

Accelerated Approval Questionnaire

[Screener and consent to be inserted]

INTRODUCTION

Thank you for agreeing to participate in this study today. We are going to show you a website with information about a prescription drug that treats a kind of cancer and then ask you some questions about it.

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

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 lymphoma.

//NEW SCREEN//

- Next we will show you the website.
- 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 website.
- After you leave the website you won't be able to return to it while answering the questions.

[Display appropriate stimuli based on randomized experimental condition: no accelerated approval disclosure, low prominence/ physician labeling disclosure, high prominence/physician labeling disclosure, low prominence/consumer-friendly disclosure, high prominence/consumer-friendly disclosure]

Accelerated Approval Language	Placement	Condition
Physician labeling version	High prominence	A
	Low prominence	B
Consumer-friendly version	High prominence	C
	Low prominence	D
None	N/A	E

[**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.]

MANIPULATION/RECALL/COMPREHENSION CHECKS

Question Type: Single Punch

Q1. Were you able to view the website?

Value	Value Label
01	Yes
00	No
02	Not Sure
-99	Refused

[If Q1=00 OR Q1=02 OR Q1=-99, Terminate]

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
-99	Refused

Question type: Text box (5)

Q3. What can Drug X do for people with acute lymphoblastic leukemia?

[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]

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
-99	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?

[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[\[Randomize order of Q6 A - E\]](#)

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_E	[Drug X] helps blood cell counts return to normal.

Value	Value Label
01	True
02	False
03	Don't Know
-99	Refused

DRUG RISKS AND BENEFITS**Question Type: Grid**[\[Randomize order: first to last or last to first\]](#)

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.
-99	Refused

[\[If Q7=02, ask Q8\]](#)

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.

(Q8_A: Open ended numeric string)

Q8_B: Unit selection answer choices

Value	Value Label
1	weeks longer
2	months longer
3	years longer
-99	Refused
-100	Valid skip

Question Type: Single Punch
[\[Randomize order of Q9 A - B\]](#)

Q9. 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
Q9_A	More research is needed before we know whether Drug X helps people with acute lymphoblastic leukemia live longer.
Q9_B	More research is needed before we know whether Drug X helps people with acute lymphoblastic leukemia feel better.

Value	Value Label
00	True
01	False
02	Don't know
-99	Refused

QUALITY OF LIFE, SYMPTOM IMPROVEMENT, AND RISK

[Randomize order of Q10, Q16, Q17]

Question Type: Single Punch

Q10. The website suggests that Drug X will improve the quality of life for people who take it.

[Randomize order of response options]

Value	Value Label
01	Disagree
02	Agree
-99	Refused

Question Type: Single Punch

Q16. The website suggests that Drug X will make a person's life:

Value	Value Label
01	1 Much less enjoyable
02	2 Somewhat less enjoyable
03	3 Somewhat more enjoyable
04	4 Much more enjoyable
05	The website doesn't suggest anything about this.
-99	Refused

Question Type: Single Punch

Q17. The website suggests that Drug X will make a person's life:

Value	Value Label
01	1 Much less painful
02	2 Somewhat less painful
03	3 Somewhat more painful
04	4 Much more painful
05	The website doesn't suggest anything about this.
-99	Refused

[Randomize order of Q12 - Q14]

Please indicate your level of agreement with the following statements.

Question Type: Single Punch

Q12. 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
-99	Refused

Question Type: Single Punch

Q13. Drug X is more likely to harm than benefit someone with acute lymphoblastic leukemia.

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

Question Type: Single Punch

Q14. Drug X might have serious side effects.

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

BEHAVIORAL INTENTIONS

Question Type: MultiPunch

Q18. If a loved one was diagnosed with acute lymphoblastic leukemia, I would suggest that they ask their doctor about(check all the apply):

[Randomize order]

Value	Value Label
00	Taking Drug X
01	Drug X's risks
02	Drug X's benefits
03	Drug X's FDA approval
-99	Refused

WEBSITE INFORMATION AND MANIPULATION CHECK

Question Type: Grid

[Randomize order of Q19 A - D]

Q19. Please check how much you agree or disagree with the following statements about the website you saw.

Q19_A	This website is a reliable source of information about the risks and benefits of [Drug X].
Q19_C	I feel I've been accurately informed after viewing this website.
Q19_D	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
-99	Refused

Question Type: Single Punch

Q20. Did you see this statement on the website?

[Display one statement based on condition; for those selected to view the control condition, randomize displaying either physician labeling or consumer-friendly disclosure condition.]

Statement: [Display this statement in physician labeling disclosure conditions]
[physician labeling disclosure]

Statement: [Display this statement in consumer-friendly disclosure conditions]
[consumer-friendly disclosure]

Value	Value Label
01	Yes
00	No
-99	Refused

Question type: Text Box
 Q21. What does this statement mean to you?
 [Display one statement based on condition; display the same statement as Q20.]

Statement: [Display in physician labeling disclosure conditions]
[physician labeling disclosure]

Statement: [Display in consumer-friendly disclosure conditions]
[consumer-friendly disclosure]

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

FAMILIARITY WITH CONDITION

Question Type: Multi Punch
 Q22. Have you or someone you know ever had acute lymphoblastic leukemia?

Value	Value Label
01	Yes, I have
02	Yes, someone I know has
00	Neither I nor someone I know has
03	Not sure
-99	Refused

Question Type: Single Punch
 Q23. How familiar were you with treatments for acute lymphoblastic leukemia before today?

Value	Value Label
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01	Not at all
02	A little bit
03	Somewhat
04	Quite a bit
05	Extremely
-99	Refused

Question Type: Single Punch

QX. Have you ever been diagnosed with cancer?

Value	Value Label
01	Yes
02	No (Skip to Q22)
-99	Refused

Question Type: Single Punch

QXa. Did you take one or more prescription drugs for your cancer?

Value	Value Label
01	Yes
02	No (Skip to Q22)
03	Don't know (Skip to Q22)
-99	Refused

Question Type: Single Punch

QXb. Did you take one or more prescription drugs **with accelerated approval from FDA** for your cancer?

Value	Value Label
01	Yes
02	No
03	Don't know
-99	Refused

TREATMENT ATTITUDES

Please indicate your level of agreement with the following statements.

[Q24 and Q25 are adapted from the Schedule of Attitudes toward Hastened Death (Rosenfeld et al., 2000). Included as a potential moderator.]

Question Type: Single Punch

Q24. If I was diagnosed with a life-threatening disease, I would want to continue living no matter how much pain or suffering my disease causes.

Value	Value Label
01	1 Strongly disagree
02	2 Disagree
03	3 Agree
04	4 Strongly agree
-99	Refused

Question Type: Single Punch

Q25. If I was diagnosed with a life-threatening disease, I would aggressively pursue all possible treatments because I'd do anything possible to continue living.

Value	Value Label
01	1 Strongly disagree
02	2 disagree
03	3 agree
04	4 Strongly agree
-99	Refused

PERSPECTIVE-TAKING

[Q26 is the perspective-taking subscale (Davis, 1983). Included as a potential moderator.]

Question Type: Grid

Q26. The following statements inquire about your thoughts and feelings in a variety of situations. For each item, indicate how well it describes you.

- Q26_A. Before criticizing somebody, I try to imagine how I would feel if I were in their place.
- Q26_B. If I'm sure I'm right about something, I don't waste much time listening to other people's arguments.
- Q26_C. I sometimes try to understand my friends better by imagining how things look from their perspective.
- Q26_D. I believe that there are two sides to every question and try to look at them both.
- Q26_E. I sometimes find it difficult to see things from the other person's point of view.

Q26_F. I try to look at everybody's side of a disagreement before I make a decision.

Q26_G. When I'm upset at someone, I usually try to "put myself in their shoes" for a while.

Value	Value Label
01	1 Does not describe me well
02	2
03	3
04	4
05	5 Describes me very well
-99	Refused

DEMOGRAPHICS

Question Type: Single Punch

Q27. In the past 12 months, how often have you used the internet to look for health or medical information?

Value	Value Label
01	Daily
02	A few times a week
03	Once a week
04	A few times a month
05	Once a month
06	Every few months
07	Less often than every few months
08	Never
-99	Refused

//NEW SCREEN//

DEBRIEF

Drug X is not a real product and is not available for sale. 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. Please see your health care professional for questions about acute lymphoblastic leukemia.

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