Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites Questionnaire (10/19/2022)

[Screener and consent to be inserted]

STIMULI INSTRUCTIONS

We will show you a website for a cancer treatment. Make sure you are comfortable and can read the screen from where you sit. The study will take about 20 minutes to complete. We ask you to complete the study in one sitting (without taking any breaks) in order to avoid distractions.

//NEW SCREEN//

We'd like to start by telling you a bit about a kind of cancer. It's called acute lymphoblastic leukemia or ALL.

The word "acute" means that this type of leukemia can progress very quickly and, if not treated, can cause death within a few months.

Cancers start when cells in the body begin to grow out of control. Acute lymphoblastic leukemia is a cancer of a certain type of white blood cell called lymphocytes. This cancer starts in the bone marrow – the soft, spongy tissue inside bones that makes lymphocytes. It can also spread to other parts of the body.

With this cancer, the body makes too many immature lymphocytes which are not able to mature and work normally. These leukemia cells crowd out the normal cells in the bone marrow. This means there is less room for mature white blood cells (which fight infection), red blood cells (which carry oxygen), and platelets (which help blood to clot).

There are few treatment options available for people with acute lymphoblastic leukemia.

//NEW SCREEN//

- Next we will show you a picture of a web page from a prescription drug website. All links on the web page are inactive.

- When you read it, imagine that someone close to you was recently diagnosed with acute lymphoblastic leukemia and you would like to learn more about their treatment options.

- Take as much time as you need to look at the web page. You may have to scroll to see all of the information on the web page.

- After you leave the web page you won't be able to return to it while answering the questions.

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Study 1 Design	
Accelerated Approval Language	Placement
Physician labeling version	Condition 1: High prominence
	Condition 2: Low prominence
Consumer-friendly version	Condition 3: High prominence
	Condition 4: Low prominence
None	Condition 5: N/A

[Physician labeling version: This indication is based on response rate. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.]

[Consumer-friendly version: In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better. We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.]

Study 2 Design			
		Confirmatory trials	
		Absent	Present
Unknown outcomes	Absent	Condition 1: In a clinical trial, [Drug X] returned blood counts to normal.	Condition 2: In a clinical trial, [Drug X] returned blood counts to normal. We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.
	Present	Condition 3: In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better.	Condition 4: In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better. We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.

//NEW SCREEN//

Question Type: Single Punch
Q1. Were you able to view the website?

Value	Value Label
01	Yes
00	No
02	Not Sure
9999	Refused

//NEW SCREEN//

Question Type: Single Punch

[Randomize order of 01-03. 04 always appears last.]

Q2. [Drug X] is a treatment option for

Value	Value Label
01	Human Immunodeficiency Virus
02	Myocardial infarction
03	Acute lymphoblastic leukemia
04	Not sure / Don't know
9999	Refused

//NEW SCREEN//

Question type: Text box

Q3. What can [Drug X] do for people with acute lymphoblastic leukemia? (Please be as detailed and specific as possible when entering your answer in the space provided.)

<div style="border:1px solid black; height:60px;"></div>

 [Open Field]

[Codes: blood cell counts return to normal, gets rid of any detectable evidence of leukemia/no signs of leukemia/remission, cure, live longer, feel better/reduce symptoms, other codes to be determined based on cognitive interviews and pretesting]

//NEW SCREEN//

Question Type: Single Punch

Q4. Did the website say that there are things we **do not know yet** about what [Drug X] can do for people with acute lymphoblastic leukemia?

Value	Value Label
01	Yes

00	No
02	Not Sure
9999	Refused

[If Q4=01, ask Q5]

Question type: Text box

Q5. What don't we know yet about what [Drug X] can do for people with acute lymphoblastic leukemia? (Please be as detailed and specific as possible when entering your answer in the space provided.)

[Codes: blood cell counts return to normal, gets rid of any detectable evidence of leukemia/no signs of leukemia/remission, cure, live longer, feel better/reduce symptoms, other codes to be determined based on cognitive interviews and pretesting]

Question Type: Grid

[Randomize order of Q6 A – D]

Q6. Based on the information on the website, mark whether each of the statements below is true, false, or you don't know:

Variable	Variable Text
Q6_A	[Drug X] has been shown to cure acute lymphoblastic leukemia.
Q6_B	[Drug X] has been shown to help people with acute lymphoblastic leukemia live longer.
Q6_C	[Drug X] has been shown to help people with acute lymphoblastic leukemia feel better.
Q6_D	[Drug X] helps blood cell counts return to normal.

Value	Value Label
01	True
02	False
03	Don't Know
9999	Refused

Question Type: Grid

[Randomize order of 00-02: first to last or last to first]

Q7. Please select one response. On average, people with acute lymphoblastic leukemia who take [Drug X]...

Value	Value Label
00	Don't live as long as people who don't take [Drug X].
01	Live **the same amount of time** as people who don't take [Drug X].
02	Live **longer** than people who don't take [Drug X].
03	No one knows yet whether people who take [Drug X] live longer or not.
9999	Refused

//NEW SCREEN//

[If Q7=02, ask Q8]

Question type: Numeric string plus drop-down option

Q8. You mentioned that [Drug X] would help people with acute lymphoblastic leukemia live longer. On average, how much longer do you think people with acute lymphoblastic leukemia who take [Drug X] would live? Your best guess is fine.

(Please write a number in the space below and choose from the dropdown list whether it is weeks, months, or years. You will need to enter a single number, so if you have a range in mind, please pick the middle number in the range.)

(Q8_A: Open ended numeric string)

Q8_B: Unit selection answer choices

Value	Value Label
1	weeks longer
2	months longer
3	years longer
9999	Refused

//NEW SCREEN//

Question Type: Single Punch

Q9. The website suggests that [Drug X] will improve the quality of life for people who take it...

Value	Value Label
01	Disagree
02	Agree
9999	Refused

Please indicate your level of agreement with the following statement.

Question Type: Single Punch

Q10. The benefits of [Drug X] outweigh any side effects it may have.

Value	Value Label
01	1 Strongly disagree
02	2 Disagree
03	3 Agree
04	4 Strongly agree
99	Don't know
9999	Refused

Question Type: Single Punch

Q12. Based on the information on the website, mark whether each of the statements below is true, false, or you don't know: **...**

Variable	Variable Text
Q12_A	Currently, more data is needed to know whether [Drug X] helps people with acute lymphoblastic leukemia live longer.
Q12_B	Currently, more date is needed to know whether [Drug X] helps people with acute lymphoblastic leukemia feel better.

Value	Value Label
00	True

01	False
02	Don't know
9999	Refused/Skipped

//NEW SCREEN//

Question Type: MultiPunch

Q13. If a loved one was diagnosed with acute lymphoblastic leukemia, I would suggest that they ask their doctor about taking [Drug X].

Value	Value Label
00	No
01	Yes
9999	Refused/Skipped

//NEW SCREEN//

Question Type: Grid

[Randomize order of Q14 A – C]

Q14. Please check how much you agree or disagree with the following statements about the website you saw.

Q14_A1	This website is a reliable source of information about the risks of ALTISOL.
Q14_A2	This website is a reliable source of information about the benefits of ALTISOL.
Q14_B	I feel I've been accurately informed after viewing this website.
Q14_C	This website provides consumers with essential information for deciding whether to ask a doctor about [Drug X].

Value	Value Label
01	Strongly disagree
02	Disagree
03	Neither
04	Agree
05	Strongly Agree
9999	Refused/Skipped

//NEW SCREEN//

Question Type: Single Punch

Q15a_1. The following statement **may or may not** have been on the website you saw.

Did you see this statement on the website?

Study 1 – condition 1, 2 display: An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

Study 1 – condition 3, 4 display: In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better. We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.

Study 1 – condition 5 - control condition: randomize displaying either physician labeling or consumer-friendly disclosure condition.

[Study 2: Unknown outcomes statement]

Study 2 – condition 1, 2, 3, 4 display: However, we currently do not know if [Drug X] helps people live longer or feel better.

Statement: [Display the disclosure that matches the programming notes above]

Value	Value Label
01	Yes, I saw it on the website
00	No, I did not see it on the website
9999	Refused/Skipped

//NEW SCREEN//

Question Type: Single Punch

[PROGRAMMER NOTE: ASK Q15a_2 in Study 2 only]

Q15a_2. The following information **may or may not** have been on the website you saw.

Did you see this information on the website?

PROGRAMMER NOTE: Study 2 – condition 1, 2, 3, 4 display: *However, we currently do not know if ALTISOL helps people live longer or feel better.*

Value	Value Label
01	Yes, I saw it on the website
00	No, I did not see it on the website
9999	Refused/Skipped

//NEW SCREEN//

Please read the statement below.

An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

In a clinical trial, [Drug X] returned blood counts to normal. However, we currently do not know if [Drug X] helps people live longer or feel better. We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.

However, we currently do not know if [Drug X] helps people live longer or feel better.

Statement: [Display the disclosure that matches the programming notes above]

Question Type: Grid

Q16a. In my opinion, the statement is…

[RANDOMIZE ORDER OF ITEMS Q16a_1 to Q16a_4]

		1	2	3	4	5	6	
Q16a_1	Confusing	☐	☐	☐	☐	☐	☐	Clear
Q16a_2	Complex	☐	☐	☐	☐	☐	☐	Straightforward
Q16a_3	Unimportant	☐	☐	☐	☐	☐	☐	Important
Q16a_4	Misleading	☐	☐	☐	☐	☐	☐	Honest

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Question type: Text Box

Q17a. What does the statement mean to you?

//NEW SCREEN//

[Show Q15b only in Study 2]

Question Type: Single Punch

Q15b. The following information **may or may not** have been on the website you saw.

Did you see this information on the website?

Study 2 condition 1, 2, 3, 4: We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.

Statement: [Display the disclosure that matches the programming notes above]

Value	Value Label
01	Yes, I saw it on the website
00	No, I did not see it on the website
9999	Refused/Skipped

//NEW SCREEN//

[Keep the text below on screen for Q16b and Q17b:

Please read the statement below.

[Study 2: Display confirmatory trials statement]

Study 2 condition 1, 2, 3, 4 display: We continue to study [Drug X] in clinical trials to learn more about [Drug X]'s benefits.

Statement: [Display the disclosure that matches the programming notes above]

[Show Q16b only in Study 2]

Question Type: Grid

Q16b. In my opinion, the statement is...

[RANDOMIZE ORDER OF ITEMS Q16b_1 to Q16b_4]

		1	2	3	4	5	6	
Q16b_	Confusing	❑	❑	❑	❑	❑	❑	Clear

1								
Q16b_2	Complex	❑	❑	❑	❑	❑	❑	Straightforward
Q16b_3	Unimportant	❑	❑	❑	❑	❑	❑	Important
Q16b_4	Misleading	❑	❑	❑	❑	❑	❑	Honest

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[Show Q17b only in Study 2]

Question type: Text Box

Q17b. What does the statement mean to you?

[Open Field]
[Codes to be determined based on cognitive interviews and pretesting]

//NEW SCREEN//

Question Type: Single Punch

Q18. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

Value	Value Label
01	Never
02	Rarely
03	Sometimes
04	Often
05	Always
9999	Refused/Skipped

//NEW SCREEN//

Question Type: Single Punch
Q19. How familiar were you with treatments for acute lymphoblastic leukemia before today?

Value	Value Label
01	Not at all

02	A little bit
03	Somewhat
04	Quite a bit
05	Extremely
9999	Refused/Skipped

//NEW SCREEN//

Q20. On average, how likely would a person diagnosed with acute lymphoblastic leukemia be to live more than 5 years?

Value	Value Label
01	Not at likely
02	Somewhat likely
03	Moderately likely
04	Very likely
9999	Refused/Skipped

//NEW SCREEN//

[CANCER CAREGIVERS ONLY]

Question Type: Single Punch

Q24c. Think about the individual for whom you are currently providing or have provided cancer-related care in the past. What is your relationship to that person? (If you have provided cancer-related care for more than one person, please think of your most recent caretaking role)

They are my:

Value	Value Label
01	Spouse/partner
02	Child
03	Parent
04	Sibling
05	Friend
06	Other, specify

//NEW SCREEN//

[CANCER CAREGIVERS ONLY]

Question Type: Single Punch

Q25c. Think about the individual for whom you are currently providing or have provided cancer-related care in the past. About how long have you provided care (or did you provide care in the past) for this person? (If you have provided cancer-related care for more than one person, please think of your most recent caretaking role)

Value	Value Label
01	Less than 6 months
02	6 months to 1 year
03	1 to 2 years
04	3 to 5 years
05	5 to 9 years
05	10 or more years

//NEW SCREEN//

Question Type: Single Punch

Q26. How much do you trust information provided by pharmaceutical companies about prescription drugs?

Value	Value Label
01	Not at all
02	A little
03	Some
04	A lot

//NEW SCREEN//

The purpose of this study is to learn about reactions to prescription drug information. To get a real-life reaction, we used a pretend product in this study. **While [Drug X] is not a real product and is not available for sale**, your participation in this important study helps FDA better understand how to communicate the benefits and risks of prescription drugs to consumers clearly and usefully. Your responses will help make prescription drug information clearer. Please see your health care professional for questions about acute lymphoblastic leukemia.

You have been very helpful. Thank you very much for your participation!