in the MDUFA V CL. FDA also met their commitment to report on shared outcome goals, and to participate, with industry, in an independent assessment of progress towards them. A detailed mapping of each commitment to status is provided in Appendix D Status of MDUFA V CL Deliverables

FDA has made substantial progress toward meeting their MDUFA V commitments, but there are a number of commitments listed in Table 5-1 with future or recurring deadlines. For example, for PSE, CDRH is funding a robust research agenda to generate modified or adapted PRO instruments that are intended to be made publicly available through published literature or planned updates to the PRO Compendium on the FDA website and began developing

three patient-friendly educational modules (one of which was published on June 3, 2026) intended to facilitate industry efforts for collaborating with patients. For Deficiencies, FDA has met all of their statement of basis goals to date, but the goals shift on an annual basis, with more aggressive targets in FY 2026 and FY 2027 that cannot be assessed in this report. Finally, for International Harmonization, FDA has committed to publishing an annual assessment starting in FY 2024, which they have achieved in FY 2024 and FY 2025, but there remain future commitments in FY 2026 and FY 2027 that cannot be assessed yet.

Table 5-1: Future and Recurring Deadlines

Assessment Area	Commitment (Excerpt)	Actions Taken	Expected Completion
Deficiencies	FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in Deficiency letters as follows...90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 28591:1999 (“Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection”).	CDRH is continuing improvement activities and consistent audit efforts to ensure Deficiency letters meet FY 2026 and FY 2027 goals	End of FY 2026 and FY 2027
Deficiencies	FDA will review each fiscal year’s audit results with industry no later than the first quarterly meeting of the following fiscal year.	CDRH will analyze and present FY 2026 and FY 2027 data to industry	No later than first quarterly meeting of FY 2027 and FY 2028
PSE	Develop case examples of modified or adapted PRO instruments to make efficient use of existing validated PRO instruments which may be improved or adapted to other subpopulations or other regulatory uses in a more streamlined and expeditious manner than creating novel PROs.	CDRH developed publications on modified and adapted PROs	Expected publication by end of MDUFA V
PSE	Facilitate industry efforts to collaborate with patients in key areas by generating patient-friendly educational modules on device trials, RWD, device development tools, and regulatory frameworks.	CDRH is developing industry training	Expected training rollout end of MDUFA V
International Harmonization	Publish an annual assessment of the international harmonization activities described in the strategic plan.	FDA will publish an annual assessment	End of FY 2026 and FY 2027

APPENDIX A: Glossary

Table 5-2: MDUFA V Report Glossary

Abbreviation or Acronym	Definition
ABHI	Association of British HealthTech Industries
ACLA	American Clinical Laboratory Association
AE	Adverse Events
AI	Artificial Intelligence
AIOLIS	Assessment of IntraOcular Lens Implant Symptoms
AIRIS	AI and International Symposium
AMDF	African Medical Devices Forum
APEC	Asia-Pacific Economic Cooperation
AQL	Acceptance Quality Limit
BCI	Brain-Computer Interface
BPI	Business Process Improvement
CBER	Center for Biologics Evaluation and Research
CCP	Customer Collaboration Portal
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDSCO	Central Drugs Standard Organization
CERSI	Centers of Excellence in Regulatory Science and Innovation
CMS	Centers for Medicare & Medicaid Services
CL	Commitment Letter
COA	Clinical Outcome Assessment
CoEs	Centers of Excellence
CoP	Communities of Practice
COU	Context of Use
CTS	Center Tracking System
DH	Digital Health
DHAC	Digital Health Advisory Committee
DHCoE	Digital Health Center of Excellence
DHT	Digital Health Technology
DI	Data Integrity
DICE	Division of Industry and Consumer Education
DPCD	Division of Patient-Centered Development
EI	Early Interaction
EIR	Establishment Inspection Reports

Abbreviation or Acronym	Definition
ELP	Experiential Learning Program
EMC	Electromagnetic Compatibility
EUA	Emergency Use Authorization
FAQ	Frequently Asked Questions
FD&C	Federal Food, Drug and Cosmetics
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FPP	Focal Point Program
FY	Fiscal Year
GMLP	Good Machine Learning Practice
GRRP	Good Regulatory Review Practices
HBD	Harmonization by Doing
HDE	Humanitarian Device Exemption
IDE	Investigational Device Exemption
IMDRF	International Medical Device Regulator Forum
IT	Information Technology
IVD	<i>In Vitro</i> Diagnostic
KCCQ	Kansas City Cardiomyopathy Questionnaire
KPI	Key Performance Indicators
LMS	Learning Management Systems
MAUDE	Manufacturer and User Facility Device Experience
MBCI	Multilateral Brain-Computer Interface
MDDT	Medical Device Development Tools
MDIC	Medical Device Innovation Consortium
MDMA	Medical Device Manufacturers Association
MDR	Medical Device Reporting
MDSAP	Medical Device Single Audit Program
MDUFA	Medical Device User Fee Amendments
MDUFMA	Medical Device User Fee and Modernization Act
MFDS	Ministry of Food and Drug Safety
MHRA	Medicine and Healthcare products Regulatory Agency
MITA	Medical Imaging & Technology Alliance
ML	Machine Learning
MR	Magnetic Resonance
NEST	National Evaluation System for health Technology
NoDEX	Network of Digital Health Experts
NSE	Not Substantially Equivalent

Abbreviation or Acronym	Definition
OBA	Oregon Bioscience Association
OCEA	Office of Clinical Evidence and Analysis
OCP	Office of Communication and Program Operations
OHT	Offices of Health Technology
OPEQ	Office of Product Evaluation and Quality
ORP	Office of Regulatory Programs
PCC	Patient and Caregiver Connection
PCCP	Predetermined Change Control Plan
PDF	Portable Document Format
PFDD	Patient-Focused Drug Development
PGHD	Patient Generated Health Data
PHE	Public Health Emergency
PMA	Premarket Approval
PMDA	Pharmaceuticals and Medical Devices Agency
POC	Points of Contact
PPI	Patient Preference Information
PREVENT	Prepare for and Respond to Existing Virus, Emerging New Threats
PRO	Patient Reported Outcomes
PROM	Patient Reported Outcome Measures
PSE	Patient Science and Engagement
Q&A	Question & Answer
QMOE	Quality Management and Organizational Excellence
QMS	Quality Management System
RAC	Regulatory Authority Council
RCC	Regulatory Cooperation Council
RCP	Reviewer Certification Program
RHSC	Regulatory Harmonization Steering Committee
RO	Review Organization
RTA	Refuse to Accept
RWD	Real-World Data
RWE	Real-World Evidence
S&P	Safety and Performance
SE	Substantially Equivalent
SMART	Submission Memo and Review Templates
SME	Subject Matter Experts
SOP	Standard Operating Procedure
SSED	Summaries of Safety and Effectiveness Data

Abbreviation or Acronym	Definition
TA	Topic Areas
TEMPO	Technology-Enabled Meaningful Patient Outcomes
TMM	Team Management Model
TPLC	Total Product Life Cycle
TS	Technical Screening
TTD	Time to Decision
UK	United Kingdom
U.S.	United States
WG	Working Group
XR	Extended Reality

APPENDIX B: MDUFA V Commitment Letter Deliverables by Report Section

Table 5-3: MDUFA V Commitment Letter Deliverables by Report Section

MDUFA V Commitment Letter Deliverable	Report Section
Premarket Review Efficiencies	Section Link
Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V.	<u>Section 4.1.2. Impact of Tools and Process Improvements on Consistency</u>
Continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants.	<u>Section 4.1.1. Effect of Programs and Policies on Premarket Review Efficiency</u>
Continue to develop electronic submission templates that will serve as guided submission preparation tools for industry.	<u>Section 4.1.2. Impact of Tools and Process Improvements on Consistency</u>
Maintain and improve on the Customer Collaboration Portal.	<u>Section 4.1.2. Impact of Tools and Process Improvements on Consistency</u>
Training and Alignment	Section Link
FDA will continue to evaluate and improve training for new and existing reviewers under this agreement.	<u>Section 4.2.1. Evaluate and Improve Training for New and Existing Reviewers</u> <u>Section 4.2.2. Quality Management and Operations Excellence Program Support Efforts</u>
Best Practices across OHTs in OPEQ	Section Link
Identify and share best practices across OHTs in OPEQ	<u>Section 4.3.1 Proactive Identification of Best Practices</u>
Deficiencies Guidance	Section Link
Update the deficiency guidance to clarify what constitutes a statement of basis and continue alignment with: - Deficiency letters should include a statement of the basis for the deficiencies (e.g., a specific reference to applicable section of a rule, final guidance, recognized standard unless the entire or most of document is applicable). In the instance when the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, FDA will cite the specific scientific issue and the information to support its position. - Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a marketing authorization decision (e.g., 510(k) clearance, PMA approval, and De Novo classification).	<u>Section 4.4.1. Deficiency Guidance</u>

MDUFA V Commitment Letter Deliverable	Report Section
FDA will train staff and managers on the updated guidance and work to make improvements (including incorporating best practices), as appropriate, to address findings from audits and consistent with the guidance.	Section 4.4.1. Deficiency Guidance
FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 2859-1:1999 (“Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection”). FDA will review each fiscal year’s audit results with industry no later than the first quarterly meeting of the following fiscal year.	Section 4.4.2. Performance Goals
Q-Submission Guidance	Section Link
Pre-Submissions will be accepted in accordance with the Pre-Submission acceptance checklist described in FDA’s guidance “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.”	Section 4.5.1. Q-Submission Guidance Changes, Implementation and Impact
By March 31, 2024, the Agency will issue draft guidance to update the guidance on “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant’s question is most appropriate for informal communication instead of a Pre-Submission. FDA will provide an opportunity for the public to comment on the updated guidance. No later than 18 months after the close of the public comment period, the Agency will issue a final guidance. FDA will implement this guidance once final. FDA will train staff and managers on the updated guidance.	Section 4.5.1. Q-Submission Guidance Changes, Implementation and Impact
Third Party Review Program	Section Link
Provide training for Third Parties seeking accreditation by FDA and provide them with access to redacted review memos	Section 4.6.1. Training for Third Parties
FDA will maintain a process to convey changes in expectations for a particular device type to the Third Parties and to industry.	Section 4.6.2. Transparency and Communication
Audit and provide tailored retraining to accredited Third Parties based on the results of audits.	Section 4.6.1. Training for Third Parties
Publish performance of individual accredited Third Parties with at least five completed submissions on FDA’s website.	Section 4.6.3. Third Party Performance
FDA will consider the factors described in the guidance, “510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review,” in determining device type eligibility for the Third Party Review Program. Consistent with that guidance, some device types that rely on clinical data to demonstrate substantial equivalence may be eligible for Third Party Review.	Section 4.6.2. Transparency and Communication
Digital Health Program	Section Link
Continue to develop software and digital health technical expertise to provide assistance for premarket submissions that include software, interoperable devices, or otherwise incorporate digital health technologies, such as artificial	Section 4.7.1. Continued Development of Digital Health Expertise to Support Review

MDUFA V Commitment Letter Deliverable	Report Section
intelligence or machine learning (AI/ML), Virtual, Mixed, and Augmented Reality (VR/MR/AR) and wearables.	Section 4.7.2. Continue Support Review of Digital Health Premarket Submissions
Strengthen efforts to expand staff understanding of digital health topics and enhance consistent evaluation in submissions through training and internal infrastructure (e.g., Focal Point Program).	Section 4.7.1. Continued Development of Digital Health Expertise to Support Review
Continue to participate in international harmonization efforts related to digital health, including work on developing software and other digital health convergence efforts.	Section 4.7.2. Continue Support Review of Digital Health Premarket Submissions
Finalize the draft guidance, “Content of Premarket Submissions for Device Software Functions,” by 18 months from close of the comment period.	Section 4.7.2. Continue Support Review of Digital Health Premarket Submissions
Publish draft guidance describing a process to evaluate a predetermined change control plan for digital health devices.	Section 4.7.2. Continue Support Review of Digital Health Premarket Submissions
Engage with stakeholders, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approach to digital health technologies.	Section 4.7.3. Engagement to Explore Regulatory Approaches to Digital Health
Patient Science and Engagement Program	Section Link
Expand clinical, statistical, and other scientific expertise and staff capacity to respond to submissions containing applicant-proposed use of voluntary patient preference information (PPI), voluntary patient reported outcomes (PROs), and/or patient-generated health data (PGHD). These staff will provide submission review and early consultation/advice to industry during study planning.	Section 4.8.1. Patient Science Expertise and Support
Issue a draft guidance providing best practices on incorporating into premarket studies clinical outcome assessments including their use as primary or co-primary endpoints. A clinical outcome assessment (COA) describes or reflects how a person feels, functions, or survives and can be reported by a health care provider or a non-clinical observer (such as a parent), through performance of an activity or task, or by the patient.	Section 4.8.1. Patient Science Expertise and Support
Support the use of innovative technologies to capture patient input and reduce patient burden to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention.	Section 4.8.3. Promoting Research and Innovation
By the end of FY 2024, hold a public meeting to explore ways to use patient-generated health data to help advance remote clinical trial data collection and support clinical outcome assessments.	Section 4.8.2. Supporting the Integration of Patient Perspectives into Medical Device Development and Regulatory Decision-Making
FDA will undertake the following activities to improve the regulatory predictability and impact of patient science: a. Develop case examples of modified or adapted PRO instruments to make efficient use of existing validated PRO instruments which may be improved or adapted to other subpopulations or other regulatory uses in a more streamlined and expeditious manner than creating novel PROs.	Section 4.8.1. Patient Science Expertise and Support Section 4.8.2. Supporting the Integration of Patient Perspectives into Medical

MDUFA V Commitment Letter Deliverable	Report Section
b. Strengthen efforts to expand staff understanding of Patient Science and Engagement (PSE) topics, and consistent evaluation in submissions through training curriculum and internal infrastructure to improve consistency (e.g., Focal Point Program). c. Update FDA’s existing guidance, “Patient Preference Information Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling,” with pragmatic insights and to address common questions for those interested in the voluntary use of PPI in regulatory submissions. d. Explore opportunities to improve patient science tools for medical devices and incorporate data and perspectives from different patient populations e. Identify high-impact opportunities to incorporate patient perspectives.	<u>Device Development and Regulatory Decision-Making</u> <u>Section 4.8.3. Promoting Research and Innovation</u>
Facilitate industry efforts to collaborate with patients in key areas by generating patient-friendly educational modules on device trials, real-world data, device development tools, and regulatory frameworks. FDA will also make these educational modules publicly available, as appropriate.	<u>Section 4.8.1. Patient Science Expertise and Support</u>
The existing dispute resolution process should be used in the event of disagreement between the applicant and the Agency on the need for PPI, PRO and/or other tools to capture PGHD.	<u>Section 4.8.1. Patient Science Expertise and Support</u>
Real-World Evidence Program	Section Link
The Agency will use user fee revenue for the continued development of RWD and RWE methods and policies to advance regulatory acceptance for premarket submissions, including expanded indications for use and new clearance/approval of new devices, and clarify related reporting requirements.	<u>Section 4.9.1. Continue Developing RWE Program</u>
FDA will update the 2017 guidance document “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices” to provide more clarity on: a. Least burdensome general expectations on what is needed to demonstrate the “Fit-for-Purpose of RWD” for premarket regulatory purposes, including expanded indications for use and new clearance/approval of new devices b. More information, including generalized examples, on previously used and accepted methodologies; and c. Best practices for RWE review.	<u>Section 4.9.1. Continue Developing RWE Program</u>
FDA will continue to advance CDRH’s RWD/RWE Training program for FDA review teams including the medical review staff. Topics will include best practices for RWE review and when to engage with CDRH RWE subject matter experts.	<u>Section 4.9.1. Continue Developing RWE Program</u>
FDA will provide transparent program development updates and financial accounting of User Fee revenue specifically intended for the activities in this section. a. FDA will update stakeholders on the RWE Program activities at two or more open public meetings during the course of MDUFA V.	<u>Section 4.9.2. Enabling Real-World Evidence Transparency</u>

MDUFA V Commitment Letter Deliverable	Report Section
b. FDA hiring of internal experts to support the review of RWD/RWE-related submissions will be tracked. c. If any portion of the user fee funding is distributed to the National Evaluation System for health Technology (NEST), the funding should be used to transparently: i. Support the development of RWD resources to facilitate appropriate access for research studies; ii. Convene experts to develop best practices and, advance innovative methodology approaches with respect to RWE development and analysis; iii. Include, on the organization’s governing board, no fewer than four representatives of the trade associations that participated in the MDUFA V negotiations (AdvaMed, MDMA, MITA, and ACLA), with each association appointing an individual to serve. Industry representation on the governing board, if applicable, will make up at least 25% of the governing board membership at all times, and shall be selected by the industry associations. The representative from each trade association may be part of the staff of the association or appointed from a member company. If any of the trade associations elects not to participate on the governing board or for any additional seats allocated to industry, the participating trade associations will determine how to fill any vacant industry positions. d. By the end of FY 2023, FDA will publish a document requesting public comment on how FDA should use any portion of the user fee funding that may be distributed to any external organization(s) other than NEST to support premarket RWE e. If any portion of the user fee funding is distributed to an external organization(s) other than NEST, the funding will be accounted for in FDA’s quarterly MDUFA report.	
International Harmonization Program	Section Link
Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.	<u>Section 4.10.1 Expanding Engagement and Outreach</u>
Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies, and practices, as needed and consistent with applicable disclosure law and policy.	<u>Section 4.10.1 Expanding Engagement and Outreach</u>
Commencing in FY 2023, assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available to enhance clarity and transparency.	<u>Section 4.10.2 Reporting on International Harmonization Efforts</u>
Support the creation of a forum to engage with relevant stakeholders, including industry representatives and other regulators, to identify	<u>Section 4.10.1 Expanding Engagement and Outreach</u>

MDUFA V Commitment Letter Deliverable	Report Section
opportunities for regulators to leverage one another's approach to decision-making.	
Participate in outreach activities to other regulatory authorities that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.	<u>Section 4.10.1 Expanding Engagement and Outreach</u>
By the end of FY 2023, issue for public comment a draft strategic plan with additional details and timelines associated with achieving the international harmonization objectives described above.	<u>Section 4.10.2 Reporting on International Harmonization Efforts</u>
Commencing with FY 2024, publish an annual assessment of the international harmonization activities described in the strategic plan.	<u>Section 4.10.2 Reporting on International Harmonization Efforts</u>
Assessment of Shared Outcome Goal Performance	Section Link
FDA will be reporting Total Time to Decision performance.	<u>4.11.1 Reporting on and Progress Toward TTD Performance Goals</u>
FDA and industry will participate in the independent assessment of progress toward this outcome.	<u>4.11.1 Reporting on and Progress Toward TTD Performance Goals</u>

APPENDIX C: Overview of Digital Health Product Development Stages

Table 5-4: Overview of the Main Stages of Digital Health Product Development and Related FDA Resources

Market Research and Ideation
• Digital Health Policy Navigator: Interactive tool that helps product developers understand if a software function is subject to the focus of FDA’s regulatory oversight. • Digital Health Frequently Asked Questions (FAQs): List of answers to common questions about digital health regulatory considerations and content to help industry navigate the regulatory landscape. • Device Advice: Webpage with text-based educational resources on medical device laws, regulations, policies, and guidances across the product lifecycle. • CDRH Learn: Multi-media educational resource on product laws, regulations, guidances, and policies. • Patient-Centered Development: CDRH Division providing strategic direction on PSE. • Digital Health Inbox: Central mailbox to submit informal policy questions related to digital health policy.
Feasibility and Risk Analysis
• Medical Device Software Guidance Navigator: Tool designed to help digital health innovators identify FDA guidance documents that are relevant to their medical device software product development. • Digital Health Guidances: Centralized repository of FDA guidance documents for digital health products. • Regulatory Science Tools: Catalog of peer-reviewed regulatory science tools developed by FDA. • Quality System and Good Manufacturing Practices: Educational website on the standards and regulation for quality system and medical device good manufacturing practices. • Small Business Assistance: Introduction and overview of the Small Business Determination Program at CDRH.
Design and Development + Verification and Validation
• Q-Submission Program: Final guidance document on the mechanisms available to medical device submitters through which they can request interactions with FDA. • Request for Information 513(g): Final guidance document outlining the procedures for requesting information regarding the class in which a device has been classified or device requirements under the FD&C Act. • Predetermined Change Control Plan for AI/ML-Enabled Device Software: Final guidance document for the recommendations of PCCPs for AI-enabled devices.
Pre-Launch Preparation
• Content of Premarket Submissions for Device Software Functions: Final guidance document on the recommended documentation for premarket submissions for device software functions. • eSTAR Program: Interactive PDF that guides applicants in the preparation of a medical device submission. • Types of Communication During the Review of Medical Device Submissions: Final guidance document describing the four types of communication that take place during the review cycle of a medical device submission. • Early Orientation: Form of interactive review that allows applicants to perform device demonstrations and provide early clarification on information related to device submission.
Launch + Post-Launch Monitoring and Iteration
• MedWatch: FDA’s public medical product safety reporting program. • Device Registration and Listing: Website outlining establishment registration requirements for medical devices.

- **Deciding When to Submit a 510(k) for a Software Change to an Existing Device:** Final guidance document to outline when a software change to a medical device may require a manufacturer to submit a new premarket 510(k) submission.
- **Medical Device Recalls:** Centralized repository of serious medical device recalls.

APPENDIX D: Status of MDUFA V Commitment Letter Deliverables

Table 5-5: Status of MDUFA V Commitment Letter Deliverables

MDUFA V Commitment Letter Deliverable	Status
Premarket Review Efficiencies	Determination
Evaluate FDA's premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V.	Met
Continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants.	Met
Continue to develop electronic submission templates that will serve as guided submission preparation tools for industry.	Met
Maintain and improve on the Customer Collaboration Portal.	Met
Training and Alignment	Determination
FDA will continue to evaluate and improve training for new and existing reviewers under this agreement.	Met
Best Practices across OHTs in OPEQ	Determination
Identify and share best practices across OHTs in OPEQ.	Met
Deficiencies Guidance	Determination
Update the Deficiency guidance to clarify what constitutes a statement of basis and continue alignment with: a. Deficiency letters should include a statement of the basis for the deficiencies (e.g., specific reference to applicable section of a rule, final guidance, recognized standard unless the entire or most of document is applicable). In the instance when the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, FDA will cite the specific scientific issue and the information to support its position. b. Deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a marketing authorization decision (e.g., 510(k) clearance, PMA approval, and De Novo classification).	Met
FDA will train staff and managers on the updated guidance and work to make improvements (including incorporating best practices), as appropriate, to address findings from audits and consistent with the guidance.	Met
FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 2859-1:1999 ("Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection"). FDA will review each fiscal year's audit results with industry no later than the first quarterly meeting of the following fiscal year.	Met for FY23-25 (FY26-27 Future Deadline)
Q-Submission Guidance	Determination

MDUFA V Commitment Letter Deliverable		Status
Pre-Submissions will be accepted in accordance with the Pre-Submission acceptance checklist described in FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."		Met
By March 31, 2024, the Agency will issue draft guidance to update the guidance on "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission. FDA will provide an opportunity for the public to comment on the updated guidance. No later than 18 months after the close of the public comment period, the Agency will issue a final guidance. FDA will implement this guidance once final.		Met
Third Party Review Program		Determination
Provide training for Third Parties seeking accreditation by FDA and provide them with access to redacted review memos.		Met
FDA will maintain a process to convey changes in expectations for a particular device type to the Third Parties and to industry.		Met
Audit and provide tailored retraining to accredited Third Parties based on the results of audits.		Met
Publish performance of individual accredited Third Parties with at least five completed submissions on FDA's website.		Met
FDA will consider the factors described in the guidance, "510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review," in determining device type eligibility for the Third Party Review Program. Consistent with that guidance, some device types that rely on clinical data to demonstrate substantial equivalence may be eligible for Third Party Review		Met
Digital Health Program		Determination
Continue to develop software and digital health technical expertise to provide assistance for premarket submissions that include software, interoperable devices, or otherwise incorporate digital health technologies, such as artificial intelligence or machine learning (AI/ML), Virtual Mixed, and Augmented Reality (VR/MR/AR) and wearables.		Met
Strengthen efforts to expand staff understanding of digital health topics and enhance consistent evaluation in submissions through training and internal infrastructure (e.g., Focal Point Program).		Met
Continue to participate in international harmonization efforts related to digital health convergence efforts, including work on developing software and other digital health convergence efforts.		Met
Finalize the draft guidance, "Content of Premarket Submissions for Device Software Functions," by 18 months from close of the comment period.		Met
Publish draft guidance describing a process to evaluate a predetermined change control plan for digital health devices.		Met
Engage with stakeholders, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approach to digital health technologies.		Met
Patient Science and Engagement Program		Determination
Expand clinical, statistical, and other scientific expertise and staff capacity to respond to submissions containing applicant-proposed use of voluntary patient preference information		Met

MDUFA V Commitment Letter Deliverable	Status
(PPI), voluntary patient reported outcomes (PROs), and/or patient-generated health data (PGHD). These staff will provide submission review and early consultation/advice to industry during study planning.	
Issue a draft guidance providing best practices on incorporating into premarket studies clinical outcome assessments including their use as primary or co-primary endpoints. A clinical outcome assessment (COA) describes or reflects how a person feels, functions, or survives and can be reported by a health care provider or a non-clinical observer (such as a parent), through performance of an activity or task, or by the patient.	Met
Support the use of innovative technologies to capture patient input and reduce patient burden to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention.	Met
By the end of FY 2024, hold a public meeting to explore ways to use patient-generated health data to help advance remote clinical trial data collection and support clinical outcome assessments.	Met
FDA will undertake the following activities to improve the regulatory predictability and impact of patient science:	
a. Develop case examples of modified or adapted PRO instruments to make efficient use of existing validated PRO instruments which may be improved or adapted to other subpopulations or other regulatory uses in a more streamlined and expeditious manner than creating novel PROs.	Future Deadline
b. Strengthen efforts to expand staff understanding of Patient Science and Engagement (PSE) topics, and consistent evaluation in submissions through training curriculum and internal infrastructure to improve consistency (e.g., Focal Point Program).	Met
c. Update FDA's existing guidance, "Patient Preference Information Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling," with pragmatic insights and to address common questions for those interested in the voluntary use of PPI in regulatory submissions.	Met
d. Explore opportunities to improve patient science tools for medical devices and incorporate data and perspectives from different patient populations	Met
e. Identify high-impact opportunities to incorporate patient perspectives.	Met
Facilitate industry efforts to collaborate with patients in key areas by generating patient-friendly educational modules on device trials, real-world data, device development tools, and regulatory frameworks. FDA will also make these educational modules publicly available, as appropriate.	Future Deadline
The existing dispute resolution process should be used in the event of disagreement between the applicant and the Agency on the need for PPI, PRO and/or other tools to capture PGHD.	Met
Real-World Evidence Program	Determination
The Agency will use user fee revenue for the continued development of RWD and RWE methods and policies to advance regulatory acceptance for premarket submissions, including expanded indications for use and new clearance/approval of new devices, and clarify related reporting requirements.	Met
FDA will update the 2017 guidance document Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices to provide more clarity on:	Met
a. Least burdensome general expectations on what is needed to demonstrate the "Fit-for-Purpose of RWD" for premarket regulatory purposes, including expanded indications for use and new clearance/approval of new devices	

MDUFA V Commitment Letter Deliverable	Status
b. More information, including generalized examples, on previously used and accepted methodologies; and c. Best practices for RWE review.	
FDA will continue to advance CDRH's RWD/RWE Training program for FDA review teams including the medical review staff. Topics will include best practices for RWE review and when to engage with CDRH RWE subject matter experts.	Met
FDA will provide transparent program development updates and financial accounting of User Fee revenue specifically intended for the activities in this section. a. FDA will update stakeholders on the RWE Program activities at two or more open public meetings during the course of MDUFA V. b. FDA hiring of internal experts to support the review of RWD/RWE-related submissions will be tracked. c. If any portion of the user fee funding is distributed to the National Evaluation System for health Technology (NEST), the funding should be used to transparently: i. Support the development of RWD resources to facilitate appropriate access for research studies; ii. Convene experts to develop best practices and, advance innovative methodology approaches with respect to RWE development and analysis; iii. Include, on the organization's governing board, no fewer than four representatives of the trade associations that participated in the MDUFA V negotiations (AdvaMed, MDMA, MITA, and ACLA), with each association appointing an individual to serve. Industry representation on the governing board, if applicable, will make up at least 25% of the governing board membership at all times, and shall be selected by the industry associations. The representative from each trade association may be part of the staff of the association or appointed from a member company. If any of the trade associations elects not to participate on the governing board or for any additional seats allocated to industry, the participating trade associations will determine how to fill any vacant industry positions. d. By the end of FY 2023, FDA will publish a document requesting public comment on how FDA should use any portion of the user fee funding that may be distributed to any external organization(s) other than NEST to support premarket RWE e. If any portion of the user fee funding is distributed to an external organization(s) other than NEST, the funding will be accounted for in FDA's quarterly MDUFA report.	Met
International Harmonization Program	Determination
Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.	Met
Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies, and practices, as needed and consistent with applicable disclosure law and policy.	Met
Commencing in FY 2023, assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available to enhance clarity and transparency.	Met

MDUFA V Commitment Letter Deliverable	Status
Support the creation of a forum to engage with relevant stakeholders, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision-making.	Met
Participate in outreach activities to other regulatory authorities that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.	Met
By the end of FY 2023, issue for public comment a draft strategic plan with additional details and timelines associated with achieving the international harmonization objectives described above.	Met
Commencing with FY 2024, publish an annual assessment of the international harmonization activities described in the strategic plan.	Met for FY24-25 (FY26-27 Future Deadline)
Assessment of Shared Outcome Goal Performance	Determination
FDA will be reporting Total Time to Decision performance.	Met
FDA and industry will participate in the independent assessment of progress toward this outcome.	Met



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