

# Patient Engagement Advisory Committee Meeting: CDRH Updates

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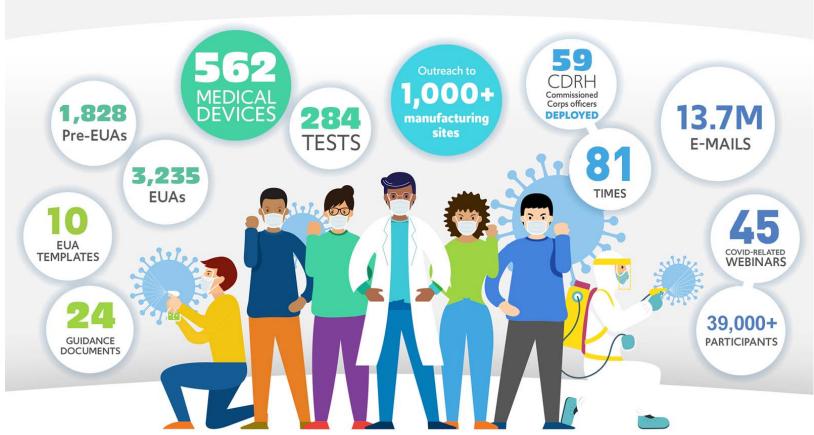








## **Impact of CDRH Staff COVID-19 Efforts**



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**



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

**Measure What is Important to Patients** 

Docket open for comments through October 30, 2020



**Ensure Patients Understand** 



**Convey Use of COA in Protocol and SAP** 



**Leverage Existing Information** 



**Consider Alternative Platforms and Parallel Development** 



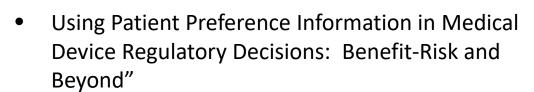
**Pre-Competitive Collaboration** 

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/medicaldevices/workshops-conferences-medicaldevices/virtual-public-meeting-patientreported-outcomes-pros-and-medical-deviceinvestigations-conception



 https://www.ispor.org/conferenceseducation/conferences/upcoming-conferences/isporfda-summit-2020/about/registration-information





## **Summary of Previous PEAC Meetings**



• Draft guidance on patient Patient Engagement in engagement in clinical studies Design, Conduct and • Video introducing medical device Communication of Medical trials to underrepresented **Device Clinical Trials** populations Patient-Generated Health • Signed open data pledge Data & Medical Device Safety Surveillance Communicating Cybersecurity Cybersecurity Framework Vulnerabilities of Medical • Cybersecurity hygiene miniseries Devices **OCTOBER 22, 2020** 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**





Video announcing launch of miniseries on cybersecurity hygiene

Docket open until December 21, 2020

Communicating Cybersecurity Vulnerabilities to Patients: Considerations for a Framework

PATIENT ENGAGEMENT ADVISORY COMMITTEE

October 2020



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







## **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/workshopsconferences-medical-devices/virtual-publicmeeting-fdas-communications-about-safetymedical-devices-11172020-11172020

- MDIC Patient Engagement Forum on November 18, 2020 from 10am-6:30pm ET
- https://mdic.org/event/patient-engagementforum-virtual/







## Thank You



