REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

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/

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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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- 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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