

Draft Survey

Docket No. 03N-0202

INTRODUCTION

We are conducting a study on behalf of the FDA (Food and Drug Administration). The FDA is trying to find out how much people know about the way new drugs and other new treatments are developed in the U.S.

We want to use the information we collect from volunteers like you to help people become better informed about how new drugs and other treatments are developed. We hope that with better information, people like you can make more informed decisions about whether to take part in studies of new drugs and treatments.

We would like to ask you some questions about yourself and what you understand about the process. Before we begin, we would like to stress that it is okay for you to say that you don't know, if you don't know the answer to anything we ask.

First, we would like to ask you some questions to get a general idea about you and your health.

Health-related questions

1. How would you describe your general health?

- (READ LIST)
- | | |
|------------------------|---|
| Excellent | 1 |
| Good | 2 |
| Fair | 3 |
| Poor | 4 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

2. Are you now taking or have you ever taken a prescription medication?

- | | |
|------------------------|---|
| Yes | 1 |
| No | 2 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

3. Which statements best describe your prescription medication use? (Check all that apply.)

- | | |
|--|---|
| Occasional, short-term use
(such as for relatively minor illnesses or infections) | 1 |
| One or more medications taken for months or years | 2 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

4. Have you ever been involved in obtaining care for yourself or anyone with a serious (life-threatening) medical condition or a condition lasting more than a year?

- | | |
|------------------------|----------------|
| Yes | 1 |
| No | 2 (skip to Q8) |
| DO NOT READ Don't know | 8 |

DO NOT READ Refused 9

[IF Q4= YES, CONTINUE, ELSE GO TO INTRO BEFORE Q5]

4a. Who was the person you were involved in obtaining care for?

You 1
A family member 2
A friend or neighbor 3
Someone else 4
DO NOT READ Don't know 8
DO NOT READ Refused 9

Now, I would like to ask you some questions about the development of new drugs and clinical trials. There are no right or wrong answers; we would just like to get your opinion.

5. Which statement best describes your level of knowledge about clinical trials?

Well informed 1
Somewhat informed 2
Not well informed 3
No knowledge 4
DO NOT READ Don't know 8
DO NOT READ Refused 9

6. Do you agree or disagree with the following definition: "A clinical trial is an experiment in people to find out if a drug or a vaccine, or other treatment, works and is safe."

Agree 1
Disagree 2
DO NOT READ Don't know 8
DO NOT READ Refused 9

Using the above definition of a clinical trial, please answer the following questions.

7. Have you, or anyone you know, ever participated in a clinical trial? Please indicate all that apply.

Yourself 1
A family member 2
A friend or neighbor 3
Someone you don't know very well 4
No one 5
DO NOT READ Don't know 8
DO NOT READ Refused 9

8. Have you ever heard or read about clinical trials from any of the following sources? You may say yes to more than one.

TV 01
Radio 02
Internet 03
Newspaper 04
Magazine 05
Book 06
Advertisement (any type) 07
Or, some other place that I haven't mentioned? 08
Don't remember 09
DO NOT READ Don't know 98
DO NOT READ Refused 99

As you may or may not know, the FDA (Food and Drug Administration) is responsible for approving all new drugs that are prescribed in the United States.

9. To the best of your knowledge, in order for a new drug to be approved by the FDA, which of the following has to be proven? You may say yes to more than one.

- | | |
|--------------------------------------|---|
| The drug is safe. | 1 |
| The drug is effective. (It "works.") | 2 |
| The drug has few side effects. | 3 |
| The drug has no side effects. | 4 |
| None of the above | 5 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

Please tell me whether you agree or disagree with the following statements about drugs that your doctor may prescribe and new drugs that are not yet available for a doctor to prescribe.

10. Before your doctor can write a drug prescription for a medical condition, that drug must be tested in people and be shown to be safe and effective. Would you agree or disagree with this statement?

- | | |
|------------------------|---|
| Agree | 1 |
| Disagree | 2 |
| Not sure | 3 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

11. Before a new drug has been approved for prescription use, clinical trials, or tests, of the new drug are made in people. (READ IF NECESSARY "Would you agree or disagree with this statement?")

- | | |
|------------------------|---|
| Agree | 1 |
| Disagree | 2 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

12. In clinical trials, the new, unapproved drug is tested in people to determine if the new drug is safe, and if it is effective (helps or improves the medical condition). (READ IF NECESSARY "Would you agree or disagree with this statement?")

- | | |
|------------------------|---|
| Agree | 1 |
| Disagree | 2 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

13. A new, unapproved drug has not yet been shown to be safe and effective. Therefore, anyone who participates in a clinical trial cannot be sure that the drug they receive in the trial will help the person's medical condition or that the drug is safe. (READ IF NECESSARY "Would you agree or disagree with this statement?")

- | | |
|------------------------|---|
| Agree | 1 |
| Disagree | 2 |
| Not sure | 3 |
| DO NOT READ Don't know | 8 |
| DO NOT READ Refused | 9 |

14. If you receive a new, unapproved drug in a clinical trial, you can expect that the drug is safe and will help your medical condition. (READ IF NECESSARY "Would you agree or disagree with this statement?")

- | | |
|-------|---|
| Agree | 1 |
|-------|---|

Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

15. You can be sure that a new, unapproved drug you receive in a clinical trial is as good as a prescription drug. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree	1
Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

16. Imagine that your personal doctor is conducting a clinical trial that involves testing an unapproved new drug against placebo (an inactive, or "sugar", pill), and your goal is to obtain the unapproved new drug instead of the placebo. Do you think your doctor would do his or her best to give you the unapproved drug rather than the placebo?

Yes	1
No	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

17. Your doctor would not ask you about taking part in a clinical trial of a new drug if he or she did not think the new drug would help you. Would you agree or disagree with this statement?

Agree	1
Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

18. A clinical investigator would not ask you about taking part in a clinical trial of a new drug if he or she did not think the new drug would help you. Would you agree or disagree with this statement?

Agree	1
Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

In a clinical trial, two different drugs, or pills, are often compared. One group of people gets one kind of pill; another group of people gets another kind of pill. Please tell me whether you agree or disagree with the following statements about clinical trials where two pills are compared.

19. To find out if an unapproved new drug or pill works, it may be compared to a placebo (an inactive, or "sugar", pill); this is done by giving one group of people the unapproved new drug, and giving other group the placebo. The placebo looks just like the unapproved new drug. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree	1
Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

20. In a clinical trial, the reason for giving one group of people the unapproved new drug, or pill, and the other group a placebo (an inactive, or "sugar", pill) is to find out which group shows a greater improvement in their medical condition. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree	1
Disagree	2

DO NOT READ Don't know 8
DO NOT READ Refused 9

21. If you are in a clinical trial in which some people receive an unapproved new drug, or pill, and others receive a placebo (an inactive, or "sugar", pill), you may not be told whether you are receiving the unapproved new drug or the placebo. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree 1
Disagree 2
DO NOT READ Don't know 8
DO NOT READ Refused 9

22. In a clinical trial in which some people receive an unapproved new drug, or pill, and others receive a placebo (an inactive, or "sugar", pill), the decision as to who will receive the unapproved new drug and who will receive the placebo is determined by chance (like a roll of the dice). (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree 1
Disagree 2
DO NOT READ Don't know 8
DO NOT READ Refused 9

23. If you are in a clinical trial and receive a placebo (an inactive, or "sugar", pill), your medical condition will improve. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree 1
Disagree 2
DO NOT READ Don't know 8
DO NOT READ Refused 9

24. If you enter a clinical trial and are in the group that receives the unapproved new drug, or pill, you can be sure that all of the unwanted or harmful side effects of the drug are known. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree 1
Disagree 2
DO NOT READ Don't know 8
DO NOT READ Refused 9

For the next set of questions, I'd like you to imagine that you have just visited your doctor because you have a medical condition. Your doctor asks if you would like to participate in a clinical trial of a new drug. This new drug is being studied but has not yet been approved for doctors to prescribe to treat your medical condition. Your doctor tells you that he/she is a clinical investigator for this clinical trial. For the following statements about doctors and clinical investigators, please tell me whether you agree or disagree with the statements made.

25. Doctors in medical practice may also be clinical investigators in clinical trials of new drugs.

Agree 1
Disagree 2
DO NOT READ Don't know 8
DO NOT READ Refused 9

26. A clinical investigator who conducts a clinical trial is required to continue to see a research subject as a regular patient after the research is completed. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree 1
Disagree 2

DO NOT READ Don't know 8
 DO NOT READ Refused 9

27. If you see your doctor, who prescribes a drug to treat your medical condition, he/she is performing a service for you, and you pay for that service, either directly or indirectly (with your health insurance, Medicare, etc).

Agree 1
 Disagree 2
 DO NOT READ Don't know 8
 DO NOT READ Refused 9

28. A clinical investigator is usually a medical doctor.

Agree 1
 Disagree 2
 DO NOT READ Don't know 8
 DO NOT READ Refused 9

29. A clinical investigator is someone who recruits people with a particular medical condition to participate in a clinical trial of a new drug that has not yet been approved for doctors to prescribe for that medical condition.

Agree 1
 Disagree 2
 DO NOT READ Don't know 8
 DO NOT READ Refused 9

30. If you enter a clinical trial and receive the drug that is being studied in that trial, the clinical investigator who enrolls you in the trial is performing a service for a drug company, and the drug company pays the clinical investigator for that service.

Agree 1
 Disagree 2
 DO NOT READ Don't know 8
 DO NOT READ Refused 9

31. If your doctor is a clinical investigator for a clinical trial of a new drug, this means that your doctor:

Is paid for your participation in the clinical trial by you (or your insurance, or Medicare) 1
 Is paid for your participation in the clinical trial by the company developing the new drug 2
 Performs an unpaid public service for your participation in the clinical trial 3
 DO NOT READ Don't know 8
 DO NOT READ Refused 9

32. If you decide to take part in a clinical trial, the clinical investigator, who is not your doctor, enrolls you into the clinical trial, gives you a drug treatment, and collects information during your participation in the clinical trial. This clinical investigator

Performs a public service without payment 1
 Is paid by the drug company that is developing the drug 2
 Is paid by you, directly or indirectly 3
 (through your insurance or through Medicare)
 DO NOT READ Don't know 8
 DO NOT READ Refused 9

33. A clinical investigator, whether or not he or she is your doctor, has something to gain financially from your participation in a clinical trial.

Agree 1
 Disagree 2
 DO NOT READ Don't know 8

34. For each of the following statements, please indicate if it best describes your doctor when he or she:

?? **provides treatment for your medical condition (1)**

?? **is a clinical investigator for a clinical trial of an unapproved new drug to treat that medical condition (2)**

OR

?? **in both situations (3)**

Prescribes drugs that are FDA-approved for your medical condition	1	2	3
Receives payment from you or your insurance company	1	2	3
Has the primary goal of treating your medical condition	1	2	3
May give you an experimental drug that is not FDA-approved	1	2	3
Receives payment from a drug company	1	2	3
Tries to find out if an unapproved new drug is safe and effective (works)	1	2	3
Has the primary goal of conducting research	1	2	3

Next, I'm going to ask you some questions about "informed consent." This refers to the process of someone giving his or her permission to participate in a clinical trial of a new drug.

If Q7 = 1, continue. If Q7 ne 1, skip to Q39

35. You previously mentioned that you yourself have participated in a clinical trial. How long ago that?

Within the past 3 months	1
Between 3 months and 1 year ago	2
Between 1 and 2 years ago	3
More than two years ago	4
DO NOT READ Don't know	8
DO NOT READ Refused	9

36. If you remember signing a consent form, which of the following best describes how you handled the consent form?

I read it and talked to others before deciding to sign it.	1
I read it and did not ask others for help in my decision about whether to sign it.	2
I relied on the clinical investigator's advice regarding whether to sign it.	3
I read it but and also used other sources of information when deciding to sign (for example, a web search or discussions with the investigator, personal physician and/or family)	4
I didn't read it carefully.	5
I relied on someone important to me to read it and followed his or her decision about whether to sign	6
DO NOT READ Don't know	8
DO NOT READ Refused	9

37. Looking back, how completely informed were you about the study and what to expect?

Sufficiently informed (no surprises)	1
Incompletely informed (some surprises)	2
Some of the information given was incorrect.	3
DO NOT READ Don't know	8
DO NOT READ Refused	9

38. During your participation in the study, did you experience any medical problems that you were not informed about before you began the study?

Yes	1
No	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

39. Consent for clinical trial participation usually must be documented through use of a written consent form. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree	1
Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

40. When informed consent for clinical trial participation is documented, how is that usually done?

Through a written consent form signed by the participant	1
Through oral agreement between the participant and the investigator running the trial	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

41. Which of the following do you agree must be included in consent forms for clinical trials of unapproved new drugs? You may say yes to more than one.

Risks, if any, of participating in the study	1
Benefits, if any, of participating in the study	2
A statement that the study involves research	3
A statement that the participant may drop out of the study at any time	4
A disclosure of alternative treatments, if any, that might be useful	5
None of the above	6
DO NOT READ Don't know	8
DO NOT READ Refused	9

42. A clinical trial of an unapproved new drug must be reviewed by a group of medical doctors and other experts before it can take place, in order to ensure that the rights and safety of the people taking part in the clinical trial are protected. (READ IF NECESSARY "Would you agree or disagree with this statement?")

Agree	1
Disagree	2
DO NOT READ Don't know	8
DO NOT READ Refused	9

Demographic questions

I'd like to ask just a few more questions for classification purposes. Remember, we are not keeping any record of your name, so this information, as well as the rest of your answers, is anonymous.

43. Which of the following categories best describes your age?

18 – 29	1
30 – 39	2
40 – 49	3
50 – 59	4
60 and over	5
Not sure	6

DO NOT READ Don't know 8
DO NOT READ Refused 9

44. Respondent gender (DO NOT ASK: RECORD BY OBSERVATION)

Male 1
Female 2

45. Which category best describes your racial or ethnic background? (You may say yes to more than one.)

African-American or Black 1
Asian 2
Caucasian or White 3
Hispanic or Latino 4
Or some other race 5
DO NOT READ Don't know 8
DO NOT READ Refused 9

46. What is the highest level of education you have completed?

Grade school or less 1
Some high school 2
Completed high school 3
Some college 4
Completed college 5
Graduate school or more 6
Other education beyond high school
(business, technical, etc.) 7
DO NOT READ Don't know 8
DO NOT READ Refused 9

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