

# FDA Drug Topics: Overview of Expanded Access (EA) Program and EA eRequest Site



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- **Explain the primary purpose of Expanded Access and how it differs from clinical trials.**
- **Distinguish between emergency and non-emergency Expanded Access requests for individual patients.**
- **Identify useful resources for preparing Expanded Access requests for individual patients.**

# What is Expanded Access (EA)?

- Expanded Access is the use of an investigational drug or biologic to treat a patient with a serious or immediately life-threatening disease or condition who **does not have comparable or satisfactory alternative therapies** to treat the disease or condition.
  - Intent is clearly treatment
- Contrast with investigational drug in a clinical trial where the primary intent is research
  - Systematic collection of data with the intent to analyze it to learn about the drug



# Expanded Access Regulations and Guidance

[Code of Federal Regulations]  
[Title 21, Volume 5]  
[Revised as of April 1, 2020]  
[CITE: 21CFR312.300]

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER D - DRUGS FOR HUMAN USE

PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION

Subpart I - Expanded Access to Investigational Drugs for Treatment Use

Sec. 312.300 General.

(a) *Scope.* This subpart contains the requirements for the use of investigational drugs where availability is limited by a risk strategy (REMS) when the primary purpose is to diagnose, monitor, or treat a disease or condition. The aim of this subpart is to facilitate access to investigational drugs to patients with serious diseases or conditions when there is no satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.

(b) *Definitions.* The following definitions of terms apply to this subpart.  
*Immediately life-threatening disease or condition* means a disease or condition for which there is a reasonable likelihood that death will occur within a matter of days if death is likely without early treatment.

*Serious disease or condition* means a disease or condition that has a substantial impact on day-to-day functioning. Short-lived morbidity is usually not sufficient, but the morbidity need not be persistent or recurrent. Whether a disease or condition is serious is a judgment, based on its impact on such factors as survival, quality of life, and the likelihood that the disease, if left untreated, will progress to a more serious one.

## Expanded Access to Investigational Drugs for Treatment Use —

### Questions and Answers

#### Guidance for Industry

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

June 2016  
Updated October 2017  
Procedural

- Describe the **general criteria** applicable to all categories of access, and additional criteria that must be met for each access category
- Describe the **requirements** for submission
- Describe the **safeguards** applicable to Expanded Access Programs (EAP), such as informed consent, IRB review, and reporting requirements

21 CFR 312.300+

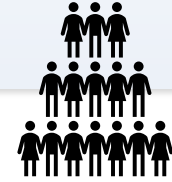
# Three General Categories of Expanded Access and Their Common Requirements



**Individual patient**  
(includes non-emergency and emergency use)



**Intermediate-size population**



**Treatment Investigational New Drug (IND)/ Investigational Device Exemption (IDE) or Treatment Protocol**



## **Common Requirements:\***

- 1. Patients have serious or immediately life-threatening disease or condition**
- 2. No comparable or satisfactory alternative therapy**
- 3. Patient is unable to participate in a clinical trial for the investigational product**
- 4. Potential benefits must justify the potential risks of the treatment**
- 5. Providing the product under EA must not interfere with or compromise the investigational product development program**

\* Under EA, access to an investigational product additionally depends on a sponsor or manufacturer choosing to make the product available to patients.

# Recent Updates to Expanded Access Guidance

- **2017 edits to the Final Guidance: *Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers***
  - **Permits IRB review for single patient INDs by a single member of the IRB instead of the full membership**
    - **Emergency: Report to IRB within 5 working days**
    - **Non-emergency: Physician can select Box in Field 10b on Form FDA 3926 (or submit waiver request with Form FDA 1571)**
  - **Clarifies how FDA reviews and uses adverse event data in the expanded access context**
  - **Explains 21st Century Cures requirement that expanded access policies be publicly posted**

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Expanded Access to  
Investigational Drugs  
for Treatment Use —

Questions and Answers

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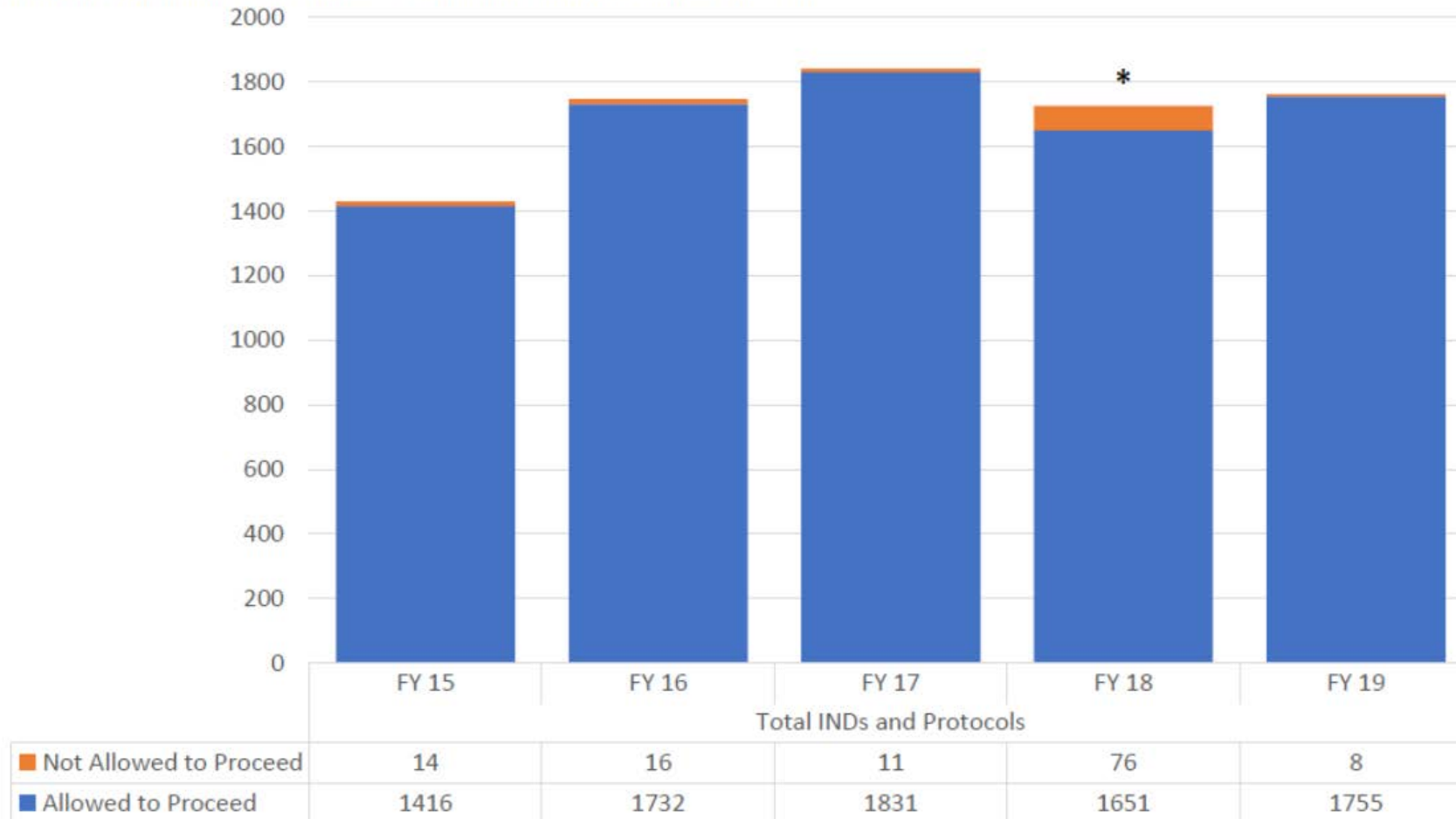
June 2016  
Updated October 2017  
Procedural

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# CDER and CBER Individual EA IND Submissions FY 2015–2019

## CBER\* and CDER Expanded Access IND Submissions Fiscal Year (FY) 2015 - 2019

*\*A large number of the FY18 single patient submissions were for non-emergency use of the same product, for which FDA determined the risks associated with its use would be unreasonable for the patients involved or there was insufficient information to make a determination. Excluding these submissions, 91% of CBER's non-emergency single patient expanded access submissions received were allowed to proceed.*



## Resources provided by FDA

# User-friendly FDA Webpages for EA

## Expanded Access

Expanded Access |  
Information for Patients

Expanded Access |  
Information for  
Physicians

Expanded Access |  
Information for Industry

Expanded Access | How  
to Submit a Request  
(Forms)

Expanded Access |  
Keywords, Definitions,  
and Resources

FDA's Expanded Access  
Contact Information



Sometimes called “compassionate use”, expanded access is a potential pathway for a patient with an **immediately life-threatening condition or serious disease or condition** to gain access to an **investigational medical product** (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.



## Key Contact Information

### 1. During Normal Business Hours (8 a.m. - 4:30 p.m. ET, weekdays)

For **specific questions** during normal business hours:

- **Investigational drugs:** 301-796-3400 or [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) [CDER's Division of Drug Information], or contact the appropriate [review division](#), if known
  - **Oncology drugs:** 240-402-0004 or [ONCProjectFacilitate@fda.hhs.gov](mailto:ONCProjectFacilitate@fda.hhs.gov)
- **Investigational medical devices:** 301-796-7100 or [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov) [CDRH's Division of Industry and Consumer Education]
- **Investigational biologics:** 240-402-8020 or 800-835-4709 or [industry.biologics@fda.hhs.gov](mailto:industry.biologics@fda.hhs.gov) [CBER's Office of Communication, Outreach and Development]

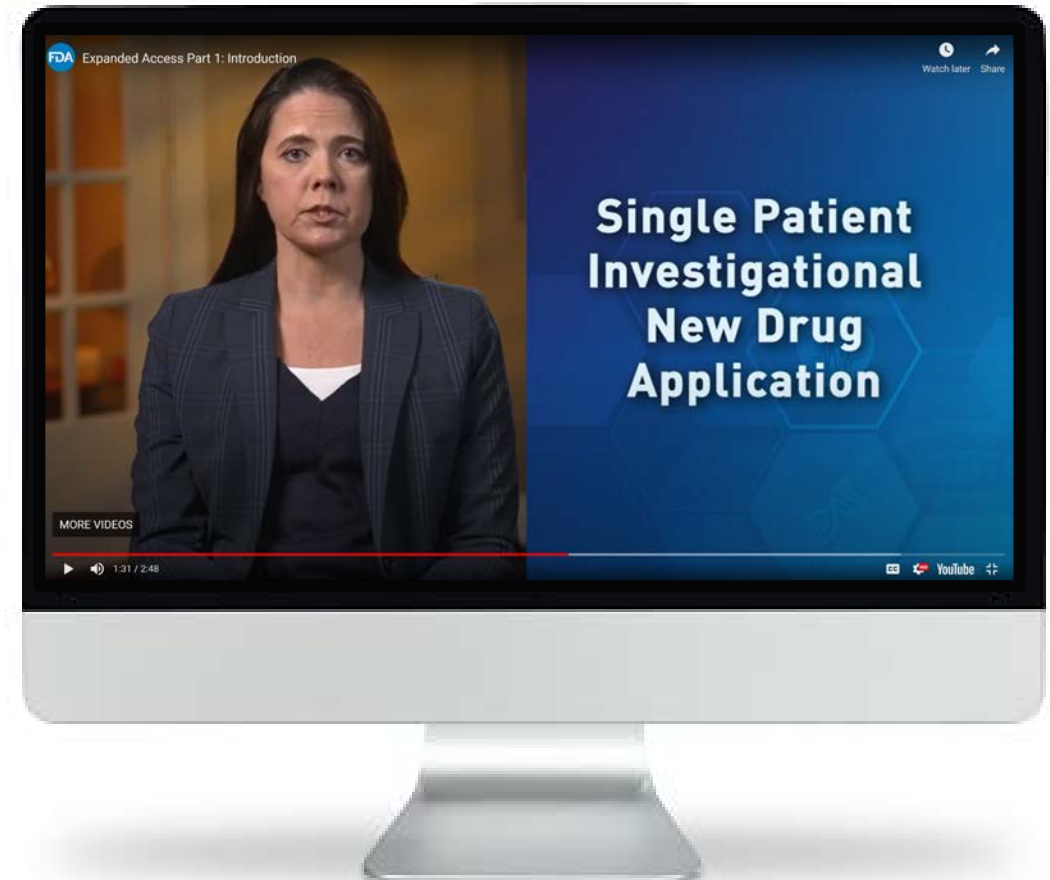
For **general questions**, or if you are unsure of who to contact, contact the Patient Affairs Staff at 301-796-8460 or [patientaffairs@fda.hhs.gov](mailto:patientaffairs@fda.hhs.gov).

### 2. After 4:30 p.m. ET weekdays and all day on weekends

For **emergency requests** for all medical products (drugs, biologics, and medical devices) contact **FDA's Emergency Call Center** at 866-300-4374.

# User-friendly FDA Webpages for EA (cont.)

- The webpages were recently updated to reflect recommendations from stakeholders
- Creation of a series of informational videos:
  - [Expanded Access Part 1: Introduction](#)
  - [Expanded Access Part 2: How to Submit a Single Patient IND](#)
  - [Expanded Access Part 3: How to Complete Form FDA 3926 for Initial Submissions](#)
  - [Expanded Access Part 4: How to Complete Form FDA 3926 for Follow-up Submissions](#)



**Additional resources on the  
Reagan-Udall Foundation for the FDA  
website**

# Expanded Access Navigator: Resources

## Expanded Access Navigator

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.



### Expanded Access eRequest

Physicians: Electronically request non-emergency use of medical products for your patients

GET STARTED



Expanded Access - 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.

Select the step-by-step guide best matching your needs.



For Patients and Caregivers



For Physicians and  
Healthcare Providers



For Companies and Sponsors



# Foundation Resources

REAGAN-UDALL  
FOUNDATION  
for the Food and Drug Administration

ABOUT GUIDES COMPANY DIRECTORY RESOURCES eREQUEST COVID-19

## Resources

ALL FOR PATIENTS/CAREGIVERS FOR PHYSICIANS/HEALTHCARE PROVIDERS FOR COMPANIES/SPONSORS FORMS

**Expanded Access eRequest App**  
Expanded Access eRequest allows physicians and other prescribers to request non-emergency use of medical products for patients. The app allows physicians to complete, sign, and submit Form 3926 online to FDA.  
[READ MORE >](#)

**Glossary of Terms**  
Active clinical trial A trial open for enrollment of patients Active, not recruiting (clinical trial) The study is ongoing but new participants are not currently being enrolled Adverse event A medical problem that happens during treatment with a drug or other therapy, which may be mild, moderate...  
[READ MORE >](#)

**Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency**  
FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic. Read FDA's Guidance for IRBs and...  
[READ MORE >](#)

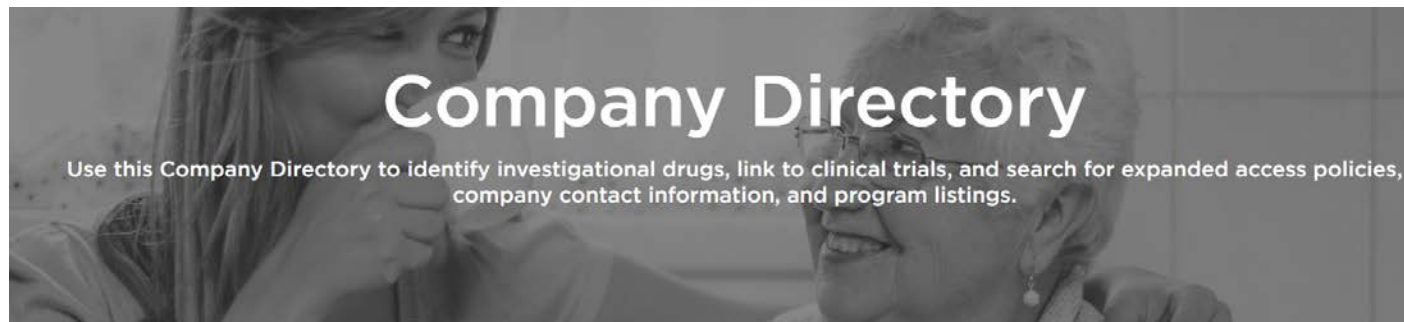
**Patients Matter: What is Expanded Access?**  
When is expanded access an option? What is the expanded access process? Find answers and hear a family's experience with EA in this new "Patients Matter" video from FDA.  
[READ MORE >](#)

**FDA CDER Project Facilitate Webinar**  
CDER's Office of Communication, Division of Drug Information shares "FDA Oncology Center of Excellence's Project Facilitate: An Overview of the Oncology Expanded Access Program," an expanded access webinar addressing the roles of oncology healthcare providers in the submission of an Expanded Access...  
[READ MORE >](#)

You can search resources by stakeholder groups

Details, common language, and abbreviations used in expanded access

# Expanded Access Navigator: Company Directory



## Begin Your Search

If you know the name of a drug manufacturer, you can easily search using the alphabetical menu below. Or you can search in free text – simply type the disease, drug, company name, or other detail into the Search bar below and click on the magnifying glass. For broadest results, type the terms without quotation marks; to narrow your search to an exact match, put your terms in quotation marks (i.e.: “breast cancer”). See [Search Tips](#) for tips and definitions to make your searches more effective.

The web links in this directory are public information provided to the Foundation and the acknowledgement times listed are the number of days or hours for a company to acknowledge receipt of request, not to make a decision. Data contained in this directory is provided either directly by the company or by ClinicalTrials.gov for the companies listed in this directory.

The Expanded Access listings provided on this website are limited to those companies currently in the Company Directory and include listings for expanded access which are *Available*, *Temporarily Not Available* and *Approved for Marketing*, which in some cases includes treatments which have not yet reached the market. In addition, many companies are willing to consider expanded access requests even if they do not show active Expanded Access Listings in this directory. Contact the company to explore the possibility of individual access to an investigational therapy.

To learn more about clinical trials and expanded access, please visit our [patient](#) and [physician](#) guides on this website.



# Expanded Access eRequest

REAGAN-UDALL  
FOUNDATION  
FOR THE FDA

Get Started Prepare EA Request Contact Info Resources Sign In

## Expanded Access eRequest

**Physicians:** Electronically request use of medical products for your patients

To submit a new request, you will need to provide patient information and a Letter of Authorization from the manufacturer (or CMC Information).

[Get Started](#)

Emergency Request? [View Instructions](#)

Not a Physician? [View Information for Patients and Caregivers](#)

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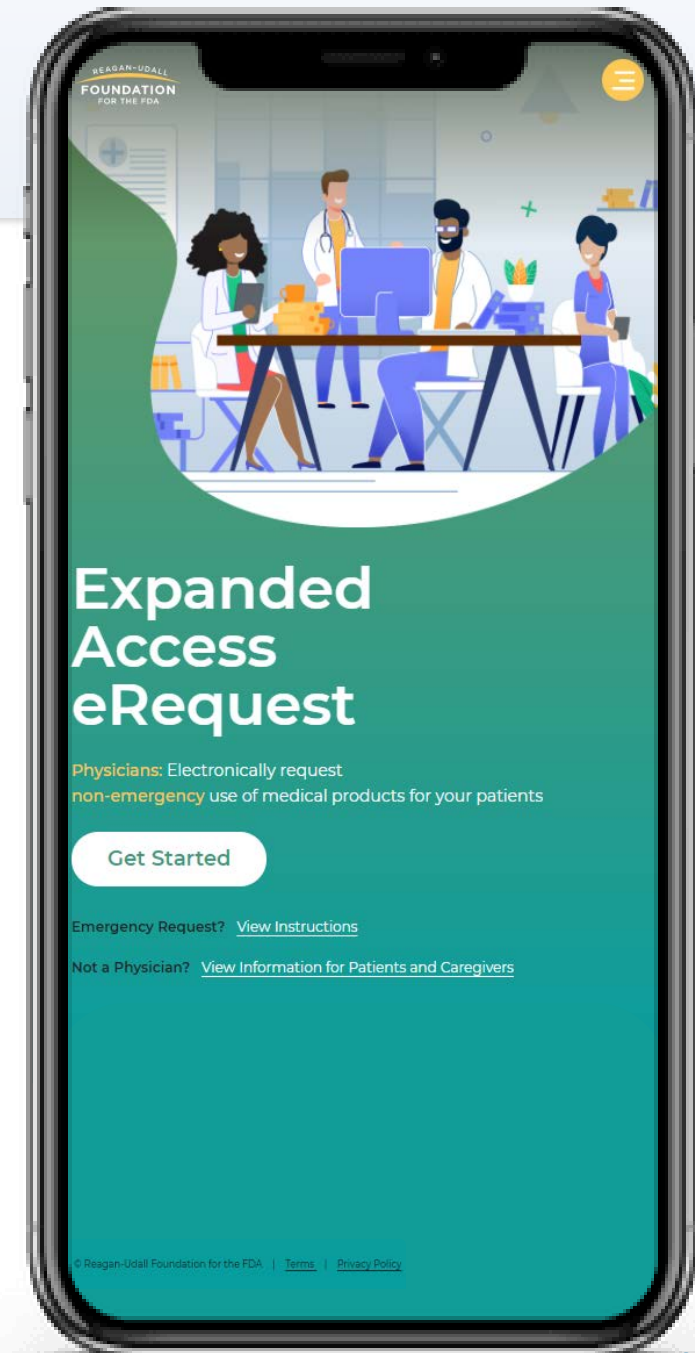
Not a Physician? [View Information for Patients and Caregivers](#)

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# EA eRequest features

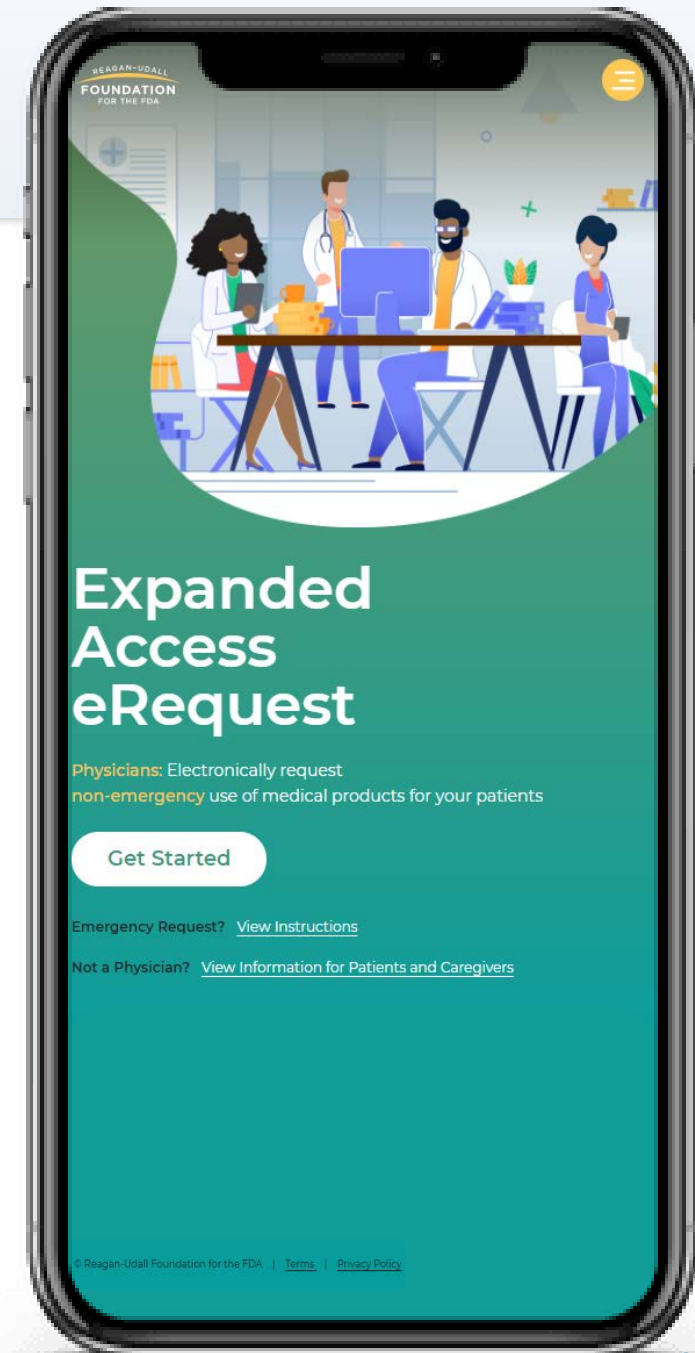
# Why Use EA eRequest?

- **Gathers resources into one place**
- **Walks users step-by-step through process**
- **Simplifies submission process**
  - **Makes online submission possible**
- **Note: eRequest is currently a one-way submission portal. It can not be used for back-and-forth communication with FDA**



# EA eRequest Scope

- **Currently available for single patient requests:**
  - Initial non-emergency requests
  - Documentation for already-authorized emergency requests (with IND)
  - Follow-up submissions
- **Currently not available for single patient emergency requests, intermediate requests, or treatment INDs**



# EA eRequest: Select FDA Center and EA request type

Please select the FDA Center that should review your request

Center for Drugs



Center for Biologics

Oncology Center of Excellence

Center for Devices

Select the type of Expanded Access (EA) request

- Initial non-emergency request (no Investigational New Drug (IND) number).**  
Prepare a non-emergency EA request for a single patient and submit the request to FDA via this site.

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- Follow-up submission (with IND number).**  
Prepare and submit a follow-up submission (e.g., annual report) to FDA via this site. You will be required to provide an IND number.

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- Previously authorized emergency request (with IND number).**  
If you have already received authorization and an IND number from FDA for your emergency EA request, you can prepare and submit documentation to FDA via this site. You will be required to provide an IND number (*For info about preparing a new (initial) emergency EA request, see below*).

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For additional information regarding emergency or non-emergency EA requests:

- > Visit the [Reagan-Udall Foundation's EA Navigator](#)
- > Visit [FDA's EA web page](#)
- > Contact FDA directly by visiting [FDA's EA Contact Information web page](#)

# EA eRequest: Determine patient eligibility for EA

## Is your patient eligible for a clinical trial?

Look for ongoing clinical trials on [ClinicalTrials.gov](https://ClinicalTrials.gov). If your patient is eligible to participate in a clinical trial, please pursue enrollment in the trial.

Have you checked for existing clinical trials?

Take me there

Show me how!

I already checked

[ClinicalTrials.gov](https://ClinicalTrials.gov)

[User Guide](#)

[Skip Search](#)

### ClinicalTrials.gov User Guide

If you are a patient, caregiver, or physician looking for investigational therapy options available through either clinical trials or expanded access, you can begin to research and identify them on [ClinicalTrials.gov](https://ClinicalTrials.gov).

Clinical trials give patients an opportunity to receive an investigational therapy for the purpose of research to determine if the therapy is safe and effective. You can use [ClinicalTrials.gov](https://ClinicalTrials.gov) to learn more about what investigational interventions are being studied, whether clinical trials are open and available for enrollment, and the eligibility criteria. You may also find whether expanded access is available for the therapy and contact information where you can obtain additional information.

This user guide will take you through the process of using [ClinicalTrials.gov](https://ClinicalTrials.gov) to:

- > Researching products in development based on clinical trials
- > Finding open clinical trials
- > Finding expanded access programs (EAPs)
- > Finding single-patient expanded access



### How to Use ClinicalTrials.gov to Research Products in Development

#### Conducting a Search

Use the [ClinicalTrials.gov](https://ClinicalTrials.gov) search function to start researching new investigational therapies. For example, if the patient has lung cancer, you can use a [ClinicalTrials.gov](https://ClinicalTrials.gov) search to find investigational therapies intended to treat specific types of lung cancer.

#### New Search

If you are conducting initial research of investigational therapies or know only the patient's condition, you may want to consider using the search feature on the homepage of [ClinicalTrials.gov](https://ClinicalTrials.gov) to receive a range of information on possible treatments.

Company	Drug Name	Condition Name	
<input type="text" value="Enter Company Name"/>	<input type="text" value="Enter Drug Name"/>	<input type="text" value="Enter Condition Name"/>	<input type="button" value="Search"/>
100 Records found		Please click the <input type="radio"/> for details	
Company ▼	Investigational Drug Name	Indications	
Eli Lilly	Bamlanivimab	COVID-19	<input type="radio"/>
Program: Expanded Access Information for Physicians for Bamlanivimab (LY3819253) Emergency Investigati...			
		Metastatic Non-Smal...	<input type="radio"/>
Non-Small Cell Lung Cancer W...			
		Glioma,H3 K27M	<input type="radio"/>
K27M-mutant and/or Midline Gl...			
		Hereditary Angioede...	<input type="radio"/>
e Attacks of Hereditary Angioe...			
		Hereditary Angioede...	<input type="radio"/>
e Attacks of Hereditary Angioe...			

## Is there an existing Expanded Access program, that can treat your patient's condition?

The Reagan-Udall Foundation's Expanded Access [Navigator Company Directory](#) provides EA policies and contact information for many drug and biological products manufacturers.

You can also check for an existing Expanded Access program on [ClinicalTrials.gov](https://ClinicalTrials.gov) and type "expanded access" into the "Other Terms" field.

To search for an existing Expanded Access program, please answer few questions:

Do you know the company?  
Enter Company Name

Do you know the drug?  
Enter Drug Name

Do you know the condition name?  
Enter Condition Name

# EA eRequest: Review helpful tools

## Fill In and Submit Form FDA 3926

Make sure you have the following information handy to complete Form FDA 3926 and your Expanded Access request:

- ✓ Your Information (ensure your profile information is up-to-date)
- ✓ Patient and drug/biological products information

## Do you have a Letter of Authorization (LOA) from the Manufacturer or Chemistry, Manufacturing, and Controls (CMC) Information?

You must have permission from the company that makes the drug/biological products to use it for EA. Additionally, a Letter of Authorization (LOA) lets FDA reference another

biological product  
in file, CMC

## Have you identified an IRB for reviewing the treatment plan and Informed Consent document?

- › Identify an Institutional Review Board (IRB) to review your proposed treatment plan and informed consent
- › Find registered IRBs in your area through the [Expanded Access Navigator](#)
- › Obtain approval from an IRB before treatment begins
  - ▶ Some Individual patient expanded access may only need concurrence by the IRB Chair or another member of the IRB
- › Obtain the patient's [Informed Consent](#) before treatment begins

Continue

requesting certain  
information)

can also search

# EA eRequest: Register once

**One-time registration collects physician information that is used for all Expanded Access requests (i.e., less duplication of effort)**

REAGAN-UDALL  
FOUNDATION  
FOR THE FDA

Get Started Submit Application Contact Us Resources Sign In

## Registration

Already have an account? [Sign In](#)

### Personal Information

Name \*  Phone \*  Fax

Address 1 (Street address, no P.O. box) \*

Address 2 (Suite, building, floor, etc.):

City \*  State \*  Zip Code \*

Country \*

### Account Information

Email (Username) \*  Password \*  Confirm password \*

I agree to the [Terms of Use](#) and [Privacy Policy](#) associated with using this portal

# EA eRequest: Provide information for a specific EA request

## 8. Physician Name, Address, and Contact Information

Please review the information below for accuracy, if you need to edit this information,

## 7. Physician's Qualification Statement

This information will be added to your Profile and re-used for future submissions as

## 6. Letter of Authorization (LOA)

## 5. Treatment Information

Name of investigational drug/biological products being requested (100 Char) \*

## 4. Clinical Information

### Basic Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Individual Patient Expanded Access Investigational  
New Drug Application (IND)**

(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0814

Expiration Date: **May 31, 2022**

Also see: PRA Statement in the last  
step of this submission

### Patient Details

1. Patient's Initials (4 Char, do not use full name to preserve confidentiality) \*

Enter Patient Initials

Age \*

Years Months Months

Gender \*

Enter Gender

Weight \*

Enter Weight lbs

Allergies

Enter information about known allergies the patient has, if any

auto-populates  
Form FDA 3926



DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration	Form Approved: OMB No. 0910-0814 Expiration Date: May 31, 2022 See PRA Statement on last page.
<b>Individual Patient Expanded Access Investigational New Drug Application (IND)</b> (Title 21, Code of Federal Regulations (CFR) Part 312)	

1. Patient's Initials

2. Date of Submission (mm/dd/yyyy)

3.a. Initial Submission

Select this box if this form is an initial submission for an individual patient expanded access IND, and complete only fields 4 through 8, and fields 10 and 11.

3.b. Follow-Up Submission

Select this box if this form accompanies a follow-up submission to an existing individual patient expanded access IND, and complete the items to the right in this section, and fields 8 through 11.

Investigational Drug Name

Physician's IND Number

4. Clinical Information

Indication

Brief Clinical History (Patient's age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options)

5. Treatment Information

Investigational Drug Name

Name of the entity that will supply the drug (generally the manufacturer)

FDA Review Division (if known)

Treatment Plan (Including the dose, route and schedule of administration, planned duration, and monitoring procedures. Also include modifications to the treatment plan in the event of toxicity.)

FORM FDA 3926 (4/20)

Page 1 of 3

PSC Publishing Services (301) 443-6740 EF

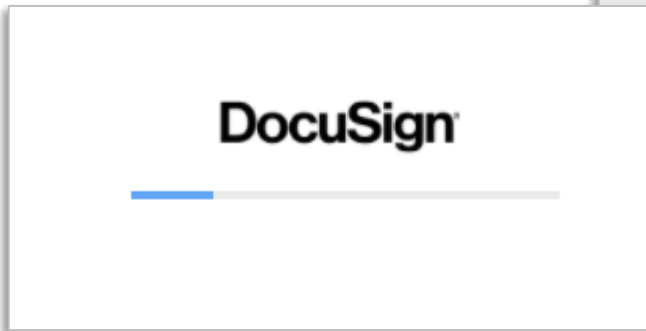
FORM FDA 3926 (4/20)

Page 2 of 3

FORM FDA 3926 (4/20)

Page 3 of 3

# EA eRequest: Review and sign Form FDA 3926



Done! Select Finish to send the completed document. **FINISH** OTHER ACTIONS ▾

05102021173613jXeYb\_Form3926.pdf 1 of 2

DocuSign Envelope ID: B4441D41-85D6-4009-A9AA-7EE5E990DDFB

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**9. Contents of Submission**

*This submission contains the following materials, which are attached to this form (select all that apply). If none of the following apply to the follow-up communications, use Form FDA 1571 for your submission.*

<input type="checkbox"/> Initial Written IND Safety Report	<input type="checkbox"/> Change in Treatment Plan
<input type="checkbox"/> Follow-up to a Written IND Safety Report	<input type="checkbox"/> General Correspondence
<input type="checkbox"/> Annual Report	<input type="checkbox"/> Response to FDA Request for Information
<input type="checkbox"/> Summary of Expanded Access Use (treatment completed)	<input type="checkbox"/> Response to Clinical Hold

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**10.a. Request for Authorization to Use Form FDA 3926**

I request authorization to submit this Form FDA 3926 to comply with FDA's requirements for an individual patient expanded access IND.

**10.b. Request for Authorization to Use Alternative IRB Review Procedures**

I request authorization to obtain concurrence by the Institutional Review Board (IRB) chairperson or by a designated IRB member, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. This concurrence would be in lieu of review and approval at a convened IRB meeting at which a majority of the members are present.

---

**11. Certification Statement:** I will not begin treatment until 30 days after FDA's receipt of a completed application and all required materials unless I receive earlier notification from FDA that treatment may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. I also certify that I will obtain informed consent, and that an Institutional Review Board (IRB) will be responsible for initial and continuing review and approval of this treatment use, consistent with applicable FDA requirements. I understand that in the case of an emergency request, treatment may begin without prior IRB approval provided the IRB is notified of the emergency treatment within 5 working days of treatment. I agree to conduct the investigational study in accordance with all applicable regulatory requirements.

**WARNING: A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).**

Signature of Physician	<small>DocuSigned by:</small> <i>A. Smith</i> <small>4909F21237E048E</small>	Date	5/10/2021   6:12:09 PM EDT
------------------------	--	------	----------------------------

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For FDA Use Only		
Date of FDA Receipt	Is this an emergency individual patient IND?	Is this indication for a rare disease (prevalence < 200,000 in the U.S.)?
Date of FDA Receipt	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

# EA eRequest: Submit EA request package via eRequest



EA eRequest



eRequest site emails EA request package securely to FDA



# EA eRequest: Get confirmation your EA request was sent

## Pop-up message

### Follow-up Submission SENT!

[Download a copy of your Follow-up Submission](#)

Please note that your Follow-up Submission will be deleted from this app in 14 days.

Your submission number is IND# 123456 (Tracking 07202021160243H2wq5\_Form3926 )

You should receive an email confirming that your Follow-up Submission was sent to FDA. If you do not receive a confirmation email, please contact the EA eRequest Help Desk at [erequest@boston-technology.com](mailto:erequest@boston-technology.com)

[Close](#)

## Confirmation email

Confirmation: EA Application 2021-00000 submitted via EA Application - Message (HTML)

File Message Help Adobe PDF Tell me what you want to do

Confirmation: EA Application 2021-00000 submitted via EA Application

[earequest@reaganudall.org](mailto:earequest@reaganudall.org)  
To: Smith, Doctor

Reply Reply All Forward

Fri 12/10/2021 4:24 PM

Dear Dr. Smith,

Your application 12092021010324zPktl has been submitted to FDA. Thank you for using Expanded Access eRequest, which is hosted by the Reagan-Udall Foundation for the FDA.

If you have not already done so, **please save the application to your device immediately**. For security reasons, the eRequest site will delete the application in 14 days

You will receive an acknowledgment from FDA once your request has been processed. If you have an urgent question about your Expanded Access application, please call or email the appropriate FDA review division directly (look up contact FDA information [here](#)). Refer to the temporary identifier below when communicating with FDA about your application; FDA will use the temporary identifier for tracking purposes until an Investigational New Drug (IND) number is assigned to your application.

Application information

- **Submit date:** DECEMBER 10, 2021
- **Product name:** ABC
- **Temporary identifier:** 2021-00000
- **eRequest number:** 12092021010324zPktl

If you have technical questions about Expanded Access eRequest, please contact the Expanded Access eRequest Support Team.

Thank you,  
Expanded Access eRequest Support Team  
[fdaexpandedaccess@gmail.com](mailto:fdaexpandedaccess@gmail.com)

-----  
**NOTE: This is an auto-generated email. Please do not reply.**

# EA eRequest: Contact for help



Email Tech Support if you do not receive a confirmation message or if you experience technical issues with the site.

## Tech Support Contact Information

- > For all technical questions or problems using the eRequest site, please contact: [erequest@boston-technology.com](mailto:erequest@boston-technology.com)

## FDA Contact Information

- > During normal business hours (8 a.m. - 4:30 p.m. ET, weekdays)  
For specific questions about submitting an EA request or follow-up:

**Drug products:** [301-796-3400](tel:301-796-3400) or [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) [Center for Drug Evaluation and Research Division of Drug Information], or contact the appropriate review division, if known

**Biological Products:** [240-402-8020](tel:240-402-8020) or [800-835-4709](tel:800-835-4709) or [industry.biologics@fda.hhs.gov](mailto:industry.biologics@fda.hhs.gov) [Center for Biologics Evaluation and Research Office of Communication, Outreach and Development]

**Oncology Products:** [240-402-0004](tel:240-402-0004) or [OncProjectFacilitate@fda.hhs.gov](mailto:OncProjectFacilitate@fda.hhs.gov) [Oncology Center of Excellence]

For general questions, or if you are unsure of whom to contact, contact the Patient Affairs Staff at [301-796-8460](tel:301-796-8460) or [patientaffairs@fda.hhs.gov](mailto:patientaffairs@fda.hhs.gov).

- > "For an emergency request during normal business hour", this info can be pulled from the first off-ramping pop-up ( if you choose emergency).

- > After 4:30 p.m. ET weekdays and all day on weekends, for emergency and non-emergency requests and information for all medical products (drugs, biological products, and medical devices) contact FDA's Emergency Call Center at [866-300-4374](tel:866-300-4374)

Contact FDA if you have questions about your Expanded Access request.

# New EA eRequest features

# EA eRequest: Return later to complete draft requests



[My Dashboard](#)

[Prepare EA Request](#)

[Contact Info](#)

[Resources](#)

[Tester 102](#)



## My Dashboard

Enter keywords



New Initial Request

Tracking #	Initial request	Condition	Product Name	Date authorized ?	IND# ?	Action ?	Notes
12102021170412a5fC9	Placeholder f...			<input type="text" value="Mon dd, yyyy"/>	<input type="text" value="555555"/>	<a href="#">Follow-up submission</a>	
12032021154722iTs11	Dec 3, 2021 <small>Draft expires in 83 days</small>			<input type="text" value="Mon dd, yyyy"/>	<input type="text" value="Enter IND#"/>	<a href="#">Initial request</a> <a href="#">Follow-up submission</a>	
120320211540341LDzM	Placeholder f...			<input type="text" value="Mon dd, yyyy"/>	<input type="text" value="000000"/>	<a href="#">Follow-up submission</a>	
09012021135723Zkp25	Sep 1, 2021 <small>Draft Expired</small>			<input type="text" value="Mon dd, yyyy"/>	<input type="text" value="Enter IND#"/>	<a href="#">Initial request</a> <a href="#">Follow-up submission</a>	
090120211357317OVdf	Sep 1, 2021 <small>Draft Expired</small>			<input type="text" value="Mon dd, yyyy"/>	<input type="text" value="Enter IND#"/>	<a href="#">Initial request</a> <a href="#">Follow-up submission</a>	

[New Follow-up](#)

« 1 2 3 4 5 »

Link to follow-up dashboard

# EA eRequest: Document already-authorized emergency EA requests (IND number required)



## 8. Physician Name, Address, and Contact Information

Please review the information below for accuracy, if you need to edit this information,

## 7. Physician's Qualification Statement

This information will be added to your Profile and re-used for future submissions as

## 6. Letter of Authorization (LOA)

## 5. Treatment

Name of investigational drug/biological products being

## 4. Clinical

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Individual Patient Expanded Access  
New Drug Application (IND)

(Title 21, Code of Federal Regulations)

### Patient Details

1. Patient's Initials ( 4 Char, do not use full name to preserve confidentiality ) \*

Enter Patient Initials

Gender \*

Enter Gender

Weight \*

Enter Weight

lbs

Allergies

Enter information about known allergies the patient has, if any



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Individual Patient Expanded Access  
Investigational New Drug Application (IND)**  
(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0614  
Expiration Date: May 31, 2022  
See PRA Statement on last page.

1. Patient's Initials

2. Date of Submission (mm/dd/yyyy)

3.a. Initial Submission  
 Select this box if this form is an initial submission for an individual patient expanded access IND, and complete only fields 4

3.b. Follow-Up Submission  
 Select this box if this form accompanies a follow-up submission to an existing individual patient expanded access IND, and complete the items to the right in this section.

Investigational Drug Name

Physician's IND Number

therapy, response to prior therapy, reason for (reasons)

med duration, and monitoring procedures. Also include

FORM FDA 3926 (4/20) Page 1 of 3

IND Number  Yes  No  Yes  No

FORM FDA 3926 (4/20) Page 2 of 3

FORM FDA 3926 (4/20) Page 3 of 3

**IND Number:** Please enter the IND number received from FDA for your patient's treatment.

IND Number

Enter IND Number

**Reminder: You must enter an Investigational New Drug (IND) number from FDA before submitting this request.**

# EA eRequest: Prepare follow-up submissions (IND number required)

## Select Follow-up Submission(s)

Please select the type(s) of follow-up submissions you intend to prepare and transmit to FDA. On later Submission Details screens, you will be asked to provide information for each follow-up type you select. If none of the following apply to the follow-up communications, use Form FDA 1571 for your submission.

[View descriptions of each follow-up type by clicking here](#)

- |  |  |
|--|--|
| <input type="checkbox"/> Initial Written IND 7 days Safety Report  | <input type="checkbox"/> Change in Treatment Plan                |
| <input type="checkbox"/> Initial Written IND 15 days Safety Report   | <input type="checkbox"/> General Correspondence                  |
| <input type="checkbox"/> Follow-up to a Written IND Safety Report  | <input type="checkbox"/> Response to FDA Request for Information |
| <input type="checkbox"/> Annual Report   | <input type="checkbox"/> Response to Clinical Hold               |
| <input type="checkbox"/> Summary of Expanded Access Use (treatment completed and/or withdrawal in treatment) |  |

# EA eRequest: Prepare follow-up submissions *(cont.)*

- **Initial Written 7-day IND Safety Report:** A report of unexpected fatal or life-threatening suspected adverse reactions, submitted no later than 7 calendar days after the sponsor's (i.e., the physician, who is considered a sponsor Investigator) initial receipt of the information.
- **Initial Written 15-day IND Safety Report:** A report of potential serious risks to be submitted as soon as possible, but no later than 15 calendar days after the sponsor determines that information qualifies for reporting.
- **Follow-up to a Written IND Safety Report:** A follow-up report to an IND safety report, to be made as soon as the information is available but no later than 15 calendar days after the sponsor receives the information.
- **Annual Report:** A brief report of the progress of the investigation, submitted within 60 days of the anniversary date that the IND went into effect.
- **Summary of Expanded Access Use (treatment completed and/or withdrawal in treatment):** A written summary of the results of the expanded access use, including adverse effects, at the conclusion of treatment. If you wish to notify FDA of a withdrawal in treatment, please use this follow-up type.
- **Change in Treatment Plan:** Also known as protocol amendments; a submission describing changes in the IND, including changes of investigators.
- **General Correspondence:** Any other communication between the sponsor and FDA pertinent to the investigation.
- **Response to FDA Request for Information:** A submission containing responses to clinical information.
- **Response to Clinical Hold:** A submission correcting deficiencies previously cited in an FDA Clinical Hold letter.

# Contact Us

- **CDER Office of Medical Policy**  
[CDEROMP@fda.hhs.gov](mailto:CDEROMP@fda.hhs.gov)
- **Lea Ann Browning-McNee**  
[Lmcnee@reaganudall.org](mailto:Lmcnee@reaganudall.org)
- **FDA's EA contact info**  
<https://www.fda.gov/news-events/expanded-access/fdas-expanded-access-contact-information>



## 1. During Normal Business Hours (8 a.m. - 4:30 p.m. ET, weekdays)

For **specific questions** during normal business hours:

- **Investigational drugs:** 301-796-3400 or [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) [CDER's Division of Drug Information], or contact the appropriate [review division](#), if known
  - **Oncology drugs:** 240-402-0004 or [ONCProjectFacilitate@fda.hhs.gov](mailto:ONCProjectFacilitate@fda.hhs.gov)
- **Investigational medical devices:** 301-796-7100 or [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov) [CDRH's Division of Industry and Consumer Education]
- **Investigational biologics:** 240-402-8020 or 800-835-4709 or [industry.biologics@fda.hhs.gov](mailto:industry.biologics@fda.hhs.gov) [CBER's Office of Communication, Outreach and Development]

For **general questions**, or if you are unsure of who to contact, contact the Patient Affairs Staff at 301-796-8460 or [patientaffairs@fda.hhs.gov](mailto:patientaffairs@fda.hhs.gov).

## 2. After 4:30 p.m. ET weekdays and all day on weekends

For **emergency requests** for all medical products (drugs, biologics, and medical devices) contact **FDA's Emergency Call Center** at 866-300-4374.

21 CFR 312.300 on Expanded Access to Investigational Drugs for Treatment Use. Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.300>.

Final guidance for industry *Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers* (2017). Available at <https://www.fda.gov/media/85675/download>.

*Individual Patient Expanded Access Applications: Form FDA 3926* (2017). Available at <https://www.fda.gov/media/91160/download>.



**U.S. FOOD & DRUG**  
ADMINISTRATION