AI-POWERED OPHTHALMIC DEVICES

Regulatory hurdles in the United States versus the European Union.

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For sponsors seeking marketing authorization in both the United States and Europe, it is critical to understand the regulatory differences between these regions, particularly in light of the EU AI Act and the US FDA Final Guidance on Predetermined Change Control Plans for AI-powered device software functions.[1,2] Both the US FDA and the European Commission continue to develop and refine their requirements and policies for AI in health care, including its application to medical devices.[3,4] This evolving regulatory landscape is particularly relevant to sponsors of AI-powered ophthalmic devices driving innovation in ophthalmology.

OPPORTUNITIES AND CHALLENGES IN DEVICE DEVELOPMENT

The AI-powered development of ophthalmic devices presents significant opportunities thanks to the wide range of potential indications, such as the diagnosis of diabetic retinopathy, heart disease, and glaucoma, but regulatory questions remain. In the United States, the absence of a federal AI Act introduces uncertainty for sponsors seeking marketing authorization for AI-powered ophthalmic devices, which are regulated under the US FDA's general device provisions and, increasingly, may be subject to regulation at the state level. To navigate this complexity, sponsors may benefit from participating in the US FDA presubmission programs. For instance, the Q-submission process, highlighted in the US FDA's Predetermined Change Control Plans AI Guidance, provides an avenue for obtaining early US FDA feedback on novel technologies. At the same time, sponsors must account for varying state laws that govern AI use in the absence of a unified federal standard.

NAVIGATING THE EU AI ACT

Publication of the EU's AI Act introduced its own set of uncertainties. Although the aim of the act is to promote innovation, reduce administrative and financial

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burdens, and establish a harmonized internal market for AI, how these general provisions will be applied to AI-powered ophthalmic devices by European health authorities remains to be seen.

HURDLES FOR SPONSORS ACROSS JURISDICTIONS

The fragmented regulatory landscape across jurisdictions presents several challenges for sponsors marketing devices in both the United States and the European Union. These include discrepancies in the type and amount of evidence required for marketing authorization, verification and validation procedures, change control processes, machine learning and device update protocols, data source and privacy requirements, product labeling, and adverse event monitoring. A key question is whether these hurdles are set at comparable levels across regions. For example, must sponsors deploy different algorithms in the European Union and United States based on differing regulatory requirements for data sources?

ADVANCING INNOVATION AND PATIENT CARE

The challenges are compounded by the unique characteristics of AI-powered devices, particularly their machine-learning components. As the field evolves, addressing these regulatory hurdles will become crucial to advancing patient care globally. AI-powered ophthalmic devices have the potential to diagnose serious or life-threatening conditions rapidly and noninvasively. This emphasizes the importance of fostering a regulatory environment that supports innovation while ensuring patient safety. ■

1. Arnold & Porter. Uniting global AI regulatory frameworks: predictions & opportunities. November 13, 2024. Accessed January 14, 2025. https://www.arnoldporter.com/en/perspectives/advisories/2024/11/uniting-global-ai-regulatory-frameworks
2. US Food and Drug Administration. Marketing submission recommendations for a predetermined change control plan for artificial intelligence-enabled device software functions: guidance for industry and Food and Drug Administration staff. December 4, 2024. Accessed January 14, 2025. https://www.fda.gov/media/166704/download
3. US Food and Drug Administration. Artificial intelligence-enabled device software functions: lifecycle management and marketing submission recommendations: draft guidance for industry and Food and Drug Administration staff. January 7, 2025. Accessed January 16 ,2025. https://www.fda.gov/media/184856/download
4. US Food and Drug Administration. Considerations for the use of artificial intelligence to support regulatory decision-making for drug and biological products: draft guidance for industry and other interested parties. January 7, 2025. Accessed January 16,2025. https://www.fda.gov/media/184830/download