# FDA issues final guidance for AI-driven medical device modifications



On December 4, 2024, the U.S. Food and Drug Administration (FDA) published its final guidance document concerning the Marketing Submissions for a Predetermined Change Control Plan (PCCP) specifically tailored for Artificial Intelligence-Enabled Device Software Functions (AI-DFS). This pivotal document elucidates the scope and framework for PCCPs, affecting how manufacturers approach modifications to AI-driven medical devices.

The final PCCP guidance aims to simplify the regulatory process, allowing device manufacturers to carry out certain preapproved modifications without the need for obtaining separate authorisations for each significant change. Essentially, a PCCP details how modifications will be executed in response to the continual learning capabilities inherent in AI-DFS, streamlining the developmental workflow for manufacturers.

In providing context to the final guidance, it was noted that the recommendations largely align with the draft guidance issued in April 2023. This iteration has benefitted from extensive input, including feedback from multiple Advisory Committee meetings and Public Workshops. While nonbinding, the PCCP Guidance offers critical insights into FDA's regulatory approach towards AI-DFS, the expected submission requirements, and effective practices for manufacturers and developers.

In contrast to the earlier draft guidance, which primarily focused on machine learning (ML)—a subset of AI-DFS—the final guidance expands its applicability to encompass all AI-DFS. However, it maintains a stronger relevance for ML-enabled devices which can gain from predetermined modifications based on ongoing learning algorithms. Furthermore, while the guidance does address combination drug-device products, it clarifies that PCCPs mostly concern the device component.

To establish a premarket authorisation for AI-DFS with an approved PCCP, various application pathways are available, including the Premarket Approval (PMA) pathway for high-risk devices, the traditional 510(k) pathway for lower-risk devices, and the De Novo pathway for novel devices. Despite previous discussions, the guidance states that PCCPs are not applicable to special 510(k) applications, which are reserved for certain predefined device modifications. It suggests that manufacturers engage in discussions with the FDA during a pre-submission process to ensure alignment, though it emphasises that the FDA will not authorise the PCCP at this point.

The guidance sets forth three essential components that must be included in PCCP applications: a detailed description of the modification, a modification protocol, and an impact assessment. Manufacturers are instructed to clarify the nature of modifications—whether they are automatic or manual and the treatment of updates on a global or local basis. They must also justify heterogeneous treatments if applied locally, and state the expected frequency of updates or modifications.

The guidance identifies three types of modifications that may be included in a PCCP: those related to performance specifications of AI-DFS, modifications for device inputs and compatibility, and certain alterations concerning the device's use and performance. Additionally, manufacturers are required to include a modification protocol detailing the methods for developing, validating, and implementing changes, including acceptance criteria to verify device safety and efficacy.

An impact assessment documenting the benefits and risks associated with post-approval modifications is also a crucial requirement. This assessment must outline the strategies manufacturers intend to adopt to mitigate potential risks.

Labeling practices are addressed within the guidance, emphasising the importance of informing consumers about the implications of post-market modifications on AI-DFS. Labels must clearly indicate that the device incorporates ML and has an authorised PCCP, thereby alerting consumers to the necessity of periodic software updates to sustain efficacy.

Moreover, the guidance notes that further modifications to the PCCP will generally mandate a new marketing submission to the FDA, due to the potential alteration in device safety or efficacy.

The release of this final PCCP guidance is significant, as it delineates a pathway for manufacturers to implement preapproved modifications to their AI-enabled medical devices without the burdensome process of separate authorisations for each change. This approach is aimed at facilitating innovation while ensuring patient safety and device efficacy within the rapidly evolving landscape of AI technology in healthcare.

Source: [Noah Wire Services](https://www.noahwire.com)

## Bibliography

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3. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence> - Official FDA guidance document outlining recommendations for PCCPs tailored to AI-enabled devices, including submission requirements and regulatory approaches.
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5. <https://www.mcdermottplus.com/insights/fda-issues-final-guidance-on-pccps-for-ai-enabled-devices/> - Details the essential components of PCCP applications, including description of modifications, modification protocol, and impact assessment.
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