



NYU Grossman School of Medicine
Division of Medical Ethics
Working Group on Compassionate Use & Preapproval Access

Single Patient Access to Investigational Therapeutic Agents Resource Guide

[Working Group on Compassionate Use & Preapproval Access \(CUPA\) Resources:](#)

Provides links to NYU preapproval access resources, as well as other access-related resources

[FDA's Expanded Access Page:](#) Descriptions of available expanded access pathways in the U.S., describing all applicable rules and regulations related to drugs, biological products, and medical devices

[Reagan Udall-Expanded Access Navigator:](#) A comprehensive resource describing options for accessing investigational treatments, and step-by-step instructions to help physicians find potential investigational treatments, secure IRB approval, and [e-filing an application for individual patients with FDA](#)

[ClinicalTrials.gov](#) is a database of clinical trials. Sponsors are also required to list available expanded access programs. Search in "[Advanced Search](#)," And use the dropdown menu under "Study Type" to find expanded access studies

Company Websites: Companies/drug sponsors are required to list their expanded access program policies and applicable contact information online. Many are listed in the [Reagan-Udall Navigator Company Directory](#). Most post this information on their websites.

[FDA Project Facilitate:](#) Provides direct assistance to health care providers with expanded access requests in oncology

For FDA help and information in areas other than oncology, contact FDA's Division of Drug Information: Email: druginfo@fda.hhs.gov | Telephone: 855-543-3784 or 301-796-3400