Single Patient Expanded Access

For patients with serious or life threatening disease who have exhausted all available treatments and are not eligible for a clinical trial, Expanded Access may be an option. Also known as Compassionate Use or Single Patient Request, this request process is a potential pathway for access to investigational medicines. This document describes the key steps for treating physicians to identify and submit such requests to pharmaceutical companies as well as the requirements for FDA and IRB review.

1 Discuss treatment options

If it is determined that all approved treatment options have been exhausted and a clinical trial is not an option, it may be an opportunity to discuss investigational medicines with the patient.

2 Identify treatment & submit request

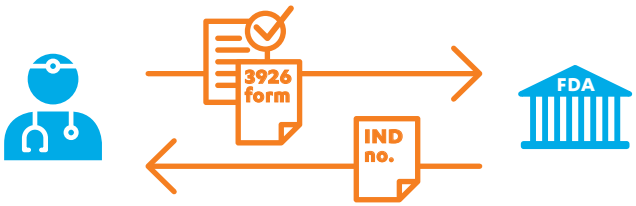
When a potential investigational medicine is identified, treating physician may submit a request to the manufacturer. Various company policies for expanded access may be found on the Expanded Access Navigator.

3 Company reviews request

If the company approves the request, physician will receive a Letter of Authorization and required documents.

4 Submit to FDA for review

If approved by the company, the requesting physician submits Form 3926 and required documentation to the FDA for evaluation. If approved, the FDA will provide an Investigational New Drug (IND) number.



5 Submit to Institutional Review Board (IRB)

The requesting physician submits all FDA and company approval documentation with an expanded access protocol and informed consent to the IRB for review.

6 Company ships investigational medicine

Once the company has all required information in hand, the company ships the investigational medicine to the requesting physician with necessary guidance.

7 Treatment & post-treatment

The treating physician documents and submits required information to the company, IRB, and FDA (e.g., follow up information, treatment summary).

If you are a physician and have questions about submitting a request for expanded access for an investigational drug or biologic, contact the Division of Drug Information at **301-796-3400** or **druginfo@fda.hhs.gov**. For emergency use of drugs, biologics and medical devices outside of business hours, contact the FDA Emergency Call Center at **866-300-4374** after 4:30pm EST weekdays and all day on weekends.