



**U.S. FOOD & DRUG**  
ADMINISTRATION

# Patient Engagement Advisory Committee Meeting: CDRH Updates

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Director, Center for Devices & Radiological Health  
(CDRH)

July 12, 2022

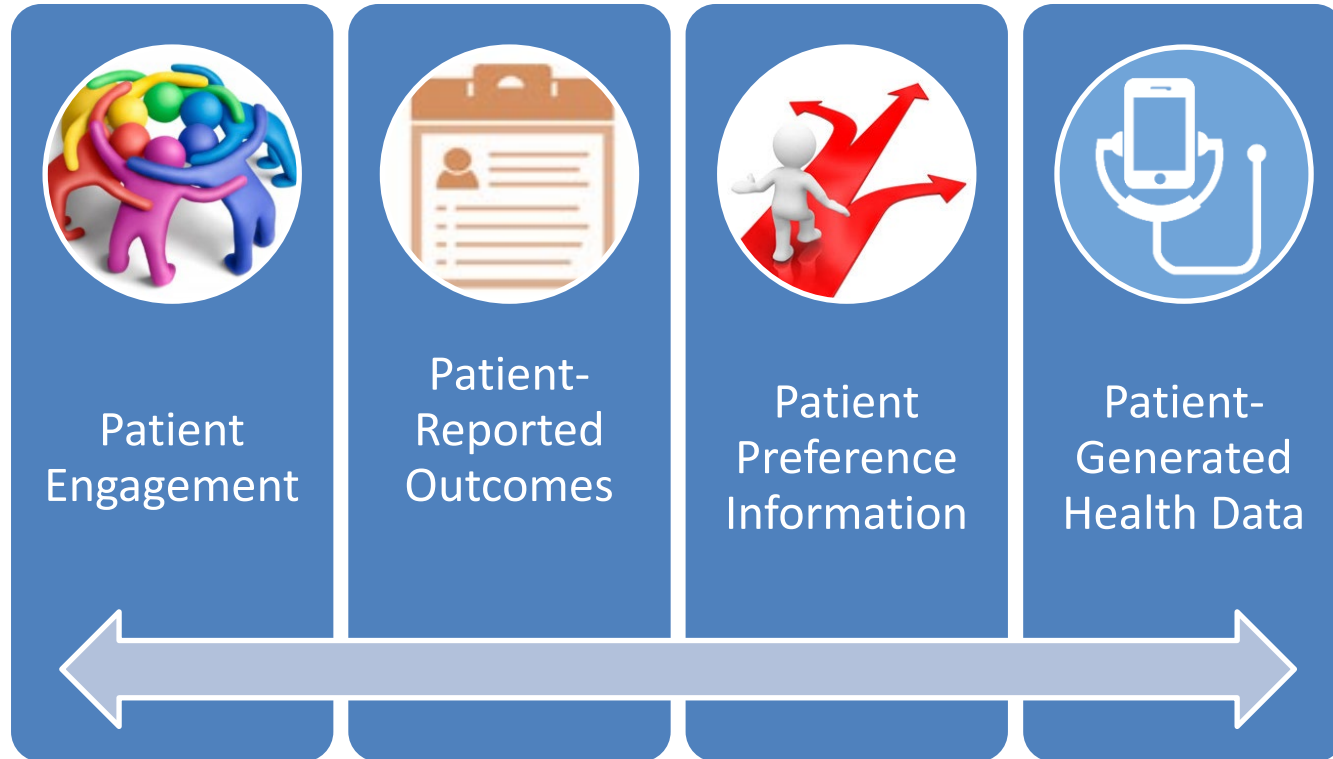
# Patients are at the Heart of What We Do



## **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](mailto: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](mailto:ocod@fda.hhs.gov).



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 PERSPECTIVES ON:**  
**Study Design Considerations for**  
**Transbronchoscopic Thermal Ablation (TTA) Devices for the**  
**Treatment of Oligometastases to the Lung (OML)**  
*APRIL 5, 2022, 3:00 P.M. – 4:00 P.M. (EST)*



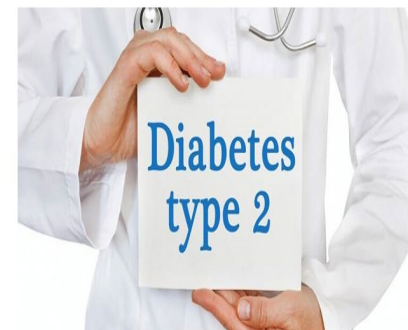
Source: <https://www.researching.com/health-science/medical-devices/lung-disease/transbronchoscopic-thermal-ablation-devices-for-the-treatment-of-oligometastases-to-the-lung>

1

**PATIENT PERSPECTIVES ON:**

## Patient Perspectives on Living with Type 2 Diabetes and Medical Device Treatment

*APRIL 28, 2022, 12:30 P.M. – 2:00 P.M. (EST)*



# 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

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**Applying Consistent & Transparent Policy**

**Building Capacity**

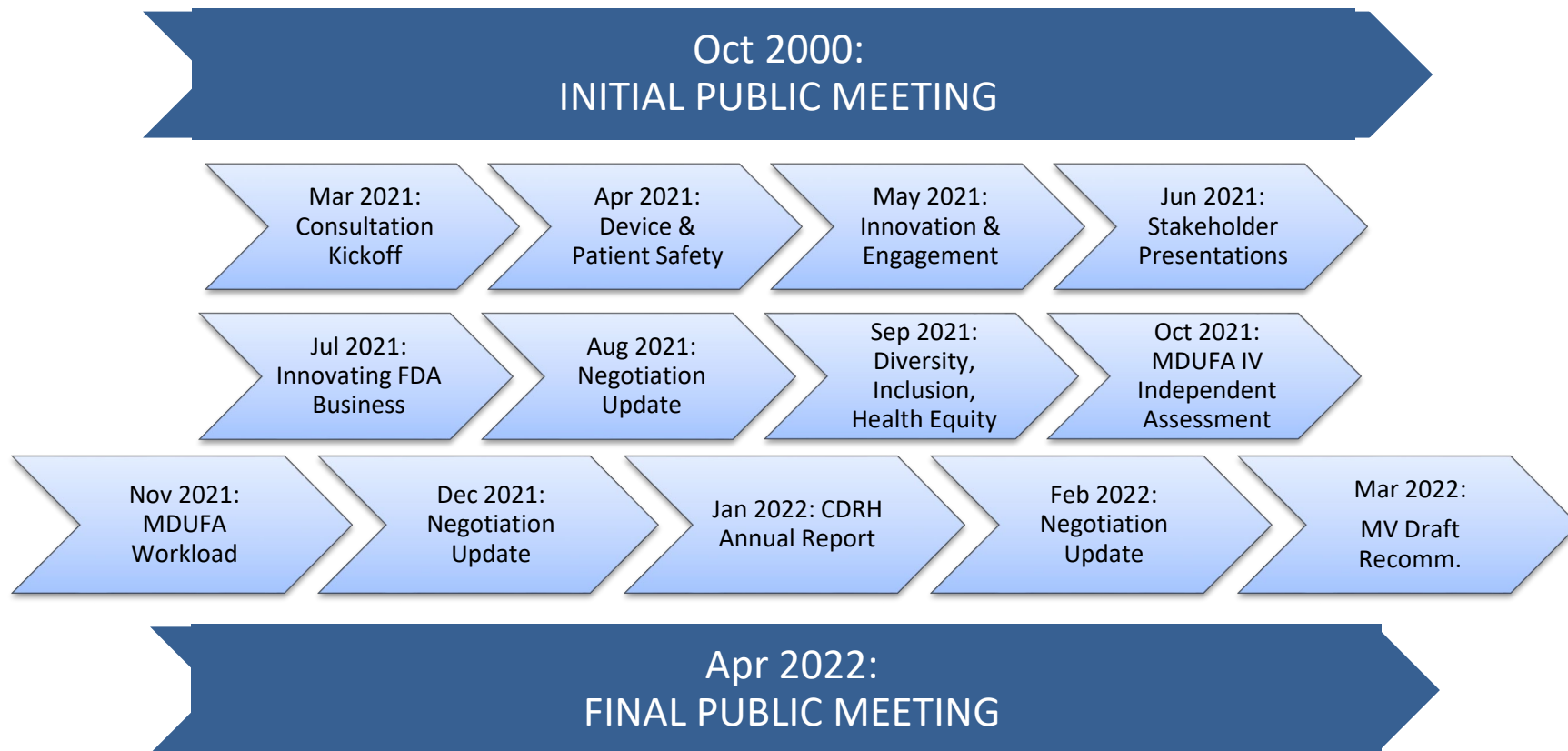
**Optimizing the Research Roadmap**

**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.

# CDRH's Digital Health Center of Excellence

Empowering digital health stakeholders to advance public health

FDA



## DIGITAL HEALTH

**CDRH Digital Health Center of Excellence**

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

[www.fda.gov/digitalhealth](http://www.fda.gov/digitalhealth)

# Focus for Today



#PEAC2022



## Augmented Reality (AR) and Virtual Reality (VR) Medical Devices

Virtual Meeting  
July 12-13, 2022

# 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

