DDI Webinar: An Overview of FDA's Expanded Access Program

A FOCUS ON INDIVIDUAL PATIENT EXPANDED ACCESS

Presenters

- Deborah Miller, PhD, MPH, MSN, RN – Cancer Patient Liaison, Office of Health & Constituent Affairs
- LCDR Lindsay Wagner, PharmD – Team Leader, Division of Drug Information, Office of Communications
- Colleen Locicero, RPh – Associate Director for Regulatory Affairs, Office of Drug Evaluation I

Learning Objectives

- Summarize the objectives of the FDA's expanded access program
- Identify the types of expanded access requests
- Describe the requirements for authorizing expanded access
- Review web resources available for patients and healthcare professionals
- Explain how a physician may submit individual patient IND expanded access requests to the FDA using FDA Form 3926

FDA U.S. FOOD & DRUG ADMINISTRATION

Expanded Access

Part 1: What is Expanded Access?

Deborah Miller

What is Expanded Access?

A process (or pathway) regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who have exhausted approved therapy, and cannot participate in a clinical trial

What is Expanded Access?

- Use of an investigational drug or biologic **to treat, diagnose, or monitor a patient** with a serious disease or condition who does not have comparable or satisfactory alternative therapies.
  - Intent is clearly **to treat, diagnose, or monitor** the patient

- 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

TREATMENT ACCESS

Named Patient Program

Special Access Programme

Compassionate Use

Individual Patient IND

Pre-approval access

Pre-launch Access

Expanded Access

Expanded Access Programs Are Considered Option of Last Resort

- Hierarchy of Access -

Approved Drugs

Studied and characterized

Labeled

Broadest availability

Reimbursement by 3rd party

Clinical Trials

Provide necessary data to determine safety & effectiveness

Most efficient path to market and broad availability

Expanded Access

Represent opportunity when other options exhausted

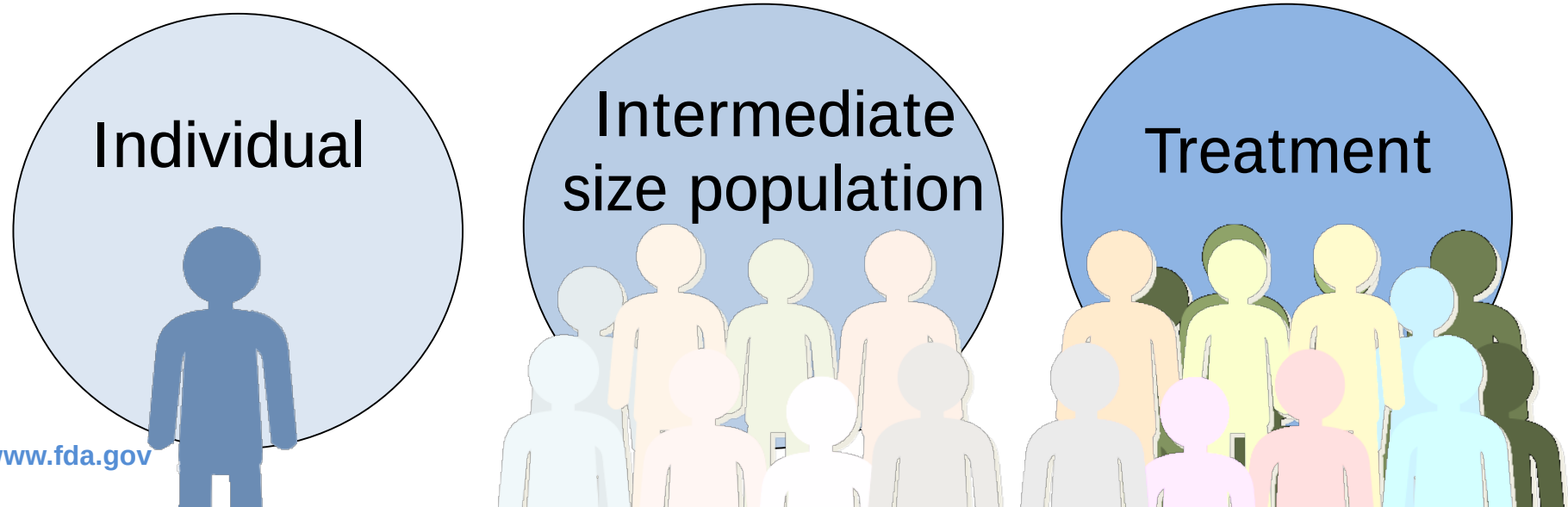
Goal is access for treatment

Three Categories of Access

code of federal regulations 21 CFR 312 / IND Regulations

- Subpart I **consolidated treatment use** into a separate subpart of the investigational new drug (IND) regulations containing all necessary information in one place
- Describes **three distinct categories** of access

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm



Expanded Access Regulations

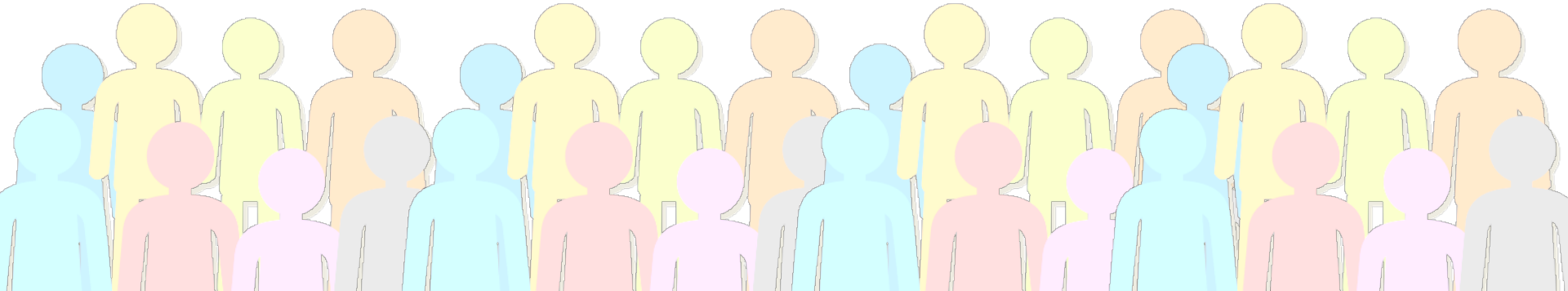
- Describes the **general criteria** applicable to all categories of access, and additional criteria that must be met for each access category
- Describes **requirements for submission**
- Describes the **safeguards** applicable to Expanded Access Programs (EAP), such as informed consent, ethics review,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

Requirements shared by all EAPs

- Serious or immediately life threatening illness or condition
- No comparable or satisfactory alternative therapy
- Potential benefit justifies the potential risks of the treatment, and those risks are not unreasonable in the context of the disease or condition being treated
- Providing drug will not interfere with or compromise development for the expanded access use

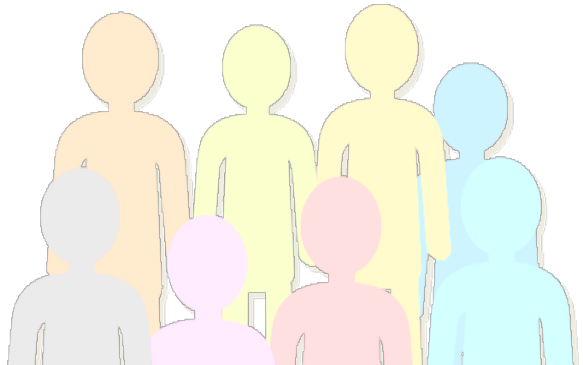
Treatment

- Drug is being investigated in clinical trial designed to support marketing, or trials are complete
- Company is actively pursuing marketing approval
- Often bridges the period between completion or near completion of drug development and approval



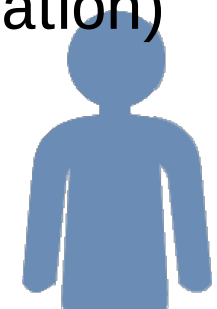
Intermediate Size Population

- No fixed numerical requirement
- More than one ... generally, less than a lot
- Can be used when a drug is
  - Being developed (e.g., patients not eligible for trial)
  - Not being developed (e.g., rare disease, cannot recruit for a trial)
  - Approved (e.g., drug withdrawn, drug shortage situation)
- Sponsor can be physician, manufacturer, or 3rd party



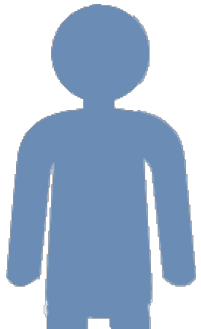
Individual Patient EAPs

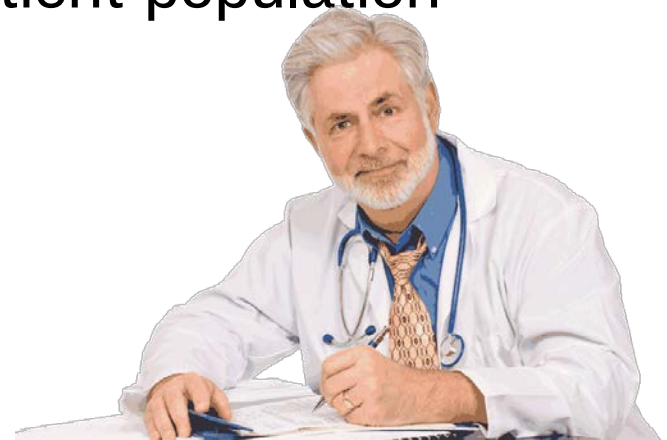
- Physician must determine probable risk from drug does not exceed that from disease
- FDA must determine that the patient cannot obtain access under another type of IND
- Procedures for emergency use (where there is not time to make a written IND submission) – FDA may authorize starting access without submission, with very quick turn-around (Follow-up written submission required within 15 working days of authorization)



Individual Patient EAPs

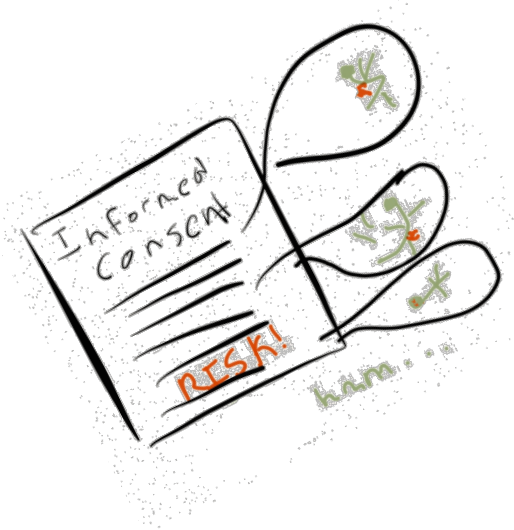
- Physician often takes role of sponsor/investigator (responsible for sponsor activities: tracking, reporting, etc.)
- FDA requires written summary report, and may require special monitoring
- FDA may request consolidation of multiple cases into a single, intermediate size patient population IND





Human Subject Protections Apply to All EAPs

Drugs in EAPs are *investigational drugs*, and they are subject to the following requirements:



- Protection of Human Subjects (informed consent)
- Institutional Review Boards (IRB)
- Clinical Holds based on safety
- Reporting requirements (adverse event reports, annual reports)

Overarching Considerations

- Unknown risks associated with access to investigational products for which there is limited information about safety and effectiveness
  - Some patients may benefit
  - Some patients may experience no effect
  - Some patients may be harmed
- FDA considers:
  - Potential harm to patients
  - Need to exhaust all existing approved treatments
  - Scientific likelihood of an efficacious response

Potential EAP Benefits

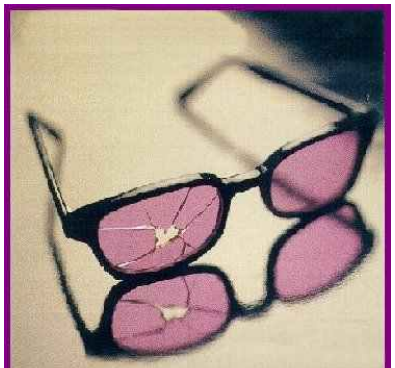
- Can provide access to patients, including children, with serious or life-threatening diseases who have no other alternatives, and are willing to accept greater risk
- Can provide patients a measure of autonomy over their own health care decision
- The treatment protocol can help bridge the gap between the latter stages of product development and approval by making a drug widely available during that period

How do patients view risk?

Potential overestimation of benefit and/or underestimation of risk

New drugs can have toxicities that cause increased suffering and pain, or the acceleration - or prolonging - of death, with no increase in quality of life

Not always considered by patients or families - Often see risks as abstract



Concerns about Trial Enrollment

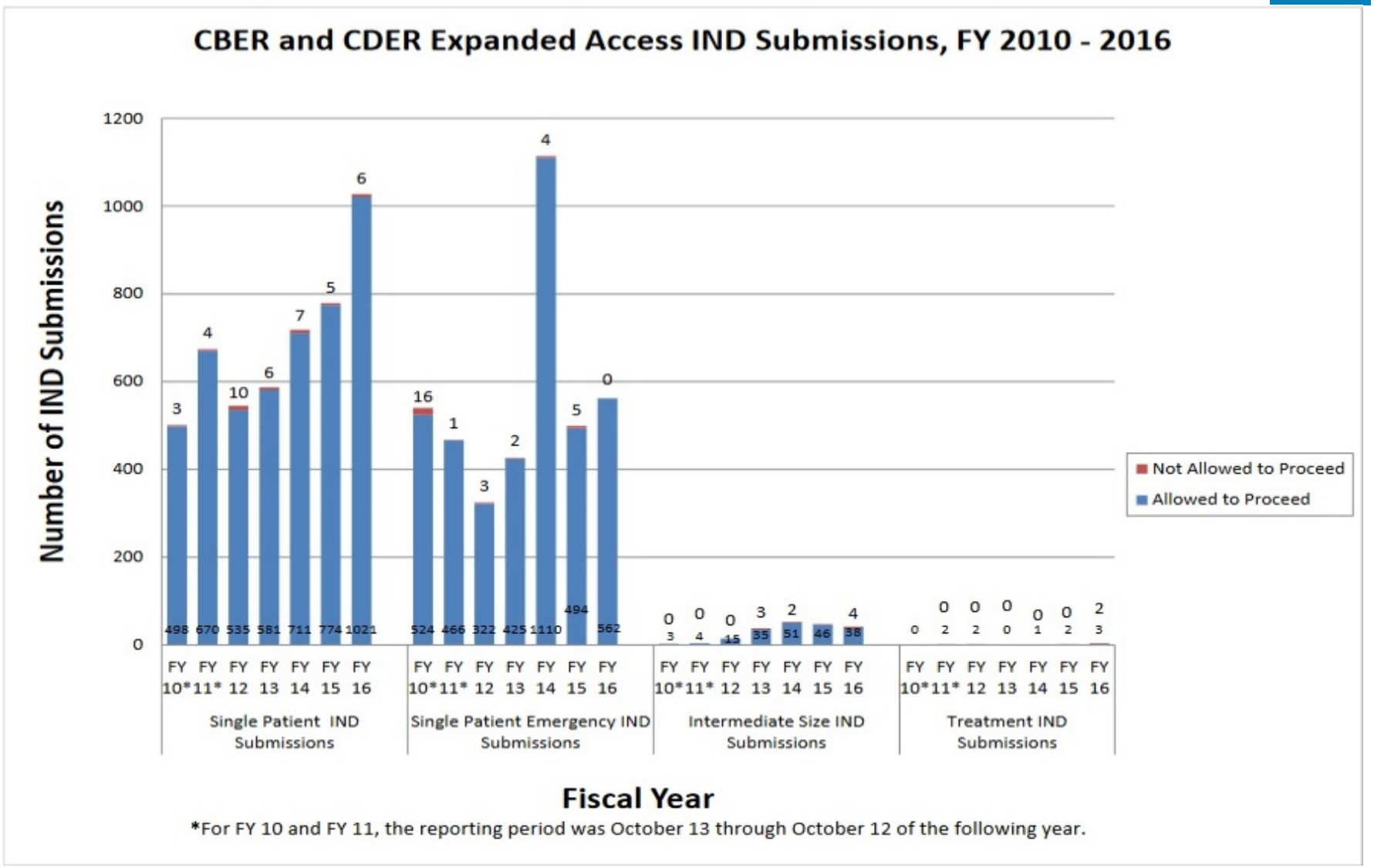
- Early access to investigational therapies could make phase 2 and 3 clinical trials more difficult to perform

- Clinical trial enrollment and conduct is a factor in consideration of treatment access to experimental drugs by manufacturers and FDA

Reasons Company May Deny Expanded Access Requests

Companies may deny a request for a number of reasons:

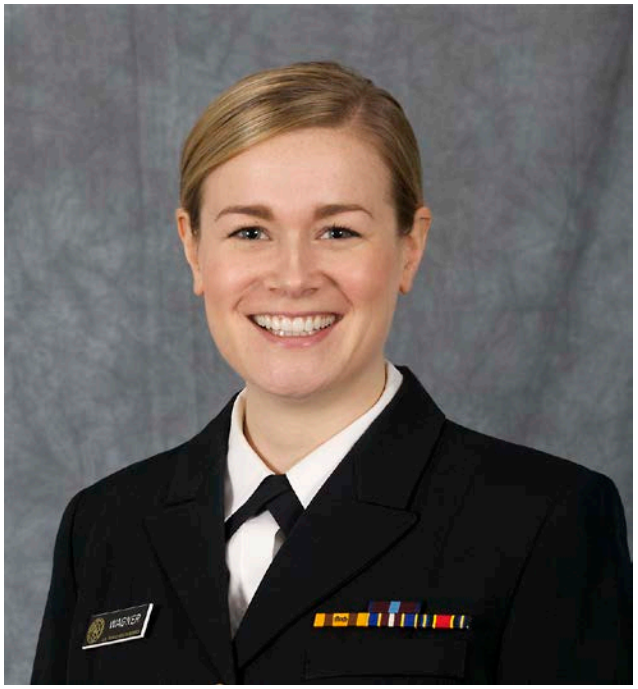
- Available clinical trials
- Manufacturing capacity is often limited in early phases – diverting drug for expanded access could limit supply for trials



https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm443572.htm#CDER_Totals3

Need for Balance

- Treatment access must be balanced against the systematic collection of clinical data to characterize safety and effectiveness
- Patient autonomy must be balanced against exposure to unreasonable risks and the potential for health fraud, and potential exploitation of desperate patients
- Individual needs must be balanced against societal needs
  - Clinical trials are the best mechanism to provide evidence of safety and effectiveness for potential new treatments
  - FDA approval for marketing is the most efficient means to make safe and effective treatments available to the greatest number of patients

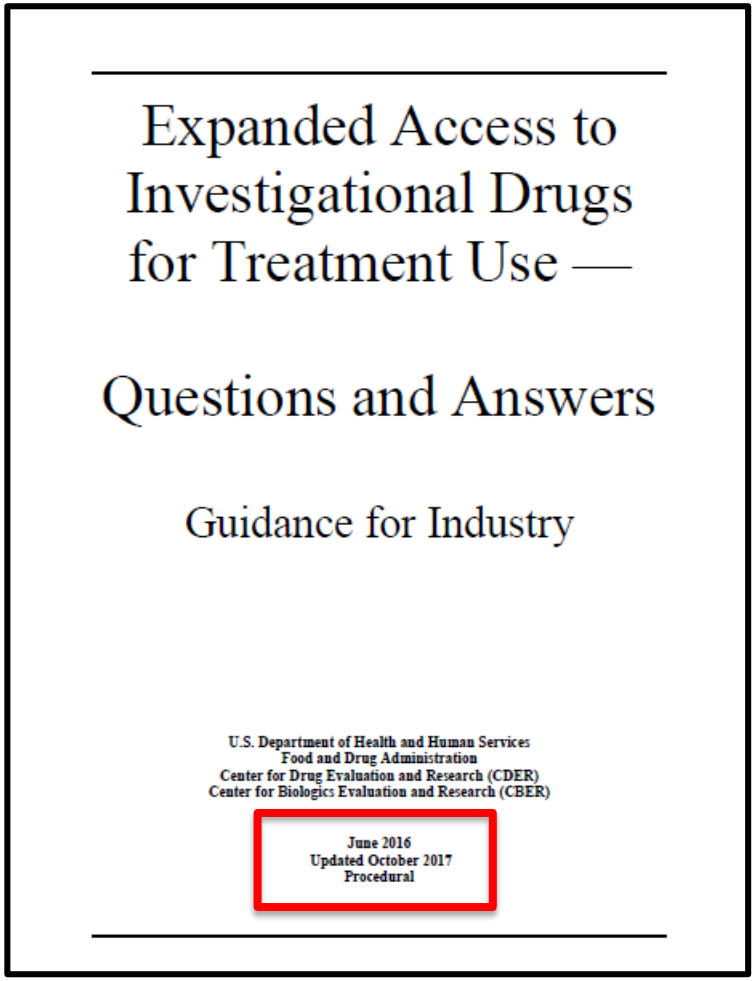


LCDR Lindsay Wagner, PharmD – Team Leader, Division of Drug Information, Office of Communications

WEB RESOURCES FOR PATIENTS AND HEALTHCARE PROFESSIONALS

Guidance Documents

- What's new?



Expanded Access to Investigational Drugs for Treatment Use —

Questions and Answers

Guidance for Industry

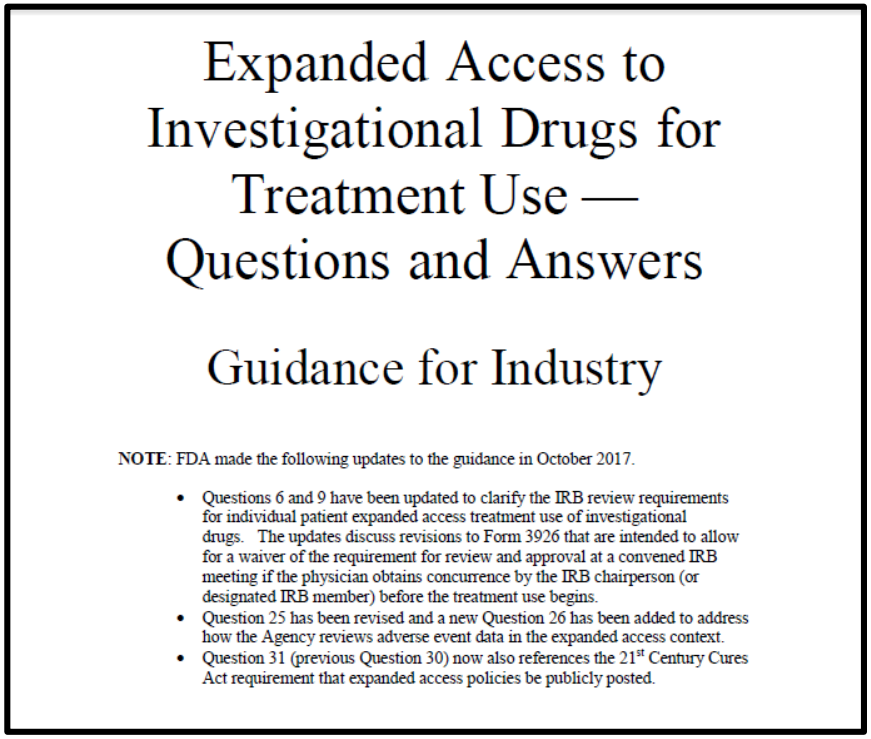
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2016
Updated October 2017
Procedural

Reference: https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf

Expanded Access Q&A Guidance

- Waiver option for convening full Institutional Review Board (IRB) for review for single patient requests
- Clarification around how adverse events are viewed that occur during Expanded Access treatment
- 21st Century Cures Act requirements for industry



Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers

Guidance for Industry

NOTE: FDA made the following updates to the guidance in October 2017.

- Questions 6 and 9 have been updated to clarify the IRB review requirements for individual patient expanded access treatment use of investigational drugs. The updates discuss revisions to Form 3926 that are intended to allow for a waiver of the requirement for review and approval at a convened IRB meeting if the physician obtains concurrence by the IRB chairperson (or designated IRB member) before the treatment use begins.
- Question 25 has been revised and a new Question 26 has been added to address how the Agency reviews adverse event data in the expanded access context.
- Question 31 (previous Question 30) now also references the 21st Century Cures Act requirement that expanded access policies be publicly posted.

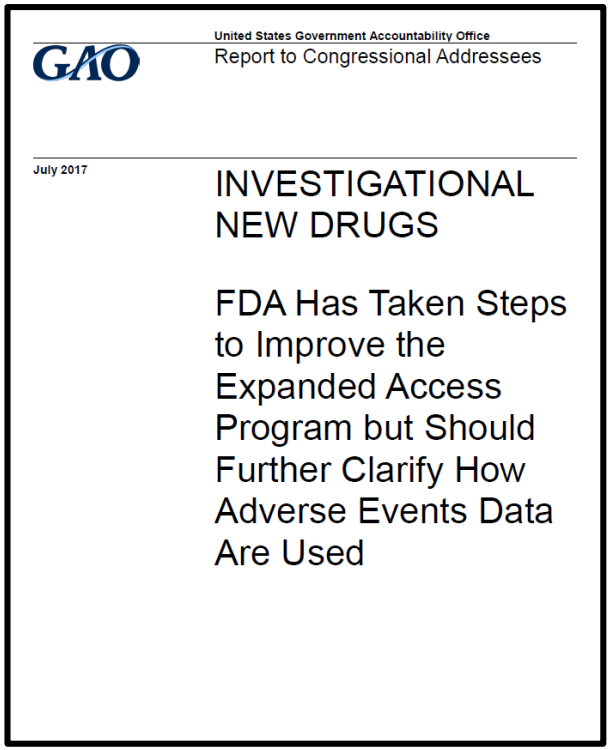
Reference: https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf

Waiver for full IRB review

- Emergency expanded access requests: report to IRB within 5 working days
  - FDA authorization still required
- Non-emergency expanded access requests: physician submitting the request can select the box on Form 3926 (or submit a waiver request with Form 1571) to obtain concurrence from the IRB chairperson, or another designated member of the IRB, before treatment use begins, in lieu of convening the full IRB

Reference: https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf

GAO Report and Adverse Events


United States Government Accountability Office

GAO

Report to Congressional Addressees

July 2017

INVESTIGATIONAL NEW DRUGS

FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used

- Clarification provided October 2017
- "FDA is not aware of instances in which adverse event information from expanded access has prevented FDA from approving a drug."

References: https://www.gao.gov/products/GAO-17-564 https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf

GAO Report and Adverse Events

- Very beneficial to learn of rare adverse events as early as possible – reporting is still of paramount importance
- 0.02% (2 cases in 10,000 expanded access authorized requests) where adverse events have led to a clinical hold, and those were later resolved
- Four key reasons added to Q&A Guidance #26 that describe why it is extremely difficult to draw a causal link between a reported AE and the expanded access treatment

Reference: https://www.gao.gov/assets/690/685729.pdf

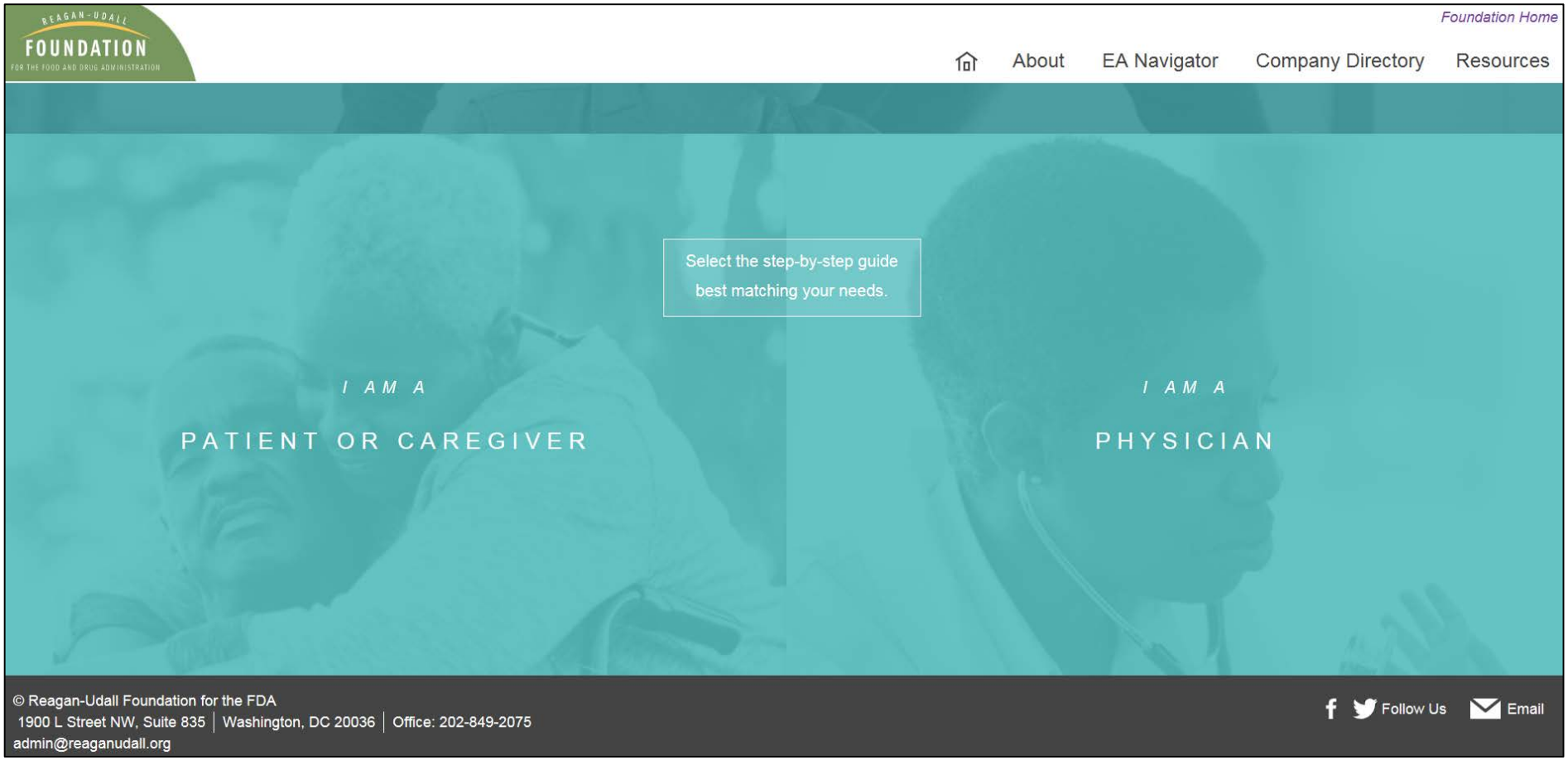
21st Century Cures Act

- Requires sponsors to make their policy for evaluating and responding to expanded access requests publicly available

- The policy must include the following:
  - contact information for the manufacturer or distributor,
  - procedures for making requests,
  - the general criteria the manufacturer or distributor will use to evaluate and respond to EA requests,
  - the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests, and
  - a hyperlink or other reference to the clinical trial record containing information that is required to be submitted to ClinicalTrials.gov about expanded access availability for the drug

Reference: https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf

Reagan-Udall Foundation's Navigator



Reference: http://navigator.reaganudall.org/

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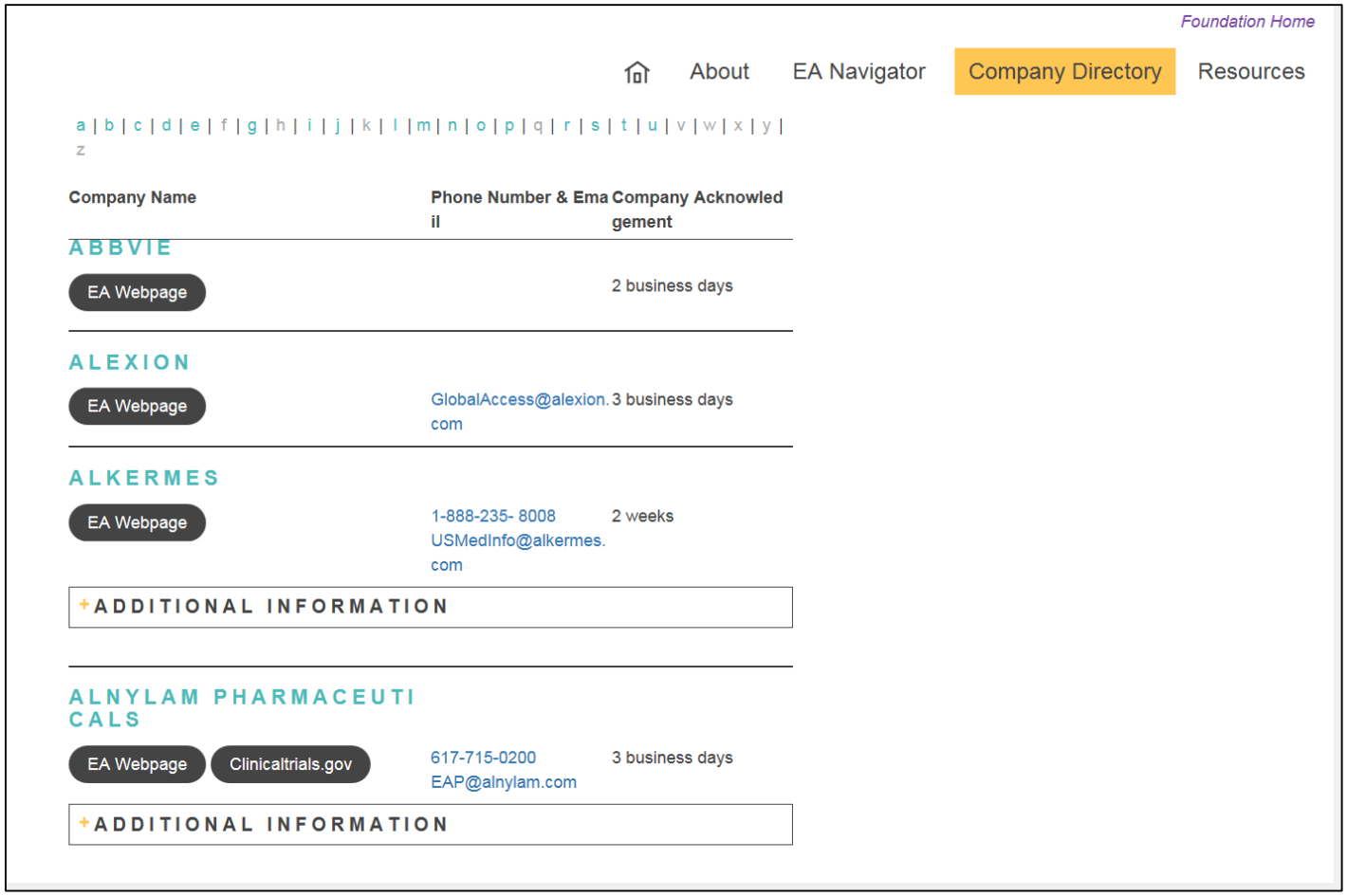

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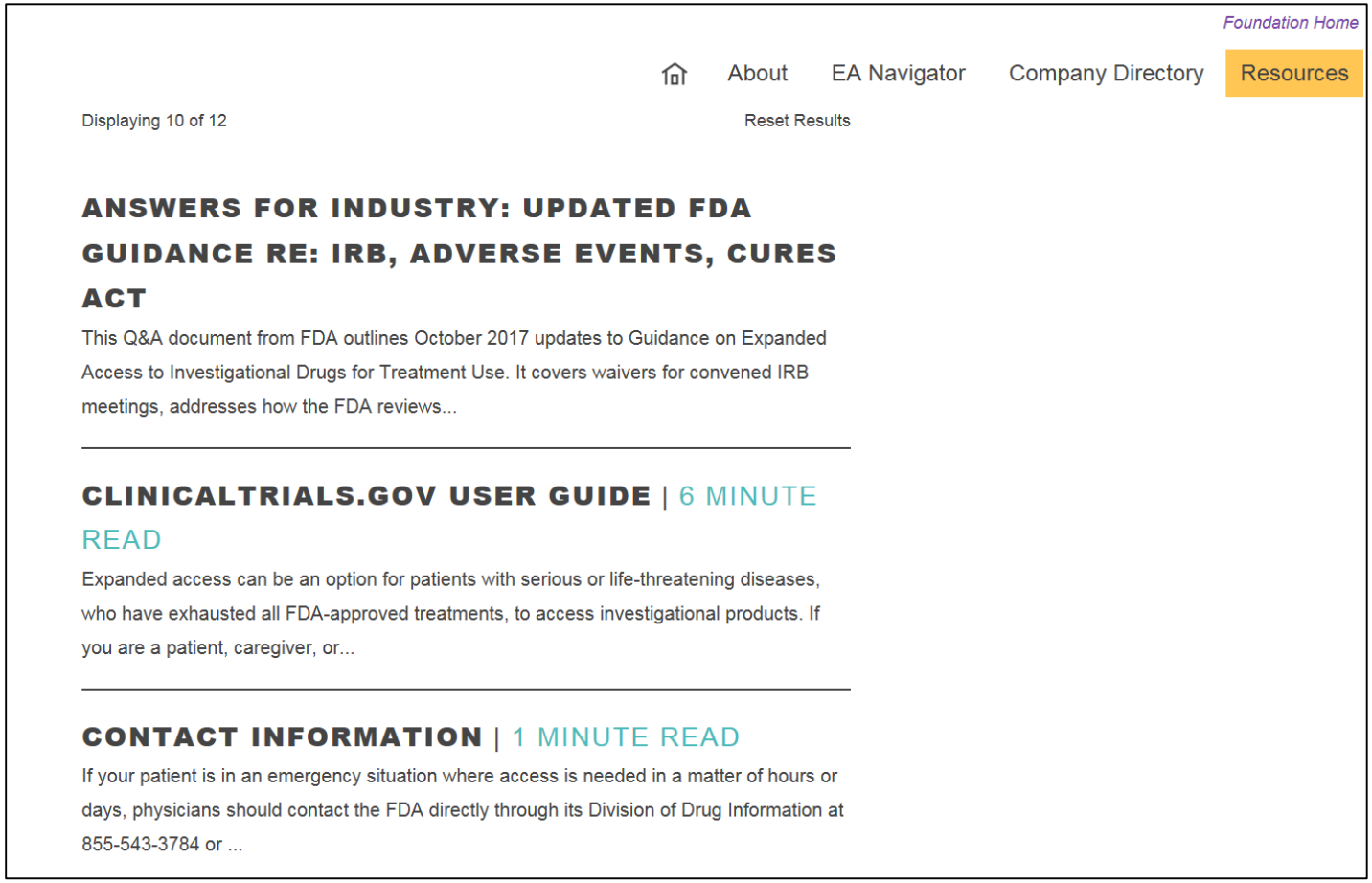

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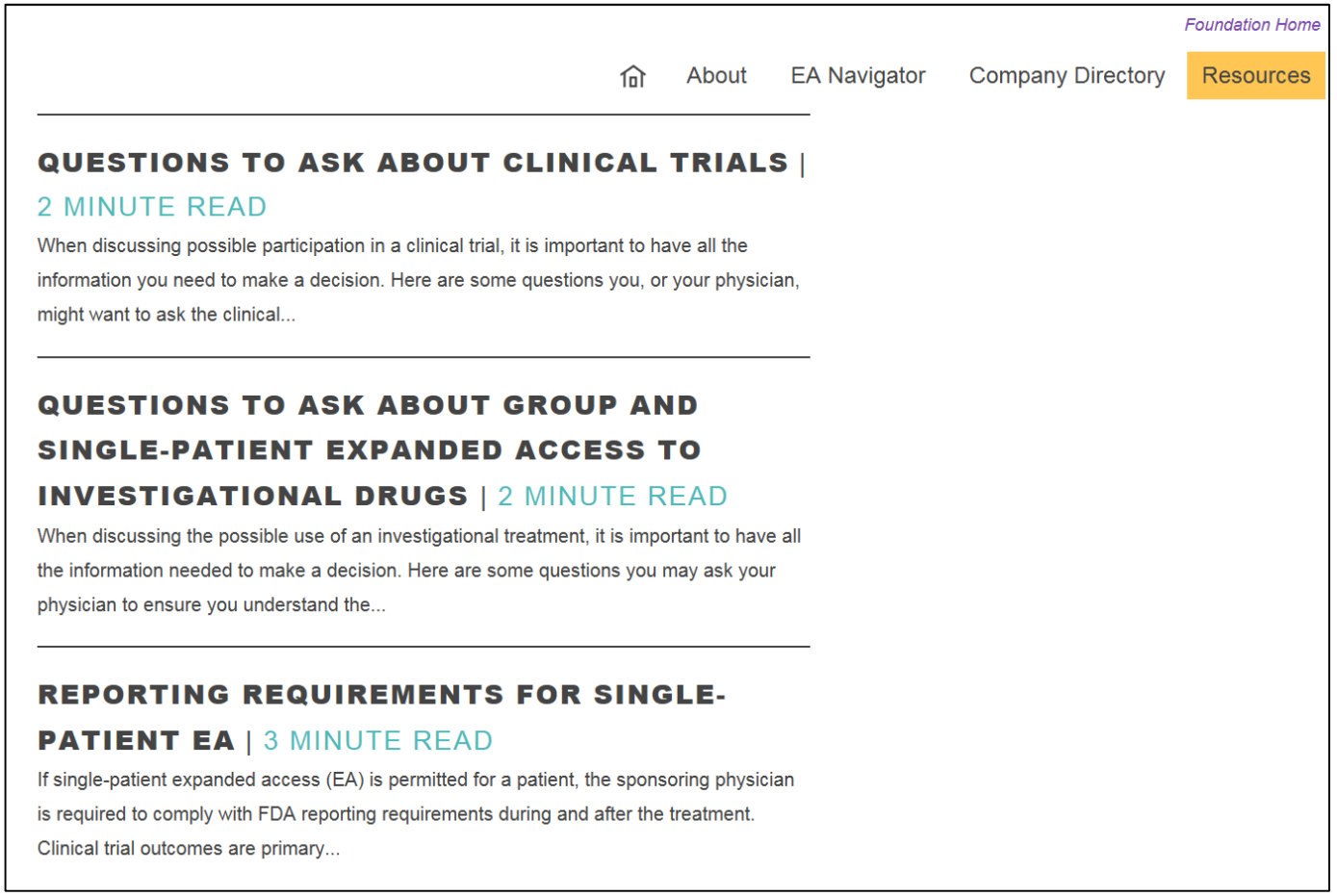
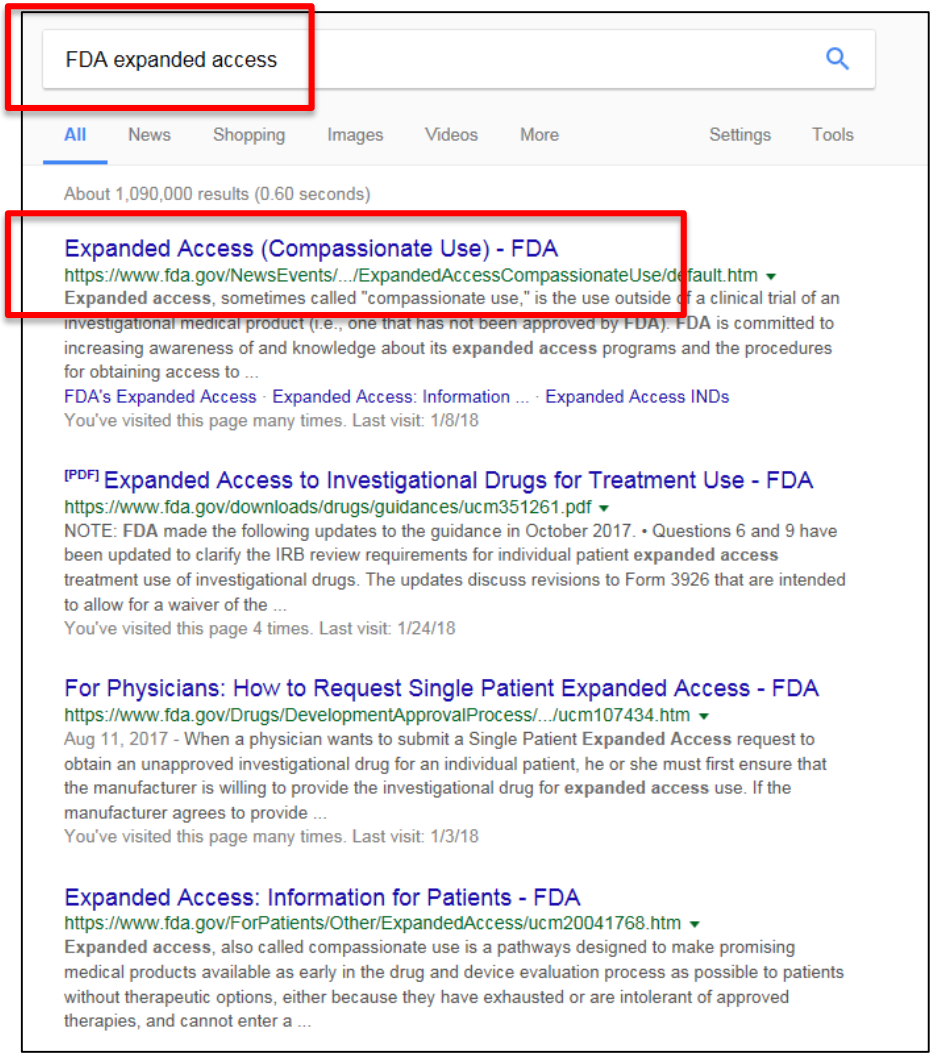


Reference: http://navigator.reaganudall.org/

FDA Websites



Reference: https://www.google.com

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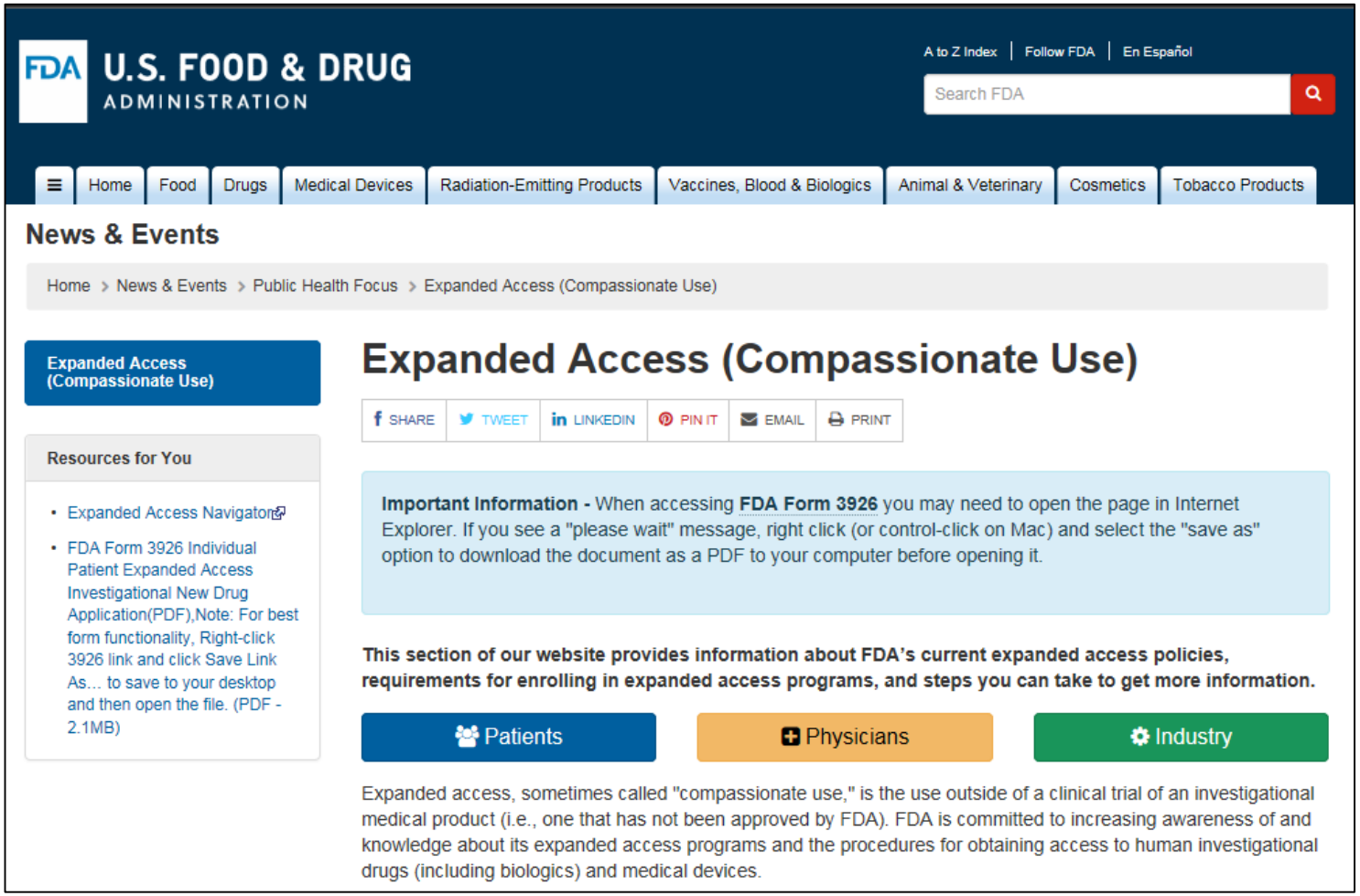
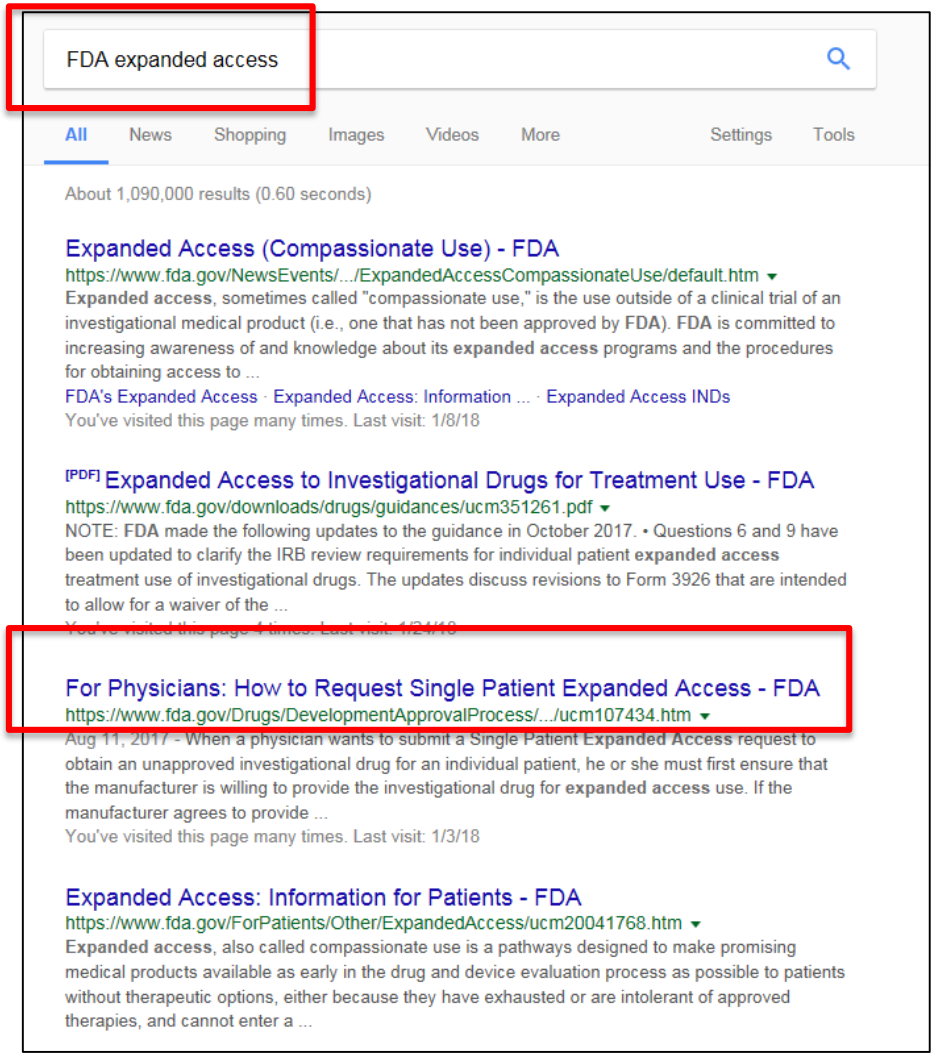


Reference: https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm

FDA Websites



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Drugs

Home > Drugs > Development & Approval Process (Drugs) > How Drugs are Developed and Approved > Types of Applications > Investigational New Drug (IND) Application

Investigational New Drug (IND) Application

- Emergency Investigational New Drug (EIND) Applications for Antiviral Products
- IND Forms and Instructions
- Investigator-Initiated Investigational New Drug (IND) Applications
- Pre-IND Consultation Program
- Regulatory Information for INDs

Resources for You

- Rare Diseases Program
- How to request Domperidone for gastrointestinal disorders
- How to request Omegaven for Expanded Access Use
- How to request Zelnorm for

For Physicians: How to Request Single Patient Expanded Access ("Compassionate Use")

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When a physician wants to submit a Single Patient Expanded Access request to obtain an unapproved investigational drug for an individual patient, he or she must first ensure that the manufacturer is willing to provide the investigational drug for expanded access use. If the manufacturer agrees to provide the drug, the physician should follow the steps below to submit an Investigational New Drug Application (IND) to the FDA.

Emergency Requests:

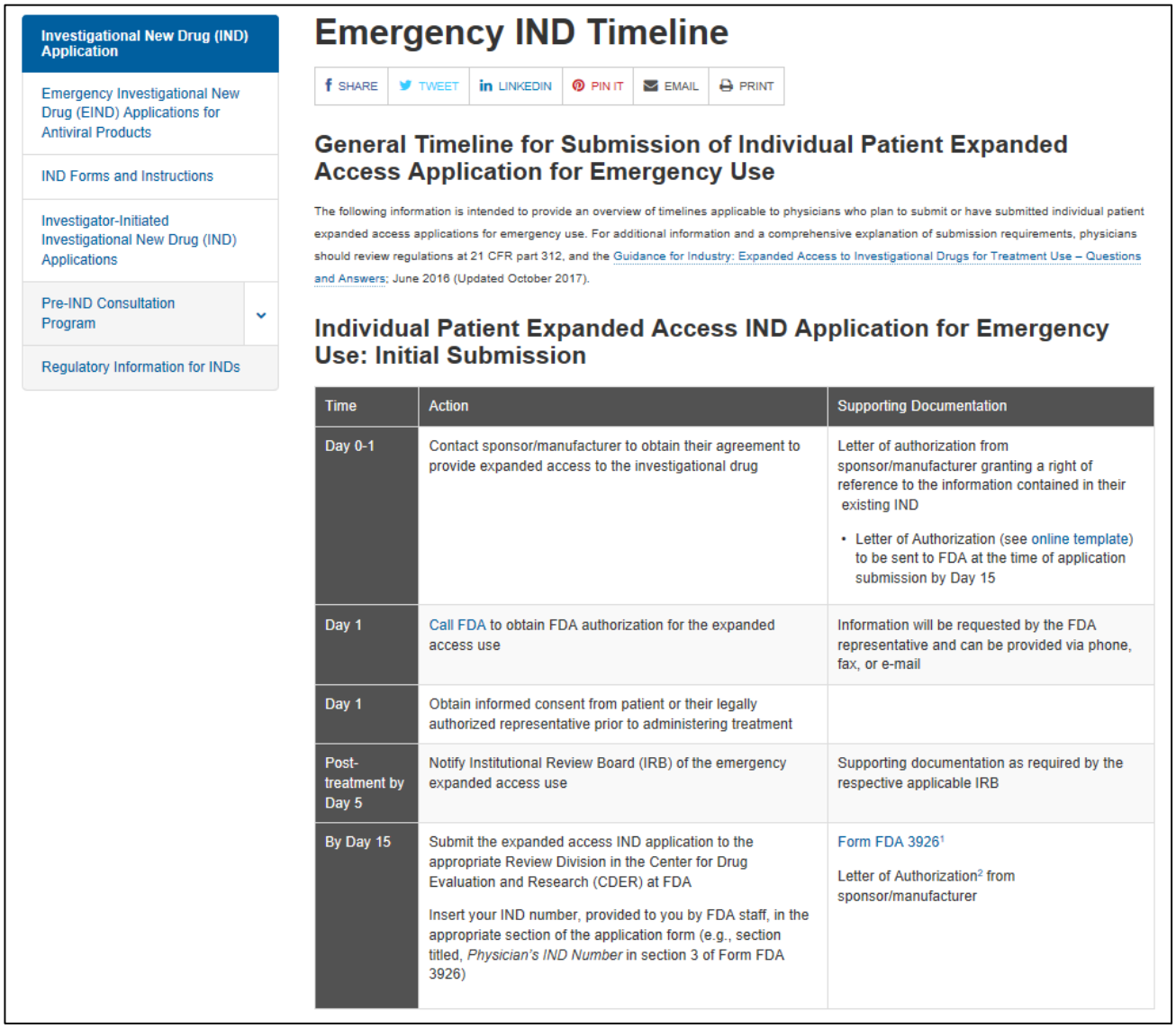
In an emergency situation, the request to use an unapproved investigational drug may be made via telephone or other rapid means of communication, and authorization to ship and use the drug may be given by the FDA official over the telephone. In these situations, known as emergency IND (eIND) requests, shipment of and treatment with the drug may begin prior to FDA's receipt of the written IND submission that is to follow the initial request. An emergency IND timeline is available online to guide you through the process.

Non-emergency Requests:

In a non-emergency situation, a written request (IND) for individual patient use of an investigational drug must be submitted to the FDA. The investigational drug may be shipped and treatment of the patient may begin 30 days after the application is received by FDA or earlier if notified by the FDA that treatment may proceed. These non-emergency requests are known as individual patient INDs, or single patient expanded access requests. A guide to initiate and maintain non-emergency requests is available for physicians online.

Reference:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm

FDA Websites



Investigational New Drug (IND) Application

- Emergency Investigational New Drug (EIND) Applications for Antiviral Products
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Emergency IND Timeline

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General Timeline for Submission of Individual Patient Expanded Access Application for Emergency Use

The following information is intended to provide an overview of timelines applicable to physicians who plan to submit or have submitted individual patient expanded access applications for emergency use. For additional information and a comprehensive explanation of submission requirements, physicians should review regulations at 21 CFR part 312, and the Guidance for Industry: Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers; June 2016 (Updated October 2017).

Individual Patient Expanded Access IND Application for Emergency Use: Initial Submission

Time	Action	Supporting Documentation
Day 0-1	Contact sponsor/manufacturer to obtain their agreement to provide expanded access to the investigational drug	Letter of authorization from sponsor/manufacturer granting a right of reference to the information contained in their existing IND • Letter of Authorization (see online template) to be sent to FDA at the time of application submission by Day 15
Day 1	Call FDA to obtain FDA authorization for the expanded access use	Information will be requested by the FDA representative and can be provided via phone, fax, or e-mail
Day 1	Obtain informed consent from patient or their legally authorized representative prior to administering treatment	
Post-treatment by Day 5	Notify Institutional Review Board (IRB) of the emergency expanded access use	Supporting documentation as required by the respective applicable IRB
By Day 15	Submit the expanded access IND application to the appropriate Review Division in the Center for Drug Evaluation and Research (CDER) at FDA Insert your IND number, provided to you by FDA staff, in the appropriate section of the application form (e.g., section titled, *Physician's IND Number* in section 3 of Form FDA 3926)	Form FDA 3926[1] Letter of Authorization[2] from sponsor/manufacturer

Reference:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm597130.htm

FDA Websites

Individual Patient Expanded Access IND Application for Emergency Use: Subsequent Submissions

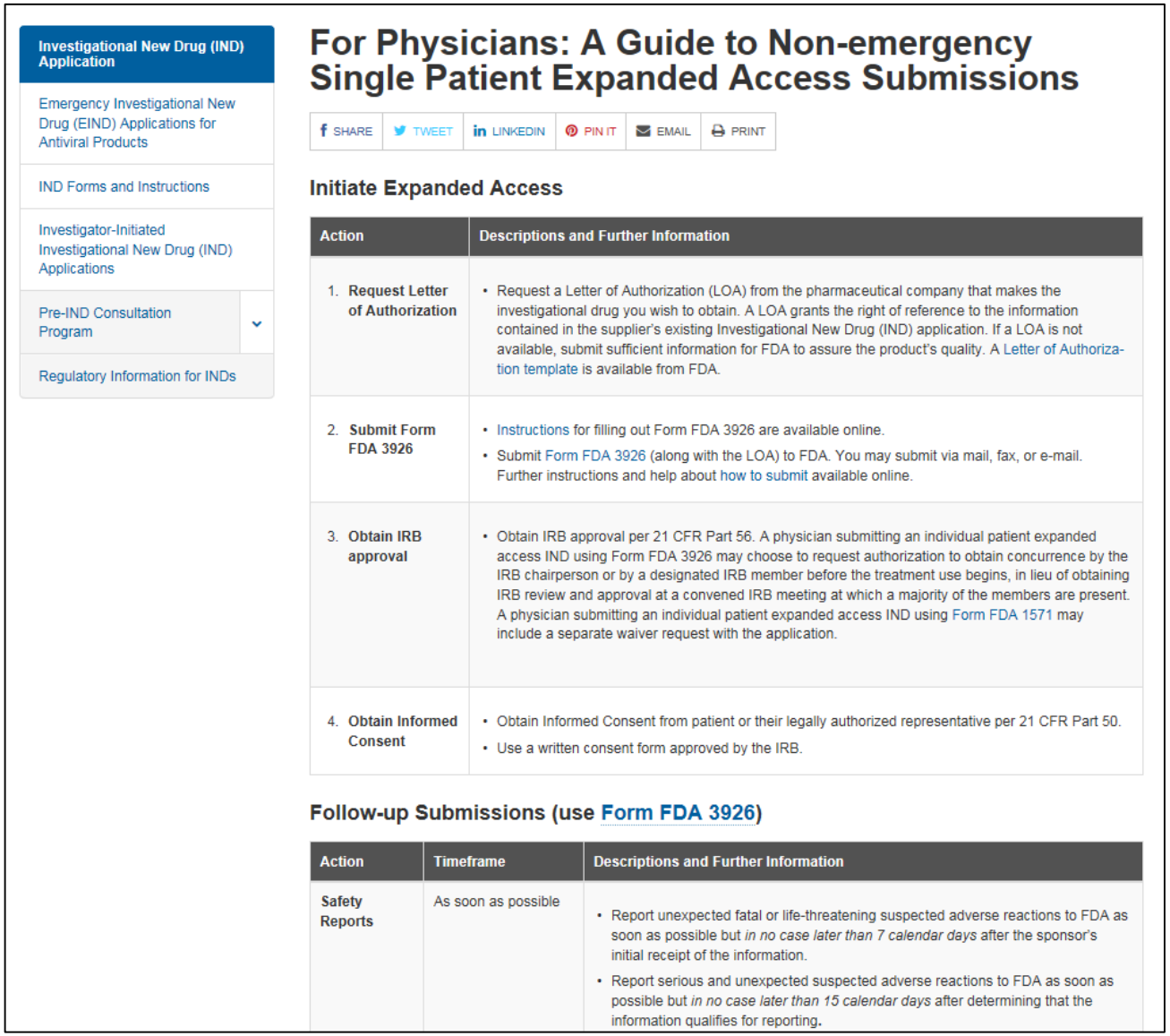
Submission/Time	Action	Supporting Documentation
Mandatory Safety Reports – Unexpected Fatal or Life-Threatening Adverse Reactions: As soon as possible but no later than 7 calendar days	Report unexpected fatal or life-threatening suspected adverse reactions[3]	• Form FDA 3926[4] (Field 9: check initial or follow-up Written IND Safety Report) • Form FDA 3500A
Mandatory Safety Reports – Other: As soon as possible but no later than 15 calendar days after determining the suspected adverse reaction qualifies for reporting	Report serious and unexpected suspected adverse reactions[3]	• Form FDA 3926[4] (Field 9: check initial or follow-up Written IND Safety Report) • Form FDA 3500A
Follow-up to a Written Safety Report: As soon as the information is available but no later than 15 calendar days after the sponsor receives the information	A follow-up report to an IND safety report	• Form FDA 3926[4] (Field 9: Follow-up to a Written Safety Report)
IND Application Amendments: Throughout the IND application life cycle	For example, any change in the patient's treatment plan (generally required to be submitted prior to implementation)	• Form FDA 3926[4] with the appropriate box checked in Field 9 Explanation of the changes
Results Summary: Following completion of the treatment for emergency use	Submit a written summary of the results of the emergency use of the investigational treatment to FDA	• Form FDA 3926[4] (Field 9: Summary of Expanded Access Use [treatment completed]) • Written report that includes the results of treatment, patient response, and all adverse effects. • At this time, a request to close the application should be sent to FDA.
IND Application Annual Reports: Within 60 days of the anniversary of FDA's original authorization date (so long as the application remains active)	Submit Annual Report to FDA	• Form FDA 3926[4] (Field 9: Annual Report) • A brief report of the treatment progress to include: Summary of treatment results, safety information, and any other information, as relevant.

[3]Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies; December 2012.

[4]Instructions for filling out Form FDA 3926

Reference:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm597130.htm

FDA Websites



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For Physicians: A Guide to Non-emergency Single Patient Expanded Access Submissions

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Initiate Expanded Access

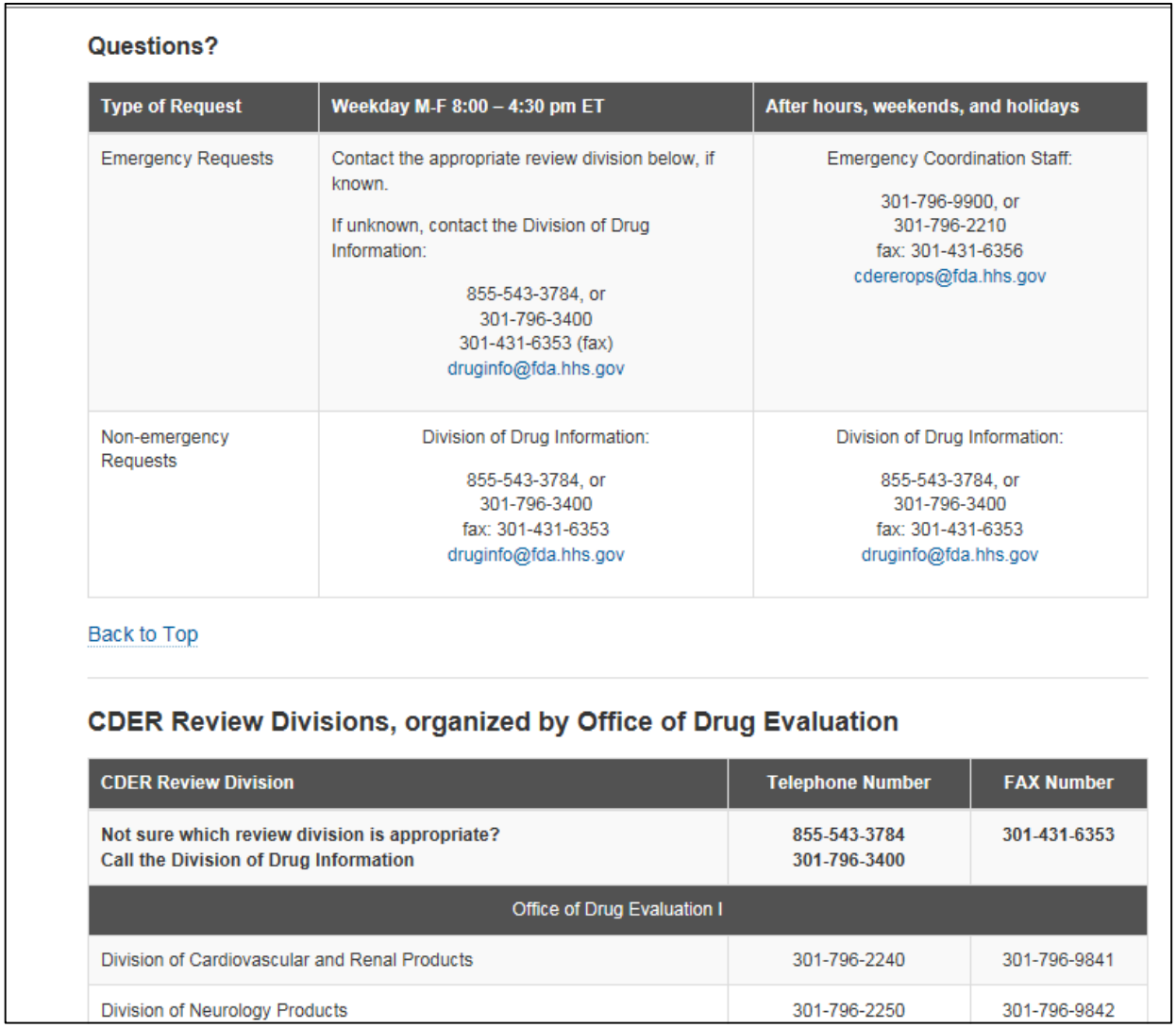
Action	Descriptions and Further Information
1. **Request Letter of Authorization**	• Request a Letter of Authorization (LOA) from the pharmaceutical company that makes the investigational drug you wish to obtain. A LOA grants the right of reference to the information contained in the supplier's existing Investigational New Drug (IND) application. If a LOA is not available, submit sufficient information for FDA to assure the product's quality. A Letter of Authorization template is available from FDA.
2. **Submit Form FDA 3926**	• Instructions for filling out Form FDA 3926 are available online. • Submit Form FDA 3926 (along with the LOA) to FDA. You may submit via mail, fax, or e-mail. Further instructions and help about how to submit available online.
3. **Obtain IRB approval**	• Obtain IRB approval per 21 CFR Part 56. A physician submitting an individual patient expanded access IND using Form FDA 3926 may choose to request authorization to obtain concurrence by the IRB chairperson or by a designated IRB member before the treatment use begins, in lieu of obtaining IRB review and approval at a convened IRB meeting at which a majority of the members are present. A physician submitting an individual patient expanded access IND using Form FDA 1571 may include a separate waiver request with the application.
4. **Obtain Informed Consent**	• Obtain Informed Consent from patient or their legally authorized representative per 21 CFR Part 50. • Use a written consent form approved by the IRB.

Follow-up Submissions (use Form FDA 3926)

Action	Timeframe	Descriptions and Further Information
Safety Reports	As soon as possible	• Report unexpected fatal or life-threatening suspected adverse reactions to FDA as soon as possible but *in no case later than 7 calendar days* after the sponsor's initial receipt of the information. • Report serious and unexpected suspected adverse reactions to FDA as soon as possible but *in no case later than 15 calendar days* after determining that the information qualifies for reporting.

Reference:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm570937.htm

Requesting Expanded Access



Questions?

Type of Request	Weekday M-F 8:00 – 4:30 pm ET	After hours, weekends, and holidays
Emergency Requests	Contact the appropriate review division below, if known. If unknown, contact the Division of Drug Information: 855-543-3784, or 301-796-3400 301-431-6353 (fax) druginfo@fda.hhs.gov	Emergency Coordination Staff: 301-796-9900, or 301-796-2210 fax: 301-431-6356 cdererops@fda.hhs.gov
Non-emergency Requests	Division of Drug Information: 855-543-3784, or 301-796-3400 fax: 301-431-6353 druginfo@fda.hhs.gov	Division of Drug Information: 855-543-3784, or 301-796-3400 fax: 301-431-6353 druginfo@fda.hhs.gov

Back to Top

CDER Review Divisions, organized by Office of Drug Evaluation

CDER Review Division	Telephone Number	FAX Number
Not sure which review division is appropriate? Call the Division of Drug Information	**855-543-3784 301-796-3400**	**301-431-6353**
Office of Drug Evaluation I		
Division of Cardiovascular and Renal Products	301-796-2240	301-796-9841
Division of Neurology Products	301-796-2250	301-796-9842

Reference:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm

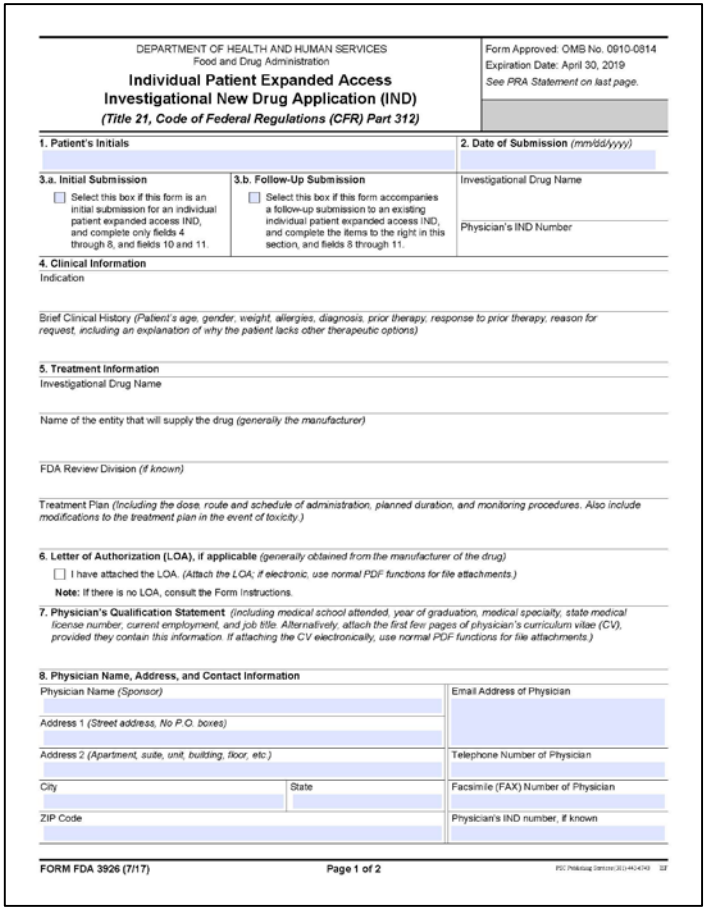
U.S. FOOD & DRUG ADMINISTRATION

Expanded Access

Part 3:

A Walk Through Form FDA 3926, Individual Patient Expanded Access IND Application

Form FDA 3926



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: April 30, 2019
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 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.)*

6. Letter of Authorization (LOA), if applicable *(generally obtained from the manufacturer of the drug)*

☐ I have attached the LOA. *(Attach the LOA; if electronic, use normal PDF functions for file attachments.)*

Note: If there is no LOA, consult the Form Instructions.

7. Physician's Qualification Statement *(including medical school attended, year of graduation, medical specialty, state medical license number, current employment, and job title. Alternatively, attach the first few pages of physician's curriculum vitae (CV), provided they contain this information. If attaching the CV electronically, use normal PDF functions for file attachments.)*

8. Physician Name, Address, and Contact Information

Physician Name *(Sponsor)*

Email Address of Physician

Address 1 *(Street address, No P.O. boxes)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

Telephone Number of Physician

City

State

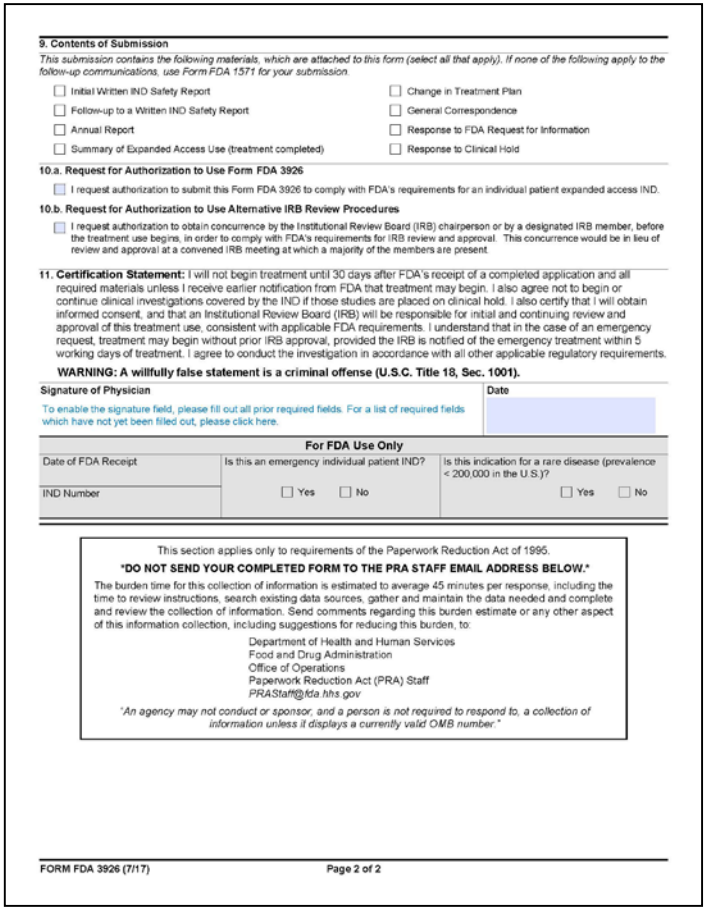
Facsimile (FAX) Number of Physician

ZIP Code

Physician's IND number, if known

FORM FDA 3926 (7/17) **Page 1 of 2**

Form FDA 3926



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.

- ☐ Initial Written IND Safety Report
- ☐ Follow-up to a Written IND Safety Report
- ☐ Annual Report
- ☐ Summary of Expanded Access Use (treatment completed)
- ☐ Change in Treatment Plan
- ☐ General Correspondence
- ☐ Response to FDA Request for Information
- ☐ Response to Clinical Hold

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 investigation in accordance with all other applicable regulatory requirements.

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

Signature of Physician	Date
To enable the signature field, please fill out all prior required fields. For a list of required fields which have not yet been filled out, please click here.	

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.)?
IND Number	☐ Yes ☐ No	☐ Yes ☐ No

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 45 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3926 (7/17) Page 2 of 2

Form FDA 3926

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: April 30, 2019
See PRA Statement on last page.

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Physician's IND Number

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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)*

Form FDA 3926

5. Treatment Information

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

FDA Review Division *(if known)*

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☐ I have attached the LOA. *(Attach the LOA; if electronic, use normal PDF functions for file attachments.)*

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Form FDA 3926

8. Physician Name, Address, and Contact Information

Physician Name *(Sponsor)*		Email Address of Physician
Address 1 *(Street address, No P.O. boxes)*		
Address 2 *(Apartment, suite, unit, building, floor, etc.)*		Telephone Number of Physician
City	State	Facsimile (FAX) Number of Physician
ZIP Code		Physician's IND number, if known

Form FDA 3926

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Form FDA 3926

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Signature of Physician	**Date**
To enable the signature field, please fill out all prior required fields. For a list of required fields which have not yet been filled out, please click here.	

For FDA Use Only

Date of FDA Receipt IND Number	Is this an emergency individual patient IND? ☐ Yes ☐ No	Is this indication for a rare disease (prevalence < 200,000 in the U.S.)? ☐ Yes ☐ No

Submission Package

An individual patient IND submitted using Form FDA 3926 may consist of only:

- Completed form
- Letter of Authorization (LOA) to reference existing IND, if applicable
- First few pages of sponsor-investigator's CV (if he/she elects to provide his/her qualifications in this way, rather than completing section 5 of the form)

Form FDA 1572 is NOT required to be submitted with Form FDA 3926

Overall Points to Remember

- To be used by sponsor-investigators (individual physicians – not drug developers)
- To be used for submission of individual patient INDs, including those for emergency use, only (i.e., no other types of expanded access)
- Sponsor-investigator may choose to use Form FDA 1571 instead

Challenge Questions

- We have a few challenge questions to ask you about what you just heard about expanded access
- We will switch to voting mode from presentation mode

Challenge Question #1

What criteria must be met in order for FDA to authorize expanded access?

a) Patient must have a serious or immediately life-threatening disease or condition

b) Patient must have no comparable or satisfactory alternative therapy available

c) Providing the drug will not interfere with or compromise commercial development for the expanded access use

d) All of the above

Challenge Question #2

Which of the following websites provides phone numbers to FDA's Review Divisions?

A. www.fda.gov
B. www.clinicaltrials.gov
C. http://navigator.reaganudall.org
D. A and C
E. All of the above

Challenge Question #3

Which of the following statements about Form FDA 3926 is false?

a) It is to be used by sponsor-investigators (individual physicians) to submit an individual patient IND

b) Form FDA 1572 is required to be submitted along with Form FDA 3926

c) It is to be used for submitting individual patient expanded access INDs only

More Information

Visit: www.fda.gov/expandedaccess

Contact

- FDA's Office of Health & Constituent Affairs at 301-796-8460 or PatientNetwork@fda.hhs.gov
- CDER's Division of Drug Information at 855-543-3784 or druginfo@fda.hhs.gov
- CBER at 800-835-4709 or industry.biologics@fda.gov

QUESTIONS?


FDA
U.S. FOOD & DRUG
ADMINISTRATION