

# A New Medical/Investigational Drugs Info Reference Resource: The Expanded Access Navigator

 [www.infodocket.com/2017/07/25/a-new-medical-info-resource-the-expanded-access-navigator/](http://www.infodocket.com/2017/07/25/a-new-medical-info-resource-the-expanded-access-navigator/)

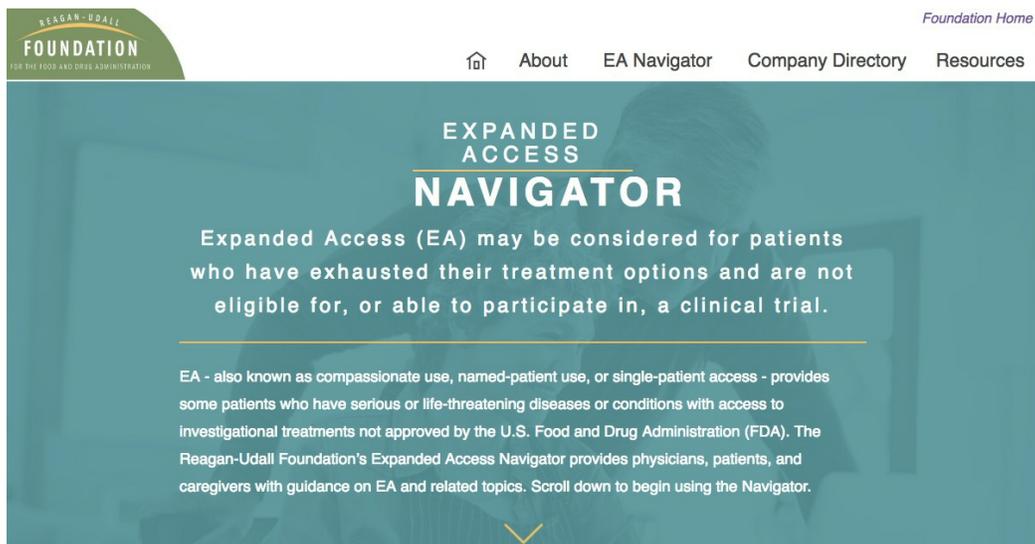
Gary Price

From the [Food and Drug Administration \(FDA\) Voices Blog](#):

*Patients with serious or immediately life-threatening diseases or conditions who have no comparable or satisfactory alternative therapy and who seek access to potentially life-saving investigational drugs will have another option to guide them through the process – thanks to the launch today of a new online tool called the [Expanded Access Navigator](#). The development of the Navigator was a team effort led by the Reagan-Udall Foundation in collaboration with patient advocacy groups, the pharmaceutical industry, FDA, and others in the Federal government.*

*[Clip]*

*The Expanded Access Navigator helps to educate patients and physicians about the process. Most of what they need to seek expanded access is now available in this single online location, including a directory where companies can submit public links to their expanded access policies, criteria used by companies to determine whether to make a drug available through expanded access, and contact information. While not a portal for applications, the directory is the first consolidated starting point for researching available investigational therapies. To help users find information quickly, the Navigator is separated into one section for patients and caregivers, and another for physicians.*



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## EXPANDED ACCESS NAVIGATOR

Expanded Access (EA) may be considered for patients who have exhausted their treatment options and are not eligible for, or able to participate in, a clinical trial.

EA - also known as compassionate use, named-patient use, or single-patient access - provides some patients who have serious or life-threatening diseases or conditions with access to investigational treatments not approved by the U.S. Food and Drug Administration (FDA). The Reagan-Udall Foundation's Expanded Access Navigator provides physicians, patients, and caregivers with guidance on EA and related topics. Scroll down to begin using the Navigator.

*The patient and caregiver section provides links to resources such as how to determine if a patient can participate in a clinical trial, the difference between an intermediate-size or larger expanded access program and a single-patient expanded access program, and their physician's role in helping them obtain an investigational drug. Patients also can reach out to FDA's Office of Health and Constituent Affairs' Expanded Access Team.*

*Physicians can use the tool to identify investigational treatment options for their patients, explore clinical trials on behalf of their patients, learn how to engage with FDA and pharmaceutical companies*

as part of the process, and read about important factors to discuss with patients when considering expanded access. After using the Navigator and deciding on an investigational drug treatment option, physicians may contact FDA's Division of Drug Information for assistance with their expanded access application.

*The site is a valuable resource for information about obtaining access to an investigational drug through an expanded access program, but it also offers a great deal of useful information about participation in clinical trials, which is the preferred option. Clinical trials help to ensure adequate patient protection and may provide the evidence of safety and effectiveness required to support approval of a marketing application.*

*The Partners who contributed to the website's development, in addition to FDA, include the American Cancer Society, the American Society of Clinical Oncology, the Biotechnology Innovation Organization, the Pharmaceutical Research and Manufacturers of America, Foundation Medicine, Susan G. Komen, Bristol-Myers Squibb, Genentech, Janssen, Lilly, Merck, and Pfizer.*

Read the [Complete Blog Post](#)

Direct to the [The Expanded Access Navigator](#)