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