



AdvaMed Releases AI White Paper

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AdvaMed, the world's largest medical technology association representing device, diagnostics and digital technology companies, released a [white paper](#) that reviews the current landscape of artificial intelligence (AI)-based applications and products in the health care sector, and identifies steps to accelerate the use of AI in medical technologies. The trade association highlights two main types of tasks that AI is uniquely well suited to tackle (1) identifying and analyzing patterns in patient charts that practitioners might miss; and (2) automating repetitive routine tasks. AI is being incorporated into a range of technologies in the health care sector, and AdvaMed's white paper focuses primarily on AI/machine learning (ML)-enabled medical devices, which are regulated by the FDA. AdvaMed anticipates that FDA will likely need to issue additional guidance to keep pace with development of AI models, including for adaptive models and approaches to mitigating bias. AdvaMed endorses FDA's use of "Predetermined Change Control Plans" (PCCPs), which permit manufacturers to outline approaches to future modifications as part of an initial submission, and states that PCCPs should evolve to allow for greater post-market modifications for adaptive algorithms. The trade association also calls for domestic and international harmonization of requirements, including development of common AI standards to advance safe, secure and trustworthy use of AI.

Categories

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AI/ML Devices

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