Revised Final Questionnaires

Physician Survey of Research Data about Prescription Drugs

Informed Consent

NOTE: do not display headings in all caps.

The Food and Drug Administration is conducting this study to better understand physicians’ opinions and preferences about the type of information that is provided about prescription drugs. Your responses, and those of your colleagues nationwide, will provide valuable insight into matters affecting the medical community. Please answer honestly and give us your best guess on answers you do not know. This survey will take 15-20 minutes to complete and your responses will be kept confidential.

This research is authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)). Confidentiality is protected by 5 U.S.C. 552(a) and (b) and 21 CFR part 20.

OMB Control #0910-0900. Expires 8/24/2024.

This survey is being conducted by Westat, an independent social science research firm, on behalf of the U.S. Department of Health and Human Services. Westat is working with SERMO to conduct this survey but is not affiliated with SERMO in any way. If you have questions about this survey, please contact the project director, Dr. Simani Price, at 301-610-5536. She can be reached between 9 AM and 5 PM Eastern Time Monday to Friday.

Privacy and Confidentiality

This survey will not collect any personal information, such as your name. Your identity will not be linked to your responses. We will be very careful to only let people working on the study see your responses, which will not be linked back to any personal information that might be used to identify you. Your information will be kept secure to the extent allowed by law. Study information will be kept in password protected files on secure servers at Westat and FDA locations. The data collected in this study will be destroyed no later than three years after the project is completed.

Possible Risks or Discomforts

There are no anticipated risks to participating in the survey. However, you can skip any questions you do not wish to answer and continue with the survey. While we will be very careful to let only members of the research team see your information, there is a small risk that others might find out what you say, despite all our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

Benefits

Your responses are very important because they will help researchers understand how people make decisions about medications. There is no direct benefit to you for your participation.

Incentive

In appreciation for your time, you will receive $**[46/62]** for completing this survey.

Rights as a Participant

This study is voluntary. You do not have to answer any questions that you do not want to and can withdraw from the study at any time. The Institutional Review Board (IRB) at Westat has reviewed this research study. If you have questions about your rights and welfare as a research participant, please call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your first name, the name of the research study that you are calling about (FDA Communication about Data), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Documentation of Informed Consent

INFORMEDCONSENT

If you have read the previous screens and agree to participate, please click the Yes button. If not, click the No button.

* Yes, I agree to participate.
* No, I do not agree to participate

Introduction

**Thank you for participating in this survey. On the next screen, you will be shown some informational material about a prescription drug.**

**Please read the material. After you finish, you will be asked some questions about it.**

Pharmaceutical Information Material

nOTE: The following terminology will be used to distinguish between the different versions of the stimuli. Please note that respondents will always see the full stimuli before being shown a blurred version.

|  |  |  |
| --- | --- | --- |
| Condition | Stimuli term | Stimuli description |
| 1 | STIM1 | Full stimuli (2 pages) |
| STIM1\_A | Disclosure box at top of page 1; all else blurred |
| STIM1\_B | Page 2 of stimuli |
| 2 | STIM2 | Full stimuli |
| STIM2\_A | Disclosure box at top of page; all else blurred |
| 3 | STIM3 | Full stimuli |
| STIM3\_A | Disclosure box at top of page; all else blurred |
| 4 | STIM4 | Full stimuli |
| STIM4\_A | Disclosure box at top of page; all else blurred |
| 5 | STIM5 | Full stimuli |

Please scroll down to read all the material. {DISPLAY FOR CONDITION1: It is two pages long.} When you have finished reading it, please click on “Next.”

DISPLAY STIM1, STIM2, STIM3, STIM4, STIM5, BASED ON EXPERIMENT ASSIGNMENT

Q1\_disclosure statement\_confirm view

NOTE: This item is intended to confirm the respondent was able to see the material.

1. Were you able to view the material?

* Yes
* No 🡺 END

Q2\_DISCLOSURESTATEMENT\_RECALL\_A

Q2\_DISCLOSURESTATEMENT\_RECALL\_B

Q2\_DISCLOSURESTATEMENT\_RECALL\_C

Q2\_DISCLOSURESTATEMENT\_RECALL\_D

Q2\_DISCLOSURESTATEMENT\_RECALL\_E

Q2\_DISCLOSURESTATEMENT\_RECALL\_F

Q2\_DISCLOSURESTATEMENT\_RECALL\_G

NOTE: Respondents will not be able to go back to material to answer questions. Each item will be presented individually on the screen.

FILL FOR [DRUG] FOR CANCER = imiquimod

FILL FOR [DRUG] FOR INSOMNIA = trazodone

FILL FOR [DISEASE] FOR CANCER CONDITION = lentigo maligna

FILL FOR [DISEASE] FOR INSOMNIA CONDITION = insomnia

PROGRAMMING: Randomize ordering of items a-G.

1. Please indicate whether any of the following were mentioned in the materials you reviewed.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | I’m not sure |
| SHOW FOR ALL CONDITIONS:   1. A brief report on a study that supports use of [DRUG] for [DISEASE] | ⬤ | ⬜ | ⬜ |
| SHOW FOR ALL CONDITIONS:   1. A discussion of the limitations of a study that supports use of [DRUG] for [DISEASE] | ⬤ | ⬜ | ⬜ |
|  |  |  |  |
| SHOW FOR ALL CONDITIONS:   1. Outcomes for a placebo group | ⬜ | ⬤ | ⬜ |
| SHOW FOR CONDITONS 1-4 ONLY:   1. The use of [DRUG] for [DISEASE] has been approved by the FDA. | ⬜ | ⬤ | ⬜ |
| SHOW FOR CONDITIONS 1-3 ONLY:   1. The materials describe other data which does not support the use of [DRUG] for [DISEASE] | ⬤ | ⬜ | ⬜ |
| SHOW FOR CONDITIONS 2-3 ONLY:   1. The materials gave a citation for a study whose result does not support use of [DRUG] for [DISEASE] | ⬤ | ⬜ | ⬜ |
| SHOW FOR ALL CONDITIONS:   1. Information about whether the described use of [DRUG] was off-label | ⬤ | ⬜ | ⬜ |

Q3\_contrary data\_validity

1. How confident are you in the validity of the conclusion that the authors draw about the use of [DRUG] for [DISEASE]?

* Not at all confident
* A little confident
* Somewhat confident
* Very confident
* Extremely confident

Meaning, Influence, and Opinion Items

DISPLAY FOR CONDITION 1:

The next question asks specifically about the box at the top of the first page. This is the same material you viewed earlier.

[DISPLAY STIM1\_A *blurred except for disclosure box on top of page 1*]

DISPLAY FOR CONDITIONS 2-4:

The next questions ask specifically about the information in the box at the top of the page. This is the same material you viewed earlier.

NOTE: We will not refer to the text as a “disclosure statement,” but will reference it descriptively (i.e., “the information in the box”).

[DISPLAY STIM2\_A, STIM3\_A, STIM4\_A *blurred except for disclosure box*]

NOTE: The blurred stimuli will be displayed for the remainder of the items in this section for Conditions 2-4.

DISPLAY FOR CONDITION 5:

The next questions ask about the same material you viewed earlier.

[DISPLAY STIM5 *entire stimuli*]

NOTE: The stimuli will be displayed for the remainder of the items in this section for Condition 5.

ONLY ASK ITEM 4 FOR CONDITIONS 1-4:

Q4\_disclosure statement\_meaning

NOTE: ASKED ONLY OF CONDITIONS 1-4

DISPLAY STIM1\_A, STIM2\_A, STIM3\_A, STIM4\_A

PROGRAMMING: Stimuli and item will be displayed on the same screen

PROGRAMMING: Open-ended text box

1. In your own words, how would you explain the information in the box to a colleague?

ASK Q5 FOR ALL CONDITIONS:

Q5\_disclosure statement\_likely

DISPLAY STIM1\_A, STIM2\_A, STIM3\_A, STIM4\_A, STIM5

PROGRAMMING: Stimuli and item will be displayed on the same screen

PROGRAMMING: Fill for Conditions 1-4 = “box”; condition 5 = “material”

1. If you were considering prescribing [DRUG] to a patient with [DISEASE], how important would the information in the [DISPLAY FILL] be in your decision-making?

* Not at all important
* A little important
* Somewhat important
* Very important
* Extremely important

DISPLAY INTRODUCTION AND Q5 FOR CONDITION 1 ONLY:

The next question asks specifically about the second page of the material. This is the same material you viewed earlier.

[DISPLAY STIM1\_B]

NOTE: Page 2 of the stimuli will be displayed for the remainder of the items in this section for Condition 1.

Q6\_disclosure statement\_likely 2nd page

NOTE: ASKED ONLY OF CONDITION 1

DISPLAY STIM1\_B

PROGRAMMING: Stimuli and item will be displayed on the same screen

1. If you were considering prescribing [DRUG] to a patient with [DISEASE], how important would the information in the second brief report be in your decision-making?

* Not at all important
* A little important
* Somewhat important
* Very important
* Extremely important

DISPLAY Q7-9 FOR ALL CONDITIONS

Q7\_disclosure statement\_useful

DISPLAY STIM1\_B, STIM2\_A, STIM3\_A, STIM4\_A, STIM5

PROGRAMMING: Stimuli and item will be displayed on the same screen

PROGRAMMING: Fill for Condition 1 = “on page 2”; Conditions 2-4 = “in the box”; Condition 5 = “in the material”

1. If you were considering prescribing [DRUG] for [DISEASE], how useful would the information [DISPLAY FILL] be?

* Not at all useful
* A little useful
* Somewhat useful
* Very useful
* Extremely useful

Q8\_disclosure statement\_clear

DISPLAY STIM1\_B, STIM2\_A, STIM3\_A, STIM4\_A, STIM5

PROGRAMMING: Stimuli and item will be displayed on the same screen

PROGRAMMING: Fill for Condition 1 = “on page 2”; Conditions 2-4 = “in the box”; Condition 5 = “in the material”

1. How clearly is the information presented [DISPLAY FILL]?

* Not at all clear
* A little clear
* Somewhat clear
* Very clear
* Extremely clear

Q9\_disclosure statement\_credible

DISPLAY STIM1\_B, STIM2\_A, STIM3\_A, STIM4\_A, STIM5

PROGRAMMING: Stimuli and item will be displayed on the same screen

PROGRAMMING: Fill for Condition 1 = “on page 2”; Conditions 2-4 = “in the box”; Condition 5 = “in the material”

1. How credible is the information presented [DISPLAY FILL]?

* Not at all credible
* A little credible
* Somewhat credible
* Very credible
* Extremely credible

Q10\_disclosure statement\_more info

DISPLAY STIM1\_B, STIM2\_A, STIM3\_A, STIM4\_A, STIM5

PROGRAMMING: Stimuli and item will be displayed on the same screen

PROGRAMMING: Fill for Condition 1 = “on page 2”; Conditions 2-4 = “in the box”; Condition 5 = “in the material”

1. After reviewing the information [DISPLAY FILL], how likely are you to search for additional information about use of [DRUG] for [DISEASE]?

* Not at all likely
* A little likely
* Somewhat likely
* Very likely
* Extremely likely

Q11\_PRESCRIBING\_DRUGS

1. Have you ever prescribed [DRUG] for [DISEASE]?

* Yes
* No

Prescribing Decisions

The next questions ask about how you decide to prescribe an approved drug for an indication that has not yet been approved by FDA, often called “off-label use.”

Q12\_OFF-LABEL USE: freq offlabel

1. How often do you prescribe a drug for an off-label use?

* One or more times a day
* 1-6 times a week
* 1-3 times a month
* 1-11 times a year
* Less than once a year
* I have never prescribed a drug for an off-label use

Q13\_OFF-LABEL USE: practice\_freq

PROGRAMMING: Ask only to participants who indicated prescribing off-label in Q12

1. Compared to you, how often do others in your practice prescribe a drug for off-label use?

* More often
* Less often
* About the same
* No other HCPs with prescribing authority in practice

Q14\_OFF-LABEL USE: practice\_yes/no

PROGRAMMING: Ask only of those who indicated never prescribing off-label in Q12

1. Do others in your practice prescribe drugs for off-label use?

* Yes
* No
* I don’t know
* No other HCPs with prescribing authority in practice

Q15\_OFF-LABEL USE: Info sources

PROGRAMMING: Ask only to participants who indicated prescribing off-label in Q12

PROGRAMMING: Randomize ordering of response options, leaving “other specify” last

1. Where do you typically first hear or learn about an off-label use for a prescription drug? (Select your top two sources.)

* Colleagues
* Medical journals
* Google or other online search engines
* Medical reference websites such as UpToDate or Epocrates
* **Display only for Oncologists:** National Comprehensive Cancer Network Guidelines
* Professional medical association conferences and communications
* FDA
* Pharmaceutical companies
* Online communities of physicians
* Key opinion leaders or thought leaders in the field
* Other, please specify:

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_COLL

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_JOURNAL

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_GOOGLE

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_REFWEB

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_NCCNG

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_ProfMEDASSN

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_FDA

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_PHARMA

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_onlinecommunity

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_opinionleader

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_OTHER

Q16\_OFFLABELUSE\_INFOSOURCES\_FREQUSE\_OTHERSPECIFY

PROGRAMMING: Ask only to participants who indicated prescribing off-label in Q12

PROGRAMMING: Randomize ordering of items a-I, leaving “other specify” (K) last

1. How often do you use the following sources to learn about off-label uses for a drug?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Never | Rarely | Sometimes | Often | Very Often |
| 1. Colleagues | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Medical journals | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Google or other online search engines | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Medical reference websites such as UpToDate or Epocrates | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| *Ask only to Oncologists*   1. National Comprehensive Cancer Network Guidelines | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Professional medical association conferences and communications | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. FDA | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Pharmaceutical companies | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Online communities of physicians | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Key opinion leaders or thought leaders in the field | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Other, please specify | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_COLL

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_JOURNAL

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_GOOGLE

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_REFWEB

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_nccng

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_profMEDASSN

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_FDA

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_PHARMA

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_onlinecommunity

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_opinionleader

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_OTHER

Q17\_OFFLABELUSE\_INFOSOURCES\_LIKELYUSE\_OTHERSPECIFY

PROGRAMMING: Ask only to participants who indicated prescribing off-label in Q12

PROGRAMMING: Randomize ordering of items a-g, leaving “other specify” (K) last

1. How likely are you to use the following sources to learn about off-label uses for a drug?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Not at all likely | A little likely | Somewhat likely | Very likely | Extremely likely |
| 1. Colleagues | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Medical journals | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Google or other online search engines | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Medical reference websites such as UpToDate or Epocrates | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| Ask only to Oncologists   1. National Comprehensive Cancer Network Guidelines | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Professional medical association conferences and communication | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. FDA | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Pharmaceutical companies | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Online communities of physicians | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Key opinion leaders or thought leaders in the field | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Other, please specify | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |

Q18\_Contrary data\_seenSUPPPORT

1. Thinking of the studies you have seen in the past, how often have you seen study findings that support an off-label use of a drug?

* Never
* Rarely
* Sometimes
* Often
* Very often

Q19\_Contrary data\_seeninconclusive

1. Thinking of the studies you have seen in the past, how often have you seen study findings that contradict or are inconclusive about an off-label use of a drug?

* Never
* Rarely
* Sometimes
* Often
* Very often

Contrary data

Q20\_CONTRARYDATA\_STUDYASPECTS\_STUDYPOP

Q20\_CONTRARYDATA\_STUDYASPECTS\_STUDYDESIGN

Q20\_CONTRARYDATA\_STUDYASPECTS\_SAMPLE

Q20\_CONTRARYDATA\_STUDYASPECTS\_FINDSAFETY

Q20\_CONTRARYDATA\_STUDYASPECTS\_FINDSIDEEFFECT

Q20\_CONTRARYDATA\_STUDYASPECTS\_SPONSOR

Q20\_CONTRARYDATA\_STUDYASPECTS\_NUMBER

Q20\_CONTRARYDATA\_STUDYASPECTS\_FINDEFFECTIVE

Q20\_CONTRARYDATA\_STUDYASPECTS\_OTHER

Q20\_CONTRARYDATA\_STUDYASPECTS\_OTHERSPECIFY

PROGRAMMING: Randomize ordering of items a-h, leaving “other specify” (i) last

1. How important is it to you to know about the following aspects of a study about an off-label use of a drug?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Not at all important | A little important | Somewhat important | Very important | Extremely important |
| 1. Study population | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Study design, e.g., randomized controlled study, observational study, study duration | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Sample size | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Findings related to safety of the off-label use | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Findings related to side effects of the off-label use | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Study sponsor | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Number of studies that contradict or are inconclusive about an off-label use of a drug | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Findings related to effectiveness of the off-label use | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |
| 1. Other, please specify: | ⬜ | ⬜ | ⬜ | ⬜ | ⬜ |

Q21\_contrary data\_circumstances

PROGRAMMING: Randomize ordering of each response option, leaving the “other specify” option last

1. Please rank the top three circumstances where you feel it would be most important for you to know about studies that contradict or are inconclusive about an off-label use of a drug.

Please write 1, 2, or 3 in the boxes below to rank your top three choices.

* There are safety concerns associated with the off-label use
* The patient being treated is part of a unique population (e.g., young, critically ill, etc.)
* Efficacy of the off-label use is not clearly established
* There is uncertainty about whether to prescribe the drug for the off-label use
* Contradictory studies have stronger study designs than studies supporting the off-label use
* The off-label use is common
* The off-label use, or the drug itself, is new
* There are concerns about drug interactions
* Other, please specify:

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_COLL

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_JOURNAL

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_GOOGLE

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_REFWEB

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_NCCNG

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_PROFMEDASSN

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_FDA

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_PHARMA

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_ONLINECOMMUNITY

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_OPINIONLEADER

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_OTHER

Q22\_CONTRARYDATA\_CONTRARYSOURCES\_OTHERSPECIFY

PROGRAMMING: Randomize ordering of each response option, leaving the “other specify” option last

1. Of the following sources, please rank the top three which you would most likely use to learn about studies that contradict or are inconclusive about an off-label use of a prescription drug.

Please write 1, 2, or 3 in the boxes below to rank your top three choices.

* Colleagues
* Medical journals
* Google or other online search engines
* Medical reference websites such as UpToDate or Epocrates
* **Display only for Oncologists:** National Comprehensive Cancer Network Guidelines
* Professional medical association conferences and communications
* FDA
* Pharmaceutical companies
* Online communities of physicians
* Key opinion leaders or thought leaders in the field
* Other, please specify:

Debrief

Thank you for taking part in this survey.

While the information presented is accurate, the information provided about {DRUG} and its off-label use for {CONDITION} is a combination of several different studies.

The Brief Report was created specifically for this survey and is not a real publication.