



U.S. FOOD & DRUG
ADMINISTRATION

Patient Engagement Advisory Committee Meeting: CDRH Updates

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CDRH COVID-19 Response

FDA



Impact of CDRH Staff COVID-19 Efforts



Data as of October 16, 2020 (emails are as of 9/18/2020)



Examples of Patients Partnering in COVID-19

COVID-19 Supplies, Device, and Access Impact Survey–May 2020

In May 2020, members of the AAKP completed a survey to inform the U.S. Food and Drug Administration (FDA) about dialysis device-related concerns. Survey responses helped the FDA to assess possible challenges kidney patients were having accessing supplies, devices, and services. This information was used to help inform CDRH's response efforts to address device shortages.



Agency Directed Assignment to PEAC members on diagnostic testing communication materials

Patient Engagement Videos



Draft CDRH PRO Guidance

FDA

“Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation”

**Docket open for
comments
through
October 30,
2020**



Measure What is Important to Patients



Ensure Patients Understand



Convey Use of COA in Protocol and SAP



Leverage Existing Information



Consider Alternative Platforms and Parallel Development



Pre-Competitive Collaboration

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use>

CDRH Patient Science & Engagement Events







- Patient-Reported Outcomes (PROs) and Medical Device Investigations: From Conception to Implementation
 - <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-patient-reported-outcomes-pros-and-medical-device-investigations-conception>
- Using Patient Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond”
 - <https://www.ispor.org/conferences-education/conferences/upcoming-conferences/ispofda-summit-2020/about/registration-information>



Summary of Previous PEAC Meetings

FDA

1	Patient Engagement in Design, Conduct and Communication of Medical Device Clinical Trials	<ul style="list-style-type: none"> • Draft guidance on patient engagement in clinical studies • Video introducing medical device trials to underrepresented populations 	
2	Patient-Generated Health Data & Medical Device Safety Surveillance	<ul style="list-style-type: none"> • Signed open data pledge 	
3	Communicating Cybersecurity Vulnerabilities of Medical Devices	<ul style="list-style-type: none"> • Cybersecurity Framework • Cybersecurity hygiene miniseries 	
4	<u>OCTOBER 22, 2020</u> Artificial Intelligence & Machine Learning		

Outcomes from PEAC 2017 on Clinical Trials



- Video of medical device clinical trials designed to encourage underrepresented populations to participate



<https://www.youtube.com/watch?v=SApXnmZlgFE>

Outcomes from PEAC 2019 on Cybersecurity

FDA



Video announcing launch of miniseries on cybersecurity hygiene





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Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)- Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback



Focus for Today:

Artificial Intelligence (AI)/
Machine Learning (ML)

Virtual Bootcamp:

Navigating the Journey from Digital Health Technologies To Meaningful Patient Outcomes

- 72 attendees from a range of small medical device and digital health companies

Hands-On practice

- Practice 1: Patient Input to Support Your DHT Development
- Practice 2: Developing Your DHT to be Used to Support Clinical Investigations
- Practice 3: Developing Your DHT to be Used Outside of Clinical Investigations



Collaborative Efforts in AI/ML Involving Patients



**Xavier Artificial Intelligence
World Consortium**



**Collaborative Community on
Ophthalmic Imaging**



Collaborative Communities Toolkit
September 2019

Digital Health Center of Excellence

Empowering digital health stakeholders to advance health care

FDA



Upcoming Meetings

FDA

- FDA's Communications about the Safety of Medical Devices on **November 17**, 2020 from 1-3pm ET
<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-fdas-communications-about-safety-medical-devices-11172020-11172020>
- MDIC Patient Engagement Forum on **November 18**, 2020 from 10am-6:30pm ET
<https://mdic.org/event/patient-engagement-forum-virtual/>





Thank You



