**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.

//NEW SCREEN//

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 optionQ8. 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 **mor**e 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** |
| 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!