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New Expanded Access eRequest App Allows Physicians to Submit EA Requests Online

Washington, DC – Submitting expanded access requests to FDA just got easier for physicians. The Reagan-Udall Foundation for the FDA, with input from experts at FDA, today launched <u>Expanded Access</u> <u>eRequest</u> to streamline expanded access for individual patients in non-emergency settings.

"Time is critical when patients have a serious or life-threatening disease or condition and do not have other therapeutic options," said FDA Principal Deputy Commissioner Amy Abernethy, MD, PhD. "We want to make it easier for physicians to apply for expanded access for their patients and allow these health care providers to focus on the clinical aspects of care."

The eRequest online app walks physicians and other healthcare providers screen-by-screen through the expanded access process – from determining if expanded access is appropriate for their patient to submitting the request to FDA. eRequest's home on the Foundation's Expanded Access Navigator means physicians can identify potential investigational therapies; access sponsor information; complete, sign, and submit FDA Form 3926; upload supporting documentation; and review additional resources all in one place. The app is compatible with multiple devices, so physicians can explore expanded access in real time with their patient and then submit the request when completed.

"The Expanded Access eRequest helps physicians and other prescribers travel easily through a process that can be confusing," says Susan C. Winckler, RPh, Esq., CEO of the Foundation. "We are pleased to work with FDA to simplify the journey for physicians, and ultimately, for patients."

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration (FDA) accomplish its mission. The Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and polices to keep pace with today's rapidly evolving science.

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