Customer Satisfaction Survey
OMB No. 0910-0360
Exp. Date: 9/30/2020

Paperwork Reduction Act Statement	Public reporting burden for this collection of information is estimated to be 20 minutes, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to Food and Drug Administration (FDA) Office Operations, 3WFN, 11601 Landsdown Street, North Bethesda, MD 20852. 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 control number. The control number for this project is 0910-0360. Your participation/nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-responders), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.
Instructions	Please answer the following questions based on your experience with Expanded Access (EA) and Compassionate Use (CU) programs and relevant stakeholders (e.g., patients, drug and device manufacturers, health system administrators, health insurance companies, institutional review boards, FDA)

A Survey respondent demographics

Demographics

1) In which state do you practice? State

2) In which medical sub-specialties do you practice? Select all that apply.

3) What is your practice affiliation? Select all that apply.

- ☐ Private – solo
- ☐ Private – group
- ☐ Academic
- ☐ Hospital affiliated
- ☐ Other

4) How did you get information about EA/CU programs? Select all that apply.

- ☐ A colleague
- ☐ A patient
- ☐ Literature search
- ☐ Medical society/conference
- ☐ Patient advocacy group
- ☐ Other (explain)
- ☐ FDA website (FDA.gov)
- ☐ ClinicalTrials.gov (ClinicalTrials.gov)
- ☐ Reagan-Udall Foundation Expanded Access Navigator (navigator.reaganudall.org)

A Survey respondent demographics

Demographics

5) Over the course of your career, how many times have you contacted a drug or device manufacturer to request access to a product through the EA/CU program?

times

6) Of those initial requests to manufacturers, how many were formally submitted to the FDA for review?

requests

When was the first time?

Year

When was the most recent time?

Year

*7) What was the most common reason that requests submitted to manufacturers were **not** submitted to the FDA?*

- ☐ Patient withdrew
- ☐ Patient died
- ☐ Manufacturer did not agree to provide investigational product
- ☐ Institutional Review Board (IRB) did not approve
- ☐ Health Care Administrators did not approve
- ☐ Paperwork was too cumbersome
- ☐ Process was too time-intensive
- ☐ Treatment wasn't covered by insurance
- ☐ Unknown
- ☐ Other (explain):

B Ease and satisfaction

Overall satisfaction

8) How satisfied are you with the entirety of the existing EA/CU program, from identifying appropriate patients through to treatment and follow-up? Please explain.

Very unsatisfied	*Unsatisfied*	*Neutral*	*Satisfied*	*Very satisfied*	*NA / don't know*
0	1	2	3	4	5

Explain:

9) Would you encourage a colleague to consider an EA/CU program if appropriate for a patient? Please explain.

☐ Yes ☐ No

Explain:

B Ease and satisfaction

Ease / difficulty of program

10a) During your most recent application for treatment through an EA/CU program, how would you rate the following:

- Identifying that the EA/CU program would be appropriate for a patient

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Finding appropriate products for that patient

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Making decisions based on preliminary/incomplete data

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Coordinating and timing contact with manufacturers, IRBs, and the FDA

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Working with the manufacturer to request access

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Working with an IRB to obtain approval

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

B Ease and satisfaction

Ease / difficulty of program

10b) During your most recent application for treatment through an EA/CU program, how would you rate the following:

- Working with the FDA to obtain authorization to treat with an investigational product

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Understanding the roles and responsibilities of all stakeholders throughout the process

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Receiving drugs/devices from the manufacturer

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Understanding who would pay for the treatment

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Covering your expenses (e.g., your time, your staff's time, medical supplies)

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Completing documentation during and after treatment (as appropriate)

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

- Attributing relatedness of adverse events to the treatment

Very difficult	*Difficult*	*Neutral*	*Easy*	*Very Easy*	*NA / don't know*
0	1	2	3	4	5

B Ease and satisfaction

Challenge identifi-cation

11) Was there anything else that was especially challenging?

Was there anything else that was especially easy that you would not want to see changed?

Process evaluation

Time estimation

12a) *On average, how much time per patient did:*

	You personally spend communicating with:	**Your staff** spend communicating with:	**You personally** spend completing paperwork for:	**Your staff** spend completing paperwork for:
Patients	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know
Manu-facturers	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know
Health system adminis-trators	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know

C Process evaluation

Time estimation

12b) On average, how much time per patient did:

	You personally spend communicating with:	**Your staff** spend communicating with:	**You personally** spend completing paperwork for:	**Your staff** spend completing paperwork for:
Insurance Companies	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know
IRBs	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know
FDA	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know	☐ No time at all ☐ 0-15 minutes ☐ 15-30 minutes ☐ 30-60 minutes ☐ 1-2 hours ☐ >2 hours ☐ Don't know

C Process evaluation

Time estimation

13) How much time did each of the following take?

- Gaining access from a drug or device manufacturer (inclusive of time to submit the request and gain access)

☐ Less than a day ☐ 1-2 days ☐ 3-7 days ☐ 1-2 weeks ☐ 2-4 weeks ☐ > 4 weeks

- Gaining authorization from FDA after submitting an application (inclusive of time to submit the request and gain approval)

☐ Less than a day ☐ 1-2 days ☐ 3-7 days ☐ 1-2 weeks ☐ 2-4 weeks ☐ > 4 weeks

- Gaining approval from an IRB after submitting a request (inclusive of time to submit the request and gain approval)

☐ Less than a day ☐ 1-2 days ☐ 3-7 days ☐ 1-2 weeks ☐ 2-4 weeks ☐ > 4 weeks

- Receiving a drug/device from a manufacturer after FDA authorization (inclusive of time to submit the request and receive the drug/device)

☐ Less than a day ☐ 1-2 days ☐ 3-7 days ☐ 1-2 weeks ☐ 2-4 weeks ☐ > 4 weeks

D Suggestions for improvement

Sugges-tions for improve-ment

14) *Which of the following would substantially improve the EA/CU program? Please rank the top five improvements.*

- ☐ Increased availability of academic literature
- ☐ More information from patient advocacy groups
- ☐ Less paperwork for requesting access from manufacturer
- ☐ Less paperwork for FDA application
- ☐ Less paperwork for IRB approval
- ☐ Option to chat online with FDA medical officers
- ☐ FDA call center to answer questions
- ☐ More responsive communication from manufacturers
- ☐ More responsive communication from FDA
- ☐ More responsive communication from IRBs
- ☐ Transparency on policies for receiving access from drug or device manufacturers
- ☐ Transparency on standards for FDA authorization of EA/CU
- ☐ Transparency on requirements for IRB approval
- ☐ Other (explain):

15) *Is there anything else you would like to add about past experiences with EA/CU programs or suggestions for improvement?*

E Right to try

Right to try

16) *"Right to try" laws enable patients to try experimental therapies that have completed Phase I testing without soliciting FDA authorization. Are you in favor of "right to try" laws being passed?*

Strongly against	*Against*	*Neutral*	*In favor*	*Strongly in favor*	*NA / don't know*
0	1	2	3	4	5