Terms and Phrases: Meaning Elicitation Survey
Interview Guide: HCPs

Overview:

1. **Introduction & Consent** (5 minutes)
   The interviewer will provide background information about the project and get consent to proceed.

2. **Discussion** (50 minutes)
   - Terms and phrases

3. **Closing** (5 minutes)**:** Thank you and incentive information.

List of Terms and Phrases for HCPs

1. Convenient
2. Straightforward/simple/easy to use
3. Prevent; vs. help prevent; vs. reduce the incidence
4. Proven to help; proven effective
5. Natural
6. Targeted; targeted therapy; acts locally; targeted mechanism of action
7. Powerful, potent
8. #1 prescribed
9. New (as in new product)
10. Novel/unique; first and only; works differently (as in novel MOA or unique properties)
11. FDA-approved
12. Reverses
13. Off-label
14. Individual results may vary
15. Significant (as in statistically significant)
16. Manageable safety profile; established safety profile; well-studied safety profile; well-tolerated
17. Restores; rebuilds; helps rebuild
18. Many/most/some/few; majority
19. Prescription drug promotion versus prescription drug advertising
20. First in class
21. Scientific exchange
22. Disease progression
23. Overall response rate
24. Response duration
25. Randomized controlled trial
26. Non-inferiority RCT
27. Intent-to-treat analysis
28. Per-protocol analysis

I.   Introduction & Consent

INTERVIEWER: Hello and thank you for making time to talk with me today.

My name is [   ] and I work for RTI International, a not-for-profit research organization located in Research Triangle Park, North Carolina.

The Food and Drug Administration has contracted with RTI to conduct interviews with health care providers and consumers to better understand how people interpret words and phrases that are commonly used in prescription drug advertising materials.

Informed Consent

Before we begin, I would like to review a few items:

Consent Form. I understand that you reviewed the informed consent form when you scheduled your appointment. Just a few highlights…

- o **Participation.** Your participation is voluntary and you can stop participating at any time. If at any time you are uncomfortable with any question, you can choose not to answer.
- o **Privacy.** Your name and contact information will not be given to anyone else and no one will contact you after our discussion is over.
- o **Audio Recording.** To make sure that we capture everything people say today, we are making an audio recording of this discussion, which will later be transcribed. We will provide the FDA with a transcription and audio recording of our discussion. However, your name and any identifying information about you will not be included nor associated with the project or the report in any way.
- o **Observation**. Members of our study team, including staff from FDA, may listen to today's discussion so they can hear your thoughts directly from you.
- o **Reporting.** As part of this study, we will write a report for the FDA summarizing what we learned from these interviews. We will not use your name or any identifying information in the report.

Do you have any questions before we begin?

Do I have your consent to participate? [get a verbal "yes" then continue]

II.   Discussion

For our discussion today, I'm going to be reading some words and phrases to you. I will also show them on the screen (confirm that the participant can see the test screen).

1. **Convenient**
   SCREEN 1:   "Taking one dose a day of Drug A is **convenient**."

   Probe: As used in this context, what does "convenient" mean to you?
   Probe: What does the word "convenient" suggest about drug A?

2. **Straightforward/simple/easy/easy to use**
   SCREEN 1:   "Drug B is **straightforward** to use."

   Probe: As used in this context, what does the phrase "straightforward" mean to you?
   Probe: What do you think about drug B when you hear that it is "straightforward"?

   SCREEN 2:   "Drug C is **simple** to use."

   Probe: As used in this context, what does the phrase "simple" mean to you?
   Probe: What do you think about drug C when you hear that it is "simple" to use?

   SCREEN 3:   "Drug D is **easy** to use."

   Probe: As used in this context, what does the phrase "easy" mean to you?
   Probe: What do you think about drug D when you hear that it is "easy" to use?

   SCREEN 4:   "Straightforward"
                      "Simple"
                      "Easy to use"

   Probe: Is there a difference between these three phrases when used to describe a drug? If so, what is the difference(s)?

3. **Prevent vs. help prevent vs. reduce the incidence**
   SCREEN 1:   "Drug E is shown to **prevent** severe asthma attacks."

Probe: As used in this context, what does "prevent" mean to you?
Probe: What does the word "prevent" suggest about drug E?

SCREEN 2:   "…shown to **help prevent** severe asthma attacks."

Probe: As used in this context, what does "help prevent" mean to you?
Probe: Is there a difference in meaning between "prevent" and "help prevent" as used in these contexts? If so, what is the difference?
Probe: Would your thoughts about drug E change depending on which phrase is used? If so, how would your thoughts change?

SCREEN 3:   *Statement 1:* "…shown to **help prevent** severe asthma attacks."

          Statement 2: "…shown to **reduce the incidence** of severe asthma attacks."

Probe: Does the phrase "reduce the incidence…" change the meaning of this claim? If so, how does it change the meaning?

4. **Proven to help vs. proven effective**

   SCREEN 1:   "Drug F is **proven to help** reduce the risk of severe asthma attacks."

   Probe: As used in this context, what does "proven to help" mean to you?
   Probe: What does the phrase "proven to help" suggest about drug F?

   SCREEN 2:   "…**proven effective** at reducing the risk of severe asthma attacks."

   Probe: As used in this context, what does "proven effective" mean to you?
   Probe: Is there a difference in meaning between "proven to help" and "proven effective" as used in these contexts? If so, what is the difference?
   Probe: Would your thoughts about drug F change depending on which phrase is used? If so, how would your thoughts change?

5. **Natural**

   SCREEN 1:   "Drug G is a prescription medication that's made from a **natural** ingredient: omega-3 fish oil."

Probe: As used in this context, what does the word "natural" mean to you?

Probe: When you hear that a drug is made from a "natural" ingredient, what does that make you think? Is it more effective than other drugs? Safer? Why?

6. **Targeted; targeted therapy; acts locally; targeted mechanism of action**

SCREEN 1: "Drug H works helps to prevent migraine by **targeting** and blocking calcitonin gene-related peptide (CGRP) receptors. . ."

Probe: As used in this context, what does the word "targeting" mean to you?

Probe: What do you think about drug H when you hear that it "targets" receptors?

SCREEN 2: "Drug I **acts locally** to help address migraine"

Probe: As used in this context, what does "acts locally" mean to you?

Probe: Is there a difference between a drug that provides "targeted therapy" vs. a drug that "acts locally"? If so, what is the difference?

SCREEN 3: "Drug J has a **targeted mechanism of action** to help address migraines."

Probe: As used in this context, what does the phrase, "targeted mechanism of action" mean to you?

Probe: What do you think about drug F when you hear that it has a "targeted mechanism of action"?

7. **Powerful; potent**

SCREEN 1:

"Drug K is a **powerful** single-tablet regimen with a high barrier to resistance."

Probe: As used in this context, what does the word "powerful" mean to you?

Probe: What do you think about drug K when you hear it being described as "powerful"?

SCREEN 2: "Drug L is a **potent** single-table regimen with a high barrier to resistance."

Probe: As used in this context, what does the word "potent" mean to you?

Probe: What do you think about drug L when you hear it being described as "potent"?

8. **#1 prescribed**

SCREEN 1:   "Drug M is the **#1 prescribed** weight loss brand"

Probe: As used in this context, what does "#1 prescribed" mean to you?
Probe: What do you think about drug M when you hear it is the "#1 prescribed" brand?
Probe: Does hearing that the drug is the "#1 prescribed" brand make you think it is safer than other drugs? More effective than other drugs? Why?

9. **New (as in new product)**

   SCREEN 1:   "Drug N is **new**"

   Probe: What do you think of a drug that is described as "new"?
   Probe: Does hearing that the drug is "new" make you think it is safer than other drugs? More effective than other drugs? Why?

10. **Novel/unique; first and only; works differently (as in novel MOA or unique properties)**

    SCREEN 1:   "Drug O **works differently**."

    Probe: As used in this context, what does the phrase "works differently" mean to you?
    Probe: What do you think about drug O when you hear that it "works differently"?
    Probe: Does hearing that the drug "works differently" make you think it is safer than other drugs? More effective than other drugs? Why?

    SCREEN 2:   "Drug P is the **first and only** drug…."

    Probe: As used in this context, what does the phrase "first and only" mean to you?
    Probe: What do you think about drug P when you hear that it is the "first and only" drug…?

    SCREEN 3:   "Drug Q has a **novel** mechanism of action."

    Probe: As used in this context, what does the word "novel" mean to you?
    Probe: What do you think about drug Q when you hear that it works in a "novel" way?
    Probe: Does hearing that the drug works in a "novel" way make you think it is safer than other drugs? More effective than other drugs? Why?

    SCREEN 4:   "Works differently"
                   "First and only"
                   "Novel"

Probe: Is there a difference between these three phrases when used to describe a drug? If so, what is the difference(s)?

Probe: Do you think one phrase suggests that a drug is more effective compared to a drug described with the other phrases? If so, which phrase(s) and how?

11. **First in class**

SCREEN 1: "Drug R is a prescription drug available for the treatment of plaque psoriasis. Drug R is **FDA approved**."

Probe: What does the phrase "first in class" mean to you when it is used in relation to prescription drugs?

Probe: What do you think about a drug when you hear that it is "first in class"?

12. **FDA-approved**

SCREEN 1: " **FDA-approved**"

Probe: What do you think of a drug that is described as "FDA-approved"?

Probe: Does hearing that something is "FDA-approved" make you think it is safer than other drugs? More effective than other drugs? Why?

13. **Reverses**

SCREEN 1: "Drug S **reverses** bone loss."

Probe: As used in this context, what does the word "reverses" mean to you?

Probe: What do you think about drug S when you hear that it "reverses" bone loss?

Probe: Does hearing that the drug "reverses" bone loss make you think it is safer than other drugs? More effective than other drugs? Why?

14. **Off-label**

SCREEN 1: "Drug T is used **off-label**"

Probe: What does "off-label" mean to you in the context of prescription drugs?

Probe: If you hear that a drug is being prescribed "off-label" does that affect your opinion on whether the drug will work? If so, how?

Probe: If you hear that a drug is being prescribed "off-label" does that affect your opinion about the drug's safety?

Probe: Does hearing that a drug is prescribed "off-label" make you think it is safer than other drugs? More effective than other drugs? Why?

15. Individual results may vary

SCREEN 1:   "Cure means no virus found in the blood 3 months after treatment ends. **Individual results may vary**."

Probe: As used in this context, what does the phrase "individual results may vary" mean to you?
Probe: What do you think about a drug when you hear that "individual results may vary"?
Probe: Would it impact your decision to prescribe the drug? If so, how would it impact your decision?

16. Significant (as in statistically significant)

SCREEN 1:   *Statement 1 (control – no term assessed):* "Compared with placebo, people taking drug U saw a slight decrease in respiratory symptoms. It is not certain if drug P was responsible for this decrease.

Now please read this statement:

Statement 2: "Compared with placebo, people taking drug U saw a slight decrease in respiratory symptoms. This change was not **statistically significant**."

Probe: What do you think of a treatment effect that is described as "not statistically significant"? One that is described as "statistically significant"?

Probe: What impact would it have on your decision to prescribe drug U?

17. Manageable safety profile; established safety profile; well-studied safety profile; well-tolerated

SCREEN 1:

> *Statement 1:* Drug V offers a manageable safety profile.
>
> *Statement 2:* Drug W offers an established safety profile
>
> *Statement 3:* Drug X offers a well-studied safety profile.
>
> *Statement 4:* Drug Y is well-tolerated.

Probe: What do the phrases [READ PHRASES] mean to you in relation to prescription drugs? Do they all mean the same thing, or are there differences in what they mean? If so, how do they differ?

Probe: What do you think about a drug when you read that it has an "established safety profile"?

18. **Restores; rebuilds**

    SCREEN 1:   "Drug Z **restores** vaginal tissue."

                     "Drug AA **rebuilds** vaginal tissue"

    Probe: As used in this context, what does "restores" mean to you? What about "rebuilds"? Do the meanings of these words differ? If so, how do they differ?
    Probe: What do you think about a drug when you hear that it "restores or rebuilds" vaginal tissue?

    SCREEN 2:   *Statement 1:* "Drug BB **rebuilds** vaginal tissue"

                     Statement 2: "Drug CC **helps rebuild** vaginal tissue"

    Probe: Is there a difference between statement 1 and statement 2? If so, what is the difference?
    Probe: How would your opinion of the drug change if you read statement 1 vs. statement 2?

19. **Many/most/some/few; majority**

    SCREEN 1:   "For **many**, drug DD cuts the number of monthly migraine days in half... or more! ...with some people being migraine-free."

    Probe: As used in this context, what does "many" mean to you? How many (or what %) of people?
    Probe: What do you think about drug EE when you hear that it works for "many" people?

    SCREEN 2:   "Many"
                     "Most"
                     "Some"
                     "Few"
                     "Majority"

    Probe: Is there a difference between the words "many," "most," and "majority"? If so, what is the difference? What about "some" and "few"?

20. **Prescription drug promotion versus prescription drug advertising**

   SCREEN 1:

           Prescription drug promotion
           Prescription drug advertising

   Probe: What does the phrase "prescription drug promotion" mean to you? What about the phrase "prescription drug advertising"?

   Probe: Is there a difference between the phrases "prescription drug promotion" and "prescription drug advertising"? If so, what is the difference?

21. **Scientific exchange**

   SCREEN 1:   "Scientific exchange"

   Probe: What does "scientific exchange" mean to you?

22. **Disease progression**

   SCREEN 1:   "In a clinical trial with cancer patients, drug FF was shown to delay **disease progression**."

   Probe: What does "disease progression" mean to you?

23. **Overall response rate**
   SCREEN 1:   "Overall response rate"

   Probe: What does "overall response rate" mean to you?

24. **Response duration**
   SCREEN 1:   "Response duration"

   Probe: What does "response duration" mean to you?

25. **Randomized controlled trial**
   SCREEN 1:   "Randomized controlled trial"

Probe: What does "randomized controlled trial" mean to you?

26. **Non-inferiority RCT**
    SCREEN 1:   "Non-inferiority RCT"

    Probe: What does "non-inferiority RCT" mean to you?

27. **Intent-to-treat analysis**
    SCREEN 1:   "Intent-to-treat analysis"

    Probe: What does "intent-to-treat analysis" mean to you?

28. **Per-protocol analysis**
    SCREEN 1:   "per-protocol analysis"

    Probe: What does "per-protocol analysis" mean to you?
    Probe: How does this differ from "intent to treat" analysis?

III.   Conclusion

These are all of my questions. Is there anything else you would like to share before we wrap up?

To obtain the most objective responses, the drug names used as examples in this survey are not for real drugs.

Thank you for your time. You will receive a check for $225 in the mail in approximately 4-6 weeks.