PREDETERMINED CHANGE CONTROL PLANS

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FDA's Collaborative Patient-Centered Approach to AI/ML-Enabled Devices

2019	2020	2021	2022	2023
• Published AI/ML-SaMD Discussion Paper	• Public Workshop on AI/ML in Radiological Imaging	• Published AI/ML Medical Device Software Action Plan	• Contributed to IMDRF's Key Terms & Definitions: Machine Learning Enabled Medical Devices	• Published Predetermined Change Control Plan for AI/ML Devices Draft Guidance
• First joined Collaborative Community related to AI/ML	• PEAC Meeting on Patient Trust in AI/ML Devices	• Posted List of Currently Marketed AI/ML Devices	• Published Clinical Decision Support (CDS) Final Guidance	• Updated List of Currently Marketed AI/ML Devices
		• Public Workshop on Transparency of AI/ML Devices	• Updated List of Currently Marketed AI/ML Devices	• Published Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles
		• Published Good Machine Learning Practice Principles	• Recognized new Consensus Standard on AI/ML	

We recognize that by working collaboratively with stakeholders we can lay out a clear path toward building a proactive patient-centered approach to the development and use of AI/ML-enabled devices.

Predetermined Change Control Plans for Devices

2022 Omnibus Appropriations Bill

Added section 515C to the FD&C Act so that changes to a device consistent with an approved predetermined change control plan do not require a supplemental application. It may also require that change control plans include labeling required for safe and effective use of the device.

Scope

This provision applies to all devices—it is not specific to software or AI/ML-enabled devices. It applies to both premarket approvals and 510(k) applications. This is consistent with what FDA has been proposing for several years in both our AI/ML Action Plan and Discussion Paper.

Predetermined Change Control Plans

Predetermined change control plans describe planned changes that may be made to the device (and that would otherwise require a supplemental application under section 515) if the device remains safe and effective without any change.

Predetermined Change Control Plans in 2024

CDRH Proposed Guidances for Fiscal Year 2024 (FY2024)

A-List: Prioritized Guidance Documents that CDRH Intends to Publish in FY2024

Final Guidance Topics

- Remanufacturing of Medical Devices
- Medical Device Shortages - Implementation of Section 506J of the Federal Food, Drug, and Cosmetic Act
- Marketing Submission Recommendations for A Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

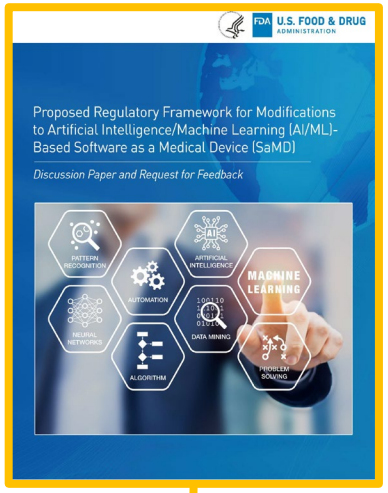
Draft Guidance Topics

- Artificial Intelligence/Machine Learning (AI/ML)-enabled Device Software Functions: Lifecycle Management Considerations and Premarket Submission Recommendations
- Select Updates for the 506J Guidance: Voluntary Notifications of Discontinuance or Interruption of Device Manufacture
- Select Updates for Premarket Cybersecurity Guidance: Cyber Devices
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (revision)
- Pulse Oximeters – Assessing Clinical and Scientific Evidence (revision)
- Predetermined Change Control Plans for Medical Devices

FDA's Collaborative Patient-Centered Approach to AI/ML-Enabled Devices

2019

Discussion Paper



Proposed regulatory framework for modifications to AI/ML-enabled medical device software to assure their safety and effectiveness, including **pre-specification of software changes to enable rapid improvement of software products**

2021

Action Plan

Holistic, patient-centered strategic approach to AI/ML-enabled devices that promotes health equity, including aims to **update the proposed regulatory framework** and **foster a patient-centered approach, including transparency to users**

2023

Draft Guidance


Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on [insert publication date of FR Notice].

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact drugmfd@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

Proposed, least burdensome approach to support safe, iterative improvement through modifications to an AI/ML-enabled device

Predetermined Change Control Plans for AI/ML-Enabled Devices

Predetermined Change Control Plans (PCCPs) can support ensuring that AI/ML-enabled devices better meet the needs of diverse populations.

Contains Nonbinding Recommendations

Draft – Not for Implementation

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FDA U.S. FOOD & DRUG ADMINISTRATION

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The FDA's proposed approach to PCCPs would:

- Put safe and effective advancements in the hands of health care providers and users faster.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial

Scope of Draft Guidance

- Applicable to machine learning-enabled device software functions (ML-DSFs) that a manufacturer intends to modify over time
- Describes proposed recommendations on information to be included in a Predetermined Change Control Plan (PCCP) provided as part of a marketing submission
- Generally, recommendations apply to device constituent part of a combination product, when the device constituent part is (or includes) an ML-DSF
- PCCP is an optional mechanism within a marketing submission for premarket authorization for modifications to an ML-DSF

Draft Policy for PCCPs

An authorized PCCP specifies planned modifications that, if not included in a PCCP, could otherwise require a new marketing submission*

The modifications can be implemented to the ML-DSF without triggering the need for a new marketing submission

Modifications made to an ML-DSF that are not specified in the authorized PCCP could require a new marketing submission*

*Note: pursuant to 21 CFR 807.81(a)(3) and 21 CFR 814.39(a), and in accordance with the "Modifications" guidances. For a list of the "Modifications" guidances, please see the Resources slide.

Proposed Components of PCCPs

Description of Modifications

"What" a manufacturer intends the algorithm to become as it learns

- Identifies specific, planned modifications to ML-DSF that the manufacturer intends to implement
- Draws a "range of FDA-authorized specifications" around initial device characteristics and performance

Modification Protocol

"How" the algorithm will learn/change while remaining safe and effective

- Describes methods that will be followed when developing, validating, and implementing the modifications to ensure the device remains safe and effective
- Methods described in Modification Protocol should be consistent with and support the modifications outlined in Description of Modifications

Impact Assessment

Describes modifications' benefits and risks, and how risks are mitigated

- Assesses benefits and risks of each individual modification, as well as collective impact of modifications, included in the Description of Modifications
- Discusses how activities proposed within Modification Protocol mitigate identified risks to continue to reasonably ensure the safety and effectiveness of the device

Predetermined Change Control Plan

Modification Protocol

- Methods described in Modification Protocol should be **consistent with and support** modifications outlined in Description of Modifications
- Four primary components of a Modification Protocol:
  - **(1) data management practices,**
  - **(2) re-training practices,**
  - **(3) performance evaluation protocols, and**
  - **(4) update procedures, including communication and transparency to users and real-world monitoring plans**
- Include description of how proposed methods are similar to, or are different from, methods used elsewhere in marketing submission

Impact Assessment

Documentation for an Impact Assessment provided to the Agency in a marketing submission containing a PCCP should:

1. Compare version of device with each modification implemented to version of device without any modifications implemented
2. Discuss benefits and risks of each individual modification
3. Discuss how activities proposed within Modification Protocol continue to reasonably ensure safety and effectiveness of device
4. Discuss how implementation of one modification impacts implementation of another
5. Discuss collective impact of implementing all modifications

Establishing a PCCP

- A PCCP is **included in a marketing submission for a device and established as part of that authorization***
- An “authorized PCCP” is one that has been reviewed and established through the device marketing authorization
- To establish a new PCCP for a previously authorized device, the marketing submission must include appropriate marketing submission requirements and the proposed PCCP for the device

*Note: The term “authorization” is used to include clearance of a 510(k), granting of a De Novo, or approval of PMA

Further Questions or Feedback

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