U.S. FOOD & DRUG ADMINISTRATION

Patient Engagement Advisory Committee Meeting: CDRH Updates

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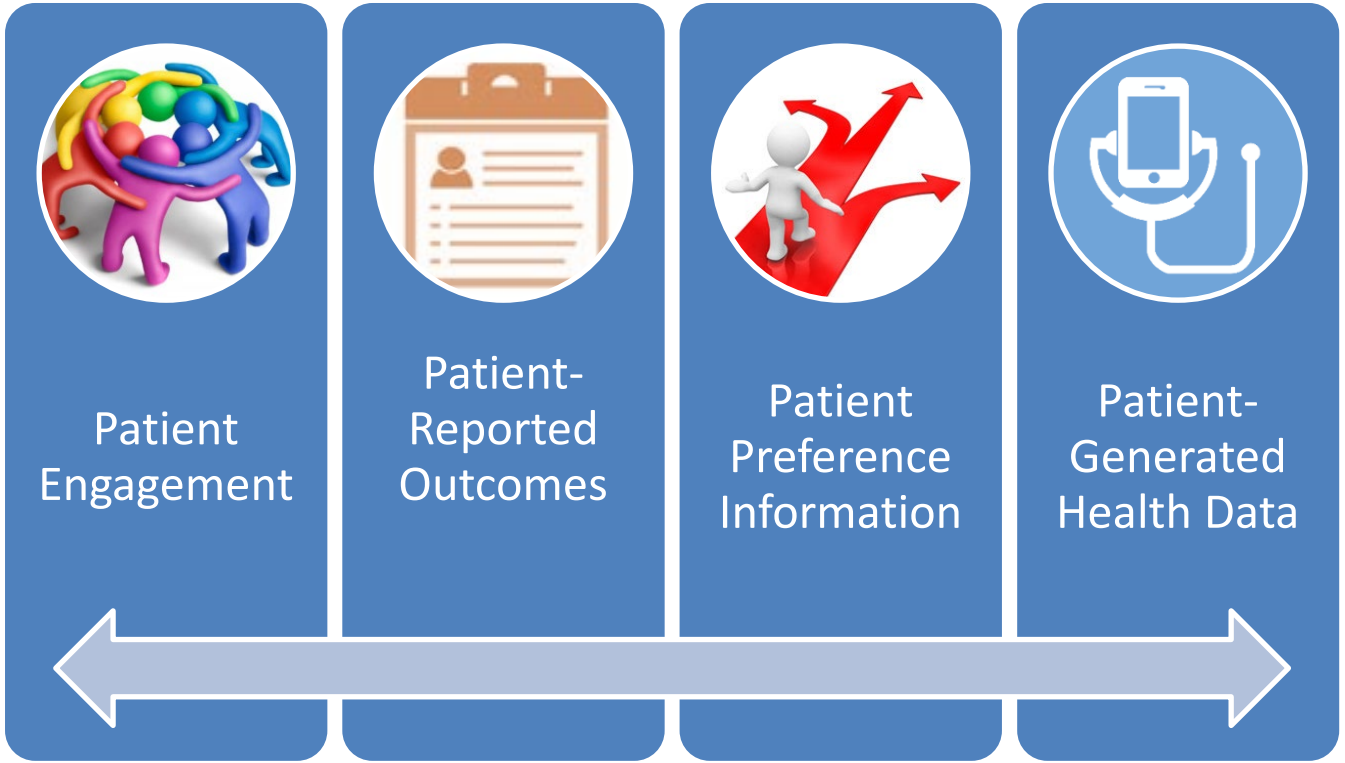
Patients are at the Heart of What We Do

CDRH Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

Patients Impact Medical Device Evaluation



Patient Engagement Involves Reciprocity and Inclusion

Contains Nonbinding Recommendations

Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

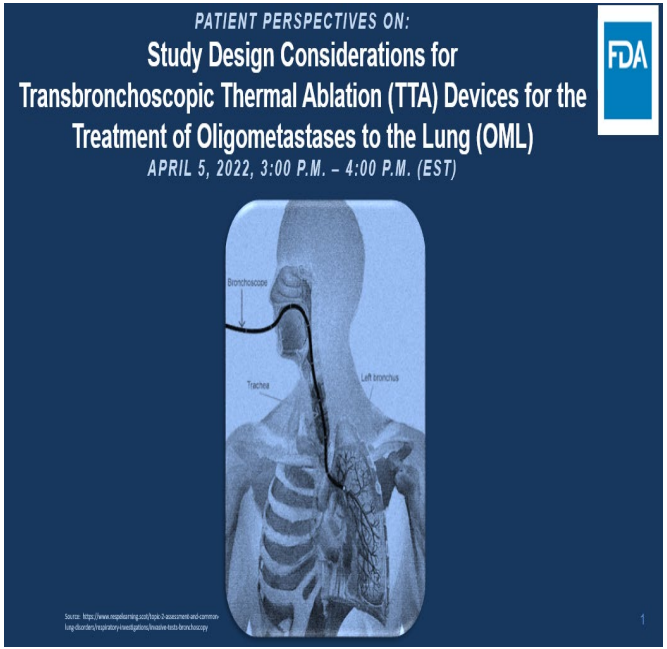
Document issued on January 26, 2022.

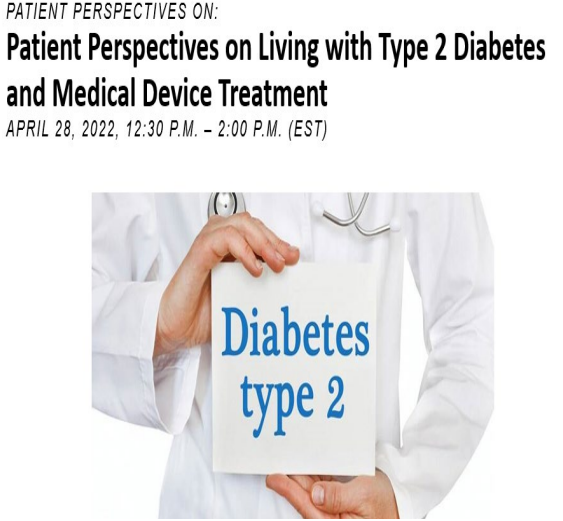
The draft of this document was issued on September 24, 2019.

For questions about this document regarding CDRH-regulated devices, contact Michelle Tarver in the Office of Strategic Partnerships and Technology Innovation (OST) at (301) 796-6884 or by email CDRH_PatientEngagement@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research





Patient and Caregiver Connection Partners

Outcomes from Previous PEAC Meetings

1	Patient Engagement in Design, Conduct and Communication of Medical Device Clinical Trials	• **Final guidance** • **Video for underrepresented populations**	
2	Patient-Generated Health Data & Medical Device Safety Surveillance	• **Open data pledge** • **PGHD public meeting on May 4, 2021**	
3	Communicating Cybersecurity Vulnerabilities of Medical Devices	• **Cybersecurity hygiene miniseries** • **Communication best practices paper**	

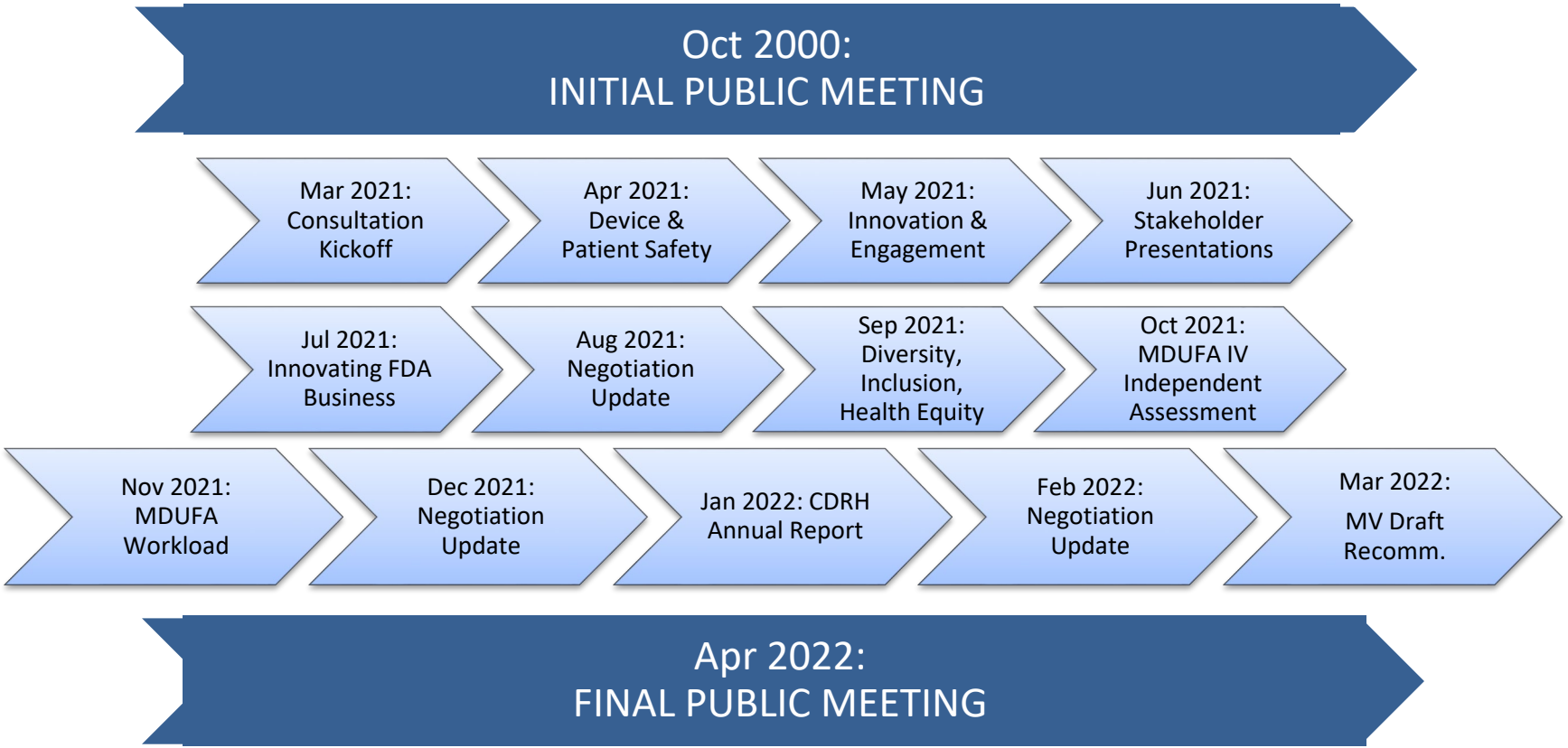
Outcomes from Previous PEAC Meetings

4	Artificial Intelligence & Machine Learning	• AI/ML action plan • AI/ML Workshop on October 14, 2021	
5	Medical Device Recalls	• In progress	

MDUFA IV Accomplishments

- Applying Consistent & Transparent Policy
- Building Capacity
- Optimizing the Research Roadmap
- Fostering a Culture of Patient Engagement
- Expanding Patient Impact in Device Evaluation

MDUFA V: Extensive Stakeholder Consultation



CDRH Strategic Priorities: 2022-2025

1. By December 31, 2025, over 50% of manufacturers of newly authorized novel technologies for the U.S. market bring their devices to the U.S. first or in parallel with other major markets.
2. By December 31, 2025, over 75% of the time, FDA identifies and acts on significant safety signals related to medical devices marketed in the U.S. and other major markets first or in coordination with regulatory agencies of other major markets.

DIGITAL HEALTH

CDRH Digital Health Center of Excellence

Center for Devices & Radiological Health (CDRH), US FDA

www.fda.gov/digitalhealth

Focus for Today

Innovative VR Devices Benefiting Patient Health

10/20/21

[FDA Authorizes Marketing of Digital Therapeutic that Uses TV Shows to Improve Vision in Children with Lazy Eye,]

Luminopia™ One

11/16/21

[FDA Authorizes Marketing of Virtual Reality System for Chronic Pain Reduction], EaseVRx

Thank You