

**Phase 3 Depression  
FDA Online Study  
Survey Instrument**

**SCREENING / INTRODUCTION**

Thank you for agreeing to participate in this study today. Make sure you are comfortable and can read the screen from where you sit. The survey will include some audio, so please make sure the sound is on and the speaker volume is turned up.

This study will take about 25 minutes to complete. We ask you to please complete the study in one sitting (without taking any breaks) in order to avoid distractions.

First, we will ask you a few health-related questions. Next, we will let you explore a Web site about a new medicine. Finally, we will ask you some questions about the medicine.

**S1. [Illness Diagnosis #1]**

Have you ever been diagnosed by a health professional with any of the following conditions? (Check all that apply)

- Arthritis
- Sleep Apnea
- Depression → [Continue]
- Crohn's Disease
- Diabetes
- None of the above

**S2. [Illness Diagnosis #2]**

Do you still have depression?

- Yes → [Skip to Web Site Instructions]
- No → [Continue to S3]

**S3. [Illness Diagnosis #3]**

Have you taken any medication for depression in the past 12 months?

- Yes → [Continue]
- No → [Terminate]

## WEB SITE INSTRUCTIONS

On the next screen, you will see a Web site for a new product. The Web site will open in a new window. Please view the site carefully and be sure to:

- Turn up your speakers
- Watch any videos
- Click any links to other pages or Web sites
- Carefully read the information on the homepage

Once you finish, please close the Web site and click *Next* to continue with the study.

Please make sure you have the speakers on your computer turned up so you can hear any audio.

**[DIRECT PARTICIPANTS TO APPROPRIATE WEB SITE]**

**[IF PARTICIPANT DID NOT CLICK DISEASE AWARENESS LINK, DIRECT TO SECOND SET OF WEB SITE INSTRUCTIONS]**

## WEB SITE INSTRUCTIONS

We noticed that you did not click the link to [www.depression-awareness.com](http://www.depression-awareness.com). [EMBEDDED PICTURE OF LINK ON ELLISTAQ.COM]

Please click the link below to return to the product Web site. On the Web site, click the link and visit the depression awareness Web site. Once you have visited [www.depression-awareness.com](http://www.depression-awareness.com), you may close the Web site and click *Next* to continue with the study.

[DIRECT PARTICIPANTS TO APPROPRIATE WEB SITE]

## SURVEY INSTRUCTIONS

Please answer the following questions based on the Web site you visited.

### Q1. [Web Site Viewing]

Were you able to view and explore the Web site for ELLISTAQ?

Yes

No → [Terminate]

### Q2. [Drug Knowledge (indication, illness)]

What condition does ELLISTAQ treat?

Major Depressive Disorder

Bipolar Disorder

Schizophrenia  
Seasonal Affective Disorder

**Q3. [Risk Info Exposure]**

**ELLISTAQ.com had information about ELLISTAQ's benefits and risks. How much of the risk information did you read?**

- All of it (100%)
- Most of it (50-99%)
- Some of it (1-49%)
- None of it (0%)

**Q4. [Benefit Recall]**

**What are the benefits of ELLISTAQ?**

(open ended)

**[DISPLAY Q5 AND Q6 ON SAME SCREEN]**

When considering a new medicine, most people ask two questions:

- (1) Will this medicine work?
- (2) If it does work, will it help a little or help a lot?

The questions below ask about these two ideas.

**Q5. [Perceived Efficacy - Likelihood of Benefit]**

**In your opinion...If 100 people take ELLISTAQ, for how many will the drug work? Please enter a number in the box below.**

\_\_\_ people

**Q6. [Perceived Efficacy - Magnitude of Benefit]**

**In your opinion...If ELLISTAQ did help a person's depression, how effective would ELLISTAQ be?**

1                      2                      3                      4                      5                      6  
Would help depression very little                      Would help depression a lot

**Q7. [Benefit Recall - Closed] [Benefit Knowledge]**

Please check which of the following were mentioned on the Web site as benefits of taking ELLISTAQ. Even if you think a statement is true, please select it only if it was mentioned on the site.

<b>[RANDOMIZE ORDER]</b>	<b>Mentioned on Web Site</b>	<b>Not Mentioned on Web Site</b>
a. ELLISTAQ treats panic disorder.	x	
b. ELLISTAQ is approved to treat major depressive disorder.	x	
c. ELLISTAQ is thought to work by correcting an imbalance of chemicals in the brain.	x	
f. ELLISTAQ treats bipolar disorder.		x
g. ELLISTAQ can help relieve symptoms of depression and anxiety.	x	
i. ELLISTAQ can prevent memory loss.		DA
j. ELLISTAQ can reduce the chance of alcohol and drug abuse among patients with depression.		DA

k. ELLISTAQ helps improve concentration and the ability to follow medical recommendations.		DA
l. ELLISTAQ can help prevent the poor physical health caused by depression.		DA

**Q8. [Risk Recall]**

**What are the side effects and negative outcomes of ELLISTAQ?**

(open ended)

**[DISPLAY Q9 AND Q10 ON THE SAME SCREEN]**

When considering a new medicine, most people ask two questions:

- (1) Will this medicine cause any side effects?
- (2) If it does cause side effects, how serious will the side effects be?

The questions below ask about these two ideas.

**Q9. [Perceived Risk - Likelihood of Risk]**

**In your opinion...If 100 people take ELLISTAQ, how many will have any side effects or negative outcomes? Please enter a number in the box below.**

\_\_\_ people

**Q10. [Perceived Risk - Magnitude of Risk]**

**In your opinion...If ELLISTAQ did cause a person to have side effects or negative outcomes, how serious would they be?**

1	2	3	4	5	6
Not at all serious					Very serious

**Q11. [Risk Recall - Closed]**

**Please check which of the following were mentioned on the Web site as warnings, side effects, or negative outcomes of taking ELLISTAQ. Even if you think a statement is true, please select it only if it was mentioned on the site.**

<b>[RANDOMIZE ORDER]</b>	<b>Mentioned on Web Site</b>	<b>Not Mentioned on Web Site</b>
a. Antidepressants like ELLISTAQ can increase suicidal thoughts in young adults.	x	
b. When taking ELLISTAQ, people who also take aspirin may have an increased risk of bleeding.	x	
c. A side effect of ELLISTAQ can be insomnia.	x	
d. A side effect of ELLISTAQ can be vomiting.		x
e. In rare cases, ELLISTAQ can cause serotonin syndrome (dangerously high levels of serotonin).	x	
f. ELLISTAQ should never be used in combination with seasonal allergy medications (antihistamines).		x
g. People with a history of high blood pressure should not use ELLISTAQ.		x
h. Smoking or using tobacco products can increase certain side effects of ELLISTAQ.		x

**Q-DA1. [Awareness of Disease Site]**

**This Web site had a link to a second Web site named [www.depression-awareness.com](http://www.depression-awareness.com).**

- True
- False

**[CONTROL GROUP - SKIP Q-DA2 THROUGH DA8]**

**Q-DA2. [Exposure to Disease Site]**

**Did you click on the link and visit this second Web site ([www.depression-awareness.com](http://www.depression-awareness.com))?**

- Yes
- No

**Q-DA3. [Awareness of Disclaimer]**

**[IF YES TO Q-DA2] Did you see a message that explained you were leaving the ELLISTAQ Web site?**

- Yes
- No

**Q-DA4. [Disclaimer Recall]**

**[IF YES TO Q-DA3]** What did this message say? Please enter as much of the message as you can remember.

(open ended)

**Q-DA5. [Disease Site Sponsorship]**

**[IF YES TO Q-DA2]** Which organization sponsored this second Web site (www.depression-awareness.com)?

- The National Institutes of Health
- KAJ Pharmaceuticals (makers of Ellistaq)
- National Alliance on Mental Illness
- It did not say who sponsored the site
- Don't know

**Q-DA7. [Disease Site Content]**

**[IF YES TO Q-DA2]** The second Web site (www.depression-awareness.com) contained information specifically about ELLISTAQ.

- True
- False

**Q-DA8. [Reason for Not Accessing Disease Site]**

**[IF NO TO Q-DA2]** Why didn't you click on the link and visit this second site (www.depression-awareness.com)?

(open ended)

The next few questions ask about ELLISTAQ's risk and benefits. By risks, we mean the drug's possible side effects and negative outcomes. By benefits, we mean the drug's ability to improve symptoms of depression.

**Q12. [Drug Balance of Risks / Benefits]**

Thinking about all its risks and benefits, how would you rate ELLISTAQ:

- |                         |   |   |   |   |                         |   |
|-------------------------|---|---|---|---|-------------------------|---|
| 1                       | 2 | 3 | 4 | 5 | 6                       | 7 |
| Risks outweigh benefits |   |   |   |   | Benefits outweigh risks |   |

**Q18. [Perceived Clarity / Understanding of Site]**

Please rate your agreement or disagreement with each of the following statements.





f. Join an online community or support group <i>sponsored by ELLISTAQ</i>					
---	--	--	--	--	--

**Q15. [Behavioral Intentions (seek drug info, talk to doc, etc.)]**

Based on what you learned, please rate how likely or unlikely you are to do each of the following behaviors.

[RANDOMIZE ORDER]	Very Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Very Likely
-------------------	---------------	-------------------	-----------------------------	-----------------	-------------

a. Look for information online about other people's experience with ELLISTAQ

b. Look for information *about ELLISTAQ* on medical Web sites

c. Look for information *about depression* on medical Web sites

d. Print information from ELLISTAQ.com to discuss with your doctor

**Q16. [Attitudes Toward Drug]**

Based on what you learned, please rate ELLISTAQ. [RANDOMIZE ORDER OF ROWS]

	1	2	3	4	5	6	7	
Bad product								Good product
Disliked a lot								Liked a lot
Unpleasant								Pleasant
Poor quality								Good quality

**Q19. [Site Skepticism]**

How likely or unlikely is it that the information about ELLISTAQ presented on the ELLISTAQ Web site is true?



Strongly  
Disagree

Strongly  
Agree

[Q24D.] I know how to find what I am looking for on the Web.

1            2            3            4            5            6            7

Strongly  
Disagree

Strongly  
Agree

**Q25. [Trust in Online Information (HMTS)]**

**In general, how much do you or would you trust information about prescription drugs from each of the following sources?**

<b>[RANDOMIZE ORDER]</b>	<b>Not at all</b>	<b>A little</b>	<b>Some</b>	<b>A lot</b>
Drug Web sites (example: ELLISTAQ.com)				
Medical Web sites (example: WebMD.com)				
Online communities for people with depression (example: Healthboards.com)				
Family and friends				
Doctors, nurses, and healthcare providers				
Food and Drug Administration (FDA)				
Pharmaceutical companies				
Prescription drug advertisements				

**Q. [Illness Knowledge – Subjective]**

**In general, how much do you know about depression? Would you say you know:**

- Nothing at all
- Only a slight amount
- Some
- A good bit
- A lot

**Q26. [Current Prescription Drug Use]**

**Are you currently taking, or have you ever taken, any prescription drugs for depression?**

- Currently taking
- Have taken in the past but not currently taking
- Have never taken

**Q27. [History of Side Effects]**

**Have you ever had a SERIOUS side effect from a prescription drug?**

- Yes
- No
- Don't Know

**Q28. [Time Since Diagnosis]**

**When did a healthcare professional first tell you that you had depression?**

- Six months ago or less
- More than six months ago but less than a year ago
- A year ago or more but less than 5 years
- Five years ago or longer

**Q29. [Severity of Illness – Subjective]**

**In general, how severe is your depression? Would you describe it as:**

- Very mild
- Mild
- Moderate
- Serious
- Severe

**Q31. [Health Literacy – Assistance (Leaflet Study)]**

**How often do you have someone (like a family member or friend) help you read instructions, pamphlets, or other written material from your doctor or pharmacy?**

- Never
- Occasionally

- Sometimes
- Often
- Always

**Q32. [Health Literacy – Self Efficacy (Leaflet Study)]**

**How confident are you filling out medical forms by yourself?**

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Extremely

**Q33. [Survey Device]**

**What did you use to complete today's survey?**

- Laptop computer / Netbook computer
- Desktop computer
- Handheld phone (iPhone, Blackberry, Droid)
- Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
- Other: \_\_\_\_\_

**CLOSING**

The purpose of this study is to learn about how individuals use information from medical Web sites. In order to get a real-life reaction, we used a pretend product in this study. ELLISTAQ is not a real product and is not available for sale.

The second Web site about depression is also not a real Web site. The negative outcomes of depression discussed on this site were used as examples only. Please see your healthcare provider for any questions about depression, treatments for depression, and outcomes of untreated depression.

If you are having any suicidal thoughts, please seek help immediately. You can call the National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255). It's free and available 24 hours a day.

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