FDA Seeks Feedback from Rare Disease Community

The U.S. Food and Drug Administration (FDA) has opened a public docket to solicit input from the rare disease community. The FDA docket, available here, invites public comments from parties engaged in the design and conduct of rare disease clinical trials, including sponsors, investigators, patients, and patient advocates.

This docket includes two distinct opportunities for feedback:

1. The Center for Drug Evaluation and Research's Accelerating Rare Disease Cures (ARC) program seeks input on the clarity, relevance, and usefulness of the Learning and Education to Advance and Empower Rare Disease Drug Developers (LEADER 3D) educational materials.
2. The Rare Disease Innovation Hub seeks feedback on existing and desired educational resources for patients and patient advocates, as well as educational materials intended for stakeholders engaged in rare disease biologics development.

Please submit comments by **April 3, 2026.**

For FDA rare diseases information, please visit:

- The LEADER 3D webpage to learn more about available rare disease drug development educational materials.
- CDER's ARC webpage for information about the Accelerating Rare disease Cures (ARC) Program.
- The Rare Disease Innovation Hub webpage for information about the Hub, answers to frequently asked questions, information about the Rare disease Innovation, Science, and Exploration (RISE) Workshop series, and access to the 2026 Strategic Agenda.