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
- Patient-Reported Outcomes
- Patient Preference Information
- Patient-Generated Health Data
Patient Engagement Involves Reciprocity and Inclusion
Patient and Caregiver Connection Partners
<table>
<thead>
<tr>
<th>Outcomes from Previous PEAC Meetings</th>
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<tbody>
<tr>
<td><strong>1</strong> Patient Engagement in Design, Conduct and Communication of Medical Device Clinical Trials</td>
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<tr>
<td>• Final guidance</td>
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<td>• Video for underrepresented populations</td>
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<td><strong>2</strong> Patient-Generated Health Data &amp; Medical Device Safety Surveillance</td>
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<td>• Open data pledge</td>
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<td>• PGHD public meeting on May 4, 2021</td>
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<td><strong>3</strong> Communicating Cybersecurity Vulnerabilities of Medical Devices</td>
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<td>• Cybersecurity hygiene miniseries</td>
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<tr>
<td>• Communication best practices paper</td>
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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

Oct 2000:
INITIAL PUBLIC MEETING

Mar 2021: Consultation Kickoff
Apr 2021: Device & Patient Safety
May 2021: Innovation & Engagement
Jun 2021: Stakeholder Presentations
Jul 2021: Innovating FDA Business
Aug 2021: Negotiation Update
Sep 2021: Diversity, Inclusion, Health Equity
Oct 2021: MDUFA IV Independent Assessment

Nov 2021: MDUFA Workload
Dec 2021: Negotiation Update
Jan 2022: CDRH Annual Report
Feb 2022: Negotiation Update

Apr 2022:
FINAL PUBLIC MEETING
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.
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