

Suggested Sample Agenda for an FDA Patient-Led Listening Session

Helpful Information:

- FDA Patient Listening Sessions are one way for the patient community to share perspectives with the FDA about their health experiences, preferences, needs, and goals in managing a disease, or condition.
- Patient Listening Sessions are not for discussion or endorsement of medical products that have not yet been reviewed and approved by the FDA.
- Patient organizations or support groups who are interested in organizing a Patient Listening Session must submit a [web form request](#) and prepare a draft meeting agenda.
- The agenda should be for a meeting lasting 60 to 90 minutes.
- Please include 5 minutes total for FDA Public Engagement Staff opening/closing remarks, as well as 10 minutes for a question-and-answer period that allows the FDA staff to ask questions.
- The FDA Public Engagement Staff will review your meeting request and follow up with next steps.

Suggested Sample Agenda (90-minute meeting)

1. Welcome/Opening Remarks (3 minutes) – *FDA Public Engagement Staff*

The FDA Public Engagement Staff will briefly welcome participants, share meeting process information, provide background on the Patient Listening Session program, and read the organization's financial interest statement.

2. Disease background/clinical information section (5 to 10 minutes) – *one Patient/Caregiver/Representative from patient advocacy organization*

During this section, one speaker, usually a representative of the requesting patient advocacy organization, can provide high-level remarks that provide FDA staff with an overview/understanding of the disease/condition. The requesting organization can allow one clinician, who works with patients with the disease, to speak.

3. Patient Perspectives section (60 to 65 minutes) – *six to eight patient and/or caregiver speakers*

- a. Patient/caregiver Perspective 1
 - Topics discussed: x, y, z
- b. Patient/caregiver Perspective 2
 - Topics discussed: x, y, z
- c. Patient/caregiver Perspective 3
 - Topics discussed: x, y, z
- d. Patient/caregiver Perspective 4

- Topics discussed: x, y, z
- e. Patient/caregiver Perspective 5
 - Topics discussed: x, y, z
- f. Patient/caregiver Perspective 6
 - Topics discussed: x, y, z

The FDA Public Engagement Staff recommends six to eight patient and/or caregiver speakers for this section. When selecting speakers, it is helpful to include those who represent a variety of perspectives (e.g., age, severity of disease, disease subtypes, etc.) to give the FDA a broad range of perspectives.

Please specify the topics that each speaker plans to cover in their remarks and the amount of time each speaker will be speaking.

Suggested topics during this section include: symptoms; treatments; clinical trial preferences; desired endpoints in clinical trials; benefit/risk perspectives.

For additional details about topics for this section please see "[Preparing Patient and Caregiver Participants for an FDA Patient-Led Listening Session and Suggested Topics.](#)"

4. Optional/additional topics (5 minutes) – *patient advocacy organization representative*

In this optional section, a requestor may wish to cover any additional topics, such as registries, clinical trial preferences, treatment goals, a summary of the remarks made by the patient speakers or closing remarks.

5. Question and Answer (10 minutes) – *Opportunity for FDA to Ask Follow-up Questions*

The FDA sets aside a portion of the meeting as a placeholder in case FDA staff has questions or comments for any of the patient/caregiver speakers. During this time, FDA staff may ask follow-up or clarifying questions to any of the speakers. Because these sessions are learning opportunities designed to educate FDA staff, the FDA **may not** have any questions or comments during the question-and-answer period.

6. Closing Remarks (2 minutes) – *FDA Public Engagement Staff*

The FDA Public Engagement Staff will share a brief thank you and closing remarks.