

## [INTRO]

We are working with RTI International (a nonprofit research organization) on a research study sponsored by the Food and Drug Administration (FDA).

We are recruiting online focus group participants who use prescription drug devices like auto-injectors to discuss their experiences with using this prescription drug device. FDA believes it is important to get feedback from many people about these devices and we would like to get your opinions and hear about your experiences using an autoinjector. We are not selling any products.

During the focus group, you will also be asked to hold an autoinjector and answer some questions about the device. If you are scheduled to participate, we will mail you a package of materials for you to use during the online focus group discussion. The package will include two autoinjectors. The autoinjectors will be trainer devices and will not contain medicine or a needle and cannot be discharged. You will be only be asked to hold and look at the device.

We are holding an online focus group using Zoom on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. The discussion will be video and audio recorded, and project team members may also join to observe the discussion. You will be given **\$125** as a token of our appreciation for your participation.

**If you are a parent:** We are also recruiting adolescent focus group participants, specifically preteens and teens ages 12-17, who use prescription drug devices like auto-injectors to discuss their experiences with using this prescription drug device. FDA believes it is important to get feedback from many people, including teens, about these devices and to understand how people use them and what they think about them. We are not selling any products.

We are holding an online focus group using Zoom on [DATE]. The focus group starts at [TIME] and will last about 90 minutes. This study involves participating in a one-time focus group discussion with about 6 adolescents who also use prescription drug devices. During the discussion, we will talk with your child about their experiences using the drug device, and we will ask the group to share their opinions about the device. Your teen will also be asked to hold a sample autoinjector and answer some questions about the device. This device will contain no medicine and no needle.

If your child is scheduled to participate, we will mail you a package of materials for them to use during the online focus group discussion that will include two autoinjectors trainer devices. The trainers will not contain medicine or a needle and cannot be discharged. We will instruct participants only to hold and look at the device. The focus group will be video and audio recorded, and project team members may also join to observe the discussion. Your teen will be given \$125 as a token of our appreciation for their participation.

**P\_Intro.** First, are you the parent or guardian of a child between the ages of 12 and 17?

- 1  Yes → [PROGRAM TO INCLUDE PARENT QUESTIONS “P” AS WELL AS PARTICIPANT QUESTIONS “Q”]  
 2  No → [PROGRAM TO ONLY ASK PARTICIPANT QUESTIONS “Q”]
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### Adult Auto-Injector Users or Caregivers

An auto-injector is a medical device designed to deliver a dose of a particular prescription drug. Most auto-injectors are spring-loaded syringes that include a needle to inject the medicine.

**Q1.** Do you have a current prescription from a doctor for an autoinjector?

- 1  Yes → *Continue to Q2 (next question)*  
 2  No → *Continue to Q2*

**Q2.** Do you take care of someone in your family who has a current prescription from a doctor for an autoinjector?

- 1  Yes → [IF Q1 = 1, “YES”], *Continue to Q3a*; [IF Q1 = 2, “NO”], *Skip to Q3c*  
 2  No → [IF Q1 = 1, “YES”], *Continue to Q3a*; [IF Q1 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]

**Q3a.** [Unaided] [IF Q1 = 1, “Yes”] What is the brand name of the autoinjector that you use? [OPEN ENDED]

\_\_\_\_\_ → *Continue to Q3b*

**Q3b.** Just to confirm, what is the brand name of the autoinjector you currently use? [LIST OPTIONS; ALLOW ONE RESPONSE]

- 1  ADRENACLICK → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]  
 2  AIMOVIG → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]  
 3  ATROPEN → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]  
 4  AUVI-Q → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]  
 5  AVONEX PEN → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]  
 6  BYDUREON BCISE → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]  
 7  EPIPEN → *SKIP TO Q4; ASSIGN TO EPIPEN USER group*  
 8  EPIPEN JR. → *SKIP TO Q4; ASSIGN TO EPIPEN USER group*  
 9  EVZIO → [IF Q2 = 1, “Yes”], *continue to Q3c*; [IF Q2 = 2, “NO” & IF P\_INTRO = 1; *SKIP TO P1*]; [IF Q1 = 2 & P\_INTRO = 2; *TERMINATE*]

- 10  IMITREX STATdose → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 11  OTREXUP → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 12  RASUVO → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 13  REBIF / REBIJECT → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 14  SURECLICK, ENBREL → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 15  XYOSTED → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 16  ZEMBRACE SymTouch [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 17  Epinephrine Injection USP (autoinjector) → SKIP TO Q4; ASSIGN TO EPIPEN USER group
- 18  Sumatriptan Injection USP (autoinjector) → [IF Q2 = 1, "Yes"], continue to Q3c; [IF Q2 = 2, "NO" & IF P\_INTRO = 1; SKIP TO P1]; [IF Q1 = 2 & P\_INTRO = 2; TERMINATE]
- 19  Both an EpiPen, EpiPen Jr., Epinephrine Injection USP AND another AI → SKIP TO Q4; ASSIGN TO EPIPEN USER group

**Q3c. [Unaided] [IF Q2 = 1, "Yes"]** What is the brand name of the autoinjector that your family member uses? [OPEN ENDED]

\_\_\_\_\_ → Continue to Q3d

**Q3d.** Just to confirm, what is the brand name of the autoinjector your family member uses? [LIST OPTIONS; ALLOW ONE RESPONSE]

- 1  ADRENACLICK → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 2  AIMOVIG → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 3  ATROPEN → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 4  AUVI-Q → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 5  AVONEX PEN → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 6  BYDUREON BCISE → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 7  EPIPEN → SKIP TO Q4; ASSIGN TO EpiPen Caregiver group
- 8  EPIPEN JR. → SKIP TO Q4; ASSIGN TO EpiPen Caregiver group
- 9  EVZIO → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 10  IMITREX STATdose → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 11  OTREXUP → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 12  RASUVO → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 13  REBIF / REBIJECT → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 14  SURECLICK, ENBREL → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 15  XYOSTED → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]
- 16  ZEMBRACE SymTouch → [IF P\_INTRO = 1; SKIP TO P1]; [IF P\_INTRO = 2; TERMINATE]

- 17  Epinephrine Injection USP (autoinjector) → **SKIP TO Q4; ASSIGN TO EpiPen Caregiver group**
- 18  Sumatriptan Injection USP (autoinjector) → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 19  Both an EpiPen, EpiPen Jr., Epinephrine Injection USP AND another AI → **SKIP TO Q5; ASSIGN TO THE EpiPen Caregiver group**

### Adult Other Market Exclusion Criteria

[Show for all potential qualifying participants: EpiPen Caregivers, Adult EpiPen Users]

**Q4.** Have you ever worked for... (check all that apply)

- 1  Any office, division or agency within the Department of Health and Human Services (HHS) → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 2  A pharmaceutical company) → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 3  A marketing or research company) → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 4  A healthcare company or in a position in the healthcare field) → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 5  A medical device company) → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 6  None of the above → **Continue to Q5a**

**Q5a.** Have you participated in an interview or focus group in the past 3 months?

- 1  Yes → **Continue to Q5b**
- 2  No → **Skip to Q6**

**Q5b.** [IF Q5a = 1, "YES"] Was the focus group or interview related to prescription or over the counter medicines, or did it have anything to do with your medical condition?

- 1  Yes → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 2  No → **Continue to Q6**

**Q6.** During the online focus group discussion, you will be asked to review written materials and offer your opinions. Do you have any condition (medical or nonmedical) that affects your ability to read and/or understand written materials in English?

- 1  Yes, I have a condition that affects my ability to read and/or understand materials → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]
- 2  No, I do not have any conditions that affect my ability to read and/or understand materials → **Continue to Q7**

**Q7.** We need to send you a package of materials for you to use during the online focus group discussion. Can you provide a mailing address where you can receive these materials?

- 1  Yes → *Continue to Q8*  
2  No, I will not provide my mailing address for this study → **TERMINATE**

**Q8.** For study purposes, the online focus group will be recorded and the video will be livestreamed to study team members. If you participate, you will be asked to keep your video on during the focus group discussion. Are you okay with us recording and livestreaming the focus group?

- 1  Yes → *Continue to Q9*  
2  No → [IF P\_INTRO = 1; **SKIP TO P1**]; [IF P\_INTRO = 2; **TERMINATE**]

**Q9.** What is your gender? [**RECRUIT A MIX**]

- 1  Male → *Continue to Q10*  
2  Female → *Continue to Q10*  
3  Prefer not to answer → *Continue to Q10*

**Q10.** Are you Hispanic, Latino/a, and or of Spanish origin? [**RECRUIT A MIX**]

- 1  Yes → *Continue to Q11*  
2  No → *Continue to Q11*  
3  Prefer not to answer → *Continue to Q10*

**Q11.** What is your race? (Check all that apply) [**RECRUIT A MIX**]

- 1  White → *Continue to Q12*  
2  Black or African American → *Continue to Q12*  
3  Asian → *Continue to Q12*  
4  Native Hawaiian or other Pacific Islander → *Continue to Q12*  
5  American Indian or Alaskan Native → *Continue to Q12*  
6  Prefer not to answer → *Continue to Q12*

**Q12.** What is the highest level of education that you have completed? [**RECRUIT A MIX**]

- 1  Less than a high school diploma → *Continue to Eligibility*  
2  High school graduate or GED → *Continue to Eligibility*  
3  Some college or 2-year degree → *Continue to Eligibility*  
4  College degree → *Continue to Eligibility*  
5  Postgraduate degree → *Continue to Eligibility*

### **Eligible Script and Scheduling**

Great! You qualify for our study. The virtual 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.

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

- Yes - *Continue to scheduling script.*  
 No - *Thank you screen.*

May I please have your mailing address, e-mail address, and telephone number? We will use this information to mail you a package containing focus group materials; we will also e-mail you with instructions on how to prepare for the online focus group on [DATE/TIME].

I will also be sending you an email with the informed consent form for the study. Please read the form carefully and reply indicating whether you agree or decline to participate. You won't be able to participate unless we get your response.

We will send you a package containing focus group materials, which you can set aside until the day of your focus group. Please look for this package within the next [TIME FRAME] days. If you do not receive the package in the next [X] days, please contact us.

I will also call you a day or two before your scheduled focus group to remind you. If you need to reschedule or cancel your appointment, please contact me at <email; phone>. We will destroy all contact information at the conclusion of the focus groups. [VERIFY CONTACT INFORMATION]

### Termination 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.

### Adolescent EpiPen Users

**P1.** [IF P\_Intro = 1] Do any of your children ages 12-17 have a current prescription from a doctor for an autoinjector?

- 1  Yes → *Continue to P2a*  
2  No → *Terminate*

**P2a.** [IF P1 = 1] How many of your children ages 12-17 have a prescription from a doctor for an autoinjector?

- 1  One → *Continue to P3a*  
2  More than one → *Continue to P2b*

**P2b.** Will your oldest child who has a prescription for an autoinjector be available for a follow up call to see if they qualify?

- 1  Yes → *Continue to P3a*  
2  No → *Terminate*

**P3a-[Unaided].** What is the brand name of the autoinjector your child currently uses? [OPEN ENDED]

\_\_\_\_\_ → Continue to P3b

**P3b.** Just to confirm, what is the brand name of the autoinjector your child currently uses? [LIST OPTIONS; ALLOW ONE RESPONSE]

- 1  ADRENACLICK → PLACE ON HOLD
- 2  AUVI-Q → Terminate
- 3  EPIPEN → Skip to P4; potential ADOLESCENT EPIPEN USER
- 4  EPIPEN JR. → Skip to P4; potential ADOLESCENT EPIPEN USER
- 5  Epinephrine Injection USP (auto-injector) → Skip to P4; potential ADOLESCENT EPIPEN USER
- 6  GENERIC ADRENACLICK → PLACE ON HOLD
- 7  GENERIC EPIPEN / GENERIC EPIPEN JR → Skip to P4; potential ADOLESCENT EPIPEN USER
- 8  Other (specify) \_\_\_\_\_ → PLACE IN HOLD GROUP AND CONTACT RTI FOR REVIEW

#### Adolescent Other Market Exclusion Criteria

[Show for all potential qualifying Adolescent EpiPen Users]

**P4.** If your child qualifies, we will need you to sign a permission form prior to their participation in the focus group. We will schedule a call to talk with you and your child so that I can get more information. When we call, we will speak to you first; we will then ask them to go somewhere quiet and private, where no one can hear their answers (we have a rule that everyone who participates in our research is assured privacy to the extent permitted by law, including children.)

Finally, if they qualify, we will give you more information during the call.

**P5.** Do we have permission to contact you by phone and to speak to your child to see if they qualify to participate in the study?

- 1  Yes → Continue to P6
- 2  No → Terminate

**P6.** Are you this child's parent or legal guardian?

- 1  Yes → Continue to P7
- 2  No → Terminate

**P7.** If your child qualifies for the study and decides to participate, the focus group will be audio and video recorded and live-streamed (via a secure connection) for study staff who will observe remotely. Your child will be asked to keep their video on during the focus group discussion. Can we video and audio record your child’s participation in the focus group?

- 1  Yes → **Continue to eligibility script.**
- 2  No → **Terminate**

### **Adolescent Eligibility and Scheduling**

#### **Eligible Script and Scheduling**

It looks like your child may qualify for our study. The discussion group will be held on [DATE] at [TIME] and will last about 90 minutes. Your child will receive \$125 as a token of our appreciation for your participation.

Please provide your telephone number so we can call you and speak to your child about their participation?

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#### **Termination 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.

What is the best phone number to reach you? Please also provide a back-up phone number if you have one.

Primary Contact Number

Back-Up Contact Number