

FDA Patient Listening Sessions



FDA Patient Affairs hosts Patient Listening Sessions. These sessions are a resource for the medical product Centers to engage with patients and their advocates. Patient Listening Sessions are one of [many ways](#) ([/patients/learn-about-fda-patient-engagement/fda-patient-engagement-opportunities](#)), the patient and advocacy community can share their experiences and perspectives by talking directly with FDA staff.

Upcoming scheduled Patient Listening Session topics:

- MEF2C Haploinsufficiency Syndrome (MCHS)
- Myhre Syndrome

What are Patient Listening Sessions?

Patient Listening Sessions can either be FDA-requested (where FDA has a specific set of questions to ask) or patient-led (when a patient community wants to share their perspectives with the FDA). Patient Listening Sessions:

- Are small, informal, non-regulatory, non-public teleconference meetings that allow participants to connect with FDA staff first-hand
- Are about patient experiences, perspectives, and needs related to their health or a disease, and not about specific medical products (drug, biologic, or device)
- Should include multiple patient groups/communities within a disease area
- Give the FDA an opportunity to connect with under-represented communities
- Help the FDA better understand what is most important to different communities and individuals who have specific health, medical, and treatment needs
- Should be of interest to medical product center staff in multiple FDA Centers/programs
- Should not be on the same set of agenda topics as a past meeting held or future meeting planned with FDA

Patient Listening Sessions help the Agency inform medical product development, clinical trial design, patient preferences, and shape our regulatory thinking. During a Patient Listening Session, FDA staff will either ask questions or simply listen to better understand your experiences and perspectives. Only the FDA, patients, caregivers, advocates, and community representatives participate in the session. FDA Patient Affairs partners with the [National Organization for Rare Disorders](https://rarediseases.org/) (<https://rarediseases.org/>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) and the [Reagan-Udall Foundation for the FDA](https://reaganudall.org/) (<https://reaganudall.org/>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

[Click here for Summaries of Patient Listening Sessions \(/patients/learn-about-fda-patient-engagement/patient-listening-session-summaries\)](/patients/learn-about-fda-patient-engagement/patient-listening-session-summaries)

Learn more about Patient Listening Sessions:

[How does FDA benefit from Patient Listening Sessions? \(/patients/learn-about-fda-patient-engagement/how-does-fda-benefit-patient-listening-sessions\)](/patients/learn-about-fda-patient-engagement/how-does-fda-benefit-patient-listening-sessions)

[How do I request a Patient Listening Session? \(/patients/learn-about-fda-patient-engagement/how-do-i-request-patient-listening-session\)](/patients/learn-about-fda-patient-engagement/how-do-i-request-patient-listening-session)

[How do I prepare for a Patient Listening Session? \(/patients/learn-about-fda-patient-engagement/how-do-i-prepare-patient-listening-session\)](/patients/learn-about-fda-patient-engagement/how-do-i-prepare-patient-listening-session)

[What happens after a Patient Listening Session? \(/patients/learn-about-fda-patient-engagement/what-happens-after-patient-listening-session\)](/patients/learn-about-fda-patient-engagement/what-happens-after-patient-listening-session)

Read about the impact Patient Listening Sessions can have on FDA's work:

- [Determining Commonalities in the Experiences of Patients with Rare Diseases: A Qualitative Analysis of US Food and Drug Administration Patient Engagement Sessions \(/media/175503/download?attachment\)](/media/175503/download?attachment)
- [FDA engages patient communities through listening session initiative \(https://www.aappublications.org/news/2020/11/01/fdaupdate110120\)](https://www.aappublications.org/news/2020/11/01/fdaupdate110120) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [How FDA is Putting the Patient Voice at the Forefront of Gene Therapy Clinical Trials for Hemophilia \(/patients/learn-about-fda-patient-engagement/how-fda-putting-patient-voice-forefront-gene-therapy-clinical-trials-hemophilia\)](/patients/learn-about-fda-patient-engagement/how-fda-putting-patient-voice-forefront-gene-therapy-clinical-trials-hemophilia)
- [Transgender teens share perspectives on health care needs during listening session \(/media/154747/download\)](/media/154747/download)

Read about the procedures for the management of Patient Listening Sessions by the Patient Affairs in [Staff Manual Guide 9006 \(/media/131716/download?attachment\)](/media/131716/download?attachment).

Discussions in Patient Listening Sessions are informal. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants.