

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.

This study is about a new medicine. The study has three parts: First, we will ask you a few health-related questions. Next, we will let you explore a Web site about the 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 Q-D1]
- No → [Continue to S3]

S3. [Illness Diagnosis #3]

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

- Yes → [Continue]
- No → [Terminate]

The next few questions ask about depression. The purpose of these questions is to find out what most people know and understand about depression. Please answer the questions to the best of your ability. If you don't know the answer to a question, it is okay to check the box that says "Don't know".

Q-D1. [Depression Knowledge #1]

Which of the following is the formal name for clinical depression?

- DES (Depressive episodic syndrome)
- **MDD (Major depressive disorder)**
- MDS (Major depressive syndrome)
- CHD (Chronic heightened depression)
- Don't know

Q-D2. [Depression Knowledge #2]

What factor might put people at risk for clinical depression?

- **Family history of depression**
- High-fat diet
- Food allergies
- Too much exercise
- Don't know

Q-D3. [Depression Knowledge #3]

Which of the following is not a sign of clinical depression?

- Changes in sleep patterns
- Poor concentration
- Loss of appetite
- **Headaches**
- Don't know

Q-D4. [Depression Knowledge #4]

Which of the following is not a common symptom of clinical depression?

- Poor motivation
- **Restlessness**
- Guilty thoughts
- Fatigue
- Don't know

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 read the information on the site. You can take as much time as you want to review it.

The Web site has 5 pages. Feel free to explore the site, click on any links, and read the information as if you wanted to learn more about the new product. Once you finish reading, please click *Next* to move to the next part of 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]

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. [Embedded Visual Recall / Risk Info Exposure Proxy]

The Web site included a picture of the ELLISTAQ pill. What did that pill look like?

The pill was blue and oval

The pill was gray and oval

The pill was white and round

The pill was green and round

I did not see the pill

Q4. [Benefit Recall]

What are the benefits of ELLISTAQ?

(open ended)

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.

[RANDOMIZE ORDER]	Mentioned on Web Site	Not Mentioned on Web Site
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.

[RANDOMIZE ORDER]	Mentioned on Web Site	Not Mentioned on Web Site
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.

- 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)?

- 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

More emphasis on risks
benefits

More emphasis on

Q14. [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. Talk to your doctor about ELLISTAQ					
b. Ask your doctor about getting a sample of ELLISTAQ					
c. Ask your doctor to prescribe ELLISTAQ					
d. Click links on ELLISTAQ.com that take you to other Web sites					
e. Join an online community or support group <i>for people with depression</i>					
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 <i>about ELLISTAQ</i> on medical Web sites					
c. Look for information <i>about depression</i> 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?

1	2	3	4	5	6	7
Extremely Unlikely						Extremely Likely

Q20. [Site Skepticism]

How skeptical or not skeptical are you about the information about ELLISTAQ presented on the ELLISTAQ Web site?

1	2	3	4	5	6	7
Not at all Skeptical						Extremely Skeptical

Q21. [Health Information Seeking - Source (HMTS)]

Have you looked for health or medical information from any of the following sources within the past 12 months? (Check all that apply)

Offline Sources

- Books, magazines, brochures, or other printed materials
- Family member, friend, or co-worker
- Health care provider
- Library or community center
- Telephone information number (1-800-Number)

Online Sources

- Search Engine (examples: Google, Bing)
- Health and medical Web site (examples: WebMd, MedlinePlus)
- Product Web site (example: Lipitor.com)
- Government organization Web site (example: National Institutes of Health)
- Non-profit organization Web site (examples: AARP, American Heart Assoc.)
- Commercial organization Web site (example: Merck, Novartis)
- Health insurance Web site (examples: Cigna, BlueCross and BlueShield)

- Other: _____
- Did not look or go anywhere

Q22. [Illness Information Seeking (Knowledge Proxy)]

In the past 12 months, how often did you use the Internet to look for health or medical information about depression or treatments for depression?

- Once a week
- Once a month
- Every few months
- Less often
- Never

Q23. [Mobile Phone or Device Ownership]

Do you own any of the following devices? (Check all that apply)

- Mobile phone
- Smart phone or PDA (i.e., iPhone, Blackberry, Droid, iPod Touch)
- Tablet computer (i.e., iPad)
- None of the above

Q24. [Web Navigation Skills]

We would like to know more about your Internet skills. For each statement below, please tell us to what extent you agree or disagree with the statement.

[Q24A.] I am extremely skilled at using the Web.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24B.] I consider myself knowledgeable about good search techniques on the Web.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24C.] I know less about using the Web than most users.

1	2	3	4	5	6	7
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?

[RANDOMIZE ORDER]	Not at all	A little	Some	A lot
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				

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!