



Patient Voice in Rare Disease Medical Product Development

Friday, October 16, 2026

1-5pm (eastern) | Hybrid Public Meeting

FDA White Oak Campus

Building 31 Great Room Conference Center

10903 New Hampshire Ave., Silver Spring, MD 20993

1pm

Welcome

Susan C. Winckler, RPh, Esq.

CEO, Reagan-Udall Foundation for the FDA

1:05pm

Opening Remarks

Amy Comstock Rick, JD

Director, Rare Disease Innovation Hub, FDA

1:10pm

Discussion

CBER & CDER HUB Co-chairs

- Michael Davis, MD, PhD, Director, Center for Drug Evaluation and Research (CDER), FDA
- Karim Mikhail, B.Pharm, MSc, Director, Center for Biologics Evaluation and Research (CBER), FDA

1:30pm

Panel Discussion

Grounding in Existing Mechanisms: Where the Patient Voice is Sought Across the Development Timeline

- Robyn Bent, MS, RN, Director of Patient-Focused Drug Development (PFDD) Program, CDER, FDA
- Cynthia Grossman, PhD, Director, Division of Patient-Centered Development, Office of Innovative Development, Office of Strategic Partnership and Technology Innovation, Center for Devices and Radiological Health (CDRH), FDA
- Carmen Matos, MA, Senior Health Scientist, Office of Public Engagement, Office of Public Affairs, Office of the Commissioner, FDA

2:00pm

Case Studies Presentations

- Terry Pirovolakis, Founder & CEO, Elpida Therapeutics/CureSPG50
- Tracy Gray, MBA, MS, RN, Health Scientist, Patient Engagement Lead, Office of Innovative Development, Office of Strategic Partnership and Technology Innovation, CDRH, FDA
- Emily Machiela-Leestma, PhD, Coordinator, HD Benefit-Risk Initiative

2:40pm

Break

2:55pm

Panel Discussion

Advancing the Patient Voice in Medical Product Development: Reflections and Opportunities

- Allyson Berent, DVM, Chief Science Officer, Foundation for Angelman Syndrome Therapeutics
- Michelle Campbell, MS, PhD, Associate Director for Stakeholder Engagement and Clinical Outcomes, Office of Neuroscience, Office of New Drugs, CDER, FDA
- Tom Croce, BSPHarm, Vice President, Global Patient Advocacy & Engagement, Jazz Pharmaceuticals
- Mona Elmacken, MD, Lead Physician, Malignant Hematology Branch, Division of Clinical Evaluation Hematology, Office of Clinical Evaluation, Office of Therapeutic Products, CBER
- Courtney Lias, PhD, Director, Office of In Vitro Diagnostics, Office of Product Evaluation and Quality, CDRH
- Jenn McNary, Principal, Co-Founder, Canary Advisors
- Katie Meyer, MPP, Vice President of Policy, Advocacy and US Market Access, Novocure
- Tamar Thompson, MS, Vice President Patient Experience & Insights, Alexion, AstraZeneca Rare Disease
- Ashley Valentine, MRes, Co-founder & CEO, Sick Cells

4:45pm

Discussion

CDRH HUB Co-chair

Michelle Tarver, MD, PhD, Director, CDRH, FDA

4:55pm

Closing/Adjourn

Winckler