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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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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