

FDA REMS Practice Setting Overview – Screener for Focus Group Participants

Location: TBD
Date(s): TBD
Times: TBD

Special Instructions:

Recruit 12 for 9 to show
Mix of genders ok (50/50 good, but 60/40 either way ok)
Mix of ages and experience preferred
Mix of roles within prescriber practice/processes
Looking for in depth knowledge and experience in (specific) prescriber setting

Screener

Participant Screener for Practitioner Focus Groups

Hello, my name is _____ and I'm calling about a prescriber setting research study sponsored by the Food and Drug Administration. As part of this study, we are recruiting participants for upcoming focus group sessions. Participants in these focus groups will be asked to share their experiences with prescription practices within a specific provider setting. This is an opportunity to share your experience, promote a common understanding of your work environment and its challenges, and potentially contribute to policies aimed at its improvement. All of the information provided will remain private to the extent permitted by law. Would you mind answering a few questions?

Screening Questions

Q1. Please describe the practice setting in which you work (see examples below)

- a. Specialty:
- b. Practice group/organization (e.g., multispecialty, academic, etc.):
- c. Size (# of physicians w/in practice):
- d. Types of prescribers (MDs, DOs, NPs, PAs):
- e. Typical patient population (e.g., indigent, rural):
- f. Physical facility (multiple offices, hospital/clinic):

Q2. Please describe the capacity in which you work

- a. Current title:
- b. Current role within practice:
- c. Specific expertise/practice focus:
- d. Specific populations served:

Q3. How long have you worked in this capacity? In this setting?

Q4. In what other settings do you have experience?

Document response: _____

Q5. In what other specialties do you have experience?

Document response: _____

Q6. Are you familiar with / have you ever heard of Risk Evaluation and Mitigation Strategies (REMS) and/or Elements to Assure Safe Use (ETASUs) for x disease [disease state TBD]?

Document response: _____

Q7. Do you participate in the prescription process?

- Yes → continue, Go to Q8
- No → Go to Q9

Q8. What is your role(s) in the prescription process?

Document response: _____

Q9: Do you or have you or anyone from your immediate family worked in or retired from any of the following:

- Market Research Firm → eliminate
- The Food and Drug Administration → eliminate
- The National Institutes of Health → eliminate
- Pharmaceutical Company → eliminate
- The Department of Health and Human Services → eliminate
- A State Health Department → eliminate

Q10. Have you participated in a focus group within the past six months?

[Interviewer: participation in telephone surveys is allowable]

- Yes → eliminate [thank respondent politely]
- No → continue

Demographic Questions

Q11. Gender

- Male
- Female

Q12. How old are you? (if under 21 or over **61**, eliminate)

- Under 21
- 21 – 30 years old (include)
- 31 – 40 years old (include)
- 41 – 50 years old (include)
- 51 – 60 years old (include)
- 61 or older

Q13. What is the highest level of education that you have completed?

- Less than high school
- High school graduate or GED
- Technical/vocational school
- Some college credit but no degree
- Associate's degree (AA, AS)
- Bachelor's degree (BA, AB, BS)
- Advanced degree (MA, MS, MEd, MEng, MBA, MSW, PhD, MD, JD, DVM, EdD)

Q14. Are you of Hispanic, Latino, or Spanish origin?

- Yes
- No

Q15. What is your race? Please select one or more.

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or other Pacific Islander

We would like to invite you to participate in a focus group to discuss the prescription practices within your provider setting with **8 or so** other participants. The focus group will take place on **(Day)**, **(Date)**, at **[6:00 or 8:00 p.m.]** at **[site location]**. The discussion will last approximately 90 minutes and will include both men and women. The group will be audio recorded and observed by staff from the FDA. However, your participation and everything you say during the discussion will be kept private and confidential to the extent permitted by law. The FDA will not have your full names and will keep all tapes locked up until they are destroyed.

Additionally, light refreshments such as [insert type of food served] before the group discussion will start.

Will you be available to participate at this time?

- Yes → continue
 - No → [Thank the person for his/her time]
-

I would like to send you a confirmation letter and directions to the focus group facility. Can you please tell me your mailing address (or fax number) and a phone number where you can be reached:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Email: _____

Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call [recruiter] at [telephone number] if this should happen.

We look forward to seeing you on [date] at [time]. If you use reading glasses, please bring them with you to the session.