Adult Focus Group Screening Questionnaire

Prescription Drug Device Perspectives

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Segment  | Minneapolis, MN (Midwest) | Atlanta, GA (South) | Bethesda, MD (East) | Phoenix, AZ (West) | Total |
| Auto Injector Groups | Adult Caregivers -EpiPen only  | 1 | 1 | 1 | 1 | **4** |
| Adult EpiPen users  |  | 1 |  | 1 | **2** |
| Adult users - other AIs  | 1 |  | 1 |  | **2** |
|  |
| Dry Powder Inhaler Groups | Naïve DPI users  |  1 |  1 |  1 |  1 | **4** |
| Experienced DPI users | 1 | 1 | 1 | 1 | **4** |
| Total |  | **4** | **4** | **4** | **4** | **16** |
| Note. We will recruit 10 individuals per focus group with the expectation that 8 participants are present for each session.  |

Hello, this is \_\_\_\_\_\_\_\_\_\_\_\_\_ from [RECRUITMENT FIRM NAME], a market research firm. May I please speak to\_\_\_\_\_\_\_\_\_\_\_\_\_?

Hello. We are working with RTI International, a nonprofit research organization on a research study sponsored by the Food and Drug Administration, or FDA and would like to get your opinions about your use of combination products. The focus groups are about the experiences of people who use [INSERT SEGMENT]. We are not selling any products. You will also be asked to hold either an autoinjector or dry powder inhaler and answer some questions about the device. Neither device has any medicine in it. The autoinjector is a trainer device; it does not contain medicine or a needle and cannot be discharged, and the dry powder inhaler does not contain medicine. You will be only be asked to hold and look at the device.

We are holding a focus group on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. The discussion will be audio recorded, and project team members may observe the discussion in person or remotely (via live-streaming). You will be given $125 as a token of our appreciation for your participation.

Can I ask you a few questions now to see if you qualify?

[ ]  Yes – ***Continue*.**

[ ]  No – ***Thank the adult and end call****.*

***Autoinjector Use***

1. Do you or a family member you take care of have a current prescription from a doctor for an autoinjector? [If needed: refer to list of autoinjectors]

[ ] 1 Yes, for myself

[ ] 2 Yes, for family member

[ ] 3 No

***Dry Powder Inhaler Use***

1. Do you have a current prescription from a doctor for a dry powder inhaler? [If needed: Dry powder inhalers are devices that deliver medication to the lungs and are usually used to treat respiratory diseases such as asthma, bronchitis, emphysema and COPD]. [If needed: refer to list of dry powder inhalers]

[ ]  Yes **🡪** ***Continue to Q3***

[ ]  No **🡪 *If Q1=3, Terminate [GO TO INELIGIBLE CLOSING SCRIPT]. IF Q1=1, Continue to Q8. IF Q1=2, Continue to Q9.***

***Dry Powder Inhaler (Experienced User; Naïve User Group Qualification)***

1. Why do you need the inhaler device (what is your diagnoses)? [RECRUIT A MIX THAT USE THE DEVICE FOR COPD OR ASTHMA]

[ ]  COPD (including chronic bronchitis, emphysema, or both)

[ ]  Asthma

1. What is the brand name of the dry powder inhaler you currently use? [NOTE BRAND NAME]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  If Advair Diskus**🡪** ***Continue to Q5 (possible Experienced DPI User Group)***

[ ]  All others **🡪** ***Continue to Q6 (possible Naïve DPI User Group)***

1. How long ago did you start using an inhaler device?

[ ]  In the last six months 🡪 ***IF Q1=3,*** ***Terminate / IF Q1=1, Continue to Q8 / IF Q1=2, Continue to Q9***

[ ]  Longer than six months 🡪 ***ASSIGN TO Experienced DPI User Group****;* ***Continue to Q10***

1. Have you ever used the Advair Diskus brand dry powder inhaler?

[ ]  Yes🡪 ***IF Q1=3,*** ***Terminate / IF Q1=1, Continue to Q8 / IF Q1=2, Continue to Q9***

[ ]  No🡪 ***ASSIGN TO Naïve DPI User Group; Continue to Q7***

1. How long ago did you start using an inhaler device?

[ ]  In the last six months 🡪 ***Continue to Q10***

[ ]  Longer than six months 🡪 ***Continue to Q10***

***Autoinjector Brand Names (Epipen User Group; Epipen Caregiver Group; Other AI User Group Qualification)***

1. What is the brand name of the autoinjector you use? [DO NOT READ LIST]

[ ]  EpiPen, EpiPen Jr., Epinephrine Injection USP**🡪** ***ASSIGN TO EpiPen User group, Continue to Q10***

[ ]  All others **🡪** ***ASSIGN TO Other AI User group, Continue to Q10***

[ ]  Both an EpiPen, EpiPen Jr., Epinephrine Injection USP AND another AI 🡪 ASSIGN TO EITHER THE ***EpiPen User group OR Other AI User based*** *ON WHICHEVER HAS FEWER CONFIRMED PARTICIPANTS*

1. What is the brand name of the autoinjector your family member uses? [DO NOT READ LIST]

[ ]  EpiPen, EpiPen Jr., Epinephrine Injection USP**🡪** ***ASSIGN TO EpiPen Caregiver group, Continue to Q10***

[ ]  All others **🡪** ***Terminate [GO TO INELIGIBLE CLOSING SCRIPT]***

***Dry Powder Inhaler Group Confirmation***

[CONFIRM FOR DPI GROUPS: *EXPERIENCED DPI USERS* STARTED USING AN INHALER DEVICE MORE THAN 6 MONTHS AGO AND CURRENTLY USE ADVAIR DISKUS]

[CONFIRM FOR DPI GROUPS: *NAÏVE DPI USER GROUPS* DO NOT CURRENTLY, AND HAVE NEVER USED ADVAIR DISKUS, NO MATTER HOW LONG AGO THEY STARTED USING AN INHALER DEVICE]

***Market Research Exclusion***

1. Have you ever worked for …? [READ LIST]

[ ]  Any office, division, or agency within the Department of Health and Human Services (HHS)**🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

[ ]  A pharmaceutical company **🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

[ ]  A marketing or market research company **🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

[ ]  A healthcare company or in the healthcare field **🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

[ ]  A medical device company **🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

1. Have you participated in an interview or focus group in the past 6 months? [READ LIST]

[ ]  Yes **🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

[ ]  No 🡪 ***Continue***

***Demographics***

1. What is your gender? [RECRUIT A MIX]

[ ]  Male

[ ]  Female

[ ]  Prefer not to answer

1. Are you Hispanic, Latino/a, or of Spanish origin? [RECRUIT A MIX]

[ ]  No

[ ]  Yes

1. What is your race? [READ LIST IF NECESSARY AND RECRUIT A MIX]

[ ]  White

[ ]  Black or African American

[ ]  Asian

[ ]  Native Hawaiian or Other Pacific Islander

[ ]  American Indian or Alaskan Native

[ ]  Prefer not to answer

1. What is the highest level of education that you have completed? [RECRUIT A MIX]

[ ]  Less than high school diploma

[ ]  High school graduate or GED

[ ]  Some college or 2-year degree

[ ]  College degree

[ ]  Postgraduate degree

1. During the focus group discussion, you will be asked to review written materials and offer your opinions, so I need to ask whether you have a medical or nonmedical condition that affects your ability to read and/or understand written materials in English.

[ ]  Yes**🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

[ ]  No **🡪 Continue**

1. For study purposes, if you participate, the focus group will be audio recorded and the video will be live streamed to study team members. Are you okay with us audio recording and live streaming the focus group?

[ ]  Yes**🡪 *Continue***

[ ]  No **🡪 *TERMINATE [GO TO INELIGIBLE CLOSING SCRIPT]***

**[Refer to this List of auto-injectors]**

ADRENACLICK

ATROPEN

AUVI-Q

BYDUREON BCISE

DUODOTE

EPIPEN

EPIPEN JR.

EVZIO

IMITREX STATdose

OTREXUP

RASUVO

XYOSTED

ZEMBRACE SymTouch

Epinephrine Injection USP (autoinjector)

Sumatriptan Injection USP (autoinjector)

**[Refer to this List of brand name DPIs]**

ADASUVE

ADVAIR DISKUS

AFREZZA

AIRDUO RESPICLICK

ANORO ELLIPTA

ARCAPTA NEOHALER

ARIDOL

ARMONAIR RESPICLICK

ARNUITY ELLIPTA

ASMANEX TWISTHALER

BREO ELLIPTA

FLOVENT DISKUS

FORADIL AEROLIZER

INCRUSE ELLIPTA

PROAIR RESPICLICK

PULMICORT FLEXHALER

RELENZA

SEEBRI NEOHALER

SEREVENT DISKUS

SPIRIVA HANDIHALER

TOBI PODHALER

TRELEGY ELLIPTA

TUDORZA PRESSAIR

UTIBRON (NEOHALER)

**Closing Scripts**

**Ineligible - Closing Script**

I’m sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

**Eligible – Closing Script**

Great! You qualify for our study. The discussion group will be held on [DATE] at [TIME] and will last about 90 minutes. You will receive $125 as a token of our appreciation for your participation. If you use reading glasses or hearing aids, please be sure to bring them with you.

Would you like to participate in the group discussion at [TIME] on [DATE]?

[ ]  Yes – ***Continue to scheduling script*.**

[ ]  No – ***Thank the adult and end call****.*

**Eligible – Scheduling script**

May I please have your mailing and/or e-mail address and telephone number to send you a confirmation letter with directions for attending the focus group on [DATE/TIME]? We will use this information to send you a reminder letter and to call and remind you of the focus group. We will destroy all contact information at the conclusion of the focus groups. ***[Verify contact information]***

**Follow-up**

**\*\*NOTE\*\* THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUPS.**

NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ADDRESS: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CITY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ZIP CODE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-MAIL\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

BEST PHONE NUMBER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is there another time and number we can try if we miss you?

ALTERNATE TIME:

ALTERNATE PHONE NUMBER:

Thank you. That’s all the questions I have today. If you have any questions or find that you are unable to attend, please call [recruiter’s phone number] as soon as possible. Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].