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FDA Announces Device Trial Participation Snapshots

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FDA's Center for Devices and Radiological Health (CDRH) recently announced a pilot program to provide consumers and health care professionals with key information about clinical trials that supported the FDA's approval of new medical devices. This program is modeled after the Center for Drug Evaluation and Research (CDER) drug trials snapshots program. The snapshots address questions about who participated in clinical studies of new medical technology and what clinical trial information is available about how it works in different groups of people. Snapshots are currently available for approvals of higher risk devices approved under original premarket approval (PMA) applications from April to July 2024. The snapshots only provide information that was available at the time of approval, and the FDA does not plan to update them over time, with real-world data, for example.

This pilot program is part of the FDA's ongoing effort to increase transparency around diversity of clinical trial participants in studies of novel medical products.

Comments on the snapshots pilot program may be submitted to www.Regulations.gov under docket number FDA-2024-N-4561 by January 13, 2025.

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