

Expanded Access Navigator

Project Facilitate:

Enhancing the Single Patient IND Process for Oncology Health Care Providers

May 16, 2019

Who We Are

Reagan-Udall Foundation for the FDA

- Created by Congress to support the FDA in its mission to promote public health and improve regulatory science
- Asked by FDA and others to create an online platform to provide clear, factual information about Expanded Access (EA), including links to companies offering EA for their investigational drugs

<http://navigator.reaganudall.org/>

How the Expanded Access Navigator Helps

Guides for Patients, Physicians and Companies

- Takes users step-by-step through the process of expanded access requests
- Serves as a roadmap for single-patient expanded access requests that inform patients, physicians and companies exploring EA

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The screenshot shows the Reagan-Udall Foundation logo at the top, followed by the title 'TREATING AND REPORTING'. Below the title is a paragraph of text explaining the process. A vertical list of yellow buttons contains the following steps: IDENTIFYING TREATMENT, EXPLORING CLINICAL TRIALS, CONSIDERING EA PROGRAMS, CONSIDERING SINGLE-PATIENT EA, REQUESTING EA, SUBMITTING TO THE FDA, SEEKING IRB APPROVAL, and TREATING AND REPORTING. The 'TREATING AND REPORTING' button is highlighted. At the bottom are two buttons: 'Download to save or print' and 'Copy Link'.

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TREATING AND REPORTING

With all approvals and proper documentation in place, EA treatment can begin. First, the pharmaceutical company will provide the investigational treatment. Then you, the treating physician, will administer the investigational treatment. There are several reporting requirements to follow as you treat your patient.

- IDENTIFYING TREATMENT
- EXPLORING CLINICAL TRIALS
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- SEEKING IRB APPROVAL
- TREATING AND REPORTING

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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.

- Promotes greater patient equity
- Makes forms downloadable for patients to help their physicians
- Explains importance of FDA reporting requirements
- Allows companies to demonstrate compliance with laws mandating their expanded access policies be publicly available

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Questions or Suggestions?

Please send an email to:

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Thanks!

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